MAPPING THE INTERSECTION OF INTELLECTUAL PROPERTY AND COMPETITION LAW: MISUSING MARKET POWER WHEN REFUSING TO LICENSE BIOMEDICAL PATENTS

By

Jane L Nielsen

B Com LLB (Hons)

Barrister and Solicitor of the Supreme Court of Tasmania

Submitted in fulfilment of the requirements for the Degree of Doctor of Philosophy

University of Tasmania

Faculty of Law

September 2005

STATEMENTS

This thesis contains no material which has been accepted for a degree or diploma by the University or any other institution, except by way of background information and duly acknowledged in the thesis, and the to best of the candidate's knowledge and belief no material previously published or written by another person except where due acknowledgement is made in the text of the thesis. This thesis contains results from an empirical study co-conducted with Dr Dianne Nicol, and extracts from papers co-authored with Dr Nicol. All material extracted and included in this thesis was written solely by the author, and due acknowledgement is given to Dr Nicol in the Acknowledgements, the Introduction and Chapter 4.

This thesis may be made available for loan and limited copying in accordance with the *Copyright Act* 1968 (Cth).

Jane L Nielsen

2 September 2005

To the best of the author's knowledge this thesis states the law as at 2 September 2005.

ABSTRACT

This thesis considers the conflict between intellectual property and competition law. There have been many attempts by noted scholars, regulatory authorities and courts to resolve this conflict, and determine how competition laws should be applied to dealings in intellectual property. Issues at the interface of intellectual property and competition law are exemplified by bargaining breakdowns in high technology, innovative industries. This thesis examines an issue arising from the balance between intellectual property and competition law in the context of a particular industry.

Specifically, it analyses competition law regulation of refusals to license patents within the Australian medical biotechnology industry. A foundation for this analysis is provided through consideration of some characteristics of the medical biotechnology industry. This preliminary material allows the conclusion that there are a number of preconditions that make the Australian medical biotechnology industry particularly prone to refusals to license patents.

Against this backdrop, the issue of refusals to license patents is considered in an empirical context. The thesis presents the results of an empirical study that investigated the preponderance of restrictive licensing practices within Australian medical biotechnology. While the potential for refusals to license exist within this industry, the empirical data suggests that this issue is occurring to only a limited extent in practice. This evidence is relevant to the analysis contained in the remainder of the thesis, because it assists in informing policy debate over the appropriate parameters for competition law in monitoring refusals to license intellectual property.

The issue of regulation of refusals to license patents is far from resolved in the literature or by the judiciary. This thesis proposes that the issue is one that must be approached flexibly, and any attempt to circumscribe rigid rules for analysis is likely to fail. As such, it considers the role competition law plays in regulating dealings in intellectual property, and establishes a flexible framework for assessing the legality of refusals to license patents. This framework provides a basis for examining existing legislative provisions under which refusals to license will be evaluated.

There is no Australian case law dealing with the issue of refusals to license intellectual property. The analysis contained in this thesis therefore proceeds from first principles. A refusal to license a patent will be dealt with pursuant to s 46 of the *Trade Practices Act* 1974 (Cth). The existing law and its limitations are considered in some detail, and it is concluded that recent judicial interpretations of this provision

have rendered it virtually redundant. Due to the lack of judicial guidance in relation to this issue in Australia, some comparative case law from the United State and European Union is examined. Consideration of this case law provides some basis for assessing the flexible framework established in the thesis, and it would be taken into account if an Australian court were required to consider the issue of refusals to license intellectual property.

The thesis considers the likely application of s 46 to refusals to license patents in medical biotechnology. It concludes that although there may be some circumstances where a refusal to license a patent will be anti-competitive, s 46 will not operate to provide redress. General deficiencies in the section are likely to be intensified where dealings in intellectual property are at issue. Accordingly, it argues that legislative amendment is necessary to rectify these problems, and makes a number of recommendations to this effect. It also considers the relevance of the empirical evidence presented in shaping regulatory policy.

ACKNOWLEDGEMENTS AND THANKS

During the course of completing this thesis, I have drawn support and inspiration from my supervisors, Professor Don Chalmer, Dr Dianne Nicol, and Lynden Griggs. I am indebted to my supervisors for their guidance and encouragement, and for their timeliness in providing comments on various drafts of this thesis. I would particularly like to thank Dr Dianne Nicol for her unwavering support throughout my candidature. I would also like to thank Professor Gino Dal Pont for providing comments on this thesis, as well as Charles Lawson for taking the time to provide feedback on Chapter 5. I also thank Daniel Stewart for visiting the University of Tasmania to discuss aspects of my research.

The empirical component of this thesis was part of a much larger study. I would like to acknowledge the University of Tasmania Institutional Research Grants Scheme for funding this study, (N0012490), and the Australian Research Council Discovery Grant Scheme for providing funding. The study was approved by the Southern Tasmania Social Sciences Human Research Ethics Committee. I would also like to thank all of the respondents who graciously gave of their time and provided valuable data. I would also like to acknowledge Dr Dianne Nicol who co-conducted the study with me, and with whom I spent many hours interviewing respondents and discussing data. I would also like to thank Mildred Cho and John Walsh for visiting the University of Tasmania and providing assistance during the early stages of the study. I would also like to acknowledge Tim Graham for his assistance in compiling a list of survey respondents, and many scholars who read drafts of the study report and provided comments and editorial assistance.

I also acknowledge receipt of the Archibald McDougall Scholarship and the Henry Baker Scholarship. These scholarships, together with financial support from the Law School, enabled me to undertake valuable research travel and meet with many national and international scholars and practitioners. I thank all of these scholars and practitioners for taking the time to meet with me and provide me with materials in relation to many aspects of this research. The work of many of them is cited throughout this thesis.

I would like to thank the staff and postgraduates at the Faculty of Law, University of Tasmania for their ongoing support and friendship. I would especially like to thank Dr Lisa Butler for her encouragement and willingness to provide ongoing editorial assistance. I am also grateful to the staff of the University of Tasmania Law Library

who have been consistently willing to assist with any enquiry. Thanks also to Leigh Wilson who provided much needed editorial assistance during the final stages of my research.

Finally, I would like to thank my family for their patience and support. In particular, I thank Rhys for his love and encouragement, for his assistance with aspects of my research, and for his belief in my ability to complete this thesis. Final thanks go to Meg for her unconditional love and for helping to ensure my life retained some balance during the last three years.

TABLE OF CONTENTS

INTRODUCTION

CHAPTER 1

THE STRUCTURE OF THE MEDICAL BIOTECHNOLOGY INDUSTRY

CHAPTER 2

BIOTECHNOLOGY RESEARCH AND THE PATENT SYSTEM IN AUSTRALIA

CHAPTER 3

THE CUMULATIVE NATURE OF BIOMEDICAL RESEARCH AND BARGAINING BREAKDOWN

CHAPTER 4

THE AUSTRALIAN EXPERIENCE: AN EMPIRICAL ASSESSMENT OF RESTRICTIVE LICENSING PRACTICES WITHN THE AUSTRALIAN MEDICAL BIOTECHNOLOGY INDUSTRY

CHAPTER 5

THE APPLICATION OF COMPETITION LAW TO DEALINGS IN INTELLECTUAL PROPERTY

CHAPTER 6

ATTACKING A REFUSAL TO LICENSE: SECTION 46(1) OF THE TRADE PRACTICES ACT 1974 (CTH)

CHAPTER 7

REFUSALS TO LICENSE INTELLECTUAL PROPERTY: A COMPARATIVE ANALYSIS OF UNITED STATES AND EUROPEAN CASE LAW

CHAPTER 8

REFUSALS TO LICENSE MEDICAL BIOTECHNOLOGY PATENTS IN THE AUSTRALIAN CONTEXT: AN ANALYSIS OF THE POTENTIAL APPLICATION OF SECTION 46

CHAPTER 9

CONCLUSION

TABLE OF CASES

AUSTRALIA

CANADA

EUROPEAN UNION

TABLE OF STATUTES

AUSTRALIA

COMMONWEALTH ACTS AND REGULATIONS

Acts Interpretation Act 1901 (Cth)

Circuit Layouts Act 1989 (Cth)

Competition Policy Reform Act 1995 (Cth)

Copyright Act 1968 (Cth)

Designs Act 1906 (Cth)

Designs Act 2003 (Cth)

Patents (World Trade Organisation) Act 1994 (Cth)

Patents Act 1990 (Cth)

Patents Amendment Act 2001 (Cth)

Patents Regulations 1991 (Cth)

Plant Breeder's Rights Act 1994 (Cth)

Therapeutic Goods Act 1989 (Cth)

Trade Practices Act 1974 (Cth)

Trade Practices Revision Act 1986 (Cth)

Trademarks Act 1995 (Cth)

COMMONWEALTH BILLS

Trade Practices Legislation Amendment Bill (No 1) (2005)

Trade Practices Legislation Amendment Bill (No 1) (2005)

COMMONWEALTH EXPLANATORY MEMORANDA

NEW ZEALAND

UNITED KINGDOM

UNITED STATES

TABLE OF TREATIES, CONVENTIONS AND AGREEMENTS

TREATIES

Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure [1977] ATS 9

Patent Cooperation Treaty [1980] ATS 6 (entered into force 24 January 1978)

Patent Law Treaty opened for signature June 1 2000 WIPO Database of Intellectual Property Legislative Texts (entered into force 28 April 2005)

Treaty Establishing the European Community [2002] OJ C 325/65

CONVENTIONS

Paris Convention for the Protection of Industrial Property [1972] ATS 12

AGREEMENTS

Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, [1995] ATS 12 (entered into force 15 April 1994)

Australia – United States Free Trade Agreement, [2005] ATS 1

Competition Principles Agreement in National Competition Council, *Compendium of National Competition Policy Agreements* (1997)

OTHER

EC Directive 98/44/EC on the Legal Protection of Biotechnological Inventions

Commission Regulation (EC) 240/96 on the Application of Article 81(3) of the Treaty to Certain Categories of Technology Transfer Agreements, [1996] OJ L 31/2

SELECTED ABBREVIATIONS

ACCC	Australian Competition and Consumer Commission
ACIP	Advisory Council on Intellectual Property
ALRC	Australian Law Reform Commission
APO	Australian Patent Office
ARC	Australian Research Council
AUSTFA	Australia-United States Free Trade Agreement
BIO	Biotechnology Industry Organisation (US)
BRCA1	Breast cancer 1 gene
cDNA	Complementary DNA
CFI	European Court of First Instance
CPA	Competition Principles Agreement
CRC	Cooperative Research Centre
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DNA	Deoxyribonucleic acid
DOJ	Department of Justice (US)
ECJ	European Court of Justice
EPO	European Patent Office
EST	Expressed sequence tag
EU	European Union
FDA	Federal Drug Administration (US)
FTC	Federal Trade Commission (US)
HCV	Hepatitis C virus
HGP	Human Genome Project

HIV	Human Immuno-deficiency Virus
IP	Intellectual Property
IPCRC	Intellectual Property and Competition Review Committee
ISOs	Independent Service Organisations
MTA	Material Transfer Agreement
NCC	National Competition Council
NHMRC	National Health and Medical Research Council
NIH	National Institutes of Health (US)
OECD	Organisation for Economic Cooperation and Development
PCR	Polymerase chain reaction
RNA	Ribonucleic acid
SNP	Single nucleotide polymorphism
SSNIP Test	Small but Insignificant and Non-Transitory Increase in Price Test
TPA	*Trade Practices Act* 1974 (Cth)
TPC	Trade Practices Commission
TRIPS	*Agreement on Trade-Related Aspects of Intellectual Property Rights 1994*
USPTO	United States Patent and Trademark Office
US	United States
WARF	Wisconsin Alumni Research Foundation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

INTRODUCTION

CONTEXT

Intellectual property and competition law are often perceived as being in conflict. Intellectual property laws convey exclusivity in the form of a privilege to use a right to the exclusion of others.[1] Competition laws promote competitive markets as the cornerstone of economic efficiency. Friction between intellectual property and competition law centres on the extent to which competition law should defer to intellectual property laws in allowing the exercise of exclusive privileges. At the heart of the debate are efficiency concerns, and a desire to determine how innovation and consequently consumer welfare may best be achieved.

This tension between the two bodies of law is not a recent phenomenon, but has been evident for the best part of the last century.[2] Competition law authorities have grappled with how to treat dealings in intellectual property, where those dealings have anti-competitive implications. At certain points in the history of the conflict, competition law regulators and courts have exhibited an overly deferential preference toward intellectual property laws. At other times, regulatory and judicial policy have favoured competition law, with many intellectual property dealings treated as highly suspect. This lengthy struggle to identify an appropriate balance has been evident in many different jurisdictions including Australia, and has given rise to a vast body of literature.[3] While it is generally recognised that the two bodies of law are reconcilable, areas of difficulty persist.

---

[1] This thesis focuses on patent protection; see further below, n9. Other forms of intellectual property protection include copyright, trade marks, and trade secrecy. In Australia, copyright is conveyed by virtue of the *Copyright Act* 1968 (Cth), which provides creators of literary, musical, dramatic and artistic works, computer software, films, sound recordings, broadcasts and printed editions of works with copyright over the works. This entitles the copyright owner to exclusively publish, copy, perform, communicate or adapt the subject matter of the protected work. The *Trade Marks Act* 1995 (Cth) allows the owner of a trade mark to register the right to exclusively use that mark. Trade secrecy, or confidential information, also protections inventors, but is governed by common law. Other forms of intellectual property protection have evolved. For example, the *Plant Breeder's Rights Act* 1994 (Cth) gives the exclusive right to produce, sell and import particular plant varieties, while the *Designs Act* 2003 (Cth) provides the owner of a design with the exclusive right to use that design.

[2] See, eg, Herbert Hovenkamp, Mark A Lemley and Mark D Janis, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2002) vol I, [1.14-1.17].

[3] For recent discussion in the Australian context, see, eg, Ian Eagles and Louise Longden, 'Competition in Information and Computer Technology Markets: Intellectual Property Licensing and Section 51(3) of the *Trade Practices Act* 1974' (2003) 3 *Queensland University Journal of Technology Law and Justice Journal* 28; Justice Kevin Lindgren, 'The Interface Between Intellectual Property and Antitrust: Some Current Issues in Australia' (2005) 16 *Australian Intellectual Property Journal* 76. Note that the matter has also been the subject of recent government review in Australia; see, eg, Independent Committee of Inquiry into Competition Policy in Australia, Parliament of Australia, *National Competition Policy* (1993); National Competition Council, Parliament of Australia, *Review of Sections*

New technologies have given rise to novel challenges at the intersection of intellectual property and competition law.[4] High technology industries are characterised by cumulative research patterns[5] and unique market structures. A hallmark of high technology industries is high levels of intellectual property protection, fuelled by the research environment in which industry participants operate, and the rapid pace at which innovation within these industries proceeds. Finding a balance between intellectual property and competition policy is invariably problematic, and these difficulties are intensified where issues associated with highly technological industries arise.[6] The question is whether competition law is adequately equipped to deal with intellectual property enforcement issues that arise in respect of new technologies.[7]

One industry that possesses the distinctive traits of a high technology industry is medical biotechnology.[8] This industry is highly innovative, and is characterised by a cumulative research structure. Increasingly, industry participants are seeking to commercialise their research results through patenting. This has resulted in an industry that relies heavily on patent protection.[9] Patents are important because they

---

51(2) and 51(3) of the Trade Practices Act *1974: Final Report* (1999); Intellectual Property and Competition Review Committee, Parliament of Australia, *Review of Intellectual Property Legislation Under the Competition Principles Agreement: Final Report* (2002).

[4] See, eg, Robert P Merges, Peter S Menell and Mark A Lemley, *Intellectual Property in the New Technological Age* (3rd ed, 2003), especially ch 8.

[5] 'Cumulative' innovation refers to a pattern of research where technological developments build on the inventiveness of others. In many industries where research is cumulative, a considerable period of time exists between initial invention and a resulting product. Some degree of follow-on invention will be required before a 'product' in the sense of a product available to consumers, can be brought to market. Other terms used in this thesis to refer to this research structure include incremental or sequential innovation.

[6] See Robert Pitofsky, 'Challenges of the New Economy: Issues at the Intersection of Antitrust and Intellectual Property' (2001) 68 *Antitrust Law Journal* 903.

[7] Ibid.

[8] The Organisation for Economic Cooperation and Development (OECD) defines biotechnology as 'the application of science and technology to living organisims, as well as parts, products, and models thereof, to alter living and non-living materials for the production of knowledge, goods and services.' This definition is used in conjunction with a list-based definition of biotechnology techniques available at http://www.oecd.org/document/42/0,2340,en_2649_37437_1933994_1_1_1_37437,00.html> at 19 August 2005. Medical biotechnology includes those techniques that have medical application.

The broad definition employed by the Australian Government generally accords with this definition:

> Biotechnology is the application of biological processes to make products that are useful to society, some of which include food, medicine and chemical compounds. Biotechnology is providing improvements in health care and the treatment of disease ...

See Biotechnology Australia, Commonwealth of Australia, Developing Australia's Biotechnology Future: Discussion Paper (1999) i.

[9] In Australia, patent protection is granted over patentable inventions by examination of an application made pursuant to the *Patents Act* 1990 (Cth). A patent provides a patent holder with the exclusive right to exploit the patent, or to make, hire, sell, use or import the invention; see further below, 2.5.

enable the realisation of revenue on biotechnology inventions. Upstream patents are also crucial inputs into more downstream research applications.[10] Combined, these factors result in difficulties in determining how innovation within the industry may best be facilitated.

This thesis examines the complex issue of the interaction between intellectual property and competition law, in addressing the particular issue of refusals to license patents. Access to a patented invention may be required in order to enable follow-on research. Whether or not there are circumstances in which a patent holder may be compelled to license a patent gives rise to difficult questions, because it impinges on a patent holder's exclusive privilege to practice an invention. The issue of refusals to license intellectual property is therefore one of the most fundamental problems arising at the intellectual property/competition law divide. Thus, this thesis takes a specific example of a potentially anti-competitive practice and examines the issue of refusals to license patents in the context of medical biotechnology. This analysis takes place within the framework of Australian legislation dealing with anti-competitive conduct, the *Trade Practices Act* 1974 (Cth) (the *TPA*). In particular, it examines the operation of s 46 of the *TPA* given that this provision will be invoked where a refusal to license a patent is alleged to be anti-competitive. Section 46 has been described as 'a potentially powerful compulsory licensing tool.'[11] This thesis will evaluate whether Australian regulators and the judiciary are equipped to deal with the issue of refusals to license in a high technology industry such as medical biotechnology.

---

[10] The terms 'upstream' and 'downstream' are used here to describe the position of institutions and companies in the research and development continuum. Researchers and companies at the furthest upstream end of the continuum produce 'raw' genomic data and broadly enabling technologies that are primarily useful as inputs into further research, while companies at the furthest downstream end produce drugs, diagnostic products and other therapeutics. Many researchers and companies fall somewhere between these two extremes, and are classified broadly as 'intermediate'. Note, however, that this distinction is not static. Some sectors of medical biotechnology operate outside the confines of the applications described. For example, the medical devices segment of the industry produce devices for consumer use, while bio-informatics research focuses on the development of enabling software. In both these instances, the divide between upstream and downstream research is narrower than in other segments of the industry described. See also Arti K Rai, 'Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust', (2001) 16 *Berkeley Technology Law Journal* 813 (Rai 2001), her n9 ('...these classifications are quite fluid. Thus, for example, research identifying a gene linked to a disease might be quite 'upstream' if the commercial goal is a drug therapy. By contrast, if the commercial goal is a diagnostic test, research identifying the gene might be relatively 'downstream'.')

[11] Henry Ergas, 'Treatment of Unilateral Refusals to License and Compulsory Licensing in Australia' (*Paper Presented to the Federal Trade Commission/Department of Justice Hearings on Antitrust and Intellectual Property Law and Policy in the Knowledge-Based Economy*, Washington, 22 May 2002), 7.

It will assess the development of intellectual property protection within the context of biomedical research, and consider how intellectual property protection within the context of this industry affects the flow of innovation and development. It will go on to look at the issues of dominance and competition. There have been a number of government surveys in Australia and internationally which have considered the development of the medical biotechnology industry.[12] Until recently, there has been no attempt to gather empirical evidence on the impact of patents within the industry on innovation. A number of recent international studies have begun to investigate issues associated with patent exploitation.[13] They have focused primarily on factors conducive to innovation, but have not to date gone on to consider the relevance of competition law within the framework of this broader debate.

Because of the international nature of this issue, there is extensive reference to overseas literature during the course of this thesis. The context of this thesis is not restricted to Australia, but is intended to be applicable within the wider international context. Nevertheless, an important component of the thesis is the presentation of the results of an empirical study co-conducted by the author that investigates patenting and licensing practices within the Australian medical biotechnology industry.[14] The focus of the empirical evidence reported is on innovation within the Australian medical biotechnology industry. A central objective is to examine issues relating to refusals to license patents from the national perspective, and provide sufficient analysis of these issues to usefully inform policy debate in the area.

Accordingly, the thesis focuses on regulatory policy from the Australian perspective, and appropriate regulatory mechanisms to evaluate the legality of refusals to license medical biotechnology patents. As a consequence, the thesis brings together international references, but makes specific reference to the Australian context. This is important, because the debate is international, but the discussion is in the context of evidence gathered in respect of the Australian industry.

---

[12] See, eg, *The Virtous Cycle-Working Together for Health and Medical Research, Health and Medical Strategic Review*, (1999); Biotechnology Australia, Commonwealth of Australia, *Australian Biotechnology: A National Strategy*, (2000).

[13] See, eg, John P Walsh, Ashish Arora and Wesley M Cohen 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in Wesley M Cohen and Stephen A Merrill (eds.), *Patents in the Knowledge-Based Economy* (2003) 287; Joseph Straus, Henrik Holzapfel and Matthias Lindenmeir, *Empirical Survey on Genetic Invention and Patent Law*, unpublished report (2002) (copy on file with author); Intellectual Property Institute, *Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice* (2004) (The UK Study).

[14] Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6.

ADVANCES IN GENETIC TECHNOLOGY AND THE MODERN MEDICAL BIOTECHNOLOGY INDUSTRY

The medical biotechnology industry has a relatively recent history. The birth of modern biotechnological inquiry can be traced to the discovery in 1953 by James Watson and Francis Crick of the double helix.[15] This discovery led to better understanding of how human genes work.

The most fundamental recent development, however, was undoubtedly the invention in 1973 of recombinant DNA technology by Stanley Cohen and Herbert Boyer. The discovery, commercialisation and widespread dissemination of this invention has enabled the development of modern biotechnology, Representing the most fundamental technology in molecular biology, recombinant DNA technology was protected by one process patent for making molecular chimeras, and two product patents for proteins produced using recombinant DNA.[16] This technology has no alternatives and is essential to all research in molecular biology.[17]

The discovery of recombinant DNA technology spawned the advent of the modern biotechnology industry. The Human Genome Project, (HGP) an attempt to map and sequence the entire human genome, commenced in 1990.[18] The implications of doing so for the human race were very significant. Commentators foresaw the mapping and sequencing of the human genome as allowing unprecedented intervention into human drug development, therapeutics and diagnostics as scientists gleaned a better understanding of how the individual genetic type of individuals determined our predisposition to disease and ill-health. An international public sequencing consortium was established in 1996 for the purpose of completing the sequencing of the human genome. Driven by the promise of profits, a number of private companies joined the race to sequence the human genome in tandem with the public sequencing effort.

---

[15] J Watson and F Crick, 'A Structure for Deoxyribose Nucleic Acid' (1953) 171 *Nature* 737. See also James D Watson, *The Double Helix: A Personal Account of the Discovery of the Structure of DNA* (2001).

[16] Comprising United States Patent and Trademark Office (USPTO) Patent No US4 237 224 (granted in 1980) and Patent No US4 740 470 (granted in 1988) (now expired). This technology does not appear to have been patented in Australia.

[17] See further National Research Council, *Intellectual Property Rights and Research Tools in Molecular Biology* (Washington DC: National Academy of Sciences, 1997) (the NRC Report), 40-42.

[18] For details of the HGP see the website of the United States National Human Genome Research Institute <http://www.genome.gov/10001772> at 26 May 2005.

See also the account in John Sulston and Georgina Ferry, *The Common Thread: Science, Politics, Ethics and the Human Genome* (2002).

The public sequencing consortium and Celera Genomics, one of the private companies involved in sequencing the human genome, announced in 2001 that a rough draft of the human genome had been completed ahead of schedule. Sequence information had been periodically released by the public sequencing consortium, and it followed by publishing a detailed description of the sequences once completed.[19] Celera Genomics followed suit soon thereafter.[20] The sequence information attained by the private genomics companies differs from that released by the public sequencing consortium both in the sequencing methodologies employed,[21] and in the nature of the information provided. The private sequencing companies claim that value has been added to the sequence information provided by them in the form of annotations to the basic sequence information.[22] Consequently, genomics companies have been careful to protect the release of this annotated information, and access to their databases is available through subscription only.[23]

A final draft of the HGP was completed in 2001,[24] and gaps in the draft sequence have now been largely eradicated.[25] This raises new possibilities for both public and privately-based researchers to explore disease potentiality and therapeutic intervention. Original estimates of the number of protein-coding human genes, put at between 100 000 and 200 000, have now been revised to between 20 000 and 25 000 genes,[26] making human genetic conditions and disease far more complex than scientists originally envisaged.[27] Genomic research, in itself is therefore of limited

---

[19] (2001) 409 (6822) *Nature* (multiple articles).

[20] (2001) 291 *Science* (multiple articles).

[21] For example, Celera Genomics employed a 'shotgun' sequencing technique developed by Craig Venter, president of the company at the time the rough draft was completed; for analysis of this technique see, for example, Xinwei She, Zhaoshi Jiang, Royden A Clark, Ge Liu, Ze Cheng, Eray Tuzun, Deanna M Church, Granger Sutton, Aaron L Halpern & Evan E Eichler, 'Shotgun Sequence Assembly and Recent Segmental Duplications Within the Human Genome' *Nature* 431, 927-930 (2004).

[22] See, eg, <http://www.celeradiscoverysystem.com/about/home.cfm> at 30 June 2005.

[23] Ibid.

[24] See 'International Human Genome Sequencing Consortium Describes Finished Human Genome Sequence', NIH News Release (20 October 2004) <http://www.genome.gov/12513430> at 26 May 2005.

[25] International Human Genome Sequencing Consortium, 'Finishing the Euchromatic Sequence of the Human Genome' 431*Nature* (2004): 931-945.

[26] Ibid.

[27] Not only are many genetic conditions likely to be multi-factorial, but more than one gene may be implicated in a particular genetic condition or disease. Further, 'differential splicing' may mean that particular genes code for numerous proteins, and that intricate links exist between genes and proteins; see, eg, T A Brown, *Genomes* (2001) 1.3 at

<http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=genomes.box.5293> at 19 August 2005.

value to consumers as such, and it is the subsequent or follow-on research which may yield valuable answers to questions about human health.[28] Nevertheless, without this basic genomic research the more downstream development would not be possible. A thriving biotechnology industry has evolved across the spectrum from research to product development, an industry which for some time now has been undergoing massive growth.[29] This is illustrative of the breadth of research possibilities, and of the hope that investors place in the success of the industry built around post-genomics research. The next phase of medical biotechnology research is the application of genomics to pharmaceutical, diagnostic and therapeutic research, and the broad scope of research opportunities in this area has driven industry development.

Broadly speaking, there are four main research areas into which biotechnology research falls:[30]

- structural genomics and proteomics;
- functional genomics and transcriptomics;
- targeted drug discovery and pharmacogenomics; and
- enabling technologies.

Private companies are active in all of these areas of biotechnology research, while research institutions[31] have primarily been involved in research that can be characterised as more upstream. This has generally involved structural genomics and proteomics, and the development of enabling technologies. The province of pharmaceutical companies has traditionally been drug discovery, although even pharmaceutical companies are increasingly venturing more into upstream research to

---

[28] See, eg, David R Bentley, 'Genomes for Medicine' *Nature* 429, 440-445 (2004); John Bell, 'Predicting Disease Using Genomics' *Nature* 429, (2004): 453; William E Evans & Mary V Relling, 'Moving Towards Individualized Medicine with Pharmacogenomics' *Nature* 429, (2004): 464; Robert L Strausberg, Andrew J G Simpson, Lloyd J Old & Gregory J Riggins, 'Oncogenomics and the Development of New Cancer Therapies' *Nature* 429, (2004): 469-471; Stephen P A Fodor, 'Packaging the Genome to Accelerate Biotechnology' in Bay Area Science and Innovation Consortium, *Biotechnology: Essays from its Heartland* (2004) 42.

[29] See, eg, Panos Kanavos, 'Determinants of Market Structure in the International Biopharmaceutical Industry' in Organisation for Economic Cooperation and Development, Economic Aspects of Biotechnologies Related to Human Health: Part II: Biotechnology, Medical Innovation and the Economy: The Key Relationships (1998), 44-53.

[30] A Julian, 'Genomics Primer' BioSpace.com 20 July 2000 <www.biospace.com/articles/genomics.primer.print.cfm> at 30 June 2005.

[31] Research institutions are defined for the purposes of this thesis as including universities, government research laboratories, public and private research institutes and hospitals.

maintain financial viability.[32] As a result, the traditional line between upstream and downstream, or basic and applied research is blurring and the crossover between public and private arenas of research is becoming more pronounced.

AIMS

As foreshadowed, the primary aim of this thesis is to examine the treatment of unilateral refusals to license medical biotechnology patents under Australian competition law by exploring the manner in which this issue is likely to be resolved on the basis of current interpretations of relevant provisions.[33] Increased levels of concentration within the medical biotechnology industry may lead to competition concerns. The structure of biomedical research and the medical biotechnology industry tends to lend itself to the possibility of contractual breakdowns when arrangements for the transfer of technology are being negotiated. The argument on which this thesis rests is that competition law should be available as a mechanism to address refusals to license patents, and that there is considerable doubt as to whether this is the case.

In order to achieve this primary aim, there are four subsidiary aims. The first is to explore whether the potential for research holdup due to refusals to license patents exists in biomedical research in Australia. The second is to examine empirical evidence gathered in respect of refusals to license in the context of the Australian medical biotechnology industry. The third is to establish a flexible framework for the application of competition law to refusals to license patents. The fourth is to critically analyse the likely application of s 46 of the *TPA* to refusals to license medical biotechnology patents, and then consider whether this application is likely to accord with the framework. The basis of this analysis is to enable consideration of whether the framework provides a justifiable foundation for dealing with unilateral refusals to license patents, and accordingly whether the legislative requirements delineated in 46 adequately address this issue.

RESEARCH METHODOLOGY

The aims of this thesis are first pursued by examining the specific characteristics of biomedical research. The purpose for undertaking this analysis is to demonstrate that

---

[32] See, eg, details on Glaxo SmithKline's research program, <http://www.science.gsk.com/research/index.htm> at 19 July 2005.

[33] Different forms of refusals to license are explained below, 3.6. This thesis will use the term 'refusals to license' to refer to unilateral refusals to license patents, except where otherwise stated.

the preconditions for restrictions on access exist in biomedical research. This analysis forms the basis for analysis of the results of an empirical study co-conducted by the author. A detailed methodology in respect of this empirical study is contained in Appendix 1 to this thesis.[34]

Chapter 1 examines the structure of the medical biotechnology industry. This structure has evolved to enable industry participants to take advantage of the many research and development opportunities available in biomedical research, and is typified by small, niche companies involved in specific areas of research within the product pipeline. Commercialisation of these research results through patent protection has become standard practice. Consideration of the structure of the industry is important within the context of the intellectual property/competition law debate, because it can have implications for levels of innovation within the market. Structure is a primary determinant of market conduct. Correspondingly, the regulation of the conduct of markets through competition law impacts on performance within markets. Accordingly, concentration levels within markets and the ability with which companies within those markets are able to compete will be an important variable in regulatory policy making.

Chapter 2 of the thesis focuses on statutory patent law requirements with specific application to biomedical research. It considers the scope of medical biotechnology patents in light of these requirements, and goes on to discuss exploitation of those patents. A large number of patents are being granted and many of these patents are broad in scope. This increases the possibility that they will be used anti-competitively. Chapter 2 therefore sets up the bounds of patentability and points out the freedom a patent holder has to deal with a granted patent.

Chapter 3 examines one of the primary methods of exploiting a patent, that of licensing. The necessity for licensing arises from the cumulative structure of biomedical research, which, as discussed in Chapter 1, has led to the evolution of various 'niche' companies to take advantage of the many research and development opportunities that exist on the path to biomedical product development. Patenting of research results at all stages of this research and development continuum means that licensing is an increasingly important method of transferring technology and enabling follow-on research and development. Bargaining breakdowns therefore have the potential to hinder innovation. Competition law is one of several methods of

[34] This methodology was published as part of the Nicol and Nielsen study, above n14. The portions of the study methodology extracted and reproduced in Appendix 1 to this thesis were written solely by the author.

regulating licensing breakdowns in certain circumstances, and in particular of compelling licensing where a licence is refused. This chapter therefore examines whether the structure of research and technology transfer patterns within the industry are conducive to bargaining breakdown and sets up the basis for a fundamental debate on the divide between intellectual property and competition law in biomedical research. As this chapter will demonstrate, it is the structure of research within this industry that makes it an example of an industry that is particularly vulnerable to contractual breakdowns, rendering consideration of it in terms of the intellectual property/competition law interface particularly valuable.

The discussion in the first three chapters is built on in Chapter 4 by considering empirical evidence of refusals to license patents within medical biotechnology. This discussion takes place in the context of data on the Australian industry, and reference is made to studies in other jurisdictions for comparative purposes. The data will demonstrate that results from Australian and comparator jurisdictions are closely aligned. The fundamental question considered in this chapter is whether the medical biotechnology industry in Australia is experiencing problems due to refusals to license technology required to conduct research, or whether the market is finding solutions in instances where this does or would occur. The data enables consideration of the difficult issue of whether competition law is necessarily to regulate the exploitation of biomedical patents, and compel licensing where licences to patents necessary for follow-on innovation are refused.

Chapter 5 provides an assessment of the manner in which refusals to license patents are treated under Australian competition law, and competition law within the US and EU. It then considers how Australian competition law should regulate refusals to license. This analysis is initially general in that the theoretical issue of the intellectual property/competition law interface is discussed, and the specific issue of refusals to license is then considered. The chapter concludes by proposing the establishment of a framework for dealing with refusals to license, and adherence to this framework in circumstances where legal consideration of the implications of a refusal to license is required. As this chapter will outline, s 46 of the *TPA* will be the primary provision considered under Australian competition law in an instance where a patent licence is refused. The remainder of the thesis will provide detailed consideration of whether the framework outlined in this chapter is likely to be adequately adhered to under jurisprudential principles established in relation to s 46.

Chapter 6 considers in some detail the elements of s 46 and the manner in which the application of these elements has been interpreted as a result of recent Australian High Court decisions. It will be argued that two of the elements of s 46 have been

interpreted in a potentially restrictive fashion, and that as a result contraventions of the provision will be extremely rare. Despite a considerable body of recent case law dealing with s 46, however, interpretation of the provision remains subject to some degree of uncertainty. Moreover, Australian case law dealing specifically with refusals to license patents is lacking, and these factors render it difficult to evaluate precisely how this issue is likely to be resolved under s 46.

An evaluation of US and EU case law dealing with that topic therefore forms the basis for Chapter 7 in that a consideration of this case law may provide some assistance by determining whether a refusal to license a patent is likely to be treated in accordance with the framework presented in Chapter 5, within those jurisdictions. There is no case law dealing specifically with refusals to license in the context of biotechnology patents, but the discussion in this chapter goes on to consider whether the principles enunciated as a result of existing case law are generalisable, and consequently applicable to refusals to license medical biotechnology patents.

Chapter 8 then analyses in some detail how the elements of s 46, as currently interpreted, would likely apply to refusals to license medical biotechnology patents, drawing on the discussion in Chapter 6, and the principles discussed in Chapter 7 where appropriate. To conclude the chapter, an assessment of the likely adherence of such application to the framework identified in Chapter 5 is made.

In the concluding chapter some policy implications of the discussion that takes place in the preceding chapters are stated. The general conclusion drawn is that there is no evidence that indicates that it would be appropriate for refusals to license patents to be exempt from s 46 of the *TPA*. Instead, it is entirely appropriate that analysis of refusal to license cases be subject to the competition law provisions and proceed on a case-by-case basis. In most cases where this occurs, competition law, via s 46, will deal adequately with the issue of refusals to license patents in medical biotechnology. This is because a vast majority of refusals to license are not, and should not be found to be, anti-competitive.

Moreover, empirical evidence in respect of the medical biotechnology industry, an industry particularly prone to bargaining breakdowns, has exhibited limited evidence of problems arising due to refusals to license patents. Despite this evidence, however, there is still significant potential for refusals to license patents to impact negatively on innovation in an industry such as medical biotechnology. In a small number of cases a refusal to license a patent will have the potential to be anti-competitive and recourse to competition law should be possible. It is unlikely, however, that such a contravention would be found on current interpretations of the section. Accordingly,

this chapter makes some conclusions and recommendations in relation to s 46 and future directions for empirical research in the area.

SCOPE

In addressing the aims of this thesis, certain boundaries have been adhered to. *First*, there is some comparative material presented in this thesis, but this thesis does not attempt a comprehensive comparative study. Instead, United States and European Union jurisprudence are considered because these bodies of law are likely to be taken into account in the event that the issue arises for consideration by Australian courts. Each of these jurisdictions has a substantial body of relevant case law. These jurisdictions also constitute major biotechnology markets for Australian researchers.[35]

Secondly, the thesis deals with only one form of intellectual property, that being patents. The issues that arise in this thesis may be generalisable in some respects to other forms of intellectual property that may be applicable to biotechnology, in particular, to copyright, plant breeders rights, and trade secrecy.[36] The thesis makes no attempt to discuss these other forms of intellectual property in any detail, except to the extent that they are relevant to issues relating to patents and competition law. In particular, there is some discussion of copyright in the case law that is the focus of Chapter 7, including some evaluation of the import of case law concerning refusals to license copyrighted material, to refusals to license patents. However, except to highlight the likely impact of this body of law on refusals to license patents, there is no detailed analysis of issues relating to copyright or other forms of intellectual property.

Finally, there is no attempt to undertake a detailed historical analysis of competition law in Australia and its application to intellectual property dealings. Instead, the thesis aims to examine a practical issue on the basis of the law as currently drafted.

---

[35] Note that the issue has also been considered in New Zealand in the context of s 36 of the *Commerce Act* 1986 (NZ) (*the Commerce Act*). Section 36 is drafted in similar terms to s 46. The Commerce Act also contains some exemptions for intellectual property dealings. Space constraints do not permit a detailed discussion of the implications of these provisions for the purpose of the issues discussed in this thesis. In addition, there is no relevant case law dealing with refusals to license under the Commerce Act. For a discussion on refusals to license intellectual property in the context of s 36 of the Commerce Act, see, eg, Abraham I van Melle, 'Refusals to License Intellectual Property Rights: The Impact of *RTE v EC Commission* (*Magill*) on Australian and New Zealand Competition Law' (1997) 25 *Australian Business Law Review* 4.

[36] See above n1.

TERMINOLOGICAL ISSUES

Although competition law is a generic international term, in other jurisdictions discussed in this thesis, the corresponding term used for regulation of competition issues is antitrust, and the terms are to some degree used interchangeably. It is acknowledged that there are important differences between the terms, and these can be attributed mainly to jurisdictional diversity in competition regimes.[37] However, the term antitrust is used as a synonym for the term competition law in this thesis.

There is also some reference during the course of the thesis to patent 'monopolies'. 'Monopoly' in this sense is simply intended to convey that a patent grants the right to exclude others. Usage of this phrase in commonplace and its use in this thesis is not intended to suggest that a patent automatically grants an economic monopoly. On the contrary, in a majority of cases a patent will not give rise to an economic monopoly, and so will not give rise to competition law issues.

The focus of this thesis is on patent protection, but some general references to 'intellectual property' are made throughout the course of the thesis. In particular, Chapter 5 contains some general discussion on the interaction between intellectual property and competition law, and references in this chapter to intellectual property are, for the most part, general references. Further, given that Chapter 7 contains discussion of some specific case law dealing with refusals to license copyrighted material, and as such, distinction is made in this chapter between particular forms of intellectual property. [38]

---

[37] Hovenkamp, Lemley and Janis, above n2, vol II, ch 45, especially [45.3b].

[38] Some material presented in this thesis has been published previously, either in its current form, or as a previous version. See Dianne Nicol and Jane Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347; Jane Nielsen 'Biotechnology Patent Licensing Agreements and Anti-Competitive Conduct' in Centre for Law and Genetics (ed) *Regulating the New Frontiers: Legal Issues in Biotechnology*, Centre for Law and Genetics Occasional Paper No 4 (2001) 35; Jane Nielsen and Dianne Nicol, 'Pharmaceuticals and Patents: The Conundrum of Access and Incentive' (2002) 13 *Australian Intellectual Property Review* 21; Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6; Jane Nielsen, 'Reach-Through Rights in Biomedical Patent Licensing: A Comparative Analysis of their Anti-Competitive Reach' (2004) 32 *Federal Law Review* 169; Jane Nielsen and Dianne Nicol, 'Gene Patenting and Human Health: The ALRC's Report on Genes and Ingenuity' (2005) 20(10) *Australian and New Zealand Trade Practices Law Bulletin* 153; Dianne Nicol and Jane Nielsen, Dianne Nicol and Jane Nielsen 'Australian Medical Biotechnology: Navigating a Complex Patent Landscape' (2005) *European Intellectual Property Review* (forthcoming).

All of the material extracted from these papers and presented in this thesis is solely the work of the author.

CHAPTER 1

THE STRUCTURE OF THE MEDICAL BIOTECHNOLOGY INDUSTRY

1.1 INTRODUCTION

> Industries vary in the speed and cost of research and development ..., in the ease with which inventions can be imitated by others, in the need for cumulative or interoperative innovation rather than stand alone development, and in the extent to which patents cover entire products or merely components of products.[1]

This comment was made in the context of the technology-specific application of patent law to various areas of technological innovation.[2] The purpose of patent protection is the production of innovative benefits. Parallel issues exist, however, in respect of the application of competition law to transactions involving inventions protected by patents. Determining the bounds of privileges granted by patents inevitably involves complex considerations. Disparities between industries serve to intensify these difficulties, because the extent to which patent holders may exercise their right to exclude may vary depending on the particular form of invention protected by patent and the impact that invention is likely to have on future research.

Australia is typical of many developed nations in that the Australian government is endeavouring to promote the medical biotechnology industry and substantial public funding has backed this support for the industry. While the devotion of public funding is commendable, no effort has yet been made to determine the market structure most conducive to innovation, and the level of regulation desirable in respect of competition law. Patent protection invariably results in technological concentration, and it is possible that increased levels of concentration may have an adverse effect on innovations. This chapter will ultimately consider evidence on the benefits of concentrated as opposed to competitive market structures.

In order to discuss the broader issue of the interaction of intellectual property and competition law within the Australian medical biotechnology industry, it is important to first map a number of factors relevant to research and development within that industry. The first is the structure of the industry, together with the associated issue of the effects of patenting within the industry, both internationally and in Australia. The second is the patentability and exploitation of biomedical inventions within that broader context. The third stage of this mapping process is to consider the incremental or cumulative pattern of research evident within the medical biotechnology industry

---

[1] Dan L Burk and Mark A Lemley, 'Policy Levers in Patent Law' (2003) 89 *Virginia Law Review* 1575, 1577.

[2] Ibid.

and its implications for future generations of research and development.[3] This chapter undertakes the first of these tasks, while Chapters 2 and 3 deal with the second and third respectively. Chapter 4 then considers whether there is empirical evidence to support any theoretical contention that refusals to license are hindering downstream research.

This chapter will consider the emphasis that has been placed on the development of a sustainable biotechnology industry in Australia at government level, and some trends impacting on modern biomedical research and the push to commercialise the products of that research. A number of government-sponsored reports that have examined the evolution of the industry will be referred to, as these reports assist in drawing a picture of the focus on development of this industry in Australia. It will then consider the structure of the medical biotechnology industry, both internationally and in Australia, and illustrate patenting trends within the industry. The aim of this chapter is to provide some background into the evolution of the industry, and a brief explanation of how research patterns within the industry have impacted on the structure of the industry.[4] The chapter will conclude by discussing studies that have sought to identify the relevance of market structure to innovation, and considering the desirability of concentration through patent protection in the context of biomedical research. This will lead into the deliberation in later chapters, of the role of competition law in curbing the monopolistic practices of biomedical patent holders to promote innovation.

1.2 BIOMEDICAL RESEARCH IN AUSTRALIA

Basic biomedical research has traditionally been undertaken primarily by the public sector. This seems certain to change forever as industry acts to capitalise on huge profits perceived to be available from post-genomic biotechnology research and product development.[5] Public sector research institutions are increasingly involved in applied research. Conversely, private companies are engaging in what would traditionally be defined as basic research. There is no doubt, however, that companies

---

[3] Cumulative research was defined in the Introduction to this thesis at n5. The nature of 'cumulative' research will be discussed in detail in Chapter 3.

[4] Although this thesis refers generally to 'companies', a number of studies referred to in this chapter make reference to 'firms'. This terminology will therefore be utilised from time to time in this and subsequent chapters, although it is recognised that this term is wider than 'companies'. Accordingly, it is not intended that 'firm' be used as a synonym for 'company'. It is recognised that this term encompasses company structures.

[5] See further below, 1.4.

within the biotechnology industry remain heavily dependent on research institutions for the provision of a significant amount of basic research output.

Australian health and medical research has a rich and proud history. This has been recognised in numerous federal government reports, which have examined the sustainability of research momentum and the ability of the Australian industry to capitalise on this research.[6] In a major review of the operation of the healthcare and medical sector in Australia, the Federal Government's *The Virtuous Cycle-Working Together for Health and Medical Research: Health and Medical Research Strategic Review*, (the Wills Review) the importance of the biotechnology industry was recognised, and it was predicted to be '...the next revolution beyond the information revolution'.[7]

It also stressed the importance of Australia's participation in this revolution, recognising that '...biotechnology has potential applications not only in the prevention, diagnosis and treatment of disease, but also in the environmental, agricultural, and manufacturing sectors.'[8] Australia's increasing $1 billion trade deficit in pharmaceuticals, medical equipment and other health and medical industries was also a major impetus for the push for the development of Australia's medical research base by the Wills Review.[9] It was considered that the opportunities available to the Australian pharmaceutical and biotechnology industries to develop and export intellectual property could assist in reducing this deficit.[10] Elsewhere, the Federal Government has stated its vision for biotechnology as:

> Consistent with safeguarding human health and ensuring human health and ensuring environment protection, that Australia capture the benefits of technology for the Australian community, industry and the environment.[11]

---

[6] See Commonwealth of Australia, *The Virtous Cycle-Working Together for Health and Medical Research, Health and Medical Strategic Review*, (1999); Biotechnology Australia, Commonwealth of Australia, *Australian Biotechnology: A National Strategy*, (2000) (the National Strategy); Biotechnology Australia, Commonwealth of Australia, *Developing Australia's Biotechnology Future: Discussion Paper* (1999) (Developing Australia's Biotechnology Future); Commonwealth of Australia, *Review of Business Taxation: A Tax System Redesigned: Final Report* (1999). See also Commonwealth of Australia, *Backing Australia's Ability: An Innovation Action Plan for the Future* (2001).

[7] Wills Review, above n6, 25.

[8] Ibid, 25.

[9] Ibid, 126-7.

[10] Ibid.

[11] The National Strategy, above n6 at 7.

From a consumer perspective, biotechnology offers major benefits in terms of development of new and improved drugs, therapies and methods of diagnosis, and opportunities for containing health-care costs. From an industry perspective, many domestic and export market opportunities for small and medium-sized, as well as large companies exist. Biotechnology also offers opportunities for environmental management.[12]

The Wills Review recognised that Australia has the undisputed capacity to succeed in biotechnological development based largely on its fundamental research base.[13] Australia's health and medical research output per capita exceeds the level that would be expected given Australia's population size, and citation levels exceed the world average in the area of public health and clinical research.[14] The Wills Review did, however, warn against complacency, and indicated that the industry's momentum was threatened by a number of factors including most notably:

- declining public and industry financial support for the industry;
- fragmented state-based support networks for the industry; and
- inadequate grants systems.

The Wills Review called for action to address these factors and highlighted strategies available to a number of stakeholders: the research sector, the industry (or private company) sector, and government.[15] At the same time, the Wills Review highlighted the need for action on the part of stakeholders to be mutually reinforcing. In particular, it envisaged a role for industry that streamlined technology transfer and new business formation practices, and importantly, stimulated the flow of medium to long-term venture capital.[16]

Both state and federal governments in Australia have been strongly supportive of the emergent biotechnology industry in recent years, principally in terms of assistance in providing capital and infrastructure. The findings of the Wills Review prompted the

---

[12] See generally The National Strategy, above n6; Developing Australia's Biotechnology Future, above n6, i; Prime Minister's Science, Engineering and Innovation Council, Commonwealth of Australia, *Third Meeting Background Paper, Innovation in Medical Biotechnology* (1999) (Innovation in Medical Biotechnology) <http://www.dest.gov.au/sectors/science_innovation/publications_resources/profiles/medical_biotech.htm> at 30 May 2005.

[13] Wills Review, above n6, 25.

[14] Ibid, 21-22.

[15] Ibid, 3-6.

[16] Ibid, 6-10

allocation by the Federal Government in its 1999 Budget of additional funds to support biotechnology research in Australia, including:

- an increase of AU$614 million to the National Health and Medical Research Council over six years;
- AU$20 million each towards the establishment of research 'centres of excellence', the establishment of a National Institute of Clinical Studies, and capital works for independent health and medical research institutes.[17]

Additional allocations of funds to biotechnology research have since been made, including funding of AU$46.5 million by Biotechnology Australia and the Australian Research Council to assist in the establishment of the Australian Stem Cell Centre.[18]

State governments have also actively promoted their respective industries with significant funding commitments. The Victorian Government, for example, released a Biotechnology Strategic Plan in 2000, which involved commissioning the Biotechnology and Bioscience-Based Industry Report in October 2000.[19] Recognising Victoria's significant biotechnology research base, The Strategic Plan also incorporated funding to establish biotechnology precincts around Victoria's existing research centres.[20] The Queensland Government has implemented a Queensland Biotechnology Strategic Plan,[21] which includes a number of funding initiatives aimed primarily at promoting innovative projects and funding start-up companies.[22] The New South Wales Government also released the NSW Biotechnology Strategy 2001 BioFirst, which has a strong focus on funding and commercialisation assistance.[23]

---

[17] Reported in Innovation in Medical Biotechnology, above n12, 3.

[18] Formerly the National Stem Cell Centre. For details on the Australian Stem Cell Centre see <http://www.nscc.edu.au/ascc_home.html> at 28 July 2005.

[19] BioAccent, *Victorian Biotechnology and Bioscience-Based Industry Report* (2000).

[20] For details see <http:www.bio21.org/> at 24 August 2005.

[21] Queensland Government, *Queensland Biotechnology Strategic Plan 2005-2015: Biotechnology – Setting New Horizons* (2005).

[22] For details on initiatives of the Queensland Government, see (2005) <http://www.sdi.qld.gov.au/dsdweb/v3/guis/templates/content/gui_cue_menu.cfm?id=129> at 28 July 2005.

[23] For details see <http://www.business.nsw.gov.au/key.asp?cid=249> at 28 July 2005.

1.3 THE TRANSLATION OF RESEARCH INTO PRODUCTS: THE PROCESS OF COMMERCIALISATION

Focus on Australia's strong research base has meant increased emphasis on investment in research. The reports discussed above emphasised that promotion of basic scientific excellence in the health and medical area is a priority, but they did not consider the protection of that scientific knowledge in any detail. A focus on capturing and capitalising on the fruits of research has only recently received extensive attention.

Australia has a number of strengths in medical biotechnology, including world class expertise in research, geographical advantages in terms of expanding regional markets, appropriate structures to promote close cooperation between the public and private sectors and an internationally recognised clinical trial system.[24] Despite this, development and commercialisation of scientific discovery has been generally weak.[25] One factor behind this is inadequate management and understanding of intellectual property.[26] Intellectual property protection is crucial to both the research and company sectors, and provides companies with a means to recoup research and development expenditure. In many cases, research is the primary activity of a research institution or company, and intellectual property protection provides a research institution or company with an important (and perhaps their main) business asset.

Increased awareness of intellectual property is evident within the Australian medical biotechnology industry, and has been expressly promoted by the Federal Government.[27] Commercialisation, where appropriate, has been actively encouraged and promoted, particularly in relation to research institutions. For example, the purpose of recently released *National Principles of Intellectual Property Management* of Publicly Funded Research was stated to be as follows:

> the purpose of developing the National Principles of [Intellectual Property] Management for Publicly Funded Research is to assist researchers, research

---

[24] Wills Review, above n6, 12; Developing Australia's Biotechnology Future, above n6, 24.

[25] National Strategy, above n6, 11, 19-20; Wills Review, above n6, 12.

[26] Ibid.

[27] See Biotechnology Australia and Spruson and Ferguson, *Biotechnology Intellectual Property Manual*, (2001); Australian Research Council, The Australian Tertiary Institutions Commercial Companies Association, The Australian Vice Chancellors' Committee, The Department of Education, Training and Youth Affairs, The Department of Industry, Science and Resources, IP Australia and The National Health and Medical Research Council, *National Principles of Intellectual Property Management for Publicly Funded Research*, 2001, (*National Principles of Intellectual Property Management*) < http://www.arc.gov.au/pdf/01_01.pdf> at 18 May 2004.

> managers and their research institutions, in ensuring that they have access to best practices for the identification, protection and management of [intellectual property], and therefore, to maximise the national benefits and returns from public investment in research.[28]

A number of initiatives by the Federal Government to encourage commercialisation of research by the company sector have also been implemented. These include:

- the Biotechnology Innovation Fund making available grants to assist companies in early stage commercialisation;[29]
- the Innovation Investment Fund providing venture capital to early-stage technology companies;[30]
- the R&D Start Program providing support by way of grants to companies;[31] and
- R&D Tax Concessions available for eligible R&D expenditure.[32]

If Australian research institutions and companies are unable to capitalise on their research output, Australia will lose the benefits of the research. The potential for benefits to flow offshore would result in real harm to the Australian industry, as well as the economy and ultimately consumers. It is this threat that has led the Federal Government to promote privatisation of the products of research.

1.4 THE INCREASING PRIVATISATION OF RESEARCH RESULTS

Medical biotechnology in Australia is moving into a newly industrialised phase. This process of industrialisation, is not unique to Australia, but is a global phenomenon that is having three interrelated effects:

- increasingly, collaborative relationships between the public and private sectors are being formed;

---

[28] National Principles of Intellectual Property Management, above n27, 2.

[29] AusIndustry, Fact Sheet: *Biotechnology Innovation Fund*, <http://www.ausindustry.gov.au/content/content.cfm?ObjectID=01A28EB4-A066-4D7E-99AAA16094536488&L2Parent=0786C9BE-08B7-4973-93429A645AEEC8E4&L3Parent=FD34329B-F6F6-4C98-B963D0A59C20A603> at 18 May 2004.

[30] Industry Research and Development Board, AusIndustry, *Annual Report* 2001-2002 (2002), 36-39.

[31] Ibid, 43-48.

[32] Ibid, 51-58.

- universities and research institutions are increasingly seeking to patent their research results;[33] and
- the traditional line between basic and applied science is being blurred.

1.4.1 Collaborative Relationships Within the Biotechnology Industry

The Wills Review highlighted the importance of company involvement in fostering the development of a sustainable health and medical industry, and the relationship between the research and company sectors is clearly an important indicator of the success of the industry. Collaborative relationships between the public and private sectors are crucial for development of research capabilities. A study commissioned by the Australian Research Council (ARC) and the Commonwealth Scientific and Industrial Research Organisation (CSIRO) found that 91 per cent of citations contained in Australian-invented patents, whether those patents were publicly or privately owned, were to public sector science.[34] This study found that public science is clearly a crucial resource for Australian research institutions and companies.[35] Importantly, the effect of these relationships is a marked increase in the tendency to seek patent protection of research results. This tendency has now extended to the public sector.

1.4.2 University and Research Institution Patenting of Research Results

Concomitant with the growth of these collaborative relationships, research institutions are being encouraged to commercialise their research results. The Federal Government has clearly demonstrated a pro-commercialisation policy in respect of publicly funded research.[36] In order to assist research institutions in commercialisation

---

[33] On university patenting of research results, particularly in relation to biomedicine see, for example, David C Mowery, Richard R Nelson, Bhaven N Sampat and Arvids A Ziedonis, 'The Growth of Patenting and Licensing by US Universities: an Assessment of the Effects of the *Bayh-Dole Act* of 1980', (2001) 1(30) *Research Policy* 99, 104, 110-116.

[34] CHI Research Inc, *Inventing Our Future: The Link Between Australian Patenting and Basic Science* (2000) (CHI Report) at 59.

[35] Ibid, 59-62.

[36] This trend is even more pronounced in the US where the patenting of university and other federally funded research is encouraged by statute, particularly the *Bayh-Dole Act* 35 USC §§200-211 (1980). On thse increased rate of patent filings in the US from publicly funded institutions, see Rebecca Henderson, Adam B Jaffe and Manuel Trajtenberg, 'Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting 1965-1988, (1998) 80 *Review of Economics & Statistics* 119. Patenting in the area of biomedicine has dominated; Mowery and Others 2001, above n33, 104, 110-116. Note, however, that US universities continue to patent far less than their industry counterparts despite generating more genetic discoveries; Michelle R Henry, Mildred K Cho, Meredith A Weaver and Jon F Merz, 'DNA Patenting and Licensing' 297 *Science* 1279 (2002).

activities, the *National Principles of Intellectual Property Management* lay down a number of principles intended to streamline and facilitate the process of commercialisation of publicly funded research.[37] The *National Principles of Intellectual Property Management* state that research institutions will have procedures that provide support to publicly funded researchers to assist them in recognising when their discoveries may have potential commercial value.[38] They also call for research institutions to implement a review process to identify intellectual property that can be protected and/or exploited.[39]

Ownership of intellectual property in the course of publicly funded research raises certain issues that may impede the process of protection and exploitation of intellectual property.[40] Ownership of intellectual property is generally governed by common law, the fundamental position being that employers will have a right of ownership over any intellectual property generated by employees during the course of their employment.[41] In particular instances this position may be modified through provisions in an employment contract to vest ownership rights in employees. Particular issues arise in research institutions in relation to students conducting research, as students are not covered under the common law principle. The *National Principles of Intellectual Property Management* state that research institutions receiving public funding should have clear policies and agreements in place regarding ownership of intellectual property generated during the course of a student's study, research and training.[42]

The *National Principles of Intellectual Property Management* require public funding bodies to have clear policies on whether they will claim any ownership and/or associated rights for intellectual property generated from research supported by

---

[37] *National Principles of Intellectual Property Management,* above n27. As to the adequacy of the *National Principles of Intellectual Property Management,* see, Andrew F Christie, Stuart D'Aloisio, Katerina L Gaita, Melanie J Howlett and Elizabeth M Webster, Commonwealth of Australia, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Institutions* (2003) (Christie and Others, *Patent Ownership in Publicly Funded Institutions*), 78-89. See also David Nyskohus, Ee-Ling Then, Paul Nicoll, Commonwealth of Australia, *Intellectual Property Policies and Practices in Commonwealth Agencies,* (2004).

[38] *National Principles of Intellectual Property Management,* above n27, Principle 1.

[39] Ibid.

[40] See generally Christie and Others *Patent Ownership in Publicly Funded Institutions,* above n37, Chapter 1.

[41] See especially, *Triplex Safety Glass Co v Scorah* (1938) 55 RPC 237; *Victoria University of Technology v Wilson and Others* [2004] VSC 33.

[42] *National Principles of Intellectual Property Management,* above n27, Principle 4.

them.[43] It is probably the case that public funding institutions would ordinarily have rights of ownership of intellectual property generated by research institutions as a result of funding provided by them. However, the main national funding bodies, the ARC and the National Health and Medical Research Council (NHMRC) have indicated that it will not be their policy to claim such rights.[44]

Finally, the *National Principles of Intellectual Property Management* state that research institutions and individual researchers are expected to consider the most appropriate way of exploiting intellectual property once protected, with each case to be considered on an individual basis.[45]

Subsequent to the release of the *National Principles of Intellectual Property Management*, the NHMRC issued a set of interim guidelines on intellectual property management during the course of research funded by it (the Interim Guidelines).[46] The Interim Guidelines emphasise the importance of a focus by funding recipients on intellectual property management for its processes of grant, report and review.[47] The Interim Guidelines make specific reference to patents, and the importance of patent protection in particular areas of medical research including blockbuster drugs and developments, and biotechnological research tools '...such as antibodies, probes, cell lines etc'.[48]

With regard to patent activity, Commonwealth agencies and publicly funded research institutions performed soundly in the period 1995-2000 in a diverse range of technology areas, but particularly in the biotechnology and pharmaceutical categories[49] Research institutions and other publicly funded bodies are actively involved in patenting the results of their publicly funded research.[50]

---

[43] Ibid, Principle 1.

[44] Ibid, 5.

[45] Ibid.

[46] National Health and Medical Research Council, *Interim Guidelines: Intellectual Property Management for Publicly Funded Research* (2001) (Interim Guidelines).

[47] Ibid, 3.

[48] Ibid, 2. The definition of 'research tools' in biomedical research has been contentious. Biotechnology research tools are the technological developments and products that enable subsequent lines of biotechnology research to be pursued. The term 'research tool' can be defined either narrowly or broadly, and varying interpretations of the term have been made. This issue is examined in more detail in Chapter 4 in the context of the empirical evidence. In this thesis, a broad definition of the term will be employed, so that any research input would be classed as a 'research tool'; see further, 4.3.1.

[49] CHI Report, above n34, 36-7, Table 4 and Table 5. See further below, 1.7.

[50] Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, (Nicol and

1.4.3 A NEW RESEARCH LANDSCAPE: THE MERGING OF BASIC AND APPLIED SCIENCE[51]

The line between basic, or fundamental research, and applied research (or what may loosely be termed downstream research) has blurred. Research institutions increasingly seek to undertake more applied, later-stage research. Increasingly, patents are being sought by both public and private institutions to protect their research results.[52] There has also been a preponderance of commercial biotechnology company start-ups in market niches between fundamental academic research and end product development. These firms are heavily reliant on licensing income from patents that are useful as inputs into subsequent research that may ultimately lead to product development.[53]

There has been considerable commentary on the decreasing divide between publicly funded research and privately funded research as companies move to fill the gap brought about by funding shortfalls in research activity and commercialisation.[54] To this end, there has been a marked increase in the amount of basic biotechnological science generated by private funding. Research has demonstrated the increasing convergence between commercial enterprises and publicly funded institutions highlights the important role of private funding.[55] In Australia, private companies are sponsoring an increasing amount of basic research,[56] although at present a majority of research performed by research institutions in Australia is still publicly funded.[57]

Nielsen Study) 125-6; Australian Law Reform Commission, Parliament of Australia, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99 (2004) (ALRC Report), 348-358.

[51] The term 'basic' research has been generally defined as research directed toward expanding human knowledge. The term 'applied' research has been generally defined as research directed toward solving practical problems; see Rebecca S Eisenberg, 'Proprietary Rights and the Norms of Science in Biotechnology Research' (1987) 97 *Yale Law Journal* 177, her n1.

[52] See Walter W Powell and Jason Owen-Smith, 'Universities and the Market for Intellectual Property in the Life Sciences' (1998) 17(2) *Journal of Policy Analysis and Management* 253-277.

[53] This issue will be considered further below, 1.6.

[54] See, eg, Rebecca S Eisenberg and Richard D Nelson, 'Public vs. Proprietary Science: A Fruitful Tension?' *Academic Medicine* 77 (2002): 1392.

[55] David Blumenthal, Nancyanne Causino, Eric Campbell and Karen Seashore Louis, 'Relationships Between Academic Institutions and Industry in the Life Sciences – An Industry Survey', (1996) *New England Journal of Medicine* 368. This study found that over 90 percent of life science companies in the United States are engaged in collaborations of some kind with academic institutions, with two thirds of surveyed companies expecting their support of life science research to increase; at 369-370. See also Walter W Powell, Kenneth W Koput and Laurel Smith-Doerr, 'Interorganizational Collaboration and the Locus of Innovation: Networks of Learning in Biotechnology' (1996) 41 *Administrative Science Quarterly* 116-145.

[56] See Nicol and Nielsen Study, above n50, 94-99.

[57] ALRC Report, above n50, 276-278.

The new research landscape is one in which open science plays a diminished role.[58] The HGP culminated in a race by the public sequencing effort against the efforts of private companies. Post-genomic research continues in the same vein. Against this competitive backdrop, both research institutions and private companies alike are seeking patents over a broad spectrum of research results. Considerable commentary has been devoted to the effects of the increasing privatisation of basic research amid concern that this privatisation has the effect of eroding the norms or values considered to have been traditionally embraced by the scientific community in the pursuit of openness.[59]

Medical biotechnology research is populated by scientists who are concerned with both the pursuit of fundamental knowledge and the solution of practical problems.[60] This represents a departure from the traditional distinction between standard analyses that place basic and applied science at opposite ends of a linear spectrum.[61] The challenge is to '...devise arrangements that preserve the great advantages of an open system for basic science while still preserving profit incentives for the creation of valuable new products.'[62]

At certain points in the duration of the HGP, the private sector has played some part in promoting open science, with, for example, Merck's sponsorship of a public cDNA sequencing effort with results to be placed in a publicly available database,[63] and the formation of the SNPs Consortium by pharmaceutical companies in conjunction with the Wellcome Trust Foundation for the purpose of identifying and disclosing SNPs in the public domain.[64] These incentives are aimed at promoting the accessibility of upstream technologies, but support the commercialisation through patenting of

---

[58] See Robert K Merton, The Normative Structure of Science, in Robert K Merton (ed), *The Sociology of Science: Theoretical & Empirical Investigation* (1973) 267. See also, eg, Warren Hagstrom, *The Scientific Community* (1965).

[59] See, for example, Eisenberg and Nelson, above n54; Rebecca S Eisenberg, 'Intellectual Property at the Public-Private Divide: The Case of Large-Scale cDNA Sequencing' (1996) 3 *University of Chicago Law School Roundtable* 557; Rebecca S Eisenberg and Robert P Merges, 'Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences' (1995) 23 *AIPLA Quarterly Journal* 1.

[60] Donald Stokes coined the term 'Pasteur's Quadrant' to describe research that combines the pursuit of basic knowledge and the quest for technological innovation; see Donald E Stokes, *Pasteur's Quadrant: Basic Science and Technological Innovation* (1997). This concept is discussed in Eisenberg and Nelson, above n54.

[61] Eisenberg and Nelson, above n54, 1393.

[62] Ibid, 1394.

[63] See Eliot Marshall, 'A Showdown Over Gene Fragments' 266 *Science* (1994): 208, 210.

[64] See Francis S Collins, Mark S Guyer and Aravinda Chakravarti, 'Variations on a Theme: Cataloguing Human DNA Sequence Variation' *Science* 278 (1997): 1580.

downstream products resulting from research using these technologies.[65] Private incentives may be as effective as public incentives in achieving an appropriate balance between intellectual property and the public domain.[66]

The strict dichotomy between basic and applied research is clearly unsustainable in any industry such as biotechnology where the two converge. However, the difficulty of pinpointing exactly where in the research spectrum privatisation may have a chilling effect on innovation results in many policy challenges.[67] Patenting allows the recovery of research and development expenditure, and product development. It has the potential to strengthen the development of the medical biotechnology industry, because it facilitates the process of commercialisation. Collaborative arrangements between the public and private sectors may also be beneficial where they assist the development and transfer of technology.

1.4.4 SUMMARY

An important aspect of the medical biotechnology industry is the tendency of both research institutions and private companies to patent research results. This trend has been driven in part by government initiatives to promote commercialisation, and in part by the requirements of capital markets. The nature of biomedical research and the push to commercialise research have impacted on the structure of the industry. At the same time, the structure of the industry will have a consequent impact on the transfer of patented technology. This has resulting implications for competition law, as it raises questions as to whether competition law has a role to play in regulating dealings in intellectual property.

---

[65] The emergence of private incentives to promote access to research results and materials has led some commentators to urge that consideration be given to achieving this balance by using legal change to reinforce efficient research norms that emerge within the research and commercial communities; See Arti K Rai, 'Regulating Scientific Research: Intellectual Property Rights and the Norms of Science' (1999) 94 *Northwestern University Law Review* 77.

[66] A number of government incentives aimed at reinforcing scientific openness in biomedicine have met with limited success. See, eg, National Institutes of Health, Basic Guidelines for the Transfer of Research Tools To and From Recipients of NIH Funds in National Institutes of Health, Report of the National Institutes of Health Working Group on Research Tools (1998), Appendix A. See also Organisation for Economic Cooperation and Development, *Draft Guidelines for the Licensing of Genetic Inventions*, (1 February 2005) <http://www.oecd.org/document> at 22 June 2005. See further below, 4.2.2.2.

[67] Eisenberg and Nelson, above n54.

1.5 INDUSTRY STRUCTURE

Assessing the structure of an industry assists in considering the effects of patent protection on innovation within that industry. This section will consider the structure of the biomedical industry, both internationally and in Australia. A consideration of industry structure is important in four related but distinct contexts:

- the Australian Government has demonstrated a clear imperative in terms of advancing the Australian biomedical industry. Regulation of the operation of the industry may be important to the development and sustainability of a viable and vibrant industry.[68]
- the size and types of companies and institutions operating in the industry drive the levels of patent contracting activity engaged in by both Australian and overseas market participants;
- the cumulative structure of the industry has implications for follow-on research;[69]
- market structure as an aspect of the study of industrial economics is important in analysing the behaviour of market participants.[70] The structure of a particular industry is one of the main determinants of competition within a market; and

Important issues arise in respect of the impact of levels of competition in a market on levels of innovation. It is therefore necessary to consider whether the industry is one that can be characterised as diffused, with each sector of the industry operating individually, or whether it is relatively concentrated. This section will demonstrate that the private sector of both the global and Australian biotechnology industries were originally characterised primarily by a large number of small entities. Although small companies and research institutions still dominate the market, there has been a

---

[68] Industrial economics is a useful tool for the formulation of policy toward the regulation of the conduct of participants within industries. For a discussion on the competing schools of economic thought that have formed the basis for (inter alia) competition policy, see Stephen G Corones, *Competition Law in Australia* (2004), 20-35. The main schools of thought are the mainstream school and the Chicago school, although recently there has been a shift from these fairly simplistic models to more complex models; see below, 1.8.

[69] This issue will be the subject of Chapter 3.

[70] Industrial economics examines the behaviour of companies within an industry in respect of matters such as pricing decisions, and the number and size of companies within an industry; see, for example, Frederic M Scherer and David Ross, *Industrial Market Structure and Economic Performance* (1990), 2 ('we seek to ascertain how market processes direct the activities of producers in meeting consumer demands, how those processes can break down, and how they adjust, or can be adjusted, to make performance conform more closely to some ideal standard').

sustained period of increased concentration resulting in increasing numbers of large, vertically integrated organisations.

1.5.1 The Structure Of The International Biotechnology Industry

Since the commencement of the Human Genome Project (HGP), the biotechnology industry has very broadly encompassed the following companies and institutions:

- pharmaceutical companies (focusing largely on targeted drug discovery);
- core biotechnology companies;
- genomic companies; and
- research institutions.

Regional sectors of the international industry are primarily comprised of core biotechnology companies,[71] which are mainly small or medium sized enterprises. A small number of large core biotechnology companies are active in the industry, as well as most of the multinational pharmaceutical companies. Although genomic companies are classified as core biotechnology companies, the focus of their business has traditionally differed to that of other core biotechnology companies in that their emphasis is on sequencing and their products are research tools. In addition, research institutions are important in the process of performing basic research and producing research tools, and providing enabling technology to core biotechnology companies.

The high costs of research and development are forcing many small companies to concentrate available resources into more narrowly defined research areas identified because of their potential for real therapeutic advantage and shorter development times. Reliance on the success of one product puts companies in jeopardy if the product fails. At the same time, it is becoming increasingly difficult to accurately characterise individual companies by their research interests because of a growing trend for them to expand into other categories. The sequencing companies, for example, who could be traditionally described as genomics companies, are now engaged in more downstream research, primarily drug discovery. Incyte now describes itself as a drug discovery company, with three significant internal research

[71] Core biotechnology companies are companies whose business is entirely or substantially biotechnology related: See Ernst & Young, *Australian Biotechnology Report* (1999) (Ernst & Young, *Australian Biotechnology Report*), 5; *Wills Review* above n6 at 131. The definition of 'core' biotechnology includes all biotechnology-related applications including agricultural and industrial, therefore figures reported in the following sections on numbers of biotechnology companies encompass applications other than human health.

programs underway.[72] Celera is involved in drug discovery and the development of therapeutics and diagnostic tests.[73] Thus, while the research taxonomy described above provides a useful means of identifying the principal activities of research institutions and companies, they will often fall into more than one category.

1.5.2 CHARACTERISTICS OF THE INTERNATIONAL INDUSTRY

The industry in the United States is well established. It comprises small recently established core biotechnology companies, and more established larger companies that have made biotechnology part of their portfolio.[74] By 2005 the number of core biotechnology companies in the US was estimated to have increased to 1 473 companies.[75] Research and funding institutions are an important component of the United States industry.[76]

The structure of the dominant United States industry has provided a model for the industry in other regions, including the European industry.[77] Initially, core

---

[72] 'Company Profile for Incyte Corporation' *Press Release*, 7 November 2003 <http://investor.incyte.com/phoenix.zhtml?c=69764&p=IROL-NewsText&t=Regular&id=467793&> at 1 June 2005. Incyte is also involved in extensive licensing of its patents and in collaborative arrangements.

[73] See generally Celera's website <http://www.celera.com/> at 2 June 2005.

Human Genome Sciences, another company initially involved in sequencing, now states that its goal is to '...build a global biopharmaceutical company that discovers, develops, manufactures and markets gene-based protein and antibody drugs to treat and cure diseases.'; < http://www.hgsi.com> at 6 June 2005.

[74] A survey of the United States biotechnology industry conducted by the United States Department of Commerce indicated that 72 per cent of respondents reported their primary activity as being human health applications; United States Department of Commerce, *A Survey of the Use of Biotechnology in US Industry* (2003) 24-27.

[75] Biotechnology Industry Association, Biotechnology Industry Statistics <http://www.bio.org/speeches/pubs/er/statistics.asp> at 1 June 2005. The number of publicly held companies was reported to be 314.

[76] See, eg, Joseph Cortright and Heike Mayer, *Signs of Life: The Growth of Biotechnology Centers in the US* (2002).

[77] Note that while this discussion is confined to the structure of the industry in the US, the EU and Australia, the structural trends discussed are also driving the development of the industry in other countries such as Canada. The Canadian industry has seen a recent increase in the level of investment in biotechnology, with the result that the industry is rapidly expanding. See generally Ernst & Young, *Beyond Borders: Global Biotechnology Report 2005* (2005) (Ernst & Young, *Global Biotechnology Report*). In contrast, the industry in Japan differs markedly from these other industry sectors. Small, core biotechnology companies have not traditionally existed in Japan. Rather, the pharmaceutical and health care related companies, and food corporations have tended to diversify into biotechnology; Panos Kanavos, 'Determinants of Market Structure in the International Biopharmaceutical Industry' in Organisation for Economic Cooperation and Development, *Economic Aspects of Biotechnologies Related to Human Health: Part II: Biotechnology, Medical Innovation and the Economy: The Key Relationships* (1998), 53. A government drive to promote biotechnology start-ups could see the Japanese industry take on a structure more akin to that in other countries, Ernst & Young, *Global Biotechnology Report*, 78-79.

biotechnology companies were a United States phenomenon, but the number in other countries is increasing. In Europe the number the number of companies during 2004-2005 has been reported at 1815.[78] The European industry has recently achieved a scale comparable to the industry in the United States. However, raising capital presents challenges, and a good deal of European investment in biotechnology is generated from the US.[79] Germany boasts the largest number of biotechnology companies with 346 companies, while the United Kingdom (UK) industry reportedly comprises 311 companies.[80]

1.5.3 Trends in the Structure of the International Industry

The structure of the biotechnology industry is not static. The industry in the United States, and to an increasing extent the European Union, is characterised by an increasing number of strategic alliances and mergers. Licensing agreements form the most common type of alliance,[81] although other forms include joint ventures, and research alliances.

Companies and institutions within the industry are involved in alliance and merger activity for a number of reasons. By far the most compelling reason is the high cost of research and development together with the increased marketing power of the allied or merged entity.[82] The industry as a whole is highly research oriented. Financing is difficult for most start-up biotechnology companies, and the high costs of research and development force many companies to either enter into strategic alliances with, or be acquired by, larger biotechnology companies or pharmaceutical companies.[83] In addition, the high technical and commercial risks of product development mean that companies need to share risk and have significant product pipelines. These agreements result in the sharing of intellectual property over genomic information and bioinformatics tools in return for funds for research and development. Indeed, access

---

[78] Ernst & Young, *Global Biotechnology Report*, above n77, 44. The number of publicly held companies was reported to be 98.

[79] Ibid, 47-55.

[80] Ibid, 46.

[81] See, eg, John P Walsh, Ashish Arora and Wesley M Cohen 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in Wesley M Cohen and Stephen A Merrill (eds.), *Patents in the Knowledge-Based Economy* (2003), 322-324; Intellectual Property Institute, UK Department of Trade and Industry, *Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice* (2004) 69; Kanavos, above n77, 51.

[82] See Ernst & Young, *Integration: Ernst & Young's Eighth Annual European Life Sciences Report* (2001) (Ernst & Young, *Integration*), 32.

[83] See Ernst & Young, *Global Biotechnology Report*, above n77, 47-55.

to intellectual property may be a major factor influencing a company's decision to enter into an alliance.

It would appear in the United States at least, that the nature of these strategic alliances is changing. As company executives become more aware of the value of their products, they are tending to develop products to a later stage before entering into alliances, and in some cases are insisting on retaining greater rights to royalties in licence agreements.[84] Technology access agreements have also assumed more importance, with many pharmaceutical and biotechnology companies showing an increased tendency toward obtaining non-exclusive licences to enabling technology.[85]

Multinational pharmaceutical companies are buying up the patents of core biotechnology companies, or entering into agreements allowing them access to the patents of smaller companies.[86] The primary reasons for this trend are considered to be a desire by pharmaceutical companies to increase their product pipelines given that many lucrative, or 'blockbuster' drug patents are about to expire, and the need to maintain revenue growth rates.[87] In line with this trend, a large proportion of the drug targets of many major pharmaceutical firms now come from genomic databases.[88]

The resultant industry structure is characterised by an increasing number of large entities with a portfolio of extensive patents comprising broad, overlapping patents. These may be consolidated entities, or vertically integrated groups of companies and institutions.

1.6 THE AUSTRALIAN INDUSTRY

This section profiles the Australian medical biotechnology industry, highlighting the significant levels of alliance activity being engaged in. While the industry has become

---

[84] Ibid, 31-32.

[85] See, eg, Ernst & Young, *Convergence: Ernst & Young's Biotechnology Industry Report: Millenium Edition* (2000) (Ernst & Young, *Convergence*). 48. An example is provided in the Report: Abgenix has licensed its technology for generating antibody product candidates to numerous biotechnology and pharmaceutical companies, notably Human Genome Sciences. Abgenix retained the right to use the technology, and at the same time has licensed the right to use technology from Human Genome Sciences.

[86] See, eg, Ernst & Young, *Global Biotechnology Report*, above n77, 12.

[87] Ibid. See also Ernst & Young, *Integration*, above n82, 34 for reasons why pharmaceutical firms seek to acquire top tier biotechnology firms.

[88] See, eg, the research profile of Merck, <http://www.merck.com/mrl/research/biology.html> at 28 July 2005.

more established, there is still significant reliance on collaborations with international and Australian companies in all sectors of the Australian industry.

1.6.1 THE SIZE AND COMPOSITION OF THE AUSTRALIAN INDUSTRY

The Australian industry is a small player in the international medical biotechnology industry. Nevertheless, it is evident that the industry is in a growth phase given recent increases in Australia in the number of core biotechnology companies. In 1999 the number of core biotechnology companies was estimated to be 20 listed companies and 100 private unlisted companies.[89] The number was recently estimated to have increased to more than 400.[90]

Most companies are of a relatively small size. There is also some representation by multinational pharmaceutical companies in Australia, such as Glaxo SmithKline, FH Faulding & Co, Novartis and Bristol Myers Squibb. Approximately 50 per cent of biotechnology companies in Australia are involved in biotechnology applications relating to human health.[91] Medical biotechnology companies in Australia are active in a range of research applications, with a majority of companies researching in human therapeutics and diagnostics, and a number of companies involved in drug development.[92] Few companies work purely in genomics and proteomics, although research institutions predominate in this area.[93] Some enabling technology is provided by a small number of biotechnology companies and research institutions.

A number of Australian states and territories have strong research bases. Government sponsored investment has promoted collaboration between the university research bases and infrastructure, and companies with the ability to commercialise products. The importance of the private sector as an investor in publicly researched innovation is well recognised.[94] Often, biotechnology products are commercialised through technology transfer companies associated with the various universities and research

---

[89] Ernst & Young, *Australian Biotechnology Report*, above n71, 10.

[90] Invest Australia/Biotechnology Australia, Australian Biotechnology: Number One in the Asia Pacific for Biotechnology Investment (2005) <http://investaustralia.hyperlink.net.au/media/IS_BIOTECH_English.pdf> at 24 August 2005.

[91] Kelvin Hopper and Lyndal Thorburn, 2002 *Bioindustry Review: Australia and New Zealand* (2002), 29.

[92] Ibid, 3.

[93] Ibid.

[94] See, eg, Commonwealth of Australia, Ernst & Young and Freehills, *Australian Biotechnology Report* (2001) (Ernst & Young, *Australian Biotechnology Report* 2001), 60-65. The importance of the research system to the sustainability of biotechnology firms is also stressed: See CHI Report, above n34, 62.

institutions, or through spin-off companies established for the purpose of commercialising research generated by research institutions.[95]

A number of Cooperative Research Centres (CRCs) are also involved in biotechnology research and the commercialisation of biotechnology products. These Centres compete by application for Commonwealth funding for a limited period, and may be self-sustaining after the completion of the funding period. CRCs comprise university researchers, government research institutes and private sector businesses. Available figures indicate that approximately one third of the 71 CRCs have significant biotechnology programs, with approximately ten of those involved in medical science and technology.[96]

The Australian biotechnology industry suffers from a shortage of venture capital, a problem which is certainly not specific to this industry.[97] There is also a limit to the extent of public investment available in Australia, a related issue being the level of investor confidence in biotechnology. This may also prove to be a barrier to commercialisation in the absence of alliance activity between firms in the life science sector in Australia. It has been stressed that the key to overcoming this lies in merger and joint venture activity amongst Australian life science or biotechnology companies, and perhaps more importantly, in foreign investment in Australian biotechnology companies.[98]

1.6.2 Investment in Australian Biomedical Research

Many major international companies, particularly US and European companies are active in Australia, through ownership of Australian companies, research collaborations with Australian companies, or licensing agreements. Even so, there is some concern that many Australian biotechnology companies suffer from a lack of international exposure.[99] The importance of investment by the international

---

[95] Ernst & Young, *Australian Biotechnology Report* 2001, above n94, 48-50.

[96] Department of Education, Science and Training, Commonwealth of Australia, *CRC Directory 2004* (2004); Ernst & Young, *Australian Biotechnology Report*, above n71, 53.

[97] *Wills Review*, above n6, 152; *Developing Australia's Biotechnology Future*, above n6, 28; Ernst & Young, *Australian Biotechnology Report*, above n71, 41. Note that levels of research and development expenditure by Australian companies are relatively low; see Ernst & Young, *Australian Biotechnology Report* 2001, above n94, 22-24.

[98] Ernst & Young, *Australian Biotechnology Report*, above n71, 21; *Wills Review*, above n6, 193.

[99] Ernst & Young, Hay Group & Strategic Industry Research Foundation, *Benchmarking Study of R&D Costs in Selected Segments of the Australian Biotechnology Industry: Final Report* (Canberra: AGPS, 2001); *Wills Review*, above n6, 193; Ernst & Young, *Australian Biotechnology Report*, above n71, 35.

pharmaceutical sector in particular, has been stressed.[100] There is a clear trend toward international business alliances outnumbering local alliances.[101]

The difficulty this presents from a national perspective is that the benefits from Australia's research base could flow offshore. This will often be compounded by Australian researchers being forced to negotiate agreements with powerful multinational companies that have superior resources and bargaining power. Nevertheless, establishing markets for their intellectual property is crucial for Australian researchers and companies. Licensing represents a popular option among biomedical patent holders for realising value from their patents, in that it allows patent holders to retain ultimate control of the patent, and in many cases realise value on an ongoing basis. Depending on the terms on which licence arrangements are entered into, rights to future inventions and intellectual property may be assured.

After conducting a study of the industry in Australia in 2002, Hopper and Thorburn noted that the growth of the industry in Australia has slowed somewhat.[102] They did, however, report a marked increase in companies that could be categorised as upstream, and that engage in the business of supplying more downstream users with, for example, gene sequence data.[103] This apparent shift in focus by the Australian industry may have the effect of bolstering the upstream segment of the industry, and this will necessarily entail an increasing reliance on patent protection in this industry sector. Participants in the Australian industry will need to ensure:

- that they obtain adequate intellectual property protection, particularly in the world's major markets;[104] and
- that they make efforts to ensure that their intellectual property is marketable and adequately exploited.

Companies face a number of hurdles in doing so.[105] However, a related threat may stem from the enforcement of patents by other industry participants to block research. Difficulties may be encountered by researchers, both public and private, in entering into contractual arrangements for the exchange of intellectual property.

---

[100] *Wills Review,* above n6, 157.

[101] Ernst & Young, *Australian Biotechnology Report* 2001, above n94, 47.

[102] Hopper and Thorburn, above n91.

[103] Ibid, 11.

[104] Ibid, 30; Ernst & Young, *Australian Biotechnology Report* 2001, above n94, 49.

[105] These include financing innovation, obtaining expertise in management, regulatory constraints and policies, marketing products and penetrating international markets.

1.7 LEVELS OF BIOTECHNOLOGY PATENTING

Obtaining accurate figures on levels of biotechnology patenting internationally or in Australia is difficult. This is due to differences in definitions of 'biotechnology' and 'gene' patents[106] across jurisdictions, and the fact that limited information is available on patent applications and granted patents.[107] Globally, there is little doubt that levels of biotechnology patenting have increased dramatically. The US biotechnology industry association BIO reported an increase in issued biotechnology patents in the US from 2,160 in 1989 to 7,763 in 2003.[108] From 1998, over 7000 biotechnology patents have been issued per year.[109] The Organisation for Economic Cooperation and Development (OECD) have reported similar growth in patenting activity; the number of biotechnology patents granted by the European Patent Office (EPO) has risen at risen at a rate of four percentage points above total EPO patents.[110] Over 6000 biotechnology patents were granted by the EPO in 2000, compared to just under 2000 patents in 1991.[111]

Many companies and research institutions have filed applications for human gene patents, with many of the companies initially involved in sequencing reporting that a very significant proportion of these applications have resulted in patent grants. Incyte has reported that it believes it has the 'largest compilation of information regarding full-length genes and the proteins they encode and also the largest commercial portfolio of issued US patents covering such genes and proteins.'[112] It is difficult to obtain precise comparable figures on the number of gene patents actually granted by

---

[106] The Organisation for Economic Cooperation and Development (OECD) has defined patented genetic inventions as inventions whose claims include nucleotide (DNA or RNA) sequences. Biotechnology patents encompass gene patents and are a broader category; Organisation for Economic Co-operation and Development (OECD), *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies*, (2002) (the OECD Report), 33.

[107] See also ALRC Report, above n50, 407.

[108] Biotechnology Industry Association, *Biotechnology Industry Facts* <http://www.bio.org/speeches/pubs/er/statistics.asp> at 30 May 2005.

[109] Ibid.

[110] Organisation for Economic Cooperation and Development, *Compendium of Patent Statistics*, Internal Working Document (2004), 29.

[111] Ibid.

[112] 'Company Profile for Incyte Corporation' *Press Release*, 7 November 2003 <http://investor.incyte.com/phoenix.zhtml?c=69764&p=IROL-NewsText&t=Regular&id=467793&> at 1 June 2005. Incyte is also involved in extensive licensing of its patents and in collaborative arrangements.

various national patent offices, but there is no doubt that there has been a steep rise in genetic patent applications.[113]

There is evidence of extensive patenting activity within the Australian biomedical industry, and the number of patents granted in the biotechnology category has steadily increased. In 1997, around 461 patents were granted in this category, and by 1998 this number had risen to 784. The number of patents granted per year peaked in 2001 at 869, before dropping slightly during 2002 and 2003 to around 765 patents per annum.[114]

A vast majority of patents granted in the biotechnology category in Australia, have been granted to non-Australians. While around ten percent of patents granted each year originate in Australia, only two percent of patent applications filed in the biotechnology category up until 1998, originated in Australia. The number of biotechnology patents filed by Australians did increase in real terms from 26 in 1988 to 46 in 1998, but it is likely that the number of biotechnology patents granted to Australians remains modest in comparison to non-Australian inventors.[115] While the number of patents granted in the biotechnology category have certainly increased since this period, it seems fair to assume that a significant number of patents are still granted to non-Australians.[116]

The CHI Report indicates that the number of Australian invented patents filed in the US closely matches the number of Australian invented patents filed in Australia.[117] During the five-year period 1994-1998 there was a 249 per cent increase in Australian invented biotechnology patents from the previous five-year period, further supporting the conclusion that Australian biotechnology is in a growth phase.[118] Nevertheless, US

---

[113] OECD Report, above n106, 34-38.

[114] IP Australia, *Top 10 Technologies of Granted Standard Patents 92-03* <http://www.ipaustralia.gov.au/pdfs/statistics/Standard%20Grants%20by%20Tech%2092-03.xls> at 30 June 2005. Note that the number of pharmaceutical patents granted per year has increased dramatically, from around 630 patents per annum in 1997, to around 1200 patent per year from 1999 onwards.

[115] Note that the biotechnology category includes both medical and agricultural biotechnology. It also includes gene patents. The author thanks Jodi Lawler and Rod Crawford from IP Australia for providing this data.

[116] Some of this data was also reported in Dianne Nicol and Jane Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 360-362.

[117] CHI Report, above n34, 29.

[118] Ibid, 32.

inventors continue to file the vast majority of biotechnology patents in the US.[119] The number of Australian co-invented patents generally is increasing, and a large number of co-invented patents are US-Australian collaborations.[120]

The Report concluded that the performance of Australian inventors in the biotechnology category was stronger than the performance of Australian inventors generally.[121] Despite this, biotechnology patent activity relative to gross domestic product remains average[122] and the number of biotechnology patents filed and held by Australian inventors remains low in relative terms.[123]

1.8 THE RELEVANCE OF MARKET STRUCTURE

In a comprehensive analysis on the structure of the international biopharmaceutical industry, Panos Kanavos identified a number of determinants of market structure specific to the biopharmaceutical industry.[124] Kanavos also examined the trends apparent in the biopharmaceutical industry and examined how these trends impact on market structure.[125] The biopharmaceutical industry is uniquely structured, and levels of concentration are low overall, but higher at sub-therapeutic or product levels.[126] This is due primarily to the nature of the technology and the fragmentation of the pharmaceutical market into a large number of therapeutic categories.[127]

The biopharmaceutical industry is particularly research-intensive and is characterised by long product development lead times and relatively limited product pipelines. As

[119] Over the five-year period 1994-1998, US inventors filed 6 847 biotechnology patents and 10 218 pharmaceutical patents; see ibid Table 6a, 71.

[120] Nearly half of all Australian co-invented patents are US-Australian collaborations. This figure has increased from five per cent in the first half of this decade to over 15 per cent in the last five years: Ibid, 26.

[121] Ibid, 26-29. In terms of general patenting activity, Australian invented patents in the US represent approximately 0.5 per cent of patents filed; at 26-29.

[122] Ibid, 28.

[123] See ibid, Fig 7.

[124] Kanavos, above n77, 41-129.

[125] Kanavos adopts a generally mainstream approach, but uses a theoretical framework that examines factors affecting structure, conduct and performance in an interrelated way. He states that this approach has been the approach of recent theoretical frameworks that have moved away from early mainstream empirical literature; Ibid, 44.

[126] Ibid, 105.

[127] Ibid, 105.

such, the interplay of a number of traditional barriers to entry unique to pharmaceuticals, impact on the structure of the industry:[128]

- the high research and development costs associated with the research intensive nature of the industry;
- the ability of companies to penetrate foreign markets;
- concentration levels within the industry and the impact of competition policy on these concentration levels;[129]
- the ability to adequately market products;
- price competition, which is generally low at sub-therapeutic level, and price differentiation which is high; and
- the ability of companies to integrate.

In addition, a number of exogenous factors related to the regulatory framework and investment and funding opportunities available to biopharmaceutical companies will play a part in the overall structure of the industry.[130] In particular, degrees of investment, and research and development support will impact on the relative size and success of the industry.[131] The ease with which intellectual property protection can be obtained is also an important factor.[132]

A number of these factors are also relevant to the structure of that portion of the medical biotechnology industry involved in the development of therapeutics and diagnostic tests and treatments. Clearly, certain factors are specific to the biopharmaceutical industry's involvement in drug development, and these relate generally to the regulatory framework within which biopharmaceutical companies must work, and the long lead-time for drug development. Despite these differences, however, the structure of that portion of the industry involved in therapeutic and diagnostic applications bears some similarities to the biopharmaceutical sector, highlighting the importance of the remaining indicators of market structure highlighted by Kanavos.

---

[128] Ibid, 53-66.

[129] This factor will be discussed in more detail below, 1.8.2.

[130] Kanavos, above n77, 67-99.

[131] Ibid, 67-87, 94-99.

[132] Ibid, 87-93.

Consideration of factors contributing to market structure is important from a competition law perspective, because market structure will have a bearing on the conduct of participants within a particular industry. Traditional competition law analysis has incorporated the structure-conduct-performance approach, which posits the examination of market power as a product of market structure, in assessing the conduct of a participant within a market.[133] Performance, in turn, is the result of the structure-conduct relationship within a particular industry.[134]

Over time, this approach has been viewed as being overly simplistic. In Australia, a modified structure-conduct-performance approach is utilised by the courts, but it would appear that strategic considerations are becoming a more pronounced consideration.[135] This echoes to some degree, the current position in the US. US antitrust policy from the 1980s was dominated by 'Chicago School' economics,[136] which advocates minimal regulation as a means to achieving allocative efficiency.[137] Antitrust policy in the US has now entered a 'post-Chicago' phase, which is reflected in greater scepticism of 'strategic anti-competitive behaviour by dominant firms ...'.[138]

Strategic considerations are likely to be taken into account by courts, (both in Australia and internationally) in determining the effect of conduct on dynamic efficiencies. Australian courts will continue to apply a structure-conduct-performance approach,[139] but strategic factors may now be an integral part of analysis of market

---

[133] This approach is based on the work of a number of Harvard economics and antitrust scholars, see, eg, Joseph Bain, *Industrial Organisation*, (1959); Scherer and Ross, above n70; Phillip Areeda and Donald F Turner, *Antitrust Law: An Analysis of Antitrust Principles and their Applications* (1978); Carl Kaysen and Donald F Turner, *Antitrust Policy* (1959).

[134] On determinants of market structure according to the Harvard or mainstream tradition, see Scherer and Ross, above n70, ch 4.

[135] See, eg, Rhonda Smith and David K Round, 'Section 46: A Strategic Analysis of *Boral*' (2002) 30 *Australian Business Law Review* 202.

[136] This school of economic thought evolved from the work of a number of scholars associated with the University of Chicago; see, eg, George Stigler, *The Organisation of Industry* (1968); Harold Demsetz, *Economic, Legal and Political Dimensions of Competition* (1982); Robert H Bork, *The Antitrust Paradox: A Policy at War With Itself* (1978); Justice Frank H Easterbrook, 'Ignorance and Antitrust' in Thomas M Jorde and David J Teece (eds) *Antitrust, Innovation, and Competitiveness* (1992) 119

[137] See, eg, Easterbrook, above n136, 119; Herbert Hovenkamp, 'Post-Chicago Antitrust: A Review and Critique' (2001) *Columbia Business Law Review* 257. As such, Chicago economists would be unlikely to support the regulation of unilateral actions; Corones, above n68, 23.

[138] Hovenkamp, above n137, 267. There remain, however, a number of important differences between the enforcement of competition law or antitrust in the US and Australia. For an explanation of antitrust regulatory policy, see generally Corones, above n68, ch 1.

[139] The application of this approach in relation to s 46 of the *Trade Practices Act* 1974 (Cth) which prohibits the misuse of market power, will be considered in Chapter 6.

power and its effect on performance. This is particularly the case in relation to barriers to entry.[140]

1.8.1 BARRIERS TO ENTRY AND MARKET STRUCTURE

Barriers to entry have been recognised as being the most important determinant of market structure when examining whether a market is competitive.[141] The ability of companies to enter an industry is important as a means of promoting competition and improving the allocation of economic resources. Barriers to entry are perceived as being anti-competitive in that they result in fewer entries and allow incumbents to enjoy above average profitability.[142] The study of entry and entry barriers is thus important in determining why the structure of any particular industry has taken on a particular form and in analysing the extent of market power possessed by an incumbent.

Varying attempts have been made to define this term, and different approaches circumscribe different guidelines for what might constitute a barrier to entry.[143] Historically, the debate centred around the views of Joseph Bain[144] who adopted a liberal definition of barriers to entry, and George Stigler,[145] a scholar of the Chicago School tradition which has traditionally taken a narrower approach. Subsequent work has built on and modified this earlier work, and the extensive economic literature on

---

[140] Corones, above n68, 32.

[141] See the definition of competition enunciated in *Queensland Co-operative Milling Association Ltd and Defiance Holdings Ltd* (1976) 25 FLR 169 at 188-89, and the elements of market structure which need to be examined in order to determine whether a market is competitive. This definition has been extensively quoted and is regarded as being the seminal definition of competition in Australian competition law. This matter will be analysed more extensively below, 6.3.3.

[142] See George Yip, *Barriers to Entry: A Corporate-Strategy Perspective* (1982), 7.

[143] As Hay points out, there is a substantive difference between the '... definition of a barrier to entry, and the elements that may constitute a barrier to entry.'; George A Hay, *Boral* – Free at Last (2003) 10 *Competition and Consumer Law Journal* 323, 330. It has also been suggested that the central issue accounting for these divergences in opinion is whether '... the definition and identification of barriers to entry must completely block entry, or whether it is sufficient if it only delays entry for some (socially acceptable) time; Antra Hood, 'Barriers and Impediments to Entry in Australian Health Care Markets After *Stirling Harbour*, *Boral* and *Melway*' (2002) 20 *Australian Business Law Review* 6, 15. See also Areeda and Hovenkamp, who suggest that it will be sufficient if entry is deterred for a 'sufficiently long time'; Phillip E Areeda and Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and their Application* (2002) (Areeda and Hovenkamp), vol 2A, [420c].

[144] Joseph Bain, *Barriers to New Competition: Their Character and Consequences in Manufacturing Industries* (1965), 12-13. Bain contends that barriers to entry may arise from product differentiation, absolute cost advantages and economies of scale.

[145] George Stigler, *The Organisation of Industry* (1968), 67-68. Stiglerian barriers comprise costs that market incumbents do not have to bear, and exclude economies of scale.

barriers to entry attests to the complexity of definition and characterisation in this field of study.[146]

While there is some dispute amongst economics scholars over the appropriate definition of barriers to entry, for the purposes of competition law, it is generally accepted that the notion of barriers to entry as articulated by Joseph Bain will usually be most appropriate.[147] This is essentially because the focus of competition law is on whether entry is likely to occur and therefore limit potentially anti-competitive practices. Those practices will be evaluated according to existing market power, regardless of how that market power came about.[148] Thus, an expansive definition of barriers to entry will be applied in determining issues of market power, so that a barrier to entry will generally be defined as any factor that permits firms already in the market persistently [to] raise their prices above a competitive level without attracting new firms to enter the industry.'[149]

This is certainly the approach that has been adopted by Australian courts,[150] so that any restraint on entry will be taken into account in assessing market power.[151] Essentially, any limitation on entry or factor that tends to raise the costs of new entrants relative to that of incumbents is capable of constituting a barrier to entry.[152] Under this definition, a number of factors may constitute structural barriers to entry, including patents.[153] It is well recognised that effective patent protection is important to this industry, primarily because biotechnology and pharmaceutical companies need

---

[146] A useful summary of some of the main studies in this area is contained in Hood, above n143, 9-15. For a more detailed exposition see Paul Geroski, Richard J Gilbert and Alexis Jacquemin, *Barriers to Entry and Strategic Competition* (1990) 68-85.

[147] Areeda and Hovenkamp, above n143, vol 2A, [420c]; Corones, above n68, 98-104.

[148] Areeda and Hovenkamp, above n143, vol 2A, [420c].

[149] Bain above n144, 5. See also ibid, vol 2A, [420a].

[150] For example, in *Stirling Harbour Services Pty Ltd v Bunbury Port Authority* (2000) ATPR 41-752, a broad definition of barriers to entry in line with the definition of Bain was preferred. The result is that *impediments* to entry will need to be considered in analysing market structure; Hood, above n143, 21. See also Corones, above n68, 98-104.

[151] See also Hood, above n143, 16-21. Exactly what might constitute a barrier to entry will vary from case to case; at 16-21.

[152] For example, one of the main barriers to entry facing biotechnology companies in Australia and in other sectors of the international industry is the prohibitive cost of research and development and the related barriers of financing and levels of investment; see, eg, Ernst & Young, *Australian Biotechnology Report*, above n71, 44-45. In addition, many companies encounter problems subsequently when further funding is required, and this has resulted in the trend of alliances and mergers described above.

[153] See, eg, Scherer and Ross, above n70, 360. Australian courts have recognised that a patent may constitute a barrier to entry; see, eg, *Queensland Wire*, 189-190 (Mason CJ and Wilson J).

to recoup substantial research and development expenditure.[154] Kanavos points out that the effectiveness of the patent systems of various countries has had an important effect on the development of the biopharmaceutical industry in those countries.[155]

At the same time, the industry is increasingly characterised by defensive patenting, and vertically integrated organisations that have as a primary goal the consolidation of patents.[156] In certain circumstances, incumbents may erect entry barriers through strategic responses to actual or potential entry.[157] Strategic behaviour by incumbent firms can potentially deter entry either by threatening to reduce post entry prices that potential entrants can expect to receive or by taking actions that raise new entrants' costs.[158] Given the trend of the international industry toward alliances and sharing of patents, the strategic use of patents within the industry could impact on market structure and the market power of incumbents.[159]

1.8.2 Concentration Versus Competition

Undoubtedly, innovation is important to consumers and to the growth of a strong economy.[160] The facilitation of innovation enhances social welfare, and the process of innovation may entail some sacrifice in static efficiency at the expense of dynamic efficiency.[161] Various studies, both theoretical and empirical, have been conducted with a view to establishing the industry structure that provides the best environment in which to facilitate innovation. Empirical examinations have been conducted under a range of conditions and with a variety of industry structures in mind.

Both patents and competition can facilitate innovation.[162] Justifications for patents will be discussed in Chapter 2, but proponents of patents consider they promote dynamic

---

[154] See below, 2.2.2.1, 2.2.2.5.

[155] Kanavos, above n77, 87-93.

[156] See further, below 2.5.4, 4.4.4.

[157] See Scherer and Ross, above n70, especially 391-396.

[158] Ibid.

[159] This issue will be examined in detail in the context of s 46 of the *Trade Practices Act* 1974 (Cth) in Chapter 6.

[160] For a useful summary of the fundamental characteristics of innovation and the innovative process see Section of Antitrust Law, American Bar Association, *The Economics of Innovation: A Survey*, July 2002 (ABA Survey) <http://www.ftc.gov/opp/intellect/0207salabasrvy.pdf> at 29 April 2004, at 4-8.

[161] Static efficiency constitutes short-term efficiency and relates to the optimal allocation of resources using existing technologies to produce existing products. In contrast, dynamic efficiency is the optimal allocation of resources in a world where it is possible to also produce new products and processes; ibid, their n3.

[162] Merges argues that shifts in organisational structure resulting in changes in firm-level distribution of research and development activity, is resulting in more integration between firms and less concentration of intellectual property within single firms. Specifically, research and development

efficiency by encouraging the process of research and development, and serve the goals of:

- protecting against free-riders and so inducing innovation;
- encouraging disclosure of inventions; and
- facilitating commercialisation of inventions.[163]

By their nature, patents restrict competition in markets through the concentration of property privileges in an individual. While this may be necessary in order to advance the goals of the patent system, it may also entail considerable cost, particularly where a patent gives a patent holder a degree of market power.[164] Specifically, patents may hinder the process of competition by:[165]

- raising price levels above competitive levels;
- reducing output of a product or technology below competitive levels;
- restricting entry into a market through enforcement of patents; or
- restricting access to products or technologies necessary for follow-on innovation.[166]

While it is inevitable that some degree of price and quantity distortion will result from the grant of patents, in some circumstances the effects mentioned above may be cause for concern. It is not clear, however, that competition necessarily has a more positive effect on innovation than concentration through the grant of patents. Competition may force market participants to innovate due to the threat of entry, and a multiplicity of

---

efforts are being increasingly dispersed across industries, and decreasingly carried out by single large firms so that patents are controlled by many rather than a few. As a result of this 'outsourcing' or 'strategic partnering', the days of the 'killer patent portfolio' are over, and intellectual property is playing an important part in this shift; see Robert P Merges, 'Antitrust Review of Patent Acquisitions: Property Rights, Firm Boundaries, and Organisation' in Robert D Anderson and Nancy T Gallini (eds) *Competition Policy and Intellectual Property Rights in the Knowledge Based Economy* (1998) 116.

[163] Below, 2.2. See also Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) (Federal Trade Commission Report), Chapter 2, 3-7.

[164] It is generally accepted that it is a fallacy to view patents as universally conferring market power. While there will be instances in which patents do confer market power, in a majority of cases they will not; see, eg, Edmund W Kitch Elementary and Persistent Errors in the Economic Analysis of Intellectual Property (2000) 53 *Vanderbilt Law Review* 1727, 1729-38. See also below, 6.3.3, 8.2.2.

[165] See generally Federal Trade Commission Report, above n163, Chapter 2, 7-8; Louis Kaplow, The Patent-Antitrust Intersection: A Reappraisal (1984) 97 *Harvard Law Review* 1813, 1821-23 (discussing the fact that questions of patent-antitrust policy must involve a detailed analysis of reward versus monopoly loss).

[166] Below, Chapter 3, especially 3.9.1.

research efforts may lead to results that could not have been foreseen at the outset.[167] Innovators may take different approaches to reach the same goal which in themselves could have social value.[168]

It is also true, however, that despite the positive effects it may have in relation to innovation, competition may also injure innovation in some instances by:[169]

- restricting the ability of inventors to appropriate value from their inventions; or
- encouraging 'patent races' or duplication of research efforts.[170]

The question, therefore, is whether concentration or competition serves as a superior inducement to innovate.[171] A great deal of conflicting economic literature exists on innovation and market structure, and whether concentration or competition is more conducive to innovation. This section does not attempt to provide a comprehensive overview of this literature, but merely aims to highlight the primary arguments presented by both monopoly theorists and advocates of competitive markets.

1.8.2.1 *SCHUMPETARIAN HYPOTHESES*

Monopoly theorists such as Joseph Schumpeter are proponents of concentration as a method of promoting innovation.[172] Schumpeter's hypothesis, in denouncing perfect competition as a model of ideal efficiency, is that large, monopolistic entities drive innovation and are likely to be motivated to innovate further by the threat of new participants entering the market with improved technology.[173] There have been two interpretations of this argument:

- larger entities are likely to innovate more profusely than smaller entities; and

---

[167] Robert P Merges and Richard R Nelson, 'On the Complex Economics of Patent Scope', (1990) 90 *Columbia Law Review* 839, 873-4.

[168] Arti K Rai, 'Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust', (2001) 16 *Berkeley Technology Law Journal* 813 (Rai 2001), 825.

[169] See Federal Trade Commission report, above n163, Chapter 2, 16-17.

[170] Patent races can also be a positive in terms of the diverse innovation they may give rise to. See also below, 1.8.2.2.

[171] It is also important to remember that the rate of innovation in an industry will invariably influence market structure; Scherer and Ross, above n70, 630.

[172] See Joseph M Schumpeter, *Capitalism, Socialism and Democracy* (1942).

[173] Ibid, 81-106.

- there is likely to be a greater level of innovation by entities in concentrated markets.[174]

Subsequent empirical studies have sought to test these two streams of Schumpeter's hypotheses, and the results of these studies are briefly outlined below.[175] Although equivocal and conflicting, the studies conducted in this area offer some empirical guidance on the types of market features most likely to be conducive to innovation.

(i) The Relationship of Firm Size to Innovation

Theoretically, large firms may have greater capacity to innovate due to economies of scale, more diversified research and development activities that allow them to spread risk across projects, better access to financing, a greater ability to penetrate markets and stronger incentives to develop process improvements.[176] Conversely, small firms may be less risk averse than their larger counterparts.[177]

Although there would appear to be a positive correlation between firm size and levels of research and development, recent studies have demonstrated that research and development levels do not rise more than proportionately with firm size. Early studies generally found firm size and research and development levels to be more than proportionate.[178] However, later studies (which, unlike the earlier studies, attempted to control for the effects of extraneous industry characteristics) contradicted these findings, and suggested that research and development levels rise 'monotonically' to a point with firm size and then rise only proportionately.[179]

Size of business units would appear to be more closely related to research and development levels than corporate size generally.[180] Recent studies have tempered

---

[174] ABA Survey, above n160, 28-30.

[175] For useful summaries see Scherer and Ross, above n70, 613-660; Ibid, 30-35. The ABA Survey also contains an annotated selected bibliography detailing a number of important studies in the area; ibid, 50). The discussion that follows utilises the discussion format in the ABA Survey, as well as the study trends reported in that survey.

[176] Scherer and Ross, above n70, 652.

[177] Ibid, 652-653.

[178] An exposition of these earlier surveys can be found in William L Baldwin and John T Scott (1987) *Market Structure and Technological Change* (1987) 64-113.

[179] See, eg, Wesley M Cohen, 'Empirical Studies of Innovative Activity' in P Stoneman (ed), *Handbook of the Economics of Innovations and Technological Change* (1995) 188-264 especially 195-196. The results of these studies led to a generally held belief that large firm size was detrimental to research and development activity; see Wesley M Cohen and Steven Klepper 'A Reprise of Size and R & D' (1996) 106 The *Economic Journal* 925, 930.

[180] Ibid, 936-946. Research and development into process innovations is likely to benefit more from firm size than research and development into product innovations; Wesley M Cohen and Steven

these findings, and suggest that it might be possible to conclude that larger firm size does in fact contribute to increased research and development, primarily because large firms have a greater capacity to realise sales revenues which allows them to fund research and development.[181]

(ii) The Relationship Between Market Structure and Innovation

Theoretical analyses have predicted that rivalry is apt to stimulate research and development spending, although at some point increased concentration is likely to be detrimental to innovation because market participants are likely to appropriate returns as profit rather than committing them to funding further research and development.[182] High levels of concentration are more likely to spur spending on research and development where technological advances occur '...quickly and unexpectedly...' rather than slowly and unexpectedly.[183]

Empirical studies have yielded contradictory results. A number of studies have supported the existence of a non-linear inverted-U relationship between concentration levels and innovation.[184] Thus, technological vigour may increase to a point with concentration, but this is likely to be at fairly low levels.[185] However, later studies suggest that inter-industry differences may impact on whether the inverted-U relationship holds within the context of a particular industry.[186] The matter is also complicated by the fact that in some industries, the level of innovation (and technological opportunity available) may itself influence entry levels into markets.[187]

Klepper, 'Firm Size and the Nature of Innovation Within Industries: The Case of Process and Product R&D' (1996) 78 *Review of Economics and Statistics* 232, 241.

[181] Ibid, 198-210.

[182] Scherer and Ross, above n70, 646.

[183] Ibid, 646.

[184] See, eg, Frederic M Scherer, 'Market Structure and the Employment of Scientists and Engineers' (1967) 57 *American Economic Review* 524. See also the discussion in Richard C Levin, Wesley M Cohen and David C Mowery, 'R&D Appropriability, Opportunity and Market Structure: New Evidence on Some Schumpeterian Hypotheses (1985) 75 *American Economic Review* 20.

[185] See, eg, Frederic M Scherer, *Innovation and Growth: Schumpetarian Perspectives* (1984), 247, suggesting that 'technological vigor' will not be enhanced by a concentration of greater than four firms.

[186] See, eg, Levin, Cohen and Mowery, above n184. See also Scherer and Ross, above n70, 646; Dennis W Carlton and Robert H Gertner, *Intellectual Property, Antitrust and Strategic Behaviour* (Working Paper No 8976, National Bureau of Economic Research, 2002) 14. Scherer and Ross caution that despite the uncertainty surrounding the empirical evidence on the existence of an inverted-U relationship, the underlying theory supports its existence and thus it should not be dismissed too rapidly; at 647.

[187] See especially Paul A Geroski, 'Innovation, Technological Opportunity and Market Structure' (1990) 42 *Oxford Economic Papers* 586, especially 597; Paul A Geroski, 'Entry and the Rate of

In others, innovation levels and market structure may be simultaneously determined by other factors.[188]

(iii) The Availability of Technological Opportunities

As discussed, recent research indicates that inter-firm factors other than firm size would appear to play a significant role in innovation levels.[189] In addition, industry characteristics other than market structure may influence innovation within an industry.[190] Indeed, recent research suggests that these factors may in fact be more fundamental in determining innovative activity and performance than market structure and firm size.[191] The ability to patent has been shown to have some correlation with levels of innovation, although the studies discussed in this section have indicated that the value and effectiveness of patent protection varies across industries.[192] Studies examining the ability to appropriate research and development do not offer any definitive conclusions about the relevance of this factor to levels of innovation.[193]

The richness of technological opportunities available to industry participants is one factor that may operate to simultaneously determine both research and development and concentration levels within an industry.[194] It may explain differences in innovation levels more effectively than factors such as concentration.[195] Again, limited data is available in relation to the effects of this factor on innovative activity, but it has been postulated that in industries characterised by high levels of technological opportunity, concentrated markets may produce more innovative activity.[196] Generally speaking,

---

Innovation' (1991) 1 *Economic Innovation and New Technology* 203; Paul A Geroski, *Market Dynamics and Entry* (1991). Breadth in innovative opportunities will invariably attract new entrants, provided entry is possible. In this case, market structure may become a product of technological progress, and determining which is causative becomes difficult.

[188] See, eg, Levin, Cohen and Mowery, above n184.

[189] Above, 1.8.2.1.

[190] See, eg, Cohen, above n179, 210-231. These factors have been classified as product market demand, technological opportunity, and appropriability conditions; at 210-211. A recent Australian study found that, consistent with overseas studies, 'factors common to all industries, such as the extent of learning, knowledge spillovers, appropriability and managerial style are more important than industry specific forces'; Elizabeth Webster, *Forces Shaping Firms' Decisions to Innovate: Evidence from Large Australian Organisations* (Working Paper No 03/03, Intellectual Property Research Institute of Australia, 2003) 17.

[191] Cohen, above n179, 183.

[192] See below n208 and accompanying text. See also the discussion in Cohen, above n179, 226-231.

[193] Cohen, above n179, 230-231, 232-233.

[194] See especially ibid, 214-226; Scherer and Ross, above n70, 646-651.

[195] Scherer and Ross, above n70, 648; Geroski, 'Innovation, Technological Opportunity and Market Structure' above n187, 599-600.

[196] Scherer and Ross, above n70, 647.

participants in concentrated markets will usually have more incentive to commit profits to innovate further (rather than retaining profits as rent) when considerable technological opportunity exists and there is a risk that competing products will be developed. A recent study, however, suggests that high concentration levels may have a negative impact on innovation, even when the richness of technological opportunity is taken into account.[197] While these conclusions are based on descriptive observations and some empirical data, this data goes some way in attempting to explain the relevance of the role of technological opportunity conditions on innovation and performance.[198] Nevertheless, it remains unclear what the impact of technological opportunities and market structure on innovative activity are likely to be within the context of particular industries.

1.8.2.2 *COMPETITION AND INNOVATION*

In contrast with monopoly theorists, competition proponents argue that incentives to invest are greater under competitive conditions than under monopolistic conditions.[199] While competitive firms are likely to innovate to protect their market position or to realise supra-normal profits, monopolists are unlikely to develop new technology that supersedes, or impinges on the market for, their product.

An early advocate of competition, Arrow argued that competitive conditions would provide a more effective incentive to develop new products than monopolistic conditions, although the incentive to invest would still be less than is socially desirable.[200] Using various models, economists have established that firms may well undertake more research and development under competitive conditions, but too much rivalry is liable to reduce the rents available to market participants and so act as a disincentive to innovate.[201] The following assumptions would also appear to have some bearing on the degree to which competitive conditions influence innovative behaviour:[202]

---

[197] Geroski, 'Innovation, Technological Opportunity, and Market Structure', above n187.

[198] Cohen, above n179, 232-233.

[199] Kenneth J Arrow, 'Economic Welfare and the Allocation of Resources for Invention' in The National Bureau of Economic Research (eds) *The Rate and Direction of Inventive Activity: Economic and Social Factors* (1962) 609.

[200] Ibid, 619-622.

[201] Scherer and Ross, above n70, 636-637. Rents are likely to be reduced because firms expect (or perceive) that they will receive a smaller share of the profits available to the market. In addition, competitive conditions will cause prices to drop, thus reducing the overall profitability of the market.

[202] A considerable number of studies have been conducted in relation to the effects of competition on innovation. The ABA Survey contains an excellent discussion of a number of the important studies in

- the scale or intensity of competition in the market;
- the nature of innovation within the industry;[203]
- the standing and characteristics of particular firms, varying from entrenched incumbents to potential entrants; and
- the likely outcome of patent races.[204]

In the end, the answer is probably that the ideal level of competition within a market will vary. It is well established that perfect competition is not a model of dynamic efficiency.[205] However some degree of competition is probably needed to maximize technical potential in an industry:

> What is needed for rapid technical progress is a subtle blend of competition and monopoly, with more emphasis in general on the former than the latter, and with the role of monopolistic elements diminishing when rich technological opportunities exist.[206]

1.8.3 Concentration Levels Within the Medical Biotechnology Industry

It is difficult to reach any definitive conclusions about the optimal level of concentration in a particular industry, and it is likely that a consideration of this issue needs to be industry-specific.[207] This aligns with analyses of patents as an incentive for innovation, which will depend largely on the particular industry being examined.[208]

---

the area; see ABA Survey, above n160, 22-28. The factors listed have been distilled from this discussion, and are not intended to be exhaustive.

[203] Innovation may be marginal or fundamental, or it may be uncertain (stochastic) as opposed to predictable (deterministic); see ibid, 25 and their n61. The state of competition may also influence whether innovation occurs in respect of product or process innovations. On process patents, see further below, 2.4.1.1.

[204] Patent races may commence on an equal footing, or may be asymmetrical. Patent races may give rise to a number of costs and benefits. Some benefits may be available to one competitor and not others; see further ibid, 25-26.

[205] See generally Schumpeter, above n172, especially 106. See also Scherer and Ross, above n70, 660.

[206] Scherer and Ross, above n70, 660.

[207] See, for example, Levin, Cohen and Mowery, above n184; Carlton and Gertner, above n186 .

[208] Rai, above n168, 828-839; Wesley M Cohen, Richard R Nelson and John P Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why US Manufacturing Firms Patent (or Not)*, (Working Paper No 7552, National Bureau of Economic Research, 2000); Richard C Levin, Alvin K Klevorick, Richard R Nelson and Sidney G Winter, 'Appropriating the Returns from Industrial Research and Development' (1987) 3 *Brookings Papers on Economics Activity* 783.

Intellectual property protection is an undeniably crucial business asset of most medical biotechnology industry participants. In many cases, genetic materials and technologies claimed in patents will be difficult to substitute. Discussion in this chapter has shown that while many biomedical companies are small enterprises with a limited product portfolio, increasing levels of licensing and alliance activity are resulting in amplified levels of vertical integration. The net effect of these levels of consolidation of patents is fewer, larger entities controlling specific areas of research through the management and enforcement of suites of patents.

It is also the case that a considerable number of patent holders in the industry are small and medium-sized, and hold relatively few patents. It is in the interests of these patent holders to assert and protect their intellectual property positions, given that this intellectual property is their primary asset. In addition, defensive or strategic[209] patenting strategies are resulting in single organisations and oligopolies[210] being in a position to control research efforts in a particular area. The question is whether increased levels of concentration are likely to have any impact on innovation, and whether this impact is likely to be positive or negative.

Trends toward concentration within specific industries are not uncommon. Technological opportunity within a market tends to lend itself to high levels of concentration. [211] In some industries, the inherent nature of the research environment may be conducive to concentration, but it may also suffer as a result of concentration. Particularly where research within an industry is cumulatively structured, concentration in more upstream segments of the industry may impact on downstream research and product development where access to upstream technology is required to enable downstream research to proceed. The strategic use of technology protected by patents will have a resultant effect on market structure and the conduct of participants within that market.

---

[209] Strategic patenting strategies involve patenting broadly in an area (through either single broad patents or a suite of patents) and are employed essentially to allow industry participants to retain freedom to operate in an area of research. Defensive patenting strategies may be the result of similar motivations to strategic patenting strategies, but may also be employed to build up a proprietary position in an area and exclude others from innovating in that area.

[210] See John H Barton, 'Antitrust Treatment of Oligopolies with Mutually Blocking Patent Portfolios' (2002) 69 *Antitrust Law Journal* 851.

[211] Scherer, above n185, 247.

1.9 CONCLUSION

This chapter has considered both global and Australian medical biotechnology activity, both in terms of market structure and patenting activity. The industry has arisen as a result of a first world push to develop the technology and the industry, and Australia is part of this push. This represents a different period to those previously witnessed in that government is sustaining a push to develop the industry. An increasingly important characteristic of the industry is its private character as evidenced by the increasing number of private companies involved within the industry. There has also been increased public and private funding of university research. A result of this factor is that both private companies and research institutions are asserting an escalating number of patents over inventions. The intellectual property focus is one of the central features of this industry, and large amounts of attention are being devoted to levels of commercialisation and privatisation of research results within the industry. In respect of this industry, the nature of intellectual property is undergoing a real renaissance.

This chapter has considered the structure of the medical biotechnology market both internationally and in Australia, and how the factors affecting market structure are relevant in the broader focus of impetus for technological innovation. The central question arising from this chapter is whether the ideal market structure for this industry is represented within a concentrated or competitive market structure. These two pillars form the core of the thesis and underline the fundamental debate about the balance between intellectual property and competition law.

CHAPTER 2

BIOTECHNOLOGY RESEARCH AND THE PATENT SYSTEM IN AUSTRALIA

INTRODUCTION

Having considered in some detail in Chapter 1 the medical biotechnology industry and the theme of concentration versus competition, it is now important to map out the centrality of the patent system to the medical biotechnology industry. Undertaking this step of the mapping process is a prerequisite to considering how the industry might operate in a competitive market situation. Having examined the public/private divide, the relevance of intellectual property to the industry and levels of patenting, this chapter will now investigate the key area of patent law.

This chapter seeks to outline standards of patentability in respect of medical biotechnology in order to consider in general terms the breadth of patents that have already been granted, and that are likely to be granted in future. The extent to which competition law should impinge on patents will vary depending on whether patent breadth is perceived to be problematic. A premise behind discussion in this chapter is that while patent law defines certain property rights, competition law may have a role to play in regulating the use of those rights. The way in which patent law circumscribes rights will partially determine the extent to which regulation through competition law should take place. The remainder of the chapter is devoted to a number of issues associated with patent use or exploitation, because it is the manner in which patents are utilised that lie at the heart of the intellectual property/competition law intersection.

This chapter will consider the patent system in Australia with particular reference to medical biotechnology. The chapter will begin by outlining the justifications for the patent system, and considering how these justifications fit within medical biotechnology research. It will then consider Australia's international patent law obligations and the requirements for patentability in Australia. Specific reference to biotechnology inventions will be made throughout the course of this discussion. Finally, the chapter will discuss exploitation and infringement, and begin to consider the manner in which patents may be used.

2.2 JUSTIFICATIONS FOR THE PATENT SYSTEM[1]

Intellectual property bears a number of similarities to tangible property. As such, the economic benefits and costs inherent in tangible property are relevant to any discussion of the patent system and whether or not its existence or extension is warranted.[2] Intellectual property does, however, possess important characteristics that distinguish it from tangible property, and therefore analyses of the economic benefits of property protection cannot be unreservedly applied to intellectual property.[3] The peculiar characteristics of intellectual property must be recognised in discussing issues relating to the grant and scope of intellectual property.[4] Therefore, a number of justifications for the patent system have evolved.

This section briefly considers the traditional justifications for the patent system, and how these justifications inform policy debate. Rationales for the imposition or retention of a patent system can be generally grouped into two categories: natural rights theories, and economic theories.

2.2.1 NATURAL RIGHTS THEORIES

Natural rights theories focus on the inherent rights of inventors to reap the benefits of their mental labours through patent protection.[5] Thus, a patent is a reward for an inventor's contribution to the inventive process.[6] The natural rights thesis has,

---

[1] This thesis concentrates on patented inventions in the area of medical biotechnology, and a consideration of alternative forms of incentives for innovation is outside its scope. For a discussion of these issues see Nancy Gallini and Suzanne Scotchmer, 'Intellectual Property: When Is It the Best Incentive System?' in Adam Jaffe, Joshua Lerner and Scott Stern, (eds), *Innovation Policy and the Economy, Vol 2*, (2000) 51.

[2] See William M Landes and Richard A Posner, *The Economic Structure of Intellectual Property Law* (2003) 11. Essentially, a cost-benefit analysis of the grant of property privileges involves weighing up the static and dynamic benefits of property ownership against transaction costs inherent in transferring privileges, the rent seeking behaviour of property owners, and the costs of protection of property privileges.

[3] Ibid, 36.

[4] These are, primarily, its non-excludable nature and ease of appropriability, and its non-rivalrous nature; see Intellectual Property and Competition Review Committee, Parliament of Australia, *Review of Intellectual Property Legislation Under the Competition Principles Agreement: Final Report* (2002) (IPCRC Report), 210. Indeed, the economic and social costs of property ownership are exacerbated in the case of intellectual property protection; ibid, 12-21. For further discussion on the concept of rivalrous as opposed to non-rivalrous technologies, see below, 3.2.

[5] These theories are based largely on the work of John Locke, a seventeenth century philosopher. For a summary see, eg, Fritz Machlup and Edith Penrose, 'The Patent Controversy in the Nineteenth Century' (1950) 10(1) *Journal of Economic History* 1 at 11-21; Robert P Merges, Peter S Menell and Mark A Lemley, *Intellectual Property in the New Technological Age* (2nd ed, 2000), 2-12.

[6] Machlup and Penrose, above n5, 11-21.

however, been less popular as a justification for the patent system than so-called public-interest rationales, or economic justifications.

2.2.2 ECONOMIC THEORIES

A consideration of the economic context in which patents operate is important not only in explaining why a patent system is in place, but also in assisting policy makers in debating and determining the appropriate parameters of patent law.[7] In 1953, Fritz Machlup undertook a review of economic analyses of the patent system. These analyses were generally pessimistic, questioning the need for a state-granted monopoly as an incentive for innovation. He concluded that despite the current patent system having some negative economic consequences, there was no alternative model to replace it, and that it had some positive aspects.[8] The patent system has been described as '...a crude and imperfect instrument...' in its role of incentive provision.[9] The economic theories can be broadly categorised as follows:[10]

- invention-inducement theory;
- disclosure theory;
- development and commercialisation theory; and
- prospect development theory.

As Mazzoleni and Nelson point out, these theories are not mutually exclusive, and different versions of the various theories are at odds.[11] A number of the theories are grounded in property rights theory, while others are premised on economic theory. The various theories differ in the fundamental assumptions they make about the conditions for invention, development and commercialisation. The invention inducement theory is the most forceful theory that has evolved to justify the existence of the patent system, and it has underpinned much of the empirical work seeking to

---

[7] See, eg, Mark A Lemley, 'Biotechnology's Uncertainty Principle' (2004) 54 *Case Western Reserve Law Review* 691.

[8] Fritz Machlup, *An Economic Review of the Patent System* (1958).

[9] Frederic M Scherer and David Ross, *Industrial Market Structure and Economic Performance*, (3rd ed (1990) 624.

[10] Roberto Mazzoleni and Richard R Nelson, 'Economic Theories about the Benefits and Costs of Patents' (1998) 32(4) *Journal of Economic Issues* 1031 (Mazzoleni and Nelson). The following discussion is based on the analysis by Mazzoleni and Nelson of the various economic theories of the costs and benefits of patents; See also Kenneth W Dam, 'The Economic Underpinnings of Patent Law', (1994) 23 *Journal of Legal Studies* 247.

[11] Mazzoleni and Nelson, above n10, 1033.

ascertain the effectiveness of patents. This theory appears to be particularly relevant to biomedical research.

The other justifications for the patent system focus on dissemination rather than encouragement of innovation, and have been referred to by one scholar as ex-post justifications for patent protection.[12] The issue of dissemination of invention and the role of competition law in this regard becomes the focus of this thesis in later chapters. A number of these other theories would appear to be equally relevant to the nature of biomedical research, as discussed in Chapter 1. In particular, the prospect theory cannot be discounted. The prospect theory has, as its exegesis the development and commercialisation theory. The invention-inducement theory represents a largely internal incentive for the generation of patents, while the prospect theory is arguably more external and focuses on the market for patented products and processes. The ability to efficiently transfer patented technology forms the core of this thesis.

2.2.2.1 *INVENTION-INDUCEMENT THEORY*

The main justification for the patent system is the argument that patents are necessary to induce innovation.[13] Implicit in invention-inducement theories, are the assumptions that patent protection is necessary to motivate innovation, and that stronger patent protection will increase the amount of invention.[14] Because they allow the exclusion of imitators, patents provide the incentive to engage in the innovative process. Earlier versions of the theory proceeded on fairly simplistic assumptions;[15] for example, that inventors simultaneously worked in diverse and non-competing areas,[16] and that the social value of most inventions lies in their final-use value.[17] In some research areas, particularly high-technology areas such as biotechnology, the situation is clearly more

---

[12] Mark A Lemley, 'Ex Ante versus Ex Post Justifications for Intellectual Property' (2004) 71 *University of Chicago Law Review* 129.

[13] There is little guidance as to how much innovation is optimal, but it has been suggested that there is unlikely to be too much innovation from an economic welfare perspective; Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) (Federal Trade Commission Report), ch 2, their n30. See also Thomas M Jorde and David J Teece, Rule of Reason Analysis of Horizontal Arrangements: Agreements Designed to Advance Innovation and Commercialise Technology, (1993) 60 *Antitrust Law Journal* 579, 584.

[14] Mazzoleni and Nelson, above n10, 1034-1035.

[15] Ibid, 1035-1036.

[16] See, eg, Kenneth J Arrow 'Economic Welfare and the Allocation of Resources for Invention' in Richard R Nelson (ed), *The Rate and Direction of Inventive Activity* (1962); 609; William D Nordhaus, *Invention, Growth and Welfare: A Theoretical Treatment of Technological Change* (1969).

[17] See, eg, Nordhaus, above n16; F Michael Scherer, 'Nordhaus's Theory of Optimal Patent Life: A Geometric Reinterpretation' (1972) 62 *American Economic Review* 422; Paul Klemperer, 'How Broad Should the Scope of Patent Protection Be?' (1990) 21 *RAND Journal of Economics* 113.

complicated, and versions of the theory have developed to attempt to take this into account.[18]

Whether patents actually encourage innovation is a difficult question in relation to which there is some limited empirical evidence. The importance of patents in this regard is often emphasised in respect of the biotechnology industry, and particularly the pharmaceutical industry. Two major studies have investigated the extent to which patent protection, as opposed to other methods of preventing imitation, is perceived as necessary to capture the benefits of technological innovations.[19] Alternatives to using patents to protect innovation include secrecy, lead time, moving quickly down the learning curve, and complementary sales and service to customers. In surveying large samples of R&D laboratory managers from industrial companies, both of these studies found that patents ranked as the second least effective means of capturing the benefits of product innovation.[20] Both of the studies found that patent protection was, however, more important to pharmaceutical companies, with pharmaceutical companies in one study ranking it the most important means of protecting innovation,[21] and pharmaceutical companies in the other study ranking it second.[22]

These results suggested that patent protection is of limited value to many manufacturing companies, but undoubtedly important to the pharmaceutical industry. Scherer suggests three probable reasons for this:[23]

- in pharmaceutical patent claims, products are defined especially precisely;[24]
- the high costs of clinical trials; and

---

[18] See generally Mazzoleni and Nelson, above n10, 1036-1038, where variations of the theory are discussed.

[19] Richard Levin, Alvin Klevorick, Richard Nelson and Sidney Winter, *Brookings Papers on Economic Activity: Microeconomics* (1987); Wesley Cohen, Richard Nelson and John Walsh, 'Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)', (Working Paper No 7552, National Bureau of Economic Research, 2000). See also Edwin Mansfield, 'Patents and Innovation: An Empirical Study' (1986) 32(2) *Management Science* 173 where patents found to be of limited value in most industries, except pharmaceuticals and chemicals, although this did not affect levels of patenting. Inventors went on to patent in most instances despite a perception that patents were unimportant.

[20] Levin, Klevorick, Nelson and Winter, above n19; Cohen, Nelson and Walsh, above n19. Levin and Others also found that for new processes, patents were considered to be the least effective method behind secrecy.

[21] Levin, Klevorick, Nelson and Winter, above n19.

[22] Cohen, Nelson and Walsh, above n19.

[23] Frederic M Scherer, 'The Economics of Human Gene Patents' 77 *Academic Medicine* (2002): 1348, 1351-2.

[24] The same argument applies to organic and agricultural chemicals; ibid, 1351-2.

- the low investment required to imitate through generic substitutes.

Indeed, data shows that pharmaceutical companies in Australia devote between $200 million and $450 million annually to research and development, with a large proportion of this amount being expended on clinical trials.[25] Currently, the cost of bringing a new drug to market is estimated to be in the vicinity of AU$900 million.[26]

The case in relation to biotechnology innovation is not so clear-cut. There is some evidence to suggest that extremely high research and development in high-technology industries such as biotechnology make patent protection crucial, particularly in order to raise venture capital.[27] Patent protection may also assist in facilitating access to capital through alliance activity,[28] although there may of course be many reasons for companies seeking to enter into collaborative arrangements.[29]

Other commentators have questioned the necessity of granting patents to protect publicly-funded research, which comprises a significant proportion of basic biomedical research. Given that this research would receive funding in any event, it may be that patents are unnecessary to promote biomedical innovation.[30] A considerable amount of biotechnology research in Australia is still publicly funded. The amount of privately funded research is increasing, but it may be that patents are important to the research community even where that research is publicly funded. Many research institutions reliant on public funding have a clear imperative to attract investment through technology transfer, and in this respect, the ability to patent inventions is an important incentive to undertake research.[31]

---

[25] Department of Industry Tourism and Resources, Commonwealth of Australia, *Pharmaceuticals Industry Profile* <http://www.industry.gov.au/content/itrinternet/cmscontent.cfm?objectID=8B4157C0-C0F3-47EE-B3C3994EECB2A4CB> at 18 May 2004.

[26] Ibid. Lawson asserts that there is no solid Australian data to support contentions by the pharmaceutical industry that it faces extremely high research and development costs; Charles Lawson, 'Some Economic Questions for Biotechnology Patenting in Australia' (2000) 41 *IP Forum* 10.

[27] Scherer, above n23, 1353; David H Hsu and Tim Bernstein, 'Managing the University Technology Licensing Process: Findings from Case Studies', (1997) 9 *Journal of the Association of University Technology Managers* 1. Cf Cohen, Nelson and Walsh, above n19, whose results suggested that smaller companies are less likely to rely on patent protection than larger companies, perhaps because of the costs associated with defending patents.

[28] See Johua Gans, David H Hsu and Scott Stern, *When Does Start-up Innovation Spur the Gale of Creative Destruction?*, (Working Paper, Intellectual Property Research Institute of Australia 2002).

[29] See generally Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 94-123.

[30] See, eg, Arti K Rai and Rebecca S Eisenberg, *Bayh-Dole* Reform and the Progress of Biomedicine, (2003) 66 *Law and Contemporary Problems* 289, 300-302.

[31] See Nicol and Nielsen, above n29, 126

Related issues arise in relation to patenting of more upstream inventions, such as human gene sequences. Scherer questions whether patents are a necessary incentive to innovate in the area of human genomics, and considers how gene sequence patents affect investment in more downstream therapeutic entities.[32] Scherer concludes that policy that supports withholding rights for gene sequences would be likely to delay, but not completely inhibit seminal invention at a more downstream level given the competitive environment in which innovation in this field is proceeding.[33] Scherer's analysis is confined to gene sequences, and it would appear that in the United States (US) at least, patenting of human DNA sequences affects only a small fraction of all research and development activity in the area of biology.[34] Thus, it may be that outside this limited area, patenting becomes more important in terms of the recoupment of research and development costs.

2.2.2.2 *DISCLOSURE THEORY*

This theory rests on the assumption that invention will not take place without the inducement of a patent. It is predicated on the ground that patents perform an important public interest function, of promoting disclosure of inventions, and without the patent system, there would be little incentive to disclose an invention.[35] As Mazzoleni and Nelson point out, the antithesis of the invention-inducement theory is the disclosure theory.[36] Unlike secrecy patents may encourage contracting and thus increased dissemination of inventions.[37]

2.2.2.3 *DEVELOPMENT AND COMMERCIALISATION THEORY*

Based on the assumption that many inventions will require extra development before they are ready for use, the development and commercialisation theory posits that many inventions will not result directly in a marketable product.[38] Instead, this theory

---

[32] Scherer, above n23. In Chapter One, the merging of basic and applied science was discussed; see above, 1.4.3. The issue of patents as an incentive to innovate may be similar in respect of both basic, upstream inventions, and more downstream, practical inventions.

[33] Ibid, 1359-1361,1363-1364.

[34] Ibid, 1356-9.

[35] As Mazzoleni and Nelson suggest, this may particularly be the case with process patents, given the findings by Levin, Klevorick, Nelson and Winter that secrecy is a more preferred method of protecting innovation than patents, Mazzoleni and Nelson, above n10, 1039.

[36] Ibid, 1038-1039.

[37] Ibid, 1039.

[38] Note that implicit in this theory is the view that many steps may be required before a 'consumer product' is available. This theory is based on the assumption that a patented invention will lead to one, ultimate commercial product; see Mazzoleni and Nelson, above n10, 1042. Chapter 3 deals with the

asserts that without proprietary rights, owners of upstream inventions would find it difficult to market their products to more downstream developers.[39] Patents may prompt an inventor to seek out opportunities to have inventions developed and commercialised, and may reduce the need for vertical integration within companies. In other words, it may enable specialisation within companies or institutions because it enables them to contract out various functions on the road to product development.

2.2.2.4 *PROSPECT DEVELOPMENT THEORY*

Following on from the development and commercialisation theory, Edmund Kitch presented a new theory of the patent system that attempted to realign the law of patents with the theory of property rights.[40] The focus of property rights theory within the context of intellectual property is the ability of owners of intellectual property to license, thus ensuring optimally efficient use of their intellectual property.[41] The distinguishing feature of Kitch's work is that previous theory had focused on intellectual property as an incentive-by-reward system. The fundamental premise of Kitch's theory is that the prospect of coordinating future research paths, rather than the initial reward generated by the grant of intellectual property, will provide an incentive for innovation.[42] Further the ability to coordinate research will reduce duplication of research efforts and eliminate patent races.[43] The theory also assumes that many inventions will be applicable to a range of follow-on uses.[44] In short, the prospect theory advocates broad, upstream patents with few limitations on their use.

The prospect theory assumes that coordinating future research will be possible, and that the transaction costs of doing so will be low. As Burk and Lemley point out, one of the economic bases of the prospect theory, is the Coasean Theorem[45] which embodies the notions of perfect information, rationality on the part of the parties to a

---

issue of cumulative innovation and its impact on contracting within the biotechnology industry. For a more detailed discussion of the process of contracting within the biomedical industry see below, 3.3.4.5.

[39] See, eg, ibid, 1040-1941.

[40] Edmund Kitch 'The Nature and Functions of the Patent System, (1977) 20 *Journal of Law and Economics* 265, 265.

[41] Ibid, 265, 275-79; Robert P Merges, 'Of Property Rules, Coase, and Intellectual Property' (1994) 94 *Columbia Law Review* 2655, 2661.

[42] Kitch, above n40, 267-271.

[43] Ibid, 278.

[44] Mazzoleni and Nelson, above n10, 1042.

[45] Ronald H Coase, 'The Problem of Social Cost' (1960) 3 *Journal of Law and Economics* 1. On the issue of transaction costs in licensing see also below, 3.3.3.

licence deal, and costless licensing.[46] The other economic foundation of the prospect theory is the tragedy of the commons, or the risk that a particular resource will be overused in the absence of a broad patent that allows the coordination of research.[47]

2.2.2.5 *SUMMARY*

The adoption of a particular justification for patents will have resulting implications for competition policy.[48] For example, reliance on the prospect theory as a basis for granting broad patent protection to upstream innovators will reduce the importance of competition regulation of those rights, because the theory is based on allowing an initial innovator to license freely. Conversely, if the grant of patents is predicated on the invention-inducement theory, there is likely to be more concern to limit the scope of those rights to what is necessary to induce innovation and prevent free-riding, thus broadening the role of competition law.

In reality, however, there is no one-size-fits-all theory. Of the theories discussed above, the invention-inducement theory is probably the 'standard justification' for intellectual property protection.[49] The invention-inducement theory alone is unlikely to provide a concrete foundation for complex questions relating to patent standards and the interplay of patent law and competition law. Indeed, other theories are arguably more likely to be suited to industries such as biomedicine that are based on a rapid flow of scientific information and techniques.[50] The development and commercialisation and prospect theories, for example, may be particularly relevant to industries where bargaining for the transfer of patents is necessary.[51] The prospect theory also appears to be suited to industries characterised by long product-development cycles where a long period precedes the practical application of an initial invention.[52] The result is that there is, as yet, extremely limited empirical evidence

---

[46] Dan L Burk and Mark A Lemley, 'Biotechnology's Uncertainty Principle' (2004) 54 *Case Western Reserve Law Review* 691, 723. The notion of 'commons' and 'anti-commons' property is dealt with further below, 3.4.2.

[47] Ibid.

[48] And of course for patent policy.

[49] Lemley, above n12, 129.

[50] Mazzoleni and Nelson, above n10, 1044-1048.

[51] Ibid, 1041, 1043. The development and commercialisation theory may be particularly relevant in relation to the commercialisation of university inventions, where patents are unlikely to be required to induce invention, but will facilitate the transfer and subsequent development of university inventions at 1041.

[52] Ibid, 1044.

with which to analyse the suitability of patent protection in a particular industry, or the respective roles that patent law and competition law should play.

It is submitted that the incentive-inducement justification provides a strong argument for patent protection on biomedical inventions.[53] In biomedical research patents are becoming key to attracting investment, and without the promise of a patent, certain research and development would not be undertaken. The automation of processes necessary for upstream biomedical innovation has, however, simplified the generation of a number of upstream products in biomedical research.[54] This throws into question the necessity for patent protection as an incentive to invest in research and development in respect of certain technologies.[55]

A number of the ex post justifications seem particularly suited to the structure of the research environment in biotechnology. In particular, the prospect theory would appear to be especially applicable.[56] The cumulative nature of innovation means that the broad dissemination of inventions is more likely to lead to rapid advancement in technology.[57] It may be that neither the invention-inducement theory nor the ex post theories provide a complete justification for biotechnology patents, but in combination they help to explain why a patent grant may be warranted in respect of particular biotechnology products and technologies. Thus, it is submitted that the following contention by Lemley with respect to the prospect theory has resonance in relation to upstream biotechnology patents:

> [P]rospect theory is most useful when conceived as a part of, rather than in opposition to, the classical public goods story. Prospect theory is needed when control over subsequent development is a necessary part of the incentive to produce the pioneering invention in the first place, as is arguably true with pharmaceuticals.[58]

---

[53] Cf Lawson, who argues that there is no systematic economic data to indicate that this is the case; Lawson, above n26.

[54] The generation of gene sequence data is an obvious example. This represents a limited portion of upstream biomedical research, and other upstream technologies may require considerably more research and development expenditure.

[55] See Dan L Burk and Mark A Lemley, 'Policy Levers in Patent Law' (2003) 89 *Virginia Law Review* 1575, 1583.

[56] Burk and Lemley have argued that the prospect theory is particularly suited to pharmaceutical invention; see, eg, ibid, 1600.

[57] This assumes that inventions will be broadly disseminated or at least disseminated to those with the best means to further develop the invention. This assumption may not always be valid. See below, 3.3.2, 3.3.3.

[58] Lemley, above n12, 141 (references omitted).

Chapter 3 will consider these issues further in analysing the private ordering of incentives in a cumulative industry such as biotechnology, and it will be argued that initial innovators cannot always be relied upon to effectively disseminate their inventions and thus ensure that necessary follow-on research is pursued.[59] There may be difficulties in conducting bargaining in order to enable follow-on research to proceed. Accordingly, it will be argued that the prospect theory has limitations that render its utility questionable. Further, in considering the application of competition law to intellectual property, Chapter 5 will draw on this discussion in examining the bounds of competition law regulation of intellectual property.

2.3 International Obligations In Relation To Patent Law

Increasing levels of globalisation have resulted in the internationalisation of intellectual property law. The boundaries of intellectual property law and protection are generally national. However, because of the increasingly international nature of intellectual property, an initial step in any examination of national patent law is to consider the international context.

Australia has certain obligations in relation to providing intellectual property protection not only for Australians, but also for foreigners wishing to obtain protection in Australia. In return, Australians can obtain intellectual property protection in a number of other countries. The international intellectual property system has operated on a reciprocal basis since its inception. The provision of intellectual property protection through a robust intellectual property system is considered to contribute to economic growth and consumer welfare. Intellectual property protection is perceived to be important in terms of promoting innovation, and enhancing dissemination of inventions. As such, efforts at international harmonisation have been premised largely on invention-inducement theory. Successive federal governments in Australia have certainly stressed this benefit of facilitating commercialisation. As such, Australia is a signatory to a number of international conventions dealing with intellectual property protection. The major conventions are:

- the *Paris Convention for the Protection of Industrial Property* 1883 (the *Paris Convention*);[60]

[59] See below Chapter 3, especially 3.3.4.5.

[60] *Paris Convention for the Protection of Industrial Property* [1972] ATS 12 (entered into force 20 March 1883).

- the *Patent Cooperation Treaty* (the PCT);[61] and
- the *Agreement on Trade-Related Aspects of Intellectual Property Rights* 1994 TRIPS).[62]
- the *Patent Law Treaty* 2000.[63]

2.3.1 THE *PARIS CONVENTION*

The *Paris Convention* was the first multilateral convention governing the grant of industrial property rights.[64] It introduced a number of important concepts, most notably, the principle of national treatment, which prevents discrimination against non-nationals from other signatory countries applying for intellectual property protection.[65] Although it did not lay down uniform standards of protection for member states, the *Paris Convention* did provide that an application for protection in one member state should not prejudice an application in other member states, that is, it provided that the priority date of the first application should count as the priority date of subsequent applications.[66] Membership of the *Paris Convention* currently stands at 164 member countries,[67] and the convention has been subject to revision on a number of occasions.[68] Australia is a signatory to the *Paris Convention.*

2.3.2 THE *PATENT COOPERATION TREATY*

Australia became a signatory to the Patent Cooperation Treaty in 1970.[69] The Treaty allows an applicant to file a single international patent application for protection, and

---

[61] *Patent Cooperation Treaty* [1980] ATS 6 (entered into force 24 January 1978).

[62] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C of the Marrakesh *Agreement Establishing the World Trade Organization*, [1995] ATS 12 (entered into force 15 April 1994).

[63] *Patent Law Treaty* opened for signature June 1 2000, WIPO Database of Intellectual Property Legislative Texts (entered into force 28 April 2005).

[64] 'Industrial' property rights as defined under the Treaty has a broad meaning and includes patents. The term 'industrial property' is derived from the French term 'propriete industrielle', with the term 'industrielle' encompassing all aspects of human labour; see the discussion in Jill McKeough, Kathy Bowrey and Philip Griffith, *Intellectual Property: Commentary and Materials*, (3rd ed 2002) 3.

[65] *Paris Convention for the Protection of Industrial Property* [1972] ATS 12 (entered into force 20 March 1883) art 2.

[66] *Paris Convention for the Protection of Industrial Property* [1972] ATS 12 (entered into force 20 March 1883) art 4.

[67] For details see <http://www.wipo.org/treaties/en/documents/pdf/d-paris.pdf> at 16 February 2004.

[68] The text of, and details of revisions to, the *Paris Convention for the Protection of Industrial Property* [1972] ATS 12 (entered into force 20 March 1883) are available at <http://www.wipo.org/clea/docs/en/wo/wo020en.htm> at 1 July 2005.

[69] Details of member states are available at <http://www.wipo.org/treaties/en/documents/word/m-pct.doc> at 16 February 2004.

designate member states in which protection is sought. Applications are sent to national offices for examination and grant of patents.

2.3.3 THE *AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS*

Pressure by developed countries to standardise international intellectual property standards led to the adoption of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) by World Trade Organisation members (WTO) in 1994. TRIPS is an annex to the *Agreement Establishing the World Trade Organisation*, and comprises part of the *General Agreement on Tariffs and Trade*. It prescribes the minimum standard of intellectual property protection that must be adhered to by WTO members.[70] The aims of TRIPS are stated in Article 7 to be the promotion of innovation and the transfer and dissemination of technology through intellectual property protection and enforcement. Fundamental principles behind TRIPS are the enhancement of free trade through adequate intellectual property protection, and ensuring that intellectual property enforcement measures do not restrain the international transfer of technology.[71] Australia's intellectual property regime was compliant with many of the TRIPS requirements, and relatively few measures were taken to ensure that Australia was in line with TRIPS standards. These changes were implemented as a result of the *Patents (World Trade Organisation) Act* 1994 (Cth).[72]

2.3.4 THE *PATENT LAW TREATY* 2000

In addition, the *Patent Law Treaty* 2000 aims to harmonise administrative procedures such as filing patent applications. The Treaty was adopted on 1 June 2000 and has 54 signatories.[73] In addition, a number of countries have bilateral or regional arrangements. In particular, the *European Patent Convention*, which includes non-European states in it membership, is concerned with the granting of European patents.

---

[70] Membership of the WTO currently stands at 148 countries (16 February 2005). See <http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm> at 1 July 2005.

[71] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C of the Marrakesh *Agreement Establishing the World Trade Organization*, [1995] ATS 12 (entered into force 15 April 1994), art 8.

[72] *Patents (World Trade Organisation) Act* 1994 (Cth) (1994).

[73] For details see <http://www.wipo.org/treaties/en/documents/pdf/u-page34.pdf> at 16 February 2004.

2.4 PATENTABILITY OF BIOTECHNOLOGY INVENTIONS IN AUSTRALIA

Notwithstanding the lack of empirical evidence as to whether patents in biomedical research are justified, this chapter will demonstrate that many biomedical inventions meet the requirements for patentability laid out in international and Australian patent law. In Australia, patentability is assessed pursuant to the *Patents Act* 1990 (Cth) (the *Patents Act* 1990), and patent applications are examined for validity by the Australian Patents Office, a division of IP Australia. An inventor may choose to file a provisional application, or a complete application. A provisional application allows an applicant to file an application with a provisional specification,[74] and gives the applicant additional time in which to finalise the specification. A complete application with complete specification must be filed within 12 months of filing a provisional application, but the priority date of the patent application will be the date of filing the provisional application.[75] Securing a priority date is crucial in Australia and Europe where the first to file rule applies. In the US this may not be the case because the first to invent rule applies.[76] Accordingly, the US legislation[77] makes provision for interference proceedings which are designed to allow the determination of a priority date under the first to invent rule.[78]

TRIPS sets out the fundamental requirements for patentability of an invention, with Article 27 stating that patents shall be available for inventions in all fields of technology provided that they satisfy the requirements of novelty, inventive step and industrial applicability. These requirements must be applied without discrimination as to the place of invention, the field of technology, or the place of production.[79] Article 29 of TRIPS further provides that the best method of performing the invention must be fully described in the patent document. In Australia, these requirements translate

---

[74] Where the applicant must describe the invention in general terms only.

[75] The priority date of a claim is defined as the date of filing of the specification, or where the Patents Regulations provide for a different date, the date determined under the regulations; *Patents Act* 1990 (Cth), s 43(2).

[76] A first to invent rule means that an inventor who is the first to invent may still be accorded priority despite not being the first party to file a patent application. The rule has been criticised because of the difficulty of determining the first to invent. For criticism of the first to invent rule and recommendation that the US conform to a first to file rule, see Stephen A Merrill, Richard C Levin and Mark B Myers (eds) *A Patent System for the 21st Century* (2004), 124-127.

[77] *Patent Act* 35 USC (1952).

[78] *Patent Act* 35 USC §135 (1952).

[79] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C of the Marrakesh *Agreement Establishing the World Trade Organization*, [1995] ATS 12 (entered into force 15 April 1994), art 27.

into the invention requirements contained in s 18(1) of the *Patents Act* 1990, and the specification requirements contained in s 40. These requirements are based significantly on the requirements for patentability contained in the *Patents Act* 1952 (Cth) (the *Patents Act* 1952), the predecessor to the 1990 legislation. A good deal of case law relevant to the interpretation of sections 18(1) and 40 was decided in the context of corresponding provisions of the *Patents Act* 1952.

Section 18(1) of the *Patents Act* 1990 sets out the requirements for patentability as follows:

> Section 18 Patentable inventions
>
> Patentable inventions for the purposes of a standard patent:
>
> (1) Subject to subsection (2),[80] an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:
>
> (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and
>
> (b) when compared with the prior art base as it existed before the priority date of that claim:
>
> (i) is novel; and
>
> (ii) involves an inventive step; and
>
> (c) is useful; and
>
> (d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

Thus, the requirements for the grant of a standard patent are that:[81]

- there must be an invention which is a manner of manufacture;

---

[80] Subsection (2) provides that human beings, and the biological processes for their generation, are not patentable inventions; see further below, 2.4.1.2(ii).

[81] The *Patents Act* 1990 (Cth) also makes provision for the grant of an 'innovation patent', the requirements for the grant being contained in s18(1A). The only point of difference is that an invention must involve an 'innovative step' rather than an 'inventive step'. As such, a lower level of inventiveness is required for an innovation patent, and the term of an innovation patent is correspondingly shorter at eight years; s 68. General references to patents during the course of this chapter will include reference to standard patents and innovation patents.

which

- is novel;
- involves an inventive step;
- is useful; and
- has not been secretly used.

Not all of these requirements are considered during the process of examination of a patent. Manner of manufacture, novelty and inventive step must all be assessed as part of the examination procedure.[82] They are also available as grounds for opposition to a patent.[83] Usefulness and secret use are not part of the examination procedure, and are not available as grounds for opposition.[84] Instead, they are, (along with the other three requirements of manner of manufacture, novelty and inventive step), available as grounds for revocation proceedings.[85] Revocation proceedings are usually instituted in response to infringement proceedings.[86] The Australian Law Reform Commission (ALRC) recently recommended amendment to the *Patents Act* 1990 so that all of the requirements for patentability be assessed on the balance of probabilities.[87] At present, only novelty and inventive step are assessed on the balance of probabilities during examination,[88] with the remaining requirements being assessed on the basis that the applicant is given the 'benefit of the doubt'.[89]

---

[82] *Patents Act* 1990 (Cth), s 45(1)(b) and s 45(1)(c).

[83] *Patents Act* 1990 (Cth), s 59. Section 59 provides any party with the opportunity to oppose the grant of a standard patent within three months of acceptance by the Patent Office of a patent application. A patent will be granted or sealed at the expiry of this three-month period.

[84] Note that the ALRC has recommended that utility be included as a ground for examination and opposition; discussed below, see below, 2.4.4.

[85] *Patents Act* 1990 (Cth), s 138. Section 138 provides that any person may apply at any time after the grant of a patent, for an order that the patent be revoked.

[86] *Patents Act* 1990 (Cth), s 121. Chapter 11 of the *Patents Act* 1990 (Cth) makes provision for the institution of infringement proceedings in certain circumstances, and specifies the procedure for those proceedings; see in particular ss 117, 120.

[87] Australian Law Reform Commission, Parliament of Australia, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99 (2004) (ALRC Report), Recommendation 8-3. The ALRC received a reference to consider issues associated with the patenting of genes and genetic technologies. See further, below, 4.2.2.4.

[88] *Patents Act* 1990 (Cth), s 49(1)(a). Prior to the changes introduced by virtue of the *Patents Amendment Act* 2001 (Cth), a patent examiner was required to give a patent applicant the benefit of doubt if they had reservations about novelty and inventive step. The *Patents Amendment Act* 2001 (Cth) tightened up a number of aspects of novelty and inventive step.

[89] *Patents Act* 1990 (Cth), s 49(1)(b).

2.4.1 THE INVENTION REQUIREMENT: MANNER OF MANUFACTURE

2.4.1.1 *THE MANNER OF MANUFACTURE TEST*

According to the definition of 'invention' contained in Sch 1 of the *Patents Act* 1990:

> invention means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the *Statute of Monopolies*, and includes an alleged invention.

As is evident from s18(1) and the definition of invention contained in Sch 1, the English *Statute of Monopolies* 1623, the precursor to all English and Australian patent legislation, retains an important role in laying down the threshold requirements for patentability. The retention of the language of manner of manufacture is an attempt to avoid circumscribing in detail the circumstances in which an alleged invention will be patentable.

The central debate in relation to the inventiveness (incorporating the manner of manufacture) requirement in s18(1), has been whether or not an invention results in a 'vendible matter'[90] or 'vendible product'.[91] The leading case is *National Research Development Corporation* v *Commissioner of Patents* (*NRDC*).[92] In considering the manner of manufacture test, the court in *NRDC* said that it is a mistake to adhere to the literal meaning of the word 'manufacture'. Rather '[t]he right question is '... is this a proper subject matter of letters patent according to the principles which have been developed for the application of s 6 of the Statute of Monopolies?''[93]

In laying down this requirement, the court was endeavouring to set out an ambit within which an alleged invention must fall, rather than delineating precisely the circumstances in which an invention will be considered to be a manner of manufacture. Further, the court commented that a process, in order to fall within the limits of patentability within s6 of the Statute of Monopolies, must offer a material advantage in the sense that the process belongs to the useful arts as distinct from the fine arts, and must convey some value in the field of economic endeavour.[94] Thus, if a process produces an '...artificially created state of affairs...' which has some

---

[90] *Boulton* v *Bull* (1795) 126 ER 651, 661 (Heath J).

[91] *GEC's Application* (1942) 60 RPC 1, 4 (Morton J).

[92] *National Research Development Corporation* v *Commissioner of Patents* (1959) 102 CLR 252.

[93] Ibid, 269.

[94] Ibid, 275.

economic utility then the threshold test for patentability will be satisfied.[95] This may include the application of newly determined properties of a previously known substance, to a new use.[96] In contrast, 'a claim for the use of a known material in the manufacture of known articles for the purpose of which its known properties make that material suitable',[97] or an application claiming simply a 'new use of a particular known product', will fail to meet the invention threshold.[98]

The principle from *NRDC* is important in the context of biological inventions because many of these inventions involve the application of a new product to a previously unknown use. It thus paved the way for process patents[99] in the biotechnology field, which comprise a significant proportion of patents in this area.[100] The test enunciated in *NRDC* would not be difficult to overcome for a large range of biotechnological and genetic inventions, including cell lines, hybridomas, viruses, genetic vectors and expression systems, mutations or genetic engineering, DNA, RNA and genes, mutant and synthetic genes and proteins expressed by a gene.[101]

The ALRC considered the manner of manufacture test, and commented that there were difficulties with its composition and implementation. Nevertheless, they declined to make specific recommendations that a new threshold test for patentability replace the manner of manufacture test in respect of genetic materials.[102] This was primarily because to do so would constitute a departure from international standards, and because of the preponderance of naturally occurring organisms (including genetic sequences) that have already been considered to satisfy the existing threshold of

---

[95] Note that the claim in *National Research Development Corporation* v *Commissioner of Patents* (1959) 102 CLR 252 involved not only a process claim, but it also involved a claim for agricultural and horticultural processes, which had traditionally not been patentable.

[96] Ibid, 268. In contrast, 'a claim for the use of a known material in the manufacture of known articles for the purpose of which its known properties make that material suitable', or an application claiming a 'new use of a particular known product', will fail to meet the invention threshold.

[97] *Commissioner of Patents* v *Microcell Ltd* (1959) 102 CLR 232, 251.

[98] *NV Philips Gloeilampenfabrieken* v *Mirabella International Pty Ltd* (1995) 183 CLR 655, 659.

[99] While a product patent covers all uses of a patented product, a process patent claims rights to all uses of a patented technology. These are the broadest forms of protection available for biomedical products and technologies, because they give protection for all uses whether or not those uses are known at the time of patenting. Product by process claims protect one particular product produced using a particular process. Use claims cover specific claimed uses; see Dianne Nicol, 'On the Legality of Gene Patents' submitted to *Melbourne University Law Review*.

[100] See IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, 1, (IP Australia Guidelines) <http://www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 6 June 2005.

[101] See ibid.

[102] ALRC Report, above n83.

patentability.[103] Instead, they recommended that the general operation of the manner of manufacture test be independently reviewed, with focus on the 'generally inconvenient' requirement.[104]

Although *NRDC* and subsequent case law broadened the extent of patentable subject matter, there are a number of statutory exclusions from patenting. These can be classified as:

- Allowable exclusions under TRIPS.
- Exclusions under the Australian *Patents Act* 1990;
- Exclusions under the Statute of Monopolies 1623; and

A number of case law exceptions have also developed for material considered to be unpatentable pursuant to the *NRDC* test. The statutory exclusions will be examined prior to the relevant case law exclusions.

2.4.1.2 *STATUTORY EXCLUSIONS FROM PATENTING*

Relevant TRIPS exclusions will be considered first, followed by specific exclusions provided for under the *Patents Act* 1990. Finally, exclusions under the Statute of Monopolies will be briefly considered.

(i) TRIPS Exclusions

Adoption of the exclusions contained within TRIPS is not obligatory,[105] but they set the limits for WTO countries on allowable exclusions by providing the basis for statutory exclusions from patentability and justifying case law exceptions.

Public Policy

TRIPS contains limited provision to exclude classes of inventions from patentability on the grounds of public policy. Article 27(2) provides:

---

[103] Ibid, 130. See also the other reasons listed at 130-131.

[104] Ibid, Recommendation 6-2.

[105] Article 27(2)(a) of *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C of the Marrakesh *Agreement Establishing the World Trade Organization*, [1995] ATS 12 (entered into force 15 April 1994) permits diagnostic, therapeutic and surgical methods for the treatment of humans and animals to be excluded from patentability. Australia has not adopted this exclusion. In relation to methods of medical treatment, see below 2.4.1.1(c)(ii) and see the *Australia – United States Free Trade Agreement*, [2005] ATS 1, art 17.9.2.b, which also permits exclusion on this ground.

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

Although not directly incorporated into Australian law,[106] the exception is provided for in Article 53(a) of the *European Patent Convention* and corresponding member state legislation. Article 53(a) has been interpreted as having the purpose of ensuring that inventions that are regarded as outrageous are not patented, and therefore the provision will be invoked only in rare and extreme circumstances.[107] As such, it is difficult to conceive of many circumstances in which the exception will apply. Article 6.2 of the *European Directive on the Legal Protection of Biotechnological Inventions* provides a number of specific examples of inventions that will not be patentable:[108]

- processes for cloning human beings;
- processes for modifying the germ line gene therapy of humans;
- use of human embryos for commercial or industrial purposes; and
- processes for modifying the genetic identity of animals where there is no substantial medical benefit to humans, as well as animals resulting from such processes.

Outside these exceptions, it is likely that the scope of the exception is limited, and this is evidenced by the reluctance of courts to take on public policy considerations in determining patentability.[109]

---

[106] Note, however, the general inconvenience exception, discussed below, which would arguably allow reference to notions of public policy; below, 2.4.1.2(iii).

[107] *Howard Florey/Relaxin* [1995] EPOR 541. The court referred to European Patent Office Guidelines, which state:

> The purpose of this is to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour ... A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patents would be inconceivable.

[108] EC Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, art 6.

[109] See, eg, *Myers Squibb v F H Faulding & Co* (2000) 46 IPR 553.

Exclusion of Plants and Animals

Article 27(3)(b) of TRIPS allows member states to exclude from patentability, plants and animals and the biological processes for their generation (excluding microbiological processes) provided separate plant protection under plant varieties legislation exists. The *Patents Act* 1990 contains such exclusion for innovation patents, but not standard patents,[110] and the *Plant Breeders Rights Act* 1994 (Cth) allows registration where new plant varieties are propagated using selective breeding techniques.

(ii) Australian Patents Act 1990 Exclusions

Human Beings and the Biological Processes for Their Generation

Section 18(2) of *the Patents Act* 1990 provides that human beings and the biological processes for their generation are not patentable subject matter. Although there has been no dispute that human beings should not be patentable,[111] the scope of the second part of the exception is unclear and remains untested. The effect of the exclusion is probably limited in practice, and although far from certain, it may operate to prevent patenting of the cloning of human embryos. It is also not clear, for example, whether human organs derived from the use of stem cell technology would be patentable.[112] This exclusion is limited to patenting of higher life forms (that is, humans), with IP Australia confirming that many lower life forms constitute patentable subject matter.[113]

---

[110] *Patents Act* 1990 (Cth) ss 18 (1A), (3) and (4). In respect of standard patents, Australia has agreed under the Australia – United States Free Trade Agreement not to exclude plants and animals, from patentability; see *Australia – United States Free Trade Agreement*, [2005] ATS 1, art 17.9.2 and 17.9.3.

[111] This has been reinforced by the Australian Patent Office. See IP Australia Guidelines, above n100, 1.

[112] See Matthew Rimmer, 'The Attack of the Clones: Patent Law and Stem Cell Research' (2003) 10 *Journal of Law and Medicine* 488; ALRC Report, above n87, 168, Chapter 15.

[113] See IP Australia Guidelines, above n100. Note that a number of transgenic, non-human animals developed using gene technology have been held to constitute patentable subject matter, the most famous example being the Oncomouse (US Patent 4 736 866). This patent is discussed below, Appendix 2. See also Karinne Ludlow, 'Genetically Modified Organisms and Their Products as Patentable Subject Matter in Australia' [1999] *European Intellectual Property Review* 298.

Discretionary Refusal to Accept Applications

Section 50 of the *Patents Act* 1990 provides the Commissioner for Patents with the discretionary right to refuse to accept patent applications where:

- the use of the invention would be contrary to law;[114]
- a claim for a substance or process producing a substance involves mere admixtures of known ingredients; and
- a claim includes the name of a person as the name, or part of the name, of the invention.

Patentability of Genes and Gene Sequences

Despite two unsuccessful attempts to exclude genes and gene sequences from the bounds of patent law,[115] genes and gene sequences remain patentable provided they are isolated from their naturally occurring environment and characterised.[116] Naturally occurring genes and gene sequences will not be patentable because they fail the test of novelty.[117]

(iii) Statute of Monopolies Exceptions

Section 6 of the *Statute of Monopolies* also precluded the grant of letters patents where the subject matter of the application was:

- contrary to law;
- mischievous to the state by raising prices or harming trade; or
- generally inconvenient

Since it is understood that the 'manner of manufacture' within s 18(1) of the *Patents Act* 1990 incorporates s6 of the Statute of Monopolies, these exceptions are incorporated into s 18(1). Arguably, however, the discretion available to the

---

[114] This is usually taken to mean the sole use of the invention is contrary to criminal law or other statutory provision or rule under the common law.

[115] The history surrounding these proposed exclusions is discussed in detail in Dianne Nicol, *Patenting of Human Genetic Material in Australia* (Masters Thesis, University of Tasmania, 1997) 182-183.

[116] See IP Australia Guidelines, above n100. This position has been supported by the ALRC; ALRC Report, Recommendation 7-1 (191). On the European position see, for example, Joseph Straus, 'An Updating Concerning the Protection of Biotechnological Inventions Including the Scope of Patents for Genes – An Academic Point of View' (2003) *Paper presented at the Conference of Patent Judges*, Special Edition.

[117] See below, 2.4.2.

Commissioner and contained in s 50(1)(a) supersedes the 'contrary to law' provision of s6 of the Statute of Monopolies.[118]

The generally inconvenient clause is sometimes referred to as the 'public policy' exception.[119] It has been used in some circumstances by the Australian judiciary, to deny patentability perhaps most notably by Heerey J (at first instance) in *Bristol-Myers Squibb v FH Faulding & Co Ltd* (*Bristol-Myers*).[120] Heerey J rejected the grant of a patent over a method of administering a known anti-cancer agent on the grounds that it would cause general inconvenience by restricting the choice of doctors in selecting most effective methods of treatment. Heerey J's decision was overturned on appeal. The appeal judges found that methods of medical treatment should be patentable, but on grounds other than general inconvenience.[121] On appeal, the majority rejected the general inconvenience ground as a basis for rejecting a claim for a method of medical treatment, although Sheppard J was prepared to rely on this ground in rejecting the patent claim.[122]

Although it is arguable that the generally inconvenient clause embraces wider notions of public policy,[123] the judiciary have been reluctant to impose public policy considerations on decision-making without clear statutory authority.[124] The legislature has similarly failed to expressly incorporate public policy considerations in relation to the question of patentability. So, for example, ethical concerns about patenting genetically modified plant and animal organisms have not, to date, been addressed by the judiciary in the context of the general inconvenience exception. The ALRC considered it arguable that the generally inconvenient clause included in the 'manner of manufacture' test provides some basis for consideration of social and ethical considerations, but declined to recommend any further exemption from patenting on

[118] William Van Caenagem, *Intellectual Property*, (2001) 137.

[119] See Miranda Forsyth, 'Biotechnology, Patents and Public Policy: A Proposal for Reform in Australia' (2000) 11(4) *Australian Intellectual Property Journal* 202.

[120] *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (1998) 41 IPR 467.

[121] *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) 46 IPR 553; discussed below, 2.4.1.3. See also *Joos v Commissioner of Patents* (1972) 126 CLR 611 per Barwick CJ; *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1993) 25 IPR 119.

[122] See *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1.

[123] Peter Drahos, 'Biotechnology Patents, Markets and Morality' (1999) 21 *European Intellectual Property Review* 441, 441.

[124] See, for example, *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 45.

ethical grounds despite doubt as to the applicability of the generally inconvenient clause.[125]

2.4.1.3 *CASE LAW EXCLUSIONS*

Mere Discoveries/Products of Nature

While patents are available for inventions, they are not available for mere discoveries or products of nature because they do not conform to the requirements of the manner of manufacture test. The High Court in *NRDC* noted the difficulty of distinguishing between discoveries and inventions:

> The truth is that the distinction between discovery and invention is not precise enough to be other than misleading in this area of discussion. There may indeed be a discovery without invention – either because the discovery is some piece of abstract information without any suggestion of a practical application of it to a useful end, or because its application lies outside the realm of "manufacture."[126]

As noted in the Australian Patent Office *Manual of Practice and Procedure Volume 2: National,*[127] discoveries having no way of carrying into effect, ideas, scientific theories, schemes and plans have generally not been considered to be per se patentable, and the critical question is whether the claimed invention relates to patentable or non-patentable subject matter.[128] In determining patentability, the APO *Manual* 2002 states that '... [t]his question can be answered by deciding whether the claimed invention lies in the intellectual or academic realm, or whether it lies in the technical or practical realm. Technical or practical matter is patentable.'[129]

In relation to biotechnological inventions, the question arises as to what will make micro-organisms and other life forms patentable. Traditionally, these biotechnological products and processes have been considered to be naturally occurring substances and

---

[125] ALRC Report, above n87, Recommendation 7-1. See also 188-190. Instead, the ALRC considered that social and ethical concerns can be more adequately addressed through regulation of research activities, and regulation of the exploitation of patented inventions; 188-190.

[126] *National Research Development Corporation* v *Commissioner of Patents* (1959) 102 CLR 252, 264.

[127] Australian Patent Office, *Manual of Practice and Procedure – Volume 2: National,* (2002) (APO *Manual* 2002). Note that the APO Manual merely sets out current examination practice as enunciated by the courts, and is not in itself definitive on patentability.

[128] Ibid, [8.2.5.1].

[129] Ibid, [8.2.5.1].

laws of nature, and therefore not patentable.[130] In line with the judgment of the High Court in *NRDC*, the Australian Patent Office directs examiners that '...a biological entity may be patentable if the technical intervention of man (ie manufacture) has resulted in an artificial state of affairs which does not occur in nature.'[131]

This reflects the position as laid down in the seminal US decision of *Diamond v Chakrabarty*, [132] in which the US Supreme Court upheld a claim for a patent for a genetically modified microorganism effective in the breakdown of crude oil spills. The essential position is that biotechnological inventions will not be patentable unless they have been artificially isolated and can no longer be said to be naturally occurring. Despite little case law in the area, it is well-accepted practice in Australia that organisms and microorganisms (including higher organisms such as genetically engineered plants and animals), elements of organisms (such as genes, gene sequences and proteins), and processes for their isolation and reproduction, are patentable and will not constitute discoveries.[133] Claims falling into these categories will, of course, be subject to all of the requirements of patentability, and the complex issues surrounding the patentability of organisms and their components have been recognised and documented in Australia.[134]

Methods of Medical Treatment

While Article 27(2) of TRIPS allows member states to expressly exclude methods of treating the human body from patentability, in Australia there is no statutory exclusion. Until recently, uncertainty surrounded the patentability of methods of treatment of the human body, with a number of judgments casting doubt on whether or not such processes should be patentable. For example, the High Court in *NRDC* tentatively doubted the patentability of methods of medical treatment, and Justice Barwick in *Joos v Commissioner of Patents*[135] allowed a patent for a substance to improve the keratinous strength of hair and nails on the express basis that cosmetic

---

[130] For example, in *Rank Hovis McDougall Ltd's Application* (1976) 46 AIJP 3915, a claim for a naturally occurring organism was rejected, although a claim for a process of isolating and manipulating the microorganism was accepted.

[131] APO Manual 2002, above n127, [8.2.14.2].

[132] *Diamond v Chakrabarty* 447 US 303 (1980).

[133] IP Australia Guidelines, above n100; APO Manual 2002, above n127, [8.2.5.3]. A similar position applies in Europe; see The European Biotechnology Directive, above n108, art 5.2.

[134] See, eg, Nicol and Nielsen, above n29, 22-34; ALRC Report, above n87, 128-132; Charles Lawson and Catherine Pickering, 'Patenting Genetic Materials – Failing to Reflect the Value of Variation in DNA, RNA and Amino Acids' (2000) 11 *Australian Intellectual Property Journal* 69.

[135] *Joos v Commissioner of Patents* (1972) 126 CLR 611.

treatment could be distinguished from medical treatment and could be classed as a field of economic endeavour. On the other hand, in *Anaesthetic Supplies Pty Ltd v Rescare Ltd*[136] the majority declined to make a distinction between cosmetic and curative procedures and considered methods of medical treatment to be a manner of manufacture.[137]

A definitive finding on the matter was made by the Full Court of the Federal Court in *Bristol-Myers*,[138] with the court unanimously holding methods of medical treatment to be patentable. The court refused to ground their decision in public policy, with Black CJ and Lehane J basing their finding on two explicit grounds:

- the insurmountable problem, from a public policy viewpoint, of allowing products for medical treatment to be patented, but denying patentability for methods of treatment; and
- the limited extent to which the matter of patenting of methods of medical treatment was dealt with by Parliament when it enacted the *Patents Act* 1990, particularly given that standard Patent Office practice in Australia was to allow patents for methods of medical treatment.[139]

Justice Finkelstein rejected the notions of public policy employed by the trial judge, Heerey J, and refused to disallow the patent on the grounds of general inconvenience.[140] The ALRC also rejected the inclusion of an exclusion from patentability for methods of medical treatment in Australia.[141]

2.4.2 THE NOVELTY REQUIREMENT

Section 18(1)(b)(i) of the *Patents Act* 1990 requires that an invention be novel, or new, when compared with the prior art base as it existed before the priority date.[142] The prior art base is defined in Schedule 1, and incorporates information available

---

[136] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 40 FCR 1.

[137] The comments made by Lockhart J and Wilcox J were obiter since the matter was decided on the grounds of fair basing; see below, 2.4.6.3.

[138] *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) 46 IPR 553.

[139] *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) 46 IPR 553, 556-559.

[140] *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) 46 IPR 553, 586-593.

[141] ALRC Report, above n87, Recommendation 7-1, 178, ch 21.

[142] In respect of innovation patents, the relevant corresponding provision is *Patents Act* 1990 (Cth), s18(1A)(b)(i). The priority date in relation to a patent application is the filing date of the patent specification, and will usually be the date of filing a complete patent application with accompanying specification.

anywhere in the world[143] and contained in any publicly available document,[144] available through doing an act, or contained in a patent specification.

In addition, s 7(1) provides that novelty will be assessed against prior art information made publicly available, either in a single document or through a single act, in two or more related documents or through the doing of two or more related acts, or in a single specification. Prior art information is defined in Schedule 1 as information that is part of the prior art base.

'Publicly available' in the context of novelty can mean made available to a very small number of people. Provided a document is available to the public, it will be publicly available, even if it is relatively obscure and not generally read by the public.[145] Commercially dealing with a product or disseminating it for use without an insistence on confidentiality will usually be an act sufficient to destroy novelty.[146] A combination of documents or acts can be taken together in considering whether a disclosure has been made, but they must be unequivocally related in some way.[147] It must be possible for a person skilled in the art to regard them as a single source of

---

[143] See the definitions of prior art base and patent area contained in *Patents Act* 1990 (Cth), Schedule 1. Note that the definition of prior art base was expanded to include acts anywhere in the world as a result of the *Patents Amendment Act* 2001(Cth), in force from 1 April 2002. Prior to the proclamation of this legislation, novelty was assessed against documents available anywhere in the world, but against domestic acts only. The move towards assessment of the prior art base against the worldwide art base, is indicative of the harmonisation of Australian patent law with the law in other jurisdictions. Cf the *Patents Act* 1952 (Cth) where assessment of the novelty of an invention took place against the domestic prior art base only. Hence, depending on the age of a particular patent, courts must be aware of each of the three tests for novelty.

[144] Document is defined in s25 of the *Acts Interpretation Act* 1901 (Cth), and includes information stored or recorded on a computer, or material that produces sound or images, as well as paper and other material containing writing. The Australian Patent Office Manual indicates that it also includes photographs; APO Manual of Practice and Procedure, vol 2, above n127.

[145] See, for example, *Sunbeam Corp v Murphy Richards (Aust) Pty Ltd* (1961) 180 CLR 98 per Windeyer J, 111-12. Although some limited public disclosure may be permissible; see *Patents Act* 1990 (Cth), s 24(1)(a), *Patents Regulations* 1991 (Cth), reg 2.2, 2.3.

[146] Note however, that as of 1 April 2002, a grace period of 12 months prior to the filing of a complete application is available to protect inventors from accidental disclosure. Note also that s24 *Patents Act* 1990 (Cth) and reg 2.2 of the *Patents Regulations* 1991 (Cth) provide inventors with a number of circumstances in which use of an invention will not be considered to be anticipation of a patent. Most notably, a period of experimental use is allowed.

[147] *Nicaro Holdings Pty Ltd and Others v Martin Engineering Co and Another* (1990) 16 IPR 545, 549 (Lockhart J). This may be through cross-referencing within the documents. Note that a combination of documents and acts will not operate to destroy novelty.

information.[148] Piecing together various unrelated documents or other disclosures, known as making a mosaic, is not permissible in terms of determining the prior art.[149]

Novelty is assessed on the balance of probabilities at the examination stage, and also in relation to opposition and revocation proceedings.[150] The question that will be asked in relation to novelty is whether the invention has been 'anticipated' by the prior art at the time of its priority date. If so, the patent application will fail for want of novelty. The traditional test for determining anticipation is the reverse infringement test. In *Meyers Taylor Pty Ltd v Vicarr Industries Ltd*,[151] Aickin J defined the reverse infringement test as follows:

> The basic test for anticipation or want of novelty is the same as that for infringement and generally one can properly ask oneself whether the alleged anticipation would, if the patent were valid, constitute an infringement.[152]

An alleged anticipation must contain all the relevant features, or essential integers, of the patent in question. The following test for anticipation was formulated by Lockhart J in *Nicaro Holdings Pty Ltd and Others v Martin Engineering Co and Another*:[153]

> If one skilled in the art is able to produce the product or process claimed in the patent through a process of trial and error by following the prior publication,[154] the patent will lack novelty. In this respect, all the essential integers of the patent are clearly mirrored in the prior publication. It may be the case that the patent has been anticipated even when it contains modifications to the prior art. If these modifications relate to inessential integers or mere mechanical equivalents that perform analogous purposes, novelty will be lacking.[155] In short, there must be a difference in respect of an essential integer for a patent applicant to succeed in establishing novelty. In that it enables the release of gene sequence information into the public domain for the first

---

[148] *Patents Act* 1990 (Cth) s 7(1)(b).

[149] *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253, 293 (Aickin J).

[150] *Patents Act* 1990 (Cth), s 49(1)(a).

[151] *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228.

[152] *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228, 235.

[153] *Nicaro Holdings Pty Ltd and Others v Martin Engineering Co and Another* (1990) 16 IPR 545.

[154] As opposed to experiments for the purpose of discovering something new; *RD Werner & Co Inc v Bailey Aluminium Products Pty Ltd* (1989) 13 IPR 513.

[155] *Sunbeam Corp v Murphy Richards (Aust) Pty Ltd* (1961) 180 CLR 98 (Windeyer J); *Nicaro Holdings Pty Ltd and Others v Martin Engineering Co and Another* (1990) 16 IPR 545 (Lockhart J); *RD Werner & Co Inc v Bailey Aluminium Products Pty Ltd* (1989) 13 IPR 513 (Lockhart J).

> time, the isolation and characterisation of a gene or gene sequence will have the requisite novelty.[156]

Similar issues arise in respect of 'combination patents' that:

> ... combine a number of elements which interact with each other to produce a new result or product. Such a combination may be one constituted by integers each of which is old, or by integers some of which are new, the interaction being the essential requirement.[157]

Novelty resides, therefore, in a new combination of known integers. Because it is the interaction between known integers that is the crux of a combination patent,[158] the combination of integers must be disclosed in a particular piece of prior art, taken alone, in order for the patent to be anticipated.[159] In relation to inventions involving genetic technologies, novelty will be established if the invention is 'new in the sense of not being previously publicly available.'[160]

2.4.3 THE INVENTIVE STEP REQUIREMENT

Section 18(1) (and its predecessor under the *Patents Act* 1952) treats novelty and inventive step as two distinct requirements for patentability. Because of the risk of confusion between the two concepts, courts have made it clear that novelty and inventive step are to be separately considered. Inventive step will also be assessed on the balance of probabilities during examination, opposition and revocation proceedings.[161]

Inventiveness, or inventive step, is required when compared with the prior art base.[162] An invention that does not meet the requirements for inventiveness is 'obvious'. As stated in s 7(2) of the *Patents Act* 1990:

> ... an invention is to be taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed in the patent

---

[156] *Nicaro Holdings Pty Ltd and Others v Martin Engineering Co and Another* (1990) 16 IPR 545, 549.

[157] *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253, 266 (Aickin J).

[158] *Nicaro Holdings Pty Ltd and Others v Martin Engineering Co and Another* (1990) 16 IPR 545, 553 (Lockhart J).

[159] *E Street Enterprises Inc v CPS Housewares Pty Ltd* (1995) 32 IPR 465, 476 (Lockhart J).

[160] IP Australia Guidelines, above n100.

[161] *Patents Act* 1990 (Cth), s 49(1)(a)

[162] *Patents Act* 1990 (Cth) s 18(1)(b)(ii).

> area before the priority date of the relevant claim, whether that knowledge is considered separately or together with the information mentioned in subsection (3).

The information subsection (3) refers to, is a single piece, or combination of two or more pieces, of prior art information. Prior art information and prior art base are defined in Schedule 1 and were discussed above in the context of novelty.[163] Determining whether there has been an inventive step involves more complexity than the question of novelty. Referring to the test under the *Patents Act* 1952, Aickin J explained the procedure for determining inventiveness:[164]

> ...the question of obviousness involves asking the question whether the invention would have been obvious to a non-inventive worker in the field, equipped with the common general knowledge in that particular field as at the priority date, without regard to documents in existence but not part of such common general knowledge.

Despite the changes to the statutory test contained in ss 18(1) and 7(2) as a result of the *Patents Amendment Act* 2001 (Cth) the steps in the process of determining whether there is sufficient inventiveness remain relatively unchanged. These steps are to:

- identify a hypothetical person skilled in the relevant art;
- determine the common general knowledge of that person; and
- assess whether, in light of that common general knowledge, the person skilled in the art would consider the invention to be obvious.

2.4.3.1 *THE PERSON SKILLED IN THE ART*

An objective assessment of inventive step is made by the court through the eyes of a normally skilled but unimaginative addressee in the relevant area of technology.[165] The court may use expert evidence to assist it, but must still make an objective assessment. In some cases, the person skilled in the art may constitute a team of workers.[166]

---

[163] Below, 2.4.2.

[164] *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262, 270.

[165] *Speedy Gantry Hire Pty Ltd v Preston Erection Pty Ltd* (1998) 40 IPR 543.

[166] *General Tire & Rubber Co Ltd v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457.

2.4.3.2 *THE COMMON GENERAL KNOWLEDGE*

'Common general knowledge' differs from the term 'public knowledge' as used when determining novelty, and has a far more limited meaning. Aickin J in *Minnesota Mining* explained common general knowledge as follows:[167]

> The notion of common general knowledge itself involves the use of that which is known or used by those in the relevant trade. It forms the background knowledge and experience which is available to all in the trade in considering the making of new products, the making of improvements in old. And it must be treated as being used by an individual as a general body of knowledge.

The background knowledge extends beyond memorised material to include material known to exist by the skilled worker, and which he or she is able to access. In addition, as outlined above, s 7(3) of the *Patents Act* 1990 allows material to be added to the common general knowledge.[168] Thus, after determining what constitutes the common general knowledge, the court must consider whether any additional information needs to be added in line with s 7(3) and the definition of prior art base. This might include information a skilled worker could reasonably have been expected to search for.[169] The knowledge the court is required to attribute to the notional skilled worker is unlikely to include information contained in relatively obscure publications, unless the inventor could reasonably have been expected to ascertain those publications.

The process of committing particular documents or acts to the common general knowledge may include combinations of pieces of information.[170] However, the relevant inquiry when examining inventiveness must be whether the invention itself is obvious, not whether a diligent searcher might be able to find and piece together the

---

[167] *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253, 292.

[168] This requirement was not contained in the *Patents Act* 1952 (Cth), and was enacted as a result of a recommendation made by the Intellectual Property Advisory Committee (IPAC); Intellectual Property Advisory Committee, Parliament of Australia, *Patents, Innovation and Competition in Australia* (1984) 45.

[169] See Australian Industrial Property Organisation, *Practice Note 1991 (No 10) Inventive Step.*

[170] *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253, 293-294, (Aickin J).

components of the invention from various sources.[171] Inventiveness may lie in piecing together a particular combination of pieces of information from various sources.[172]

Amendments to s 7(3) as a result of the *Patents Amendment Act* 2001 (Cth) mean that consideration may now be made of 'a combination of any 2 or more pieces of prior art information' that a skilled person could '...be reasonably expected to have ascertained, understood, [and] regarded as relevant...'.[173]

2.4.3.3 *OBVIOUSNESS*

In considering inventive step, the court is determining, in effect, whether the prior art would have made the invention obvious to the hypothetical skilled worker in the field. In practice, a relatively small degree of inventiveness will suffice. Provided some small or simple inventive idea can be identified, inventive step will be established.[174] The correct question for the court is: 'was the subject of the patent so obvious that it would at once occur to anyone acquainted with the subject, and desirous of accomplishing the end'.[175] Objective evidence of a course of research and development efforts directed toward satisfying a 'long-felt want' in a particular area of research may assist in establishing inventive step.[176]

Where the invention is made up from a combination of pieces of prior art, the proper question to ask is whether it would have been obvious to the person skilled in the art, to select from a very large range of publications the combination chosen by the inventor, and to select from those publications, the same combination of integers chosen by the inventor.[177]

While the level of inventiveness required to satisfy the inventive step requirement is relatively low, the changes to the prior art base arguably enable a more realistic

---

[171] This test was adopted in the *Patents Act* 1990 (Cth), ss 7(2) and 7(3) as a result of the *Patents Amendment Act* 2001 (Cth).

[172] *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253, 293-294 (Aickin J).

[173] Note that the *Patents Amendment Act* 2001 (Cth) significantly increased the stringency of the inventive step test by allowing pieces of prior art to be combined, known as 'mosaicing'. This amendment was made as a result of recommendations made by the Intellectual Property and Competition Review Commitee; see IPCRC Report, above n4, 154-156.

[174] *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228, 249.

[175] *Elconnex Pty Ltd v Gerard Industries Pty Ltd* (1993) 25 IPR 173.

[176] *Elconnex Pty Ltd v Gerard Industries Pty Ltd* (1993) 25 IPR 173, 182 (Lockhart J); *Wellcome Foundation v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262.

[177] *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253, 293 (Aickin J).

assessment of the prior art comprised in the common general knowledge.[178] With regard to gene patents, Australian Patent Office practice has been to grant patents on the basis that there is an element of inventiveness in isolating and purifying a particular gene or gene sequence despite the availability of automated sequencing procedures. This area is still, however, subject to some degree of uncertainty given inter-jurisdictional inconsistencies in the degree of inventiveness required, and a lack of specific judicial guidance in Australia.

Some guidance may be available from the case of *Aktiebolaget Hassle v Alphapharm Pty Ltd*,[179] (*Aktiebolaget Hassle*) a case concerned with the patentability of a formulation containing the compound known as omeprazole. The compound itself had been the subject of a previously expired patent, and the patent that was the subject of litigation was challenged because it was alleged it had been arrived at by the exercise of scientific ingenuity and experimental research, and thus, it lacked inventiveness. The High Court, by majority, affirmed the approach of Aickin J in *Minnesota Mining*, and concluded that the inventive step in this case arose from the process of experimenting with different combinations of integers until a successful formulation was arrived at.[180] The legislation[181] did not direct an inquiry as to whether the course taken by the inventor was obvious, nor whether each of the integers in the combination was obvious.[182]

In this respect, the High Court aligned with US authority, and said the correct question in relation to obviousness is to ask whether the outcome or invention itself is obvious, not whether the method of obtaining it was obvious or worthwhile to try.[183] Pursuant to this approach, gene sequences are likely to be patentable despite the arguably routine manner of generating gene sequence information.

In Europe, the opposite position applies: an invention that is obvious to try will not involve a sufficiently inventive step. Consequently, certain modern methods of isolating gene sequences and identifying function (for example in silico techniques

---

[178] See, eg, Sam Ricketson and Megan Richardson, *Intellectual Property: Cases, Materials and Commentary*, (1998) 664.

[179] *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411 (*Aktiebolaget Hassle*).

[180] *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411, 436. The majority stated (at 436) that '[t]he tracing of a course of action which was complex and detailed, as well as laborious, with a good deal of trial and error, with dead ends and the retracing of steps is not the taking of routine steps to which the hypothetical formulator was taken as a matter of course.'

[181] The High Court was considering the relevant provision of the *Patents Act* 1952 (Cth).

[182] *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411, 436-443.

[183] *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411, 441-443.

which compare publicly available computer generated human DNA sequences to sequences from animal genomes with known function) would not to be patentable under European law.[184] Although this matter has yet to be judicially tested in any specific way in Australia, it is likely that a low level of inventiveness would be required in relation to patenting DNA sequences in line with *Aktiebolaget Hassle.*[185]

There has been some criticism of this test for inventiveness on the basis that it creates a per se rule for assessing obviousness, and ignores the presence or absence of technical obstacles to the invention.[186] It does not allow the obviousness requirement to be tailored to a particular field of technical endeavour.[187] In Australia, the ALRC received a number of submissions that raised similar concerns, and that highlighted the low level of inventiveness likely to be required for assessing gene sequence patent applications.[188] In focusing on the method of obtaining a particular gene sequence, some submissions raised the concern that IP Australia would be likely to grant patents for gene sequence information derived from automated sequencing techniques that are well known in the field.

The ALRC acknowledged these submissions but considered that changes to the inventive step requirement were presently unnecessary.[189] The ALRC's view was that the current test allows assessment on a case-by-case basis absent assumptions about the particular field of technology involved. Furthermore, they accepted that the 2001 amendments that had the effect of increasing the information available to be assessed as part of the prior art information is likely to have the offsetting effect that the obviousness standard will be raised.[190] Finally, they allowed that IP Australia requires '... more than the identification and isolation of a genetic sequence to grant a gene patent, in line with the current state of the art in the genetics field.'[191] Accordingly, they declined to make any recommendations that the standard for assessing obviousness be raised.[192]

---

[184] See, eg, Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper*, (2002) (Nuffield Discussion Paper), 29-30.

[185] See ALRC Report, above n87, 138-141.

[186] Merrill, Levin and Myers, above n76, 93-95.

[187] Ibid, 93.

[188] ALRC Report, above n87, 139-141.

[189] Ibid, 141-142.

[190] Ibid, 141-142. See also, Centre for Law and Genetics, *Submission to the Australian Law Reform Commission Public Inquiry, Gene Patenting and Human Health* (2004).

[191] ALRC Report, above n87, 141.

[192] Ibid, 141-142.

2.4.4 THE USEFULNESS OR UTILITY REQUIREMENT

The usefulness requirement is related to the disclosure requirements contained in s 40. This requirement does not stipulate that the invention be useful, or worthwhile in a social or commercial sense as such. Rather, it requires that the invention work as claimed if the specifications are adhered to. Gummow J in *Anaesthetic Supplies Pty Ltd v Rescare Ltd*[193] compared the concept of usefulness with the requirement of sufficiency encapsulated by s 40:

> The distinction between insufficiency and ambiguity on the one hand, and inutility on the other is said to be that insufficiency occurs when the apparatus cannot be made, and inutility occurs when the apparatus can be made but, when made, does not work. However, as has been pointed out, the distinction is often less clear in practice...[194]

Usefulness is not assessed at examination or re-examination, and is not available as a ground for opposition. It is available to applicants in revocation proceedings.[195]

In many other jurisdictions, commercial usefulness, or industrial applicability is a criterion of patentability. In the US, for example, one of the requirements for patentability is utility. Recently released guidelines on the utility requirement state that a patent application must demonstrate specific, substantial and credible utility of the claimed invention.[196] The European Biotechnology Directive also requires an applicant for a patent to satisfy a test of industrial applicability.[197] The industrial applicability requirement has received significant attention in relation to patenting whole or partial gene sequences,[198] because it generally precludes a patent being granted for a gene sequence or partial sequence where the function of that particular sequence is unknown. The utility requirement has significantly increased the stringency of patent examination in the US, and aligns the US with the European Union (EU) on what is patentable subject matter.[199]

---

[193] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1992) 25 IPR 119.

[194] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1992) 25 IPR 119, 142 (Gummow J).

[195] *Patents Act* 1990 (Cth), s 138.

[196] *Guidelines for Examination of Patent Applications* (2001) 66 *Federal Regulations* (US) 1092 (US Utility Guidelines). 'Credible' has been interpreted as meaning 'theoretically possible', even if not demonstrated in the claims. This interpretation has been criticised as setting the threshold for utility too low; see Nuffield Report, above ,178, 31.

[197] EC Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, (the European Biotechnology Directive), art 5.

[198] See, eg, Nuffield Discussion Paper, above n184, 31-34.

[199] Albeit through different grounds (utility as opposed to industrial applicability); see ibid, 31.

It was recommended in a recent review into intellectual property and competition laws in Australia, that the approach under the US Utility Guidelines be incorporated into the examination process under the *Patents Act* 1990.[200] To some degree, the manner of manufacture test discussed above makes provision for an industrial applicability requirement in that the manner of manufacture test has been interpreted as requiring some economic utility.[201] The Intellectual Property and Competition Review Committee (the IPCRC) considered the coverage of utility in the *Patents Act* 1990 to be adequate, although they recommended that utility (or industrial applicability) be considered during examination.[202] The Government announced that it would accept this recommendation, and direct that all aspects of specific, substantial and credible use be considered during the course of patent examination.[203]

In response to submissions that urged that a utility requirement be adopted as a requirement for patentability in Australia,[204] the ALRC recommended that 'usefulness' be included as a requirement to be satisfied during examination.[205] The ALRC further recommended that 'usefulness' be interpreted to mean 'specific, substantial and credible' use, and that this requirement be assessed on the balance of probabilities.[206] Finally, the ALRC recommended that usefulness be specifically included as a ground for opposition, and that guidelines be prepared by IP Australia to assist examiners in applying the usefulness requirement.[207]

---

[200] IPCRC Report, above n4, 16, 152-4. Specifically, the IPCRC recommended that the Patent Office ensure in its examination practice that the use described in the specification is specific, substantial and credible to a person skilled in the art.

[201] *National Research Development Corporation* v *Commissioner of Patents* (1959) 102 CLR 252, 275. See also Australian Patent Office, *Manual of Practice and Procedure*, above n127, [8.4.1]-[8.4.2].

[202] IPCRC Report, above n4, 16, 152-4.

[203] Commonwealth of Australia, *Government Response to Intellectual Property and Competition Review Recommendations*, Information Package (Government Response) <http://www.ipaustralia.gov.au/pdfs/general/response1.PDF> at 31 May 2004.

At the date of writing, the Government had not yet proceeded with this recommendation.

[204] Another ground on which the ALRC proposed amendment was that the *Australia – United States Free Trade Agreement*, [2005] ATS 1 may require that utility be a requirement for patentability. It may also require that the grounds listed as grounds for revocation in the Patents Act 1990 also be available as grounds on which a patent may be examined or opposed; see ALRC Report, above n87, 148-149; Australia and United States, *Australia – United States Free Trade Agreement*, [2005] ATS 1, art 17.9.5, 17.9.13.

[205] ALRC Report, above n87, Recommendation 6-3. See also the discussion at 142-159. Note that the ALRC did not consider that it was necessary to recommend that utility be included as a ground for opposition; at 156.

[206] Ibid, 156.

[207] Ibid.

The result of the ALRC's recommendation, if accepted, would be that an applicant for a patent would be required to demonstrate specific function in relation to an invention. Given that there is some provision for such consideration in respect of the manner of manufacture test, the implications of this recommendation may be limited. In any case, as the ALRC pointed out, the primary area in which concern has arisen in respect of the utility requirement is gene sequence patents, and these concerns are, to a certain extent, redundant now that many gene sequences have been patented or released into the public domain.[208]

2.4.5 THE SECRET USE REQUIREMENT

Despite provision being made in the *Patents Act* 1990 for experimental use or trial of an invention where necessary, secret use of the invention by the patentee before the priority date may be used as a basis for revocation of the patent. The basis of the secret use requirement is to prevent patent holders from extending their monopoly through exploiting the invention prior to the priority date. Section 9 of the *Patents Act* 1990 identifies a number of uses of an invention, which will not constitute secret use, these being:

- reasonable trial or experiment;
- use occurring in the course of a confidential disclosure;
- uses for purpose other than trade or commerce; or
- use by or on behalf of the Commonwealth, a state or territory where disclosure to the Commonwealth, a state or territory has been made by the patentee.

While secret use will generally be taken to mean commercial use, the threshold for commercial use is relatively low so that offering a patented invention for sale or licence under limited circumstances and conditions of confidentiality may be sufficient grounds for revocation.[209]

2.4.6 THE DISCLOSURE REQUIREMENTS

A patent application must be accompanied by a specification which describes the invention claimed by an applicant for a patent. Specifications must conform to disclosure requirements prescribed by Section 40 of the *Patents Act* 1990:

---

[208] Ibid, 158.

[209] But see *Azuko Pty Ltd v Old Digger Pty Ltd* (2001) 52 IPR 75. The court found, by majority, that manufacturing for subsequent sale after the priority date had a commercial aspect but did not amount to a use of the patented invention or de facto extension of the term of the patent; at 183. The fact that the goods were manufactured for the party testing the invention was a relevant factor.

40 (1) A provisional specification must describe the invention.

(2) A complete specification must:

(a) describe the invention fully, including the best method known to the applicant of performing the invention; and

(b) where it relates to an application for a standard patent—end with a claim or claims defining the invention; and

(c) where it relates to an application for an innovation patent—end with at least one and no more than 5 claims.

(3) The claim or claims must be clear and succinct and fairly based on the matter described in the specification.

(4) The claim or claims must relate to one invention only.

Three requirements contained in s 40 require elucidation:

- the requirement for full description. Claims that do not provide a full description are said to be insufficient;
- the requirement for clear and succinct claims. Claims that are not clear and succinct are said to be ambiguous and lack clarity; and
- the fair basing requirement, which requires correlation between the claims and the specification.

The requirements of s 40 are considered on examination,[210] and are available as grounds for opposition[211] and revocation.[212] Patents are often challenged on the basis of the matters specified in s 40, however the Commissioner of Patents may allow the specification to be amended so that deficiencies can be rectified.

2.4.6.1 *FULL DESCRIPTION AND BEST METHOD OF PERFORMANCE: INSUFFICIENCY*

The specification must provide a sufficient description of the invention to allow the invention to be carried out by a person familiar with the area of technology. If the written instructions are insufficient to allow a person versed in the relevant area to

[210] *Patents Act* 1990 (Cth), s 40.

[211] *Patents Act* 1990 (Cth), s 59(c).

[212] *Patents Act* 1990 (Cth), s 138(3)(f).

make the invention, the patent application will fail for insufficiency.[213] If someone skilled in the art can rectify any mistakes in the specification and supply any omissions without any inventive faculty, the description of the specification will be sufficient.[214] In the invention can be performed by a person skilled in the art without any new inventions or additions of their own or prolonged study of matters presenting difficulty, there will be sufficient disclosure.[215]

Note should also be made of sections 41 and 42 *Patents Act* 1990, which allow for the deposit of micro-organisms in place of a written description in a patent specification.[216] The sections were enacted due to the difficulty in providing an adequate description of micro-organisms or particular uses of them. In light of this, Australia became a signatory to the *Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure* 1977, in 1987 (*the Budapest Treaty*).[217] The *Budapest Treaty* provides an international system for the deposit of micro-organisms by allowing the deposit of samples with recognised authorities. Sections 41 and 42 were enacted to give effect to the *Budapest Treaty*.

2.4.6.2 *AMBIGUITY AND LACK OF CLARITY*

Mere errors in grammatical construction will not be problematic, but 'vagueness of description, want of particularity and evident indistinctness of thought...' which are incapable of resolution by a skilled addressee will render claims ambiguous.[218] The terms in a claim will be interpreted pursuant to a '...practical commonsense approach...',[219] and the body of the specification may be considered.[220]

---

[213] This differs from the utility requirement discussed above. A specification might enable a person familiar with the area of technology to carry out the invention, but if the invention does not work it will not have the requisite utility.

[214] *No-Fume Ltd v Pitchford* (1935) 52 RPC 231, 243.

[215] See, eg, *No-Fume Ltd v Pitchford* (1935) 52 RPC 231, *Kimberley-Clark Australia Pty Ltd v Worrell* (1961) 106 CLR 588.

[216] Previously s 40(3)-(7) of the *Patents Act* 1952 (Cth).

[217] *Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure* [1977] ATS 9.

[218] *Kauzal v Lee* (1937) 58 CLR 670, 685 (Dixon and McTiernan JJ).

[219] *Elconnex Pty Ltd v Gerard Industries Pty Ltd* (1993) 25 IPR 173, 188.

[220] See, eg, *Rehm Pty Ltd v Websters Security Systems (International) Pty Ltd* (1988) 11 IPR 289.

2.4.6.3 *FAIR BASING*

The claims within a specification must define the invention described in the body of the specification.[221] A patent applicant is limited, therefore, to what is specified within the claim, when subsequently exploiting the patent. In the words of Lockhart J, '...[t]he function of the claims is to define clearly and precisely the monopoly claimed. Their primary object is to limit and not to extend the monopoly...'[222] The claims must provide a 'workable standard suitable to the intended use.'[223] If a provisional application has been filed, the claims in the complete specification must be fairly based on the invention defined in the provisional specification or the earlier priority date will be lost.[224]

Genetics Institute v Kirin-Amgen Inc (No 3) (Kirin-Amgen)[225] is an important Australian authority which provides guidance in relation to the issue of breadth of claims in the field of biotechnology. Amgen's patent claimed the use of recombinant DNA techniques to produce commercial quantities of erythropoietin, a protein which is important in the regulation of the rate of red blood cell formation. The invention enabled the abundant production of erythropoietin, a rare protein in naturally occurring circumstances. The patent claimed the right to control erythropoietin production in human, monkey and other mammalian cells, which would include alternative methods of producing erythropoietin should they be discovered. The issue was whether the disclosure of the DNA coding sequence for erythropoietin provided a 'principle capable of general application', in that Amgen had disclosed only the isolation from a cDNA library of the gene that encodes monkey erythropoietin. Genetics argued that the claims were too broad in that they claimed human erythropoietin cDNA which was not disclosed in the specification. Instead, the specification revealed that the gene that codes for human erythropoietin had been isolated from a genomic library.

Because the specification disclosed the coding sequence for erythropoietin, Heerey J agreed that the patent disclosed a principle capable of general application and a beneficial property which was common to the class. In doing so, His Honour relied on

---

[221] *Patents Act* 1990 (Cth), s 40(2)(b).

[222] *Décor Corp Pty Ltd v Dart Industries Inc* (1988) 13 IPR 385, 391.

[223] *Décor Corp Pty Ltd v Dart Industries Inc* (1988) 13 IPR 385, 414 (Lockhart J) citing Aickin J in *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253.

[224] See *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1; *CCOM Pty Ltd v Jeijing Pty Ltd* (1994) 28 IPR 481.

[225] *Genetics Institute v Kirin-Amgen Inc (No 3)* (1998) 156 ALR 30. The appellant will be referred to as Genetics, while the respondent will be referred to as Amgen.

the principle laid down in a recent decision of the House of Lords, *Biogen Inc v Medeva plc* (*Biogen*).[226] Heerey J did, however, distinguish that case.[227] In *Biogen*, Lord Hoffman, with whom the other members of the House of Lords agreed, said that:

> If the invention discloses a principle capable of general application, the claims may be in correspondingly general terms. The patentee need not show that he has proved its application in every individual instance.[228]

Lord Hoffman defined the critical issue in *Biogen* as follows:

> ...It is not whether the claimed invention could deliver the goods, but whether the claims cover other ways in which they might be delivered: ways which owe nothing to the teaching of the patent or any principle which it disclosed...The patent may claim results which it does not enable, such as making a wide class of products when it enables only one of those products and discloses no principle which would enable others to be made. Or it may claim every way of achieving a result when it enables only one of those products and it is possible to envisage other ways of achieving that result which make no use of the invention.[229]

Thus, applying these principles, Heerey J found that the sequence information provided in the Amgen patent provided other inventors with the opportunity to pursue other methods of obtaining the result claimed in the patent. Thus, Amgen was entitled to claim production of erythropoietin unlimited by species or structure.[230]

Kirin-Amgen suggests that gene patents may be interpreted broadly by the courts. Applicants will generally seek to claim all subsequent uses of the particular gene sequence claimed. In addition to the issues of novelty and inventive step, fair basing

---

[226] *Biogen Inc v Medeva plc* [1997] RPC 1. This case concerned a general principle for enabling plasmids to control the expression of polypeptides in bacteria, and claimed the principle in relation to any plasmid, bacterium or polypeptide. The crucial point of difference distinguishing Biogen's patent from the Amgen patent was that the coding sequence was not revealed in Biogen's patent.

[227] *Genetics Institute v Kirin-Amgen Inc (No 3)* (1998) 156 ALR 30, 46.

[228] *Biogen Inc v Medeva plc* [1997] RPC 1, 48-49 (Hoffman J).

[229] *Biogen Inc v Medeva plc* [1997] RPC 1, 50 (Hoffman J). Note that a later decision of the House of Lords, *Kirin-Amgen Inc and Others v Hoescht Marion Roussel Limited and Others* [2004] All ER (D) 286, dealt with the same invention as the invention in issue in *Kirin-Amgen*. The House of Lords decided that what had been claimed by Kirin Amgen was not a principle of general application. The decision was based in part on Lord Hoffman's view in *Biogen Inc v Medeva plc* [1997] RPC 1 that the gene sequence claimed in Table VI in the patent specification was a discovery and not an invention. This marks a departure from established jurisprudence in relation to this issue in other jurisdictions. For discussion of the judgment see Luigi Palombi, 'The Impact of TRIPS on the Validity of the European Biotechnology Directive' (2005) 2(2) *Journal of International Biotechnology Law* 62.

[230] *Genetics Institute v Kirin-Amgen Inc (No 3)* (1998) 156 ALR 30, 46-48 (Heerey J).

may become an issue where the claims made in the application cannot be said to be fairly based on the descriptive information provided in the specification. Concern has arisen that claims to uses of gene sequences (including products deriving from those gene sequences) have been overly broad. Nevertheless, where coding sequences are disclosed, broad claims to general principles are likely to be upheld by the judiciary, and accordingly, are being granted by the Australian Patent Office.[231] Of importance here is the extent to which broad patent claims may enable a patent holder to control subsequent use of an invention.

2.4.7 SUMMARY – STANDARDS OF PATENTABILITY

In medical biotechnology, there have been many instances where extremely broad patents have been granted on important inventions. This has led to calls for more stringent standards of patentability and examination. In some respects, amendments to the standards of patentability have alleviated concerns about the breadth of patents in this area. For example, the 2001 amendments to the *Patents Act* 1990 have had the effect of increasing the stringency of the inventive step requirement. Whether they go far enough is another matter, and concerns about the breadth of patent grants in the medical biotechnology area persist.[232] The current standards begin to provide some basis for circumscribing a role for competition law. Relatively broad patent claims may continue to be allowed and are likely to be upheld by the courts. The granting of broad rights may strengthen arguments that competition law should be available to regulate the use of patents. Further, the quantity of patents being granted in the biotechnology category is a basis for monitoring their use.

---

[231] In contrast, in the US, new written description and enablement guidelines provide more stringent rules in relation to the breadth of claims that may be made; *Guidelines for Examination of Patent Applications* (2001) 66 *Federal Regulations* (US) 1092; *Manual of Patent Examining Procedure*, (8th ed, Feb 2003 revision 2003); §2107, <http://www.uspto.gov/web/offices/pac/mpep/index.html> at 25 August 2005 (US Examination Guidelines).

US courts have also traditionally been less willing to uphold broad, upstream claims; see *Regents of the University of California v Eli Lilly & Co* (1997) 119 F3d 1159.

[232] It was these concerns that prompted the ALRC to seek a reference to inquire into the impact of patenting laws and practices in relation to genetic and related technologies; see ALRC Report, above n87, 11-12.

2.5 EXPLOITATION AND INFRINGEMENT

A patent gives a patent holder the exclusive right to exploit an invention in Australia for a period of twenty years, and to authorise another party to exploit the invention.[233] Exploit is defined in Schedule 1 to the *Patents Act* 1990 as follows:

> "exploit" in relation to an invention, includes:
>
> (a) where the invention is a product – make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
>
> (b) where the invention is a method or process – use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.

Pursuant to s 13(2) of the *Patents Act* 1990, a patent holder may assign or licence a patent to another party to allow that party to exploit the patent. While an assignment essentially constitutes sale of a patented product or process,[234] a licence does not vest ownership in a licensee but allows the licensee to exploit the patent. This may be to the exclusion of all others (an exclusive licence), in conjunction with the patent holder (a sole licence), or in conjunction with a number of other licensees (a non-exclusive licence). Because licences are contractual arrangements, the terms on which licences are entered into are variable, and are subject to principles of freedom of contract. A licence may be granted to allow the licensee to conduct follow-on research. Follow-on research is research that uses the patented invention in some way in order to develop a new invention.[235]

The scope of a patented invention will, of course, be subject to what has been claimed in the specification. This highlights the importance of patent breadth and a focus on exactly what has been claimed. In the case of gene sequences, for example, because broad applications of the particular sequence might be claimed, any use of these inventions without the authority of the patent holder will constitute infringement.[236]

Pursuant to the *Patents Act* 1990, the circumstances in which a patent may be infringed are where:

---

[233] *Patents Act* 1990 (Cth), s 13(1). Note the provisions in relation to innovation patents, which are granted for a period of eight years; above, n81.

[234] An assignment must be in writing and signed by the parties to the assignment; *Patents Act* 1990 (Cth), s 14(1).

[235] The concept of follow-on innovation will be discussed further in Chapter 3.

[236] This will depend of course on whether the patent is valid. In particular, see the discussion above, 2.4.6.3.

- a person exploits a patent without the authorisation of the patent holder;
- a person authorises another person to exploit a patent without the authorisation of the patent holder; or
- a patented product is supplied to another person and use of that product would constitute an infringement of the patent.[237]

Where a patentee or licensee brings infringement proceedings against an alleged infringer, a purposive approach will be adopted in comparing the combination of essential integers in the claims of the invention, and the infringing invention.[238] This section considers two issues central to patent exploitation: the research exemption and the compulsory licensing provisions contained in the *Patents Act* 1990. These issues are important in terms of the use that may be made of patents and access to patents for the purpose of conducting follow-on innovation. While a detailed analysis of them will not be provided, they require some consideration because they assist in demarcating the bounds of non-infringing use of a patent. Finally, this section will briefly consider some issues associated with the weight that should be placed on the validity of issued patents, and the importance to the medical biotechnology industry of strong, valid patents.

2.5.1 THE RESEARCH EXEMPTION

An exemption from infringement would provide a potential infringer with a basis for exploiting a patent without the permission of the patent holder. This may be particularly important where a patent is required for follow-on innovation. The bounds of such an exemption are important because research that is not covered by the exemption will continue to infringe. If a researcher is unable to obtain a license, they will not be entitled, in the absence of some alterative form of regulation, to conduct follow-on research.

2.5.1.1 *THE RESEARCH EXEMPTION IN PRACTICE*

The *Patents Act* 1990 makes no provision for a research exemption, and there has been no judicial pronouncement on the subject.[239] Any research with a commercial

---

[237] *Patents Act* 1990 (Cth), s 117. Infringement under s 117 is referred to as infringement by supply, or contributory infringement.

[238] See, for example, *MJA Scientifics International v SC Johnson & Son* (1999) 43 IPR 287.

[239] Although s 9 of the *Patents Act* 1990 (Cth) allows a patent applicant to undertake 'reasonable trial and experiment' prior to filing a patent application by excluding such trial and experiment from the definition of 'secret use'; *Patents Act* 1990 (Cth), ss 9(a), 18(1)(d). As such, a patent applicant is permitted to undertake experimental use of their invention.

purpose which relies on a patented product or process, would infringe that patent in the absence of a licence. What is not so clear is the extent to which non-profit research may infringe a patent. Instead, many users of patented products and technologies (particularly in the medical biotechnology industry) rely on a practice-based research exemption,[240] although the scope of this exemption is subject to considerable uncertainty.[241]

In reality, few patent holders in the medical biotechnology industry pursue academic researchers for infringement if their research is clearly non-profit.[242] A number of patent holders have shown an increased willingness in recent times to enforce their patents against academic researchers.[243] The increasing tendency of academic researchers to pursue research with a commercial aim would take the conduct of this research outside the exemption. It is clear that the practice-based exemption would offer little assistance to any researcher conducting research with a hint of commerciality.

2.5.1.2 *THE RESEARCH EXEMPTION IN OTHER JURISDICTIONS*

In the US, a case-based exemption exists.[244] The scope of the research exemption in the US is 'truly narrow',[245] although understanding of the true scope of the exemption within the research community has traditionally been limited.[246] The ambit of the exemption was recently explored by the Court of Appeals for the Federal Circuit (CAFC) in *Madey v Duke University* (*Madey v Duke*),[247] where the CAFC stated that

---

[240] See Nicol and Nielsen, above n29, 218-222; ALRC Report, above n87, 326-327.

[241] Indeed, the basis of such an exemption is far from clear; see ALRC Report, above n87, 318-319.

[242] Nicol and Nielsen, above n29, 219-222.

[243] For example, Dr Mervyn Jacobson, the Chief Executive Officer of Genetic Technologies Limited (GTG) has suggested that GTG will take infringement proceedings against academic institutions for infringement of their junk DNA patents if necessary; see ABC Television, 'Patently a Problem' *Four Corners,* 11 August 2003 <http://www.abc.net.au/4corners/content/2003/transcripts/s922059.htm> at 11 March 2004.

[244] The doctrine originated in 1813 as a result of the case of *Whittemore v Cutter* 29 F Cas 1120 1121 [CCD Mass 1913] (No 17 600) per Story J.

[245] *Roche Products Inc v Bolar Pharmaceuticals Co Inc* 733 F 2d (1984).

[246] See generally Rebecca S Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use 56 *University of Chicago Law Review* 1017 (1989).

[247] *Madey v Duke University*, 307 F 3d 1351, 1360–1 (Fed Cir, 2002). Note the issue of the use of patented drugs to conduct clinical trials in accordance with US Food and Drug Administration (FDA) regulations was recently considered by the US Supreme Court in *Merck KGAA v Integra Lifesciences I Ltd* 125 S Ct 1728 (2005). The case considered a provision of the *Hatch-Waxman Act* 1984 35 U.S.C. §271(e)(1)), which provides an exemption for the use of patented compounds for the purpose of testing drugs pursuant to Federal Drug Administration legislation. In considering the breadth of the exemption, the Supreme Court said that '[t]here is simply no room in the statute for excluding certain information

the experimental use rule would only support research conducted solely for the purpose of '...amusement, to satisfy idle curiosity, or for strictly philosophical inquiry...'.[248] The Court made it clear that the profit or non-profit status of the user will not be determinative, and the test will be whether the act of alleged infringement is '...in furtherance of the alleged infringer's legitimate business...'.[249] The result of *Madey v Duke* is an exemption that will operate to protect non-profit research institutions in very narrow circumstances. Given that the business of research institutions is the conduct of research for scientific inquiry, any research other than 'philosophical inquiry' will fail to attract the exemption. This broad definition of business interests means that most researchers conducting research at higher research institutions will not be able to utilise the exemption.[250]

A less restrictive position exists in most EU countries, with researchers in the United Kingdom (UK), for example, being entitled to rely on a statutory defence.[251] This defence could be read as having two limbs, one that relates to private, non-commercial use, and the other that relates to experimental use 'relating to the subject matter of a patented invention'.[252] This is the manner in which the defence has been interpreted, so that the two limbs are treated separately,[253] although the first limb has received little judicial consideration.[254] The second limb has been interpreted as being applicable to research that is potentially commercial, provided the research is

---

from the exemption on the basis of the phase of research in which it is developed ...'; at 9. Despite a later comment that '[b]asic scientific research on a particular compound, performed without the intent to develop a particular drug ...' would not be covered by the exemption, the ruling has raised concerns about the extent to which patented upstream research tools are likely to be subject to the exemption; see, for example, Andrew Pollack, 'Justices Expand Rights to Experiment with Patented Drugs' *The New York Times* (14 June 2005).

[248] *Madey v Duke University*, 307 F 3d 1351, 1360–1 (Fed Cir, 2002), 1362.

[249] *Madey v Duke University*, 307 F 3d 1351, 1360–1 (Fed Cir, 2002), 1362.

[250] Tom Saunders 'Renting Space on the Shoulders of Giants: *Madey* and the Future of the Experimental Use Doctrine' (2003) 113 *Yale Law Journal* 261 at 265. For criticism of the exemption see Merrill, Levin and Myers, *A Patent System for the 21st Century*, above n76, 108-117; Katherine Strandburg, 'What Does the Public Get? Experimental Use and the Patent Bargain' (2004) *Wisconsin Law Review* 81.

[251] *Patents Act* 1977 (UK), s 60(5). Section 60(5) provides that:

> An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –
>
> (a) it is done privately and for purposes which are not commercial;
>
> (b) it is done for experimental purposes relating to the subject matter of the invention;
>
> ...

[252] *Patents Act* 1977 (UK), s 60(5).

[253] See, eg, *Smith Kline & French Laboratories Ltd v Evans Medical Ltd* [1989] 1 FSR 513.

[254] *Smith Kline & French Laboratories Ltd v Evans Medical Ltd* [1989] 1 FSR 513, 517.

technical in nature. Thus, it will apply to in-house experiment for the purpose of improvement and modification.[255]

Generally, the position in most jurisdictions appears to be that a research exemption will apply where research with commercial possibilities is being conducted *on* an invention, rather than where research is being conducted that *uses* an invention. It has been suggested that restricting experimentation with an invention (for example to improve on the invention) while allowing experimentation on an invention is the appropriate parameter around which to define a research exemption, and that any such distinction should be applied in a flexible rather than formalistic manner.[256]

2.5.1.3 *DEFINING THE RESEARCH EXEMPTION*

The OECD has recently called for confirmation and clarification of the research exemption in OECD countries in response to concerns that access to basic inventions be ensured.[257] As a consequence of the uncertainty surrounding the exemption in Australia, the Advisory Council on Intellectual Property (ACIP) recently received a reference to consider the desirability of a more clearly delineated experimental use exemption.[258] The ALRC also considered this issue in the context of access to gene patents.[259]

The ALRC recommended that a statutory exemption should be enacted that aligns the *Patents Act* 1990 more closely with UK and EU law.[260] Accordingly, the ALRC recommended the adoption of '... an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention; for

---

[255] *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515, especially 542.

[256] See Saunders, above n250, 267-8; Janice Mueller, 'No "Dilletante" Affair: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools' (2001) 76 *Washington Law Review* 1, especially 9, 54-66; Eisenberg, Patents and the Progress of Science, above n246, 1076-77.

[257] Organisation for Economic Cooperation and Development (OECD), *Patents and Innovation: Trends and Policy Challenges* (2004), 21, 23, 27. The OECD also recommended an international comparative study on the research exemption; at 27.

[258] See Advisory Council on Intellectual Property (ACIP), *Patents and Experimental Use*: Options Paper, Australian Government Printing Service (2004) (ACIP Options Paper). ACIP's final report is due to be presented to the Government in early October 2005, and publicly released in late October 2005; Email from Sean Applegate to Jane Nielsen, 25 August 2005.

[259] See ALRC Report, above n87, Chapter 13.

[260] Ibid, 340. The ALRC rejected the restrictive position adopted in US case law. There is a degree of pessimism as to whether Congress would be likely to pass legislation providing for a more extensive research exemption under US law; Merrill, Levin and Myers, *A Patent System for the 21st Century*, above n76, 115.

example, to investigate its properties or improve upon it.'[261] Importantly, the ALRC's exemption would continue to apply where research with a commercial purpose or objective is undertaken.[262] Further, the ALRC recommended that the exemption should not '...derogate from any study or experimentation that may otherwise be permitted under the *Patents Act*'.[263] There is some indication that ACIP will make a similar recommendation, the Options Paper released by ACIP stating that the options preferred by it were to:

- make no change to the experimental use exemption;
- modify the definition of exploitation to not include experimental use without further defining experimental use;
- provide an exemption for fair experimentation with inclusive permitted uses; or
- provide an exemption for experimenting on the subject matter of the inventions, with inclusive permitted uses.[264]

The ALRC's recommendation, if accepted, provides a limited research exemption for research on a patented invention even when it is likely to lead to a commercial outcome.[265] In the case of genetic technologies, the ALRC gave some guidance as to what is likely to constitute an act 'done to study or experiment on the subject matter of the invention'. In the view of the ALRC, research that investigated the properties of a particular genetic technology or material would be exempt, such as research on a patented genetic sequence to investigate function or association with disease, or relationship with other genetic sequences.[266] Most research falling into this category would probably be conducted with a commercial endpoint in mind (even where it is conducted by public sector research institutions), and a licence to use the technology would be required at some point.

Although the exemption would provide a researcher with protection from infringement liability during the early period of research, as soon as a commercial outcome appears likely a licence to use the protected technology would be necessary.

---

[261] ALRC Report, above n87, Recommendation 13-1, 341.

[262] Ibid.

[263] Ibid.

[264] ACIP Options Paper, above n258, 17.

[265] Though in the event that a commercial outcome is reached, a licence to use the patented product would be necessary.

[266] ALRC Report, above n87, 343-343.

The research exemption proposed will therefore only protect a researcher for a limited time, because at some point they will need to negotiate a licence to use the patented technology. The effect of the research exemption would in effect be to defer the necessity for negotiations. In this case, an exemption in line with that proposed by the ALRC would be of limited application, and is likely to be narrower than the current practice-based research exemption. It would not, for example, operate to cover the use of research tools for experimental purposes.

It is submitted that a clearly defined exemption from infringement should be enacted. Such a research exemption is particularly necessary in an industry such as medical biotechnology where access to upstream research tools far removed from commercial product development, may be restricted.[267] There are many intermediate steps between upstream invention and downstream development, and research during these intermediate stages may not be covered by the exemption proposed. Further, the exemption will have limitations, some of which may not be known nor tested.[268] It may not be clear precisely which uses are covered by the exemption, and which are not.

Despite the benefits of more clearly circumscribing the circumstances in which researchers are infringing patents, doing so could have the effect of encouraging infringement litigation. Because patent holders will have a clear statutory basis on which to bring proceedings for infringement, the 'grey area' in which many researchers now operate could be lost.

Even a broadly defined research exemption would have limitations. The research exemption will be of limited value if access to a patented product is refused, because it may be impossible to create the invention from the patent specification. Many biotechnology products are difficult to reverse engineer, and the patent holder may possess additional information without which the invention cannot be practised. For these reasons, it is submitted that while a broadly defined research exemption will assist researchers in determining whether research is likely to infringe a patent, a research exemption alone will not provide a solution where access to a patented biotechnology invention is required in order to conduct follow-on research.

---

[267] See also Merrill, Levin and Myers, *A Patent System for the 21st Century*, above n76.

[268] The ALRC pointed out, for example, that clinical trials conducted to satisfy regulatory requirements for new pharmaceuticals or genetic tests may fall outside the exemption; ALRC Report, above n87, 343-344.

2.5.2 COMPULSORY LICENSING

A compulsory licence is an order requiring the patentee to grant a licence to work an invention, in effect limiting the patentee's exclusive right to exploit the invention. The circumstances in which compulsory licences may be granted are limited, and the term for which they are effective depends on how long the reasons for their granting continue to exist.

Article 31 of TRIPS implicitly allows compulsory licensing of patents.[269] The circumstances in which TRIPS allows the issue of compulsory licences are:

- situations of national emergency or extreme urgency;
- cases of non-public commercial use;
- cases of anti-competitive practices;
- dependent patent cases where the exercise of one patent will infringe another.

The grounds referred to in Article 31 are not exhaustive, and WTO member states may determine other relevant grounds. Generally, the grounds found in national legislation fall into the following categories:[270]

- refusal to deal;
- non-working and inadequate supply;
- public interest;
- anti-competitive practices;
- governmental use;
- facilitation of the use of dependent patents;
- specific compulsory licenses for patented medicines; and
- licences of right, which allow importation by a licensee where the patentee imports a major portion of the product into the member state and carries out a minor production step in the member country.

---

[269] Article 31 also contains detailed conditions for the grant of compulsory licenses. Most importantly, in many cases a prior request for a license must have been made, and the licensee must provide adequate compensation to the patent holder.

[270] Carlos Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, Working Paper 5, (1999), 10-21, <http://www.southcentre.org/publications/complicense/toc.html> at 19 April 2001.

Article 31 of TRIPS specifies that prior to the issue of a compulsory licence, a proposed user must have made attempts to obtain a licence on reasonable commercial terms and conditions. These attempts must have been unsuccessful over a reasonable period of time. This requirement may be waived in circumstances of national emergency, other circumstances of extreme urgency, or public non-commercial use. The compulsory licensing provisions are being relied on by developing countries to manufacture drugs in response to the HIV/AIDS pandemic.[271] While there is no doubt that this is an appropriate circumstance in which the compulsory licensing provisions should be utilised,[272] the availability of compulsory licensing as a solution to general access issues (such as access to patents over genes required to develop diagnostic tests) is traditionally more contentious given the potential for reduction in incentives to innovate.

2.5.2.1 *COMPULSORY LICENCES – THE AUSTRALIAN POSITION*

The *Patents Act* 1990 allows for the issue of compulsory licences on the first three grounds.[273] In the US, the primary ground on which compulsory licences are issued is to remedy anti-competitive conduct,[274] and many licences have been issued under anti-trust decrees.[275]

Section 133 of the *Patents Act* 1990 provides for the issue of non-exclusive compulsory licenses for:

- failure to work an invention where exploitation of the patent is necessary to satisfy the 'reasonable requirements of the public' (provided reasonable attempts have been made to obtain a license by the applicant and the patent holder has not provided a satisfactory explanation for failing to work the invention);[276] and

---

[271] See generally Jane Nielsen and Dianne Nicol, 'Pharmaceuticals and Patents: The Conundrum of Access and Incentive' (2002) 13 *Australian Intellectual Property Journal* 21.

[272] Indeed, the TRIPS Council has gone further and authorised the supply of drugs to countries without sufficient capacity to manufacture the requisite drugs themselves; TRIPS Council (2003) *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm> at 25 August 2005.

[273] These being refusal to supply, non-working, and inadequate supply, and public interest.

[274] F Michael Scherer, 'Comments', in Robert Anderson and Nancy Gallini, (eds), *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (1998) 104-109, 106.

[275] Ibid.

[276] *Patents Act* 1990 (Cth), ss133(2) and (3A).

- cases where an applicant seeks access to a dependent patent and also a patent that blocks exploitation of that patent.[277] The applicant will only be successful in obtaining a compulsory licence where the new invention involves an important technical advance of considerable economic importance on the other invention.[278] This ground would not appear to be available to an owner of a dependent patent who would infringe another patent by working their invention. Instead, an owner of a dependent patent would have to rely on the 'reasonable requirements of the public' ground.

Section 135 defines what is meant by 'reasonable requirements of the public'. Essentially, where a new or existing trade or industry in Australia is unfairly prejudiced, or the demand in Australia for a patented product is not reasonably met, this will provide grounds for the grant of a compulsory licence. However, the compulsory licensing provisions under the *Patents Act* 1990 have rarely been utilised, and there is no judicial guidance on the circumstances in which a compulsory licence may be issued or what the 'reasonable requirements of the public' might be.[279] Compulsory licensing provisions are used far more extensively in other jurisdictions.[280]

The IPCRC accepted that a compulsory licensing system, by its very existence, may have the effect of influencing the terms on which licenses are negotiated.[281] Studies have shown that a compulsory licensing scheme, rather than inhibiting research and development, actually acts as a spur to innovation.[282] The threat of an application for a compulsory licence probably provides an impetus to patent holders to enter into licensing negotiations and ultimately into contractual arrangements.[283] Note, however, that given the under-utilisation of the Australian scheme, this aim may not be met. The inequality in bargaining power between many companies, particularly start-up

[277] Patents Act 1990 (Cth), ss 133(2) and 133(3B)(a).

[278] *Patents Act* 1990 (Cth), s133(3B). For further details on when a compulsory licence may be granted, and the conditions on which a grant is predicated, see ALRC Report, above n87, 617-621; Dianne Nicol and Jane Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review*, 347, 370-71.

[279] The only reported case is *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Co* (1969) 119 CLR 572.

[280] See Correa, above n270.

[281] IPCRC Report, above n4, 162. Scherer, above n274, 106; Nuffield Discussion Paper, above n184, 55.

[282] See, in particular Scherer, above n274, 106.

[283] See also Nuffield Discussion Paper, above n184, 55. Cf ALRC Report, above n87, 614.

companies, may mean that the threat of a compulsory licensing application is non-existent.

The IPCRC recommended changes to the compulsory licensing provisions within the *Patents Act* 1990 including the repeal of s 135, and the amendment of s 133(2).[284] The effect of this amendment would be to replace the 'reasonable requirements of the public' provision with a provision allowing for the grant of a compulsory licence where the public interest would be met by enhanced competition in the market.[285] The Report recommended that compulsory licensing orders be obtainable on application to the Australian Competition Tribunal with rights of appeal to the Full Federal Court.[286] Presumably this would go some way towards expediting the application process.

The Federal Government announced that it would accept these recommendations in part, accepting the IPCRC's recommendation to include a competition test as a ground for the issue of a compulsory licence, but declining to repeal s 135 and the broader grounds for issue of a compulsory licence contained in that provision.[287] The Federal Government also considered that applications for compulsory licences should continue to be considered by the Federal Court in the first instance.[288] As at the date of writing, the relevant provisions had not been amended.

---

[284] IPCRC Report, above n4, 162-163. The basis of the recommendation was a view that the provision as currently drafted is outmoded and fails to secure the goals of a compulsory licensing system. The terms of s133 were considered to be concerned with the promotion of domestic industry rather than '...securing the best use of resources and achieving high levels of productivity.' Further, it was considered that s133 is deficient in that it lacks an explicit competition test; at 162.

[285] The conditions specified by the IPCRC for the grant of a compulsory licence in these circumstances were:

(a) access to the patented invention is required for competition in the (relevant) market;

(b) there is a public interest in enhanced competition in that market;

(c) reasonable requirements for such access have not been met;

(d) the order will have the effect of allowing these reasonable requirements to be better met; and

(e) the order will not compromise the legitimate interests of the patent owner, including that owner's right to share in the return society obtains from the owner's invention, and to benefit from any successive invention, made within the patent term, that relies on the patent.

See ibid, 163. Without attempting to draft the conditions that would need to be met, the IPCRC stated that these conditions should be necessarily stringent, and that the expression, 'required for competition in the (relevant) market would 'amount to there being no other option for competition in that market, and that the enhancement of competition that would be secured by the grant would have to be material and substantial; at 163.

[286] Ibid, 163. Currently applications for compulsory licences must be made to the Federal Court.

[287] Government Response, above n203.

[288] Ibid.

Enhanced access to the compulsory licensing provisions is highly desirable. It is particularly encouraging to note the focus on the importance of compulsory licensing to the competitive process. It is unclear as to the form the amendment would take, and how it would interact with the restrictive trade practices provisions in Part IV of the *Trade Practices Act* 1974 (Cth) (the TPA), or whether the provision would only be invoked where there is a contravention of Part IV.[289] Although the notion of compulsory licences as a remedy for anti-competitive conduct may provide the necessary impetus for increased utilisation of the remedy, there is no guarantee that this provision would increase the number of applications for compulsory licences given a number of factors that will remain unchanged:

- the meaning of 'reasonable requirements of the public' will still be subject to uncertainty and (at present) devoid of judicial interpretation;
- owners of dependent patents will continue to have to rely on the 'reasonable requirements of the public' proviso; and
- the fact that application must be made to the Federal Court is likely to discourage a number of potential applicants due to the expense associated with any judicial process together with uncertainty as to the outcome.

The ALRC also considered the compulsory licensing provisions, and recommended that the competition ground proposed by the IPCRC be inserted as an additional ground for the grant of a compulsory licence.[290] The ALRC also recommended that the scope of the 'reasonable requirements of the public' test be clarified.[291]

It is submitted that further amendment to the compulsory licensing provisions is warranted. Specifically, provision should be made for owners of dependent patents to apply for a compulsory licence to exploit an original invention on which the dependent patent relies.[292] The fact that provision is not made for the owner of a dependent patent to apply for a compulsory licence, when an inventor who does not own a patent may, gives rise to an anomaly. Uncertainty over the application of the 'reasonable requirements of the public' test means that this ground is an inadequate

---

[289] It would appear from the recommendation made by the IPCRC that they intended the grounds set out in the recommendation to be decisive; IPCRC Report, above n4, 163.

[290] ALRC Report, above n87, Recommendation 27-1; 624-625.

[291] Ibid.

[292] In this case, a blocking patents situation may arise. For discussion of blocking patents and their legal definition, see below, 3.5; 4.4.1.

basis on which to ground an application where the owner of a dependent patent seeks access to an original patent.[293]

It should be noted that the Australia - United States Free Trade Agreement (AUSTFA)[294] apparently restricts the circumstances in which provision for compulsory licensing may be made. Under the AUSTFA, provision for compulsory licensing may be made:

- to remedy a practice determined after judicial or administrative process to be anti-competitive under the party's laws relating to prevention of anti-competitive practices; or
- in the case of public non-commercial use or national emergency or circumstances of extreme urgency, subject to specified circumstances.[295]

If these are the only circumstances which may be specified as grounds for compulsory licences, the existing grounds under the *Patents Act* 1990 fall outside their ambit. There has been no indication the Government intends amending the compulsory licensing provisions, although there can be no guarantee this will not occur in future. Given that the existing grounds for application for compulsory licence have been virtually unused and are of questionable value, this may not have a significant impact on the effect of the compulsory licensing provision. The AUSTFA still makes provision for application in the case of anti-competitive conduct, which is an important ground on which compulsory licence applications should be permitted.[296] It also, however, limits any expansion of the compulsory licensing provisions in future.

2.5.2.2 *Some Practical Limitations of Compulsory Licences*

Compulsory licenses appear to be an appropriate mechanism by which to solve some access problems, but in practical terms their utility must be questioned. The problem faced by any government bold enough to enforce the issue of compulsory licences is generally censure from major trading partners under pressure from powerful patent holders.[297] In addition, for a compulsory licensing scheme to be effective, a licensee would need to be able to obtain compulsory licences in all those jurisdictions in which

---

[293] Cf ALRC Report, above n87, 627-628.

[294] *Australia – United States Free Trade Agreement*, [2005] ATS 1.

[295] *Australia – United States Free Trade Agreement*, [2005] ATS 1, art 17.9.7.

[296] On the issue of compulsory licensing as a remedy under the TPA, see below, 6.6.

[297] The fact that compulsory licences are a 'contentious and politically sensitive' TRIPS issue was recognised by the Federal Government in their response to the IPCRC Report; see Government Response, above n203.

patents have been granted, principally in the US, the EU and Japan. At present there is no international consensus on the circumstances for the granting of compulsory licenses. Obtaining a compulsory license in Australia would not enable commercialisation on an international basis.

2.5.3 CROWN USE

Section 163(1) of the *Patents Act* 1990 permits the exploitation of a patented invention by the Commonwealth or a State, or by a person authorised by the Commonwealth or a State, without liability for infringement of that patent, provided that the exploitation is 'for the services of the Commonwealth or the State'. Detailed conditions govern use by the Crown pursuant to s 163(1). Relevantly, notification must be provided to the patent holder,[298] and adequate remuneration must be agreed upon.[299] The Crown use provisions provide a mechanism for access to patented inventions by Crown authorities.[300]

The ALRC considered that the Crown use provisions have the potential to be particularly useful when access to a patented genetic invention is required in the provision of public healthcare. Similarly, the ALRC stated that these provisions might be usefully invoked where access to a patented biotechnology product is required for public research purposes.[301] The ALRC recognised that the application of the provisions will be limited to bodies that fall within the definition contained within s 163(1), and that there may be some uncertainty as to when exploitation is for the services of the Crown.[302] Accordingly, they made a number of recommendations in relation to the Crown use provisions.

The first was that the Australian Health Ministers' Advisory Council should develop policies regarding the circumstances in which the Crown use provisions might be appropriately invoked.[303] The ALRC also recommended that amendment be made to s 167 (1) to clarify that 'for the services of the Commonwealth or of a State' include the

---

[298] *Patents Act* 1990 (Cth), s 164.

[299] *Patents Act* 1990 (Cth), s 165.

[300] Defined as the Commonwealth or a State, an authority of the Commonwealth or a State, or a person authorised in writing by the Commonwealth or a State; *Patents Act* 1990 (Cth), s 162.

[301] ALRC Report, above n87, 601-602.

[302] Ibid, 601-608. For a discussion of case law relevant to when a body is likely to fall within the definition of the 'Commonwealth or a State', at 598-599; Advisory Council on Intellectual Property (ACIP), *Review of Crown Use Provisions in Patents and Design Legislation*, Discussion Paper, (2003) (ACIP Discussion Paper), 5-6.

[303] ALRC Report, above n87, Recommendation 26-1.

provision of healthcare services or products to members of the public.[304] The ALRC's final recommendation in relation to the Crown use provisions related to the remuneration payable to the patent holder in the event of Crown use or acquisition. Specifically, the ALRC recommended amendment to the *Patents Act* 1990 to provide that remuneration be paid by a public authority promptly, and be just and reasonable having regard to the economic value of the use.[305]

ACIP is also currently conducting a review into the Crown use provisions in intellectual property legislation. Although their Final Report has not been released, ACIP have indicated their preliminary views in a Discussion Paper released in December 2003.[306] In particular, ACIP is considering whether restrictions on the use of the Crown use provisions might be appropriate in light of the detrimental effect that over-use of the provisions may have on incentives to innovate, especially in light of the commercial nature of many activities undertaken by Commonwealth and State authorities.[307]

The ALRC considered the Crown use provisions to be particularly appropriate for ensuring access by public sector organisations to patented genetic materials. Nevertheless, the provisions are limited to publicly funded bodies, and any privately funded body[308] or company would fall outside their scope. In addition, the provisions are most likely to be useful where access is sought to downstream products, for example, drugs or diagnostic tests. Their application may be more problematic in the case of access to upstream research tools for research purposes, due to the original objectives behind the provisions, and a perception that the provisions should be invoked rarely, for example, in cases of public health emergency or other pressing public interest situations.[309] In addition, the AUSTFA does not permit the transfer of associated know-how related to a patented invention, so that exploitation of a patented invention may be difficult even in the event the Crown use provisions are utilised.[310]

---

[304] Ibid, Recommendation 26-2, 606-608. Such as the provision of genetic testing services.

[305] Ibid, Recommendation 26-3, 608.

[306] ACIP Discussion Paper, above n302. A report has been drafted and is likely to be forwarded to the relevant Minister during October 2005; email from Jeff Roberts to Jane Nielsen, 15 June 2005.

[307] Ibid, 5-9.

[308] This may include research institutions affiliated with public hospitals that nonetheless receive private funding.

[309] ACIP Discussion Paper, above n302, 8.

[310] *Australia – United States Free Trade Agreement*, [2005] ATS 1, art 17.9.7(b)(iii).

2.5.4 PATENT VALIDITY

A degree of criticism has been levelled at the Australian Patent Office on the basis that it lacks the resources and expertise to adequately examine the massive numbers of complex patent applications that have been filed in the area of medical biotechnology.[311] The problem is certainly not unique to Australia: similar problems exist in the US and Europe, with a huge preponderance of patent applications being filed in the biotechnology category over the last decade or so.

Interestingly, a recent comparative study found few differences between the practices of patent offices in Australia, Japan, Europe and the US in relation to granting patents over expressed sequence tags (ESTs).[312] The OECD nevertheless recently affirmed the importance of high quality patents where those patents are important to innovation, and called for exploration of stricter examination as one means of discouraging low-quality patent applications.[313] Low quality patents were defined as '...those that protect inventions of limited novelty, or that provide overly broad protection.'[314] The OECD considered that defensive patenting (patenting to avoid others patenting first) and strategic patenting (patenting to allow freedom to operate) in particular, contribute to problems associated with patent quality.[315] Allowing broad patents to issue may give patent holders unreasonably strong bargaining positions with downstream users of technology.[316]

In response to general concerns about patent quality in Australia, the IPCRC recently recommended:

- a more stringent 'balance of probabilities' test to replace the 'benefit of doubt' test during patent examination.[317] This recommendation has been

---

[311] Nicol and Nielsen, above n29, 81-2.

[312] Melanie J Howlett and Andrew F Christie, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTS)* (2003) IPRIA Working Paper 09/03.

[313] OECD, *Patents and Innovation*, above n257, 28-29.

[314] OECD, *Patents and Innovation*, above n257, 18.

[315] Ibid, 9, 29. See John H Barton, 'Reforming the Patent System' 287 *Science* (2000): 1933 who argues that a general reduction in the number of granted patents would assist in solving the problem of defensive patent portfolios; at 1933.

[316] OECD, *Patents and Innovation*, above n257, 23; See also Nuffield Discussion Paper, above n184, 58-59. Patent breadth is defined in OECD, *Patents and Innovation* as '...the extent of protection granted to patent holders against imitators and follow-on innovators.' This entitles patent holders to protection on their own inventions and also inventions that are deemed to be 'functionally equivalent' to their inventions, as well as follow-on inventions that rely on use of the patented technology; OECD, *Patents and Innovation*, above n257, 10.

[317] IPCRC Report, above n4, 18, 166-7.

implemented[318] with the result that granted patents are more likely to be valid; and

- the devotion of additional resources to improving the quality of examination, focusing in particular on improved prior art searches.[319]

In response to concerns about the quality of examination of patents in respect of genetic technologies, the ALRC recommended the devotion of effort by IP Australia to ensure ongoing education and training,[320] as well as the development of additional guidelines to assist examiners in applying the criteria for patentability to applications involving genetic materials and technologies.[321] The ALRC also recommended change to the standard of proof to be applied in assessing patent applications, in that a balance of probabilities test be applied in respect of all the requirements for patentability.[322] In making these recommendations, the ALRC considered that issued patents would be more likely to be valid.

In addition, interested parties have the opportunity under the *Patents Act* 1990 to challenge patents, either in opposition or revocation proceedings.[323] Although opposition proceedings are used fairly infrequently, they have been utilised on a number of occasions to challenge biotechnology patents.[324] The IPCRC was satisfied that the pre-grant opposition procedure is sufficiently transparent that its efficacy is ensured.[325] Revocation proceedings remain an important method of challenging the validity of patents, and can be brought at any time throughout the life of a patent. In

---

[318] As a result of the *Patents Amendment Act* 2001 (Cth).

[319] IPCRC Report, above n4, 18, 167-8. While the Federal Government accepted these recommendations in principle, it declined to enact specific legal changes. Instead, the Government considered that IP Australia's current initiatives to improve quality of examination and searching were sufficient; Government Response, above n203.

[320] ALRC Report, above n87, Recommendation 8-1, 199-206.

[321] Ibid, Recommendation 8-2, 206-210. The ALRC made no specific recommendations in relation to IP Australia's practices in searching the prior art, but supported the recommendations made in the IPCRC Report; at 211-212.

[322] Ibid, Recommendation 8-3, 212-217. At present, only novelty and inventive step are assessed on the balance of probabilities, with the other requirements for patentability being assessed on the basis that the applicant is given the 'benefit of doubt'.

[323] See above n83, n85.

[324] A number of these decisions are reviewed in Lawson and Pickering, above n134.

[325] The IPCRC declined to give detailed consideration to the desirability of replacing pre-grant opposition with post-grant opposition. This was based partly on the views of the Advisory Council on Industrial Property (ACIP) in a recently conducted review, that industry groups were generally supportive of retaining a system of pre-grant opposition; Advisory Council on Industrial Property, *Review of Enforcement of Intellectual Property Rights* (1999). The IPCRC also recommended that the pre-grant opposition procedure should continue to be the responsibility of IP Australia rather than an independent specialist body; see IPCRC Report, above n4, 171-75.

considering the procedures for challenging the validity of gene patents under the *Patents Act* 1990, the ALRC considered that the mechanisms available were adequate and did not require change.[326]

One commentator has argued that expending additional resources during the process of examination is wasteful given the modest number of patents granted that should not be.[327] Instead, Lemley argues against increased attention to validity and increased resources in the assessment of patent applications by the USPTO, primarily on the grounds that:

- a massive increase in USPTO resources would be required to ensure validity of issued patents;[328]
- the number of patent holders who go on to license their patents would appear to be quite modest.[329] Most patent holders obtain patents for a host of reasons unrelated to licensing;[330]
- in high-technology and start-up industries, licensing has become a strategic exercise with many patent holders entering into tacit agreements not to sue rather than conforming to the typical model of licensing for royalties. Those patent holders who do choose to licence will frequently seek to maximize revenue by approaching a number of potential licensees who will challenge the patent if its validity is uncertain;[331]
- many patents are allowed to lapse prior to their expiry;[332] and

---

[326] ALRC Report, above n87, 227-228.

[327] Mark A Lemley, 'Rational Ignorance at the Patent Office' (2001) 95 *Northwestern University Law Review* 1495, 1497.

[328] Ibid, 1531. It has been estimated that approximately 74 per cent of patent applications in the United States result in granted patents, and that this figure is comparable to Europe and Japan; Robert A Clarke, 'US Continuity Law and its Impact on the Comparative Patenting Rates of the US, Japan and the European Patent Office (2003) 85 *Journal of the Patent and Trademark Office Society* 335.

[329] Lemley, Rational Ignorance, above n327, 1506-7. Lemley acknowledged that there is little empirical evidence on the numbers of patents that are licensed for revenue, or the number of licensees per patent, and concluded that establishing the social cost of patents is impossible without some idea of these figures; at 1507, 1531.

[330] Uncertainty about the future value of particular inventions, or the value of patents as financing tools may prompt a patent application. Patenting may also enhance a company's reputation as a market leader or constitute company policy. Patents may be sought simply for the sake of obtaining patent protection; Ibid, 1505-1506.

[331] Ibid, 1504-5.

[332] Ibid, 1503.

- few patents are ever litigated and those that are litigated are frequently subject to out-of-court settlement.[333]

Lemley argues that few patents are ever used in a manner that calls their validity into question,[334] and the objective number of patents of doubtful validity that are enforced is likely to be limited. Consequently, litigation is a more efficient way to examine validity than more comprehensive examination.[335] Lemley's views are not universally shared.[336] Many in the biotechnology industry view patent validity to be paramount[337] and general recommendations for improved examination processes have been made.[338] The US Federal Trade Commission (FTC) endorsed the strengthening of post-grant procedures to test validity, while at the same time recommending the implementation of some improved procedures throughout the examination process.[339]

In an industry such as the biotechnology industry in Australia, research institutions and small companies rely heavily on patent protection. Many Australian companies are shifting into small niche areas of research, and protection of their proprietary position is crucial. While these industry participants engage in defensive and strategic patenting strategies, at the same time they have fairly modest patent portfolios.[340] In many cases, patents are the lifeblood of these institutions and companies and represent their primary assets. At the same time, most smaller companies lack the resources to litigate competitors' patents, or even to adequately enforce their own patents. Detecting infringement is often difficult.[341] Because of the high costs

---

[333] Ibid, 1501-1503.

[334] Ibid, 1510-11. Lemley estimates that as many as 95 per cent of issued patents will never be used, or will be used in circumstances where their validity is not called into question; at 1511. It should be queried whether the fact that patents are not exploited should provide a basis for arguing that the validity of patents should not be ensured.

[335] Ibid, 1531-2.

[336] See, eg, Arti K Rai, 'Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform' (2003) 103 *Columbia Law Review* 1035, 1081-1084.

[337] See also Biotechnology Industry Organisation, 'Patent Fee Bill Will Help Ensure Continued Biotech Innovation' *Press Release*, 3 April 2004 at <http://www.bio.org/news/> at 15 June 2005. The Biotechnology Industry Organisation (BIO) showed support for the passage of the United States *Patent and Trademark Fee Modernisation Act* 2003 (HR 1561) on the grounds that the Bill would provide additional resources to the USPTO and allow them to issue quality, enforceable patents, which are crucial in ensuring investment for the biotechnology industry.

[338] See, for example, Merrill, Levin and Myers, *A Patent System for the 21st Century*, above n76, 103-108. See also Barton, above n315, 1934,

[339] Federal Trade Commission Report, above n13, Chapter 5, specifically 31-32. A similar recommendation was made in Merrill, Levin and Myers, *A Patent System for the 21st Century*, above n76, 95-103.

[340] Nicol and Nielsen, above n29, 76-81.

[341] Ibid, 215-216.

involved, commencing opposition or revocation proceedings is not an option for many industry participants, and the industry is correspondingly risk-averse.[342] This reinforces that patent validity is an important issue for this industry, and that having some confidence in the validity of granted patents is paramount. It is submitted, therefore, that patent validity should be ensured to the highest possible degree, and that providing adequate resources to IP Australia is, in effect an alternative way of subsidising industry participants.

2.6 CONCLUSION

In considering which of the theories discussed within the context of justifications for the patent system is most relevant to medical biotechnology, it is important to consider which theory gives the most cohesive explanation for the emergence of patents within biomedical research. The patent system is important to the development and sustainability of the industry, and to the central issue discussed in this thesis. While the incentive-inducement theory provides the primary basis on which patents in this industry can be defended, the other theories, particularly the prospect theory, remain significant and must be considered in light of the effects of broad initial patents on follow-on innovation. This has resulting implications for competition law. Because there is some degree of reliance on the invention-inducement theory, a role for competition law must be considered. However, this role must be tempered because there is a need to encourage dissemination of inventions within this industry.

There is no doubt that having a sound intellectual property system encourages international investment in domestic industry, and allows trade relationships to flourish. The rejection by Australia of a harmonised approach to intellectual property protection would mean a decline in investment in Australia. Australian inventors are able to make use of these relationships in conducting research and development activities, for example through importing technologies subject to patent protection for use in research, or through exporting for use or sale to other TRIPS compliant countries. The patent system is characterised by uniformity internationally. Nevertheless, the substantive law requirements for patentability differ markedly across jurisdictions, as do the procedures for obtaining patents.

The reluctance of developed world patent holders to export their technologies to countries without TRIPS compliant patent legislation is illustrative of the effect a

[342] Ibid, 216-217.

reduction in patent protection would have on investment in domestic industry. At present, a considerable number of patents filed in Australia are foreign-owned, demonstrating that strong intellectual property protection not only boosts domestic productivity, but also encourages foreign investment activity. These attempts to harmonise intellectual property law have undoubtedly assisted inventors by streamlining the process of applying for patents across jurisdictions, and laying down minimum standards to which member states must adhere. They are also consistent with the Government's push to promote commercialisation through intellectual property protection.

Despite extensive discussion of the requirements for patentability in Australia, the application of these standards remains uncertain, particularly in relation to developing technologies involving genetic and biomedical advances. It is likely to be some time before the criteria for patent grant become more certain, and the potential for broad claims exists. This highlights the necessity of examining other areas of law such as competition law to address the negative effects of broad patents on innovation.

Ensuring that inventions can be commercialised may not in itself promote innovation, and patent holders may use patents in a way that precludes access. This chapter also considered issues associated with exploitation and infringement. The aim of this discussion was to highlight some measures that may be available to researchers wishing to avail themselves of biomedical technology necessary for research they are conducting. As has been illustrated, these measures are likely to provide limited assistance where access is refused. The research exemption and the compulsory licensing provisions are subject to uncertainty and lack uniformity. The application of competition law remains an important consideration for intermediate and downstream users of technology.

CHAPTER 3

THE CUMULATIVE NATURE OF BIOMEDICAL RESEARCH AND BARGAINING BREAKDOWN

3.1 INTRODUCTION

The first two chapters have examined a number of factors relevant to biomedical research and the facilitation of innovation within that broader context. Chapter 1 considered the promotion of medical biotechnology by the Australian government, and the structure of the medical biotechnology industry. Chapter 2 outlined the patent environment in which the industry operates, and the bases on which patents in medical biotechnology can be justified. Following on from the discussion in Chapters 1 and 2, there is a need to delve into another aspect. The final feature of biomedical research as discussed in this chapter is its cumulative nature and the pattern of follow-on innovation characteristic of this industry.

'Cumulative' innovation refers to a pattern of research where technological developments build on the inventiveness of others.[1] Medical biotechnology provides a striking example of an industry characterised by cumulative research patterns, as demonstrated in Chapter 1.[2] In many industries where research is cumulative, a considerable period of time exists between initial invention and a resulting product, and an initial inventor will not always have the capabilities to develop an invention past a particular point. Some degree of follow-on invention by other (often multiple) parties will be required before a 'product' in the sense of a product available to consumers, can be brought to market.[3] Frequently, a downstream innovator will find it necessary to bargain to gain access to patents held by an upstream patent holder in order to conduct research or develop downstream products or technologies. Cumulative inventions may be '(i) improvements of previous products, (ii) cost reductions for producing earlier products, (iii) applications of earlier basic technologies, or (iv) enabling technologies such as research tools.'[4] Most commonly, a new invention will constitute a minor improvement over a previously patented invention, but it may also constitute a new application, or a separate and discrete invention.[5] In biomedical research, there remains significant scope for the

---

[1] Cumulative innovation was defined in the Introduction to this thesis; see Introduction, n5. Synonyms used in this thesis to refer to this research structure include incremental or sequential innovation.

[2] See above, Chapter 1, especially 1.5.

[3] This factor partly drives the alliance and integration activity reported in Chapter 1; see above 1.5.3.

[4] Suzanne Scotchmer, *Cumulative Innovation in Theory and Practice*, (Working Paper 240, Goldman School of Public Policy, 1999) 1.

[5] In this and following chapters, reference will generally be made to improvements or follow-on inventions. This is intended to be a general reference to all those categories of inventions that constitute follow-on inventions. Where appropriate, the discussion will make specific references to improvements, new applications or discrete inventions, particularly in later chapters of this thesis.

development of new applications of upstream technologies, and enabling technologies.

This chapter discusses the implications of a cumulative research structure and highlights the importance of contracting in order to enable follow-on research to proceed. Where bargains for the exchange of patents break down, there may be some consequent impact on follow-on research. It will be argued that providing incentives for initial or upstream research is an important consideration for the Australian medical biotechnology industry. Nevertheless, this should not preclude the availability of mechanisms to facilitate follow-on research. While the focus of the Australian industry is currently upstream research, this may not be the case indefinitely. This chapter will demonstrate that there is potential for access to technologies necessary to conduct follow-on research to be hindered.

The question this thesis addresses is whether patent law is adequately dealing with this research pattern. If not, there is a need to look outside the realms of patent law at solutions offered by competition law. The basis for considering the operation of competition law in this context is that governments have demonstrated an imperative to facilitate wealth promotion within this industry. Implementing an appropriate level of competition law regulation is a necessary part of this process.

3.2 The Role Of Contracting in The Biotechnology Industry

While patent protection has been touted as being important to provide incentives for biomedical research,[6] contracting for the exchange of rights represents an important method of assisting in the efficient dispersion of patents.[7] Licensing allows the exploitation by licensees of patented technology in circumstances where the patent holder may not exploit the invention. Non-exclusive licensing will allow the exploitation of a patented invention by a number of licensees.

The Intellectual Property and Competition Review Committee (IPCRC), who were recently charged with investigating the interaction between intellectual property and competition law under Australian law, identified a number of reasons why allowing

[6] See the discussion above, 2.2.

[7] Indeed, the 'ex post' justifications for that patent system considered in Chapter 2 are predicated on the assumption that licensing of inventions will take place where appropriate; see above, 2.2.2.2, 2.2.2.3 and 2.2.2.4. The commercialisation and prospect theories, in particular, recognise the importance of fostering further innovation through the dissemination of inventions.

relatively unrestricted contracting in relation to intellectual property is important in any industry:[8]

- Initial inventors are often not best placed to exploit their inventions.[9] This is particularly relevant in a cumulative industry such as biomedicine;
- In many cases, it is necessary to assemble and combine a considerable number of research inputs in order to produce one commercial product;[10] and
- There may be considerable social cost if the ability of parties to contract freely is impeded; the non-rivalrous nature of many (but not all) intellectual property makes their wide dissemination desirable and social cost associated with inventing around potentially high.[11]

Licensing in particular, allows the generation of revenue for a patent holder, while allowing the exchange of rights for the development of the next generation of products. This is particularly important in an industry such as the biomedical industry where innovation occurs on a sequential or cumulative basis. Challenges exist in achieving a balance between allowing efficient and free licensing in relation to the development of particular products, and maintaining a competitive environment to enhance the innovative process at each generation of product development.

3.3 THE CUMULATIVE INNOVATION LITERATURE

Much scientific research, particularly in high technology industries, builds upon prior research.[12] In some cases, this prior knowledge makes follow-on research possible. In

---

[8] Intellectual Property and Competition Review Committee, Review *of Intellectual Property Legislation under the Competition Principles Agreement: Final Report* (2000) (IPCRC Report) 210-11.

[9] See also Robert P Merges and Richard R Nelson, 'On the Complex Economics of Patent Scope' (1990) 90 *Columbia Law Review* 839, 843; John H Barton, 'Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation', (1997) 65 *Antitrust Law Journal* 449, 453-55.

[10] See also Edmund W Kitch, 'The Nature and Functions of the Patent System', (1977) 20 *Journal of Law and Economics*, 266; Merges and Nelson, above n9; Michael Heller and Rebecca S Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' *Science* 280 (1998): 698, 699.

[11] Non-rivalrous, or non rival-in-use technologies refer to those technologies or research tools, the use of which by one party will not normally reduce the profits of others from using it in that resulting products generally will not compete. Conversely, rivalrous or rival-in-use technologies will usually be used to develop products that will compete with one another. It may not be clear at the time that many biomedical patents are granted precisely what they are useful for, so it may be difficult to determine whether a particular technology is rivalrous or non-rivalrous.

[12] Note that the pattern of biomedical research has parallels in other high-technology industries. The computer software industry, for example, also involves heavy reliance on research tools to facilitate follow-on innovation.

other cases, follow-on research would simply be slowed or made more expensive if the researcher did not have the prior research to build on.[13] In each case, the social value of first generation inventions will include part of the social value of follow-on inventions.[14] This will comprise, respectively, the incremental social surplus provided by follow-on products,[15] the value of getting the invention sooner, or the cost reduction.[16] First generation inventors may require a portion of the social surplus of follow-on inventions as an incentive to invest in research and development of first-generation products, as developing the first-generation product will often be socially worthwhile even if the cost of developing it exceeds its stand-alone value.[17]

The biotechnology industry relies heavily on the process of cumulative or sequential innovation.[18] Although pharmaceutical products fit more into a model of discrete invention,[19] Merges and Nelson treat biotechnology as a science-based technology,[20] given that the industry is:

> ... built around two different sets of technologies: recombinant DNA and monoclonal antibodies. Both of these are based on prior, more general advances in molecular

---

[13] See Frederic M Scherer, 'The Economics of Human Gene Patents' *Academic Medicine* 77 (2002): 1348, 1361-2; Suzanne Scotchmer 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law' (1991) 5 *The Journal of Economic Perspectives* 29, 31.

[14] Scotchmer, above n13, 31.

[15] The social surplus is taken to mean profit available to firms, plus consumers' surplus; see ibid, 31; Jerry R Green and Suzanne Scotchmer 'On the Division of Profit in Sequential Innovation' (1995) 26 *The RAND Journal of Economics* 20, 23.

[16] Scotchmer, above n13, 31.

[17] Ibid.

[18] See Merges and Nelson, above n9. Merges and Nelson undertook a study of follow-on innovation in a number of industries. The industries examined by Merges and Nelson were grouped into four categories: the discrete invention model, cumulative technologies, chemical technologies and science-based technologies. One or more of these models will be relevant to any one industry at a given time, but the mix will generally be industry-specific; at 880-884. While inventions in the categories of discrete invention, cumulative technologies and chemical industries may be driven by scientific development, some technologies fit into a separate category because their advance is driven primarily by "... recent developments in science ..."; at 883-4.

[19] Ibid, 880, 882-3. See also Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) (Federal Trade Commission Report), ch 3, 23 ('Unlike the pharmaceuticals industry, in which major aspects of the innovation process are relatively discrete, biotechnology innovations typically form the basis of, or provide the tools for, independent follow-on R&D.'). Note that as pharmaceutical companies rely more heavily on upstream biotechnology inventions, pharmaceutical research may fit more neatly into the same model as biotechnology.

[20] Merges and Nelson, above n9, 897, 902-904.

biology and both were initially discovered and employed by scientists concerned with pure research.[21]

Groundbreaking inventions in science-based industries usually tend to focus research efforts around the area of invention as new entrants see commercial possibilities.[22] Patent breadth is a fundamental issue as cumulative innovation becomes an important aspect of these industries.[23] The following factors are indicative of the importance of cumulative innovation in biomedical research:

- the diverse range of actors within the industry;
- the range of technologies impacting on the industry, including science-based and information-based technologies; and
- the push to commercialise upstream developments as independently valuable products.

The importance of basic discoveries to follow-on biomedical research has been demonstrated by a United States (US) study that asked researchers how reliant they were in developing products, on recent research (recent equating to a period within the last 15 years).[24] Of seven industry groups surveyed, researchers developing drugs and medical products indicated a strong reliance on recent academic research.[25] The ability to access prior research will often be an important determinant of whether follow-on research proceeds, and the rate at which it proceeds. The breadth of rights granted at the initial stages of the innovative process will impact on the amount of research conducted downstream.

3.3.1 Cumulative Innovation and the Grant of Patents

A good deal of the cumulative innovation literature focuses on the breadth of patents that are granted at each stage of the innovation process. This literature forms a subset of the literature dealing generally with the optimal design of intellectual property.[26]

---

[21] Ibid, 905.

[22] Ibid.

[23] Ibid, 904-905.

[24] Edwin Mansfield, 'Academic Research Underlying Innovations: Sources, Characteristics, and Financing' (1995) 77 *Review of Economics and Statistics*, 55.

[25] Twenty seven percent of respondents researching in the area of pharmaceuticals reported a linkage between prior academic research and the development of a new product, with 17 percent reporting that they received "very substantial aid" from recent academic research. This figure was higher than the mean for all seven industries surveyed.

[26] There is extensive literature dealing with the question of optimal patent breadth, much of which considers the issue where only one innovator is involved; see, eg, Richard Gilbert and Carl Shapiro, 'Optimal Patent Length and Breadth' (1990) 21 *The RAND Journal of Economics* 106; Mark A

Clearly, the advance of science and technology is dependent on both initial and follow-on innovation.[27] Many commentators have sought to identify the appropriate parameters of patent protection at various stages of the innovation process. The breadth of patents granted at any particular stage is important, not only in determining the returns to be granted at various stages of the discovery pipeline, but also because it may impact on the ability of subsequent innovators to obtain access to upstream discoveries essential to their research.[28] In other words, patent protection '...sets bargaining positions for the...licences that will form, and therefore determines the division of profit in these contracts.'[29]

Various options for intellectual property policy makers exist in decisions about the grant of intellectual property, and complex economic considerations are involved in this question.[30] Much analysis, particularly economic, has been devoted to how intellectual property can be allocated to provide optimal incentives for both initial and follow-on inventions. The only way to encourage inventors to undertake every socially useful project would be to ensure they are able to collect all of the social value of a particular project as revenue.[31] This raises well-documented problems. *First*, providing strong patent protection leads to socially inefficient monopoly pricing.[32] *Secondly*, firms may over-invest if the patent is worth more than the cost of gaining the patent, leading to inefficiencies. Scotchmer points out, however, that it is impossible under certain assumptions to provide incentives under the patent system to both an initial inventor and sequential innovators. Because the social surplus from the first invention 'spills-over' into follow-on inventions, neither the initial inventor nor

---

Lemley, 'An Empirical Study of the Twenty-Year Patent Term' (1994) 22 AIPLA Quarterly Journal 369; Paul Klemperer, 'How Broad Should the Scope of Patent Protection Be?' (1990) 21 *The RAND Journal of Economics* 113. Different considerations apply where innovation is cumulative. In addition, many of these analyses focus on the simple tradeoff between the perceived benefits (via inventive activity) and deadweight costs associated with extended patent life; see, eg, William D Nordhaus, *Invention, Growth, and Economic Welfare: A Theoretical Treatment of Technological Change* (1969).

[27] See generally Rebecca S Eisenberg 'Patents and the Progress of Science Exclusive Rights and Experimental Use' (1989) 56 *University of Chicago Law Review* 1017.

[28] See Rebecca S Eisenberg, 'Bargaining Over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?' in Rochelle C Dreyfuss, Diane L Zimmerman and Harry First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001) 223, 226; Scotchmer, above n13, 32.

[29] Scotchmer, above n13, 32.

[30] Scherer, above n13, 1361-1363.

[31] Scotchmer, above n13, 31.

[32] Ibid.

sequential inventors will be able to individually recover the entire social surplus their inventions generate.[33]

3.3.2 Providing Incentives to Maximise Upstream Innovation

The challenge, then, lies in determining the appropriate division of social surplus between innovators operating at various stages of the cumulative innovation process. Some commentators would provide greater incentives to the initial innovator. For example, in developing his prospect theory, Edmund Kitch argued for greater incentives for the initial innovator due to the importance of this initial work in shaping and co-ordinating subsequent research.[34] Given the low commercial value of many initial inventions, Kitch argued that the prospect theory provides a better justification for the grant of a broad patent to an initial innovator than rewards-based theory.[35] As discussed in Chapter 2, this theory has been an emerging and supportable theory, and seems to have application to an industry such as biotechnology.[36]

One of the most fundamental assumptions Kitch makes is that co-ordination of research efforts, even multiple research efforts, through licensing will be possible.[37] Similarly, Suzanne Scotchmer and Jerry Green argue for the provision of incentives for the initial innovator through the grant of broad patents,[38] although unlike Kitch, their analysis is based on the invention-inducement theory.[39] Green and Scotchmer

---

[33] Ibid, 31, 34. See also Green and Scotchmer, above n15. Cf Clarisa Long, 'Patents and Cumulative Innovation' (2000) 2 *Washington University Journal of Law and Policy* 229. 237-245, who argues that the patent system should be sufficiently dynamic to ensure adequate reward to inventors at each stage of the innovation process. Although Long does not purport to investigate how such a system would work, she does advocate caution in optimising incentives for either basic researchers or follow-on researchers in an industry that she characterises as '...complex, non-linear, variable and uncertain.'; at 246.

[34] Kitch, above n10. The prospect theory as a justification for the grant of patents is discussed in Chapter 2; see above, 2.2.2.4. A patent would also provide the patent holder with the opportunity to work on improvements and prevent rivals from duplicating these research and development efforts.

[35] Ibid, 124-271. Arguably, however, a rewards-based theory can support broad patent grants to initial inventors in that the social value of many initial inventions exceeds their commercial value; see, eg, Howard F Chang, 'Patent Scope, Antitrust Policy, and Cumulative Innovation' (1995) 26 *The RAND Journal of Economics* 34, 48-49. See also Scotchmer, above n4, who states that; 'Kitch does not distinguish whether the pioneer inventions are cheap or expensive, and he does not emphasise that "efficient" means efficient for the patentholder rather than for society. What is efficient for the patentholder might not be efficient for society'; 17

[36] Above, 2.2.2.5.

[37] Kitch, above n10, especially 276.

[38] See Suzanne Scotchmer, 'Protecting Early Innovators: Should Second-Generation Products be Patentable?' (1996) 27 *The RAND Journal of Economics* 322; Green and Scotchmer, above n15; Scotchmer, above n13.

[39] See generally above, 2.2.2.1, 2.2.2.4.

argue that it is important to reward initial inventors where their inventions facilitate follow-on inventions, whether these follow-on inventions are improvements or competitors to the initial invention, or applications of the initial invention.[40] This is on the basis that surplus profits created by initial inventions can be redistributed to follow-on inventors through licensing arrangements. Specifically, granting broad patents to initial inventors (and denying them to follow-on inventors) maximises efficiencies provided ex ante agreements[41] can be negotiated and concluded prior to investment in research and development by a follow-on inventor.[42] While ex-post licences are usually negotiated after costs have been sunk and patents issued, ex ante or prior agreements[43] are likely to be more efficient and increase profits for both firms through benefiting from economies of scale, sharing know-how or avoiding patent races.[44] Similarly, although they are guarded in their conclusions, Gallini and Scotchmer argue for broad initial patents where ex ante contracting is available.[45] They do, however, acknowledge that what is crucial is the ability of firms under antitrust law to enter into private contractual arrangements.[46]

Initial and follow-on innovators will rarely have equal bargaining power. Because the breadth of the first invention will determine whether or not the second invention infringes, bargaining power often stems from the breadth of patents.[47] Another factor

---

[40] Green and Scotchmer, above n15, 20-33.

[41] Ex ante or prior agreements are essentially contracts entered into prior to the development of an invention.

[42] Green and Scotchmer, above n15, 21-22; Scotchmer, above n13, 35; Scotchmer, above n38, 323. Scotchmer notes that the ideal solution would be complete vertical integration prior to the first innovation, although this carries with it a number of difficulties concerning the identification and coordination of interested parties; Scotchmer, above n13, 35-36.

[43] Green and Scotchmer go on to consider how the issues of patent breadth, patent length and antitrust policy may be used to transfer profit from the second innovator to the first innovator; Green and Scotchmer, above n15, 25-30. A consideration of the competition law implications of ex ante agreements is outside the scope of this thesis, although the question is important in the context of the level of competition that is desirable in a particular market. For a discussion of United States antitrust treatment of research joint ventures that combine intellectual property, see, eg, Suzanne Scotchmer, 'R&D Joint Ventures and Other Cooperative Arrangements' in Robert D Anderson and Nancy T Gallini (eds) *Competition Policy and Intellectual property in the Knowledge Based Economy*, (1998) 203. See also Scotchmer, above n13, 35-37.

[44] Scotchmer, above n13, 35; Green and Scotchmer, above n15, 21-23, 31. Chang argues against allowing collusive ex ante agreements because doing so may create incentives for inefficient entry by imitators who manage to invent around the invention; see Chang, above n35, 49.

[45] Nancy Gallini and Suzanne Scotchmer, 'Intellectual Property: When is it the Best Incentive Mechanism?' in Adam Jaffe, Joshua Lerner and Scott Stern (eds) *Innovation Policy and the Economy*, vol 2 (2002), 69.

[46] Ibid, 69. That is, antitrust law should refrain from imposing undue restriction on collusive licensing.

[47] See Scotchmer, above n13, 32.

relevant to bargaining power will be the degree of inventiveness inherent in the follow-on invention. A premise of the work of Green and Scotchmer is that follow-on innovators generally have greater bargaining power than initial innovators because:[48]

- the follow-on product may not infringe. If this is the case, the follow-on innovator will compete with the initial inventor and the initial inventor will be unable to collect any royalties on the second product;
- the follow-on product may infringe but its incremental benefits may greatly outweigh its costs, so that the follow-on innovator is likely to invest and negotiate an ex-post agreement; and
- if the follow-on inventor has the sole ability to develop the second product, they may decide not to invest unless they are assured of a positive amount of incremental profit.

A crucial factor to all of the analyses presented above is the ability of inventors to negotiate agreements, preferably ex ante.[49] Patent protection may be viewed as a conduit to the establishment of a bargaining position to enable the resolution of conflicts over patent infringement.[50] In some industries,[51] sequential processes of innovation are complex and licensees will subsequently become licensors of their own technology. In this respect, strengthening patent protection for a particular sequential innovator will impact of the ability of that innovator to license-on its technology.[52] The importance of bargaining in facilitating follow-on innovation cannot be understated.

3.3.3 The Importance of Successful Bargaining in Restructuring Innovation Incentives

If successfully negotiated ex ante agreements with appropriate follow-on inventors could be guaranteed,[53] this would represent a strong ground for concentration of broad

---

[48] Green and Scotchmer, above n15, 23-25. See also ibid, 38.

[49] Although the focus of the prospect theory is not necessarily on ex ante licensing. This theory assumes that licensing ex post will be non-problematic.

[50] See generally Scotchmer, above n4.

[51] Biotechnology is a prime example of such an industry.

[52] See Scotchmer, above n4, 3.

[53] Note that an alternative response to an initial patent that blocks follow-on research is to invent around the initial patent. Empirical data on inventing around is considered below, 4.5.2.

patents in initial inventors. Whether ex ante or ex post agreements are being negotiated, there may be a number of impediments to successful bargaining:[54]

- in order to negotiate ex ante agreements, a patent holder will be required to identify and license improvers, a difficult task under the best of circumstances. Difficulties in predicting invention, particularly worthwhile invention, make searching for improvers a costly and time-consuming exercise;
- improvers are less likely to present at the bargaining table ex ante if this would mean revealing information about an improvement;[55]
- transaction costs associated with licensing improvements will mean that in many cases licensing will not take place in an efficient manner. In the absence of transaction costs, parties are likely to bargain to a mutually agreeable position.[56] Transaction costs may outweigh marginal cost, or may discourage improvers or potential improvers from seeking a licence, or even from the process of innovation.[57] Broadly defined, transaction costs of licensing intellectual property include the costs of searching for a licensee or licensor, negotiating a licence, monitoring performance, and enforcing the terms of the licence and protecting against infringement.[58];
- difficulties in putting a future value on patents, and uncertainties about the value of future patents, are major factors standing in the way of viable bargains;[59]
- potential improvers may not have sufficient incentive to seek licences for improvements that have social value[60] that exceeds their commercial value;

---

[54] See generally Mark A Lemley, 'The Economics of Improvement in Intellectual Property Law', (1997) 75 *Texas Law Review* 989, 1048-1067.

[55] Referred to as Arrow's information paradox; see Kenneth J Arrow, 'Economic Welfare and the Allocation of Resources for Invention' in The National Bureau of Economic Research (eds) *The Rate and Direction of Inventive Activity: Economic and Social Factors* (1962) 609, 614-5. Given that a seller of information is liable to withhold some information, a buyer will always purchase that information with incomplete information resulting in non-optimal allocation of the information; at 615.

[56] Known as the 'Coase Theorem'; Ronald H Coase, 'The Problem of Social Cost' (1960) 3 *Journal of Law and Economics* 1. An important contribution of the Coase Theorem is its recognition of the importance of transaction costs, and the fact that attention must be paid to them in initial allocations of rights; see Robert P Merges, 'Intellectual property and Bargaining Breakdown: The Case of Blocking Patents' (1994) 62 *Tennessee Law Review* 75, 82.

[57] See Lemley, above n54, 1053-1056.

[58] Clarisa Long 'Proprietary Rights and Why Initial Allocations Matter' (2000) 49 *Emory Law Journal* 823, 827-8.

[59] See Coase, above n56; ibid, 833-836.

[60] In other words, improvements that produce 'positive externalities'.

- strategic[61] and non-economic considerations[62] may be infused into the bargaining process; and
- patents over original inventions may give market power either due to the importance of the technology or the breadth of the patent, so that these original inventors have the power (and an economic incentive) to hold up innovation in improvements.[63]

The debate over cumulative entitlements highlights the importance of private bargaining to shift surplus from one innovator to another in order to provide adequate incentives to a particular innovator. There are clearly risks in assuming that successful bargaining will take place. This reduces the bargaining power available to follow-on inventors. On the basis, largely, of this factor, a number of commentators have argued for stronger protection for follow-on inventors.

Perhaps most notably, Merges and Nelson have argued that granting broader rights to follow-on innovators will provide a greater benefit to society by way of increased downstream innovation.[64] Merges and Nelson, like Kitch, view the important issue as strengthening the future development of technology rather than an individual invention.[65] However they disagree with Kitch that broad privileges granted to an initial patent holder are the best way to ensure this development.[66] In an examination of a number of industries, they were unable to find an instance where strong patent protection over an initial invention fostered effective development of follow-on R&D due to concerted coordination by the initial patent holder.[67] Despite conceding that there may be some duplication of research efforts through patent races,[68] their view is

---

[61] See Merges, above n56, 82-82; Robert Cooter, 'Decentralised Law for a Complex Economy: The Structural Approach to Adjudicating the New Law Merchant' (1996) 144 *University of Pennsylvania Law Review* 1643, 1676-77; Robert Cooter and Steven Marks, 'Bargaining in the Shadow of the Law: A Testable Model of Strategic Behaviour' (1982) 11 *Journal of Legal Studies* 225, 243.

[62] For example, irrational motivations with regard to licensing particular parties and not others; Lemley, above n54, 1059-61.

[63] By barring the development of improvements entirely, or charging prices considerably above marginal cost thus reducing incentives to improve; ibid, 1066-67.

[64] Robert P Merges and Richard R Nelson, 'Market Structure and Technical Advance: The Role of Patent Scope Decisions' in Thomas M Jorde and David J Teece, *Antitrust, Innovation and Competitiveness* (New York: Oxford University Press, 1992) 185.

[65] See, eg, Merges and Nelson, above n9, 843.

[66] Ibid, 872-878.

[67] Ibid, 908-909. One of the important characteristics of the analysis undertaken by Merges and Nelson is their implicit assumption that invention differs between industries. Thus, the model utilised for a particular industry depends in part on the relationship between technical advances in the industry and the extent of licensing within the industry; at 843.

[68] Ibid, 877-884.

that favouring a competitive environment for improvements is a more effective mechanism for accelerating innovation than giving a patent holder the ability to develop a prospect.[69]

Their concern is that the prospect of broad patents on fundamental inventions may hinder the technological advance of science-based industries,[70] although they do recognise that as these industries mature and settle into a pattern of cumulative innovation, issues relevant to patent scope tend to shift.[71] It is certainly the case that the biotechnology industry has evolved to the point where a significant amount of innovation within the industry is incremental. Nevertheless, groundbreaking inventions continue to be patented and broad patents on pioneering inventions may continue to impact on subsequent innovators.

3.3.4 Providing Adequate Incentives in Biomedical Research[72]

The preceding sections have considered in general terms the debate over entitlements at various stages of the research continuum. The central justification for the patent system appears to be that it will incentivise research and development. The question is whether innovation will be best facilitated through the grant of broad patents to upstream innovators, or through ensuring that follow-on innovators are able to obtain access to patents necessary to conduct research. This section now makes specific reference to biomedical research, and attempts to demonstrate that given the patent landscape, the research environment and the industry structure evident in Australian biomedical research, it is vital that attention be given to ensuring that adequate incentives for follow-on research exist. This section therefore completes the theoretical construct to enable consideration of the application of competition law to biomedical patents in Australia.

There may be particular reasons why broad rights on upstream inventions may benefit innovation in the medical biotechnology industry, particularly the biopharmaceutical industry.[73] Firstly, there may be a need to protect upstream inventions that are

---

[69] Ibid, 843-4.

[70] Ibid, 905-907, 915.

[71] Ibid, 908.

[72] One option available under United States case-law to ameliorate the effects of broad patents is the application of the 'doctrine of equivalents' rule. The doctrine of equivalents allows a broad reading of initial patents when considering the claims of follow-on patents. Conversely, the reverse doctrine of equivalents allows a court to interpret an initial patent narrowly where a follow-on invention is a substantial advance in the state of the art; see, eg, ibid, 860-867; Merges, above n56, 76-78.

[73] See generally Arti K Rai, 'Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust' (2001) 16 *Berkeley Technology Law Journal* 813, 828-31. See also the discussion above, 2.2.2.1.

considerably removed from inventions with commercial prospects, from competition. Secondly, there are benefits (both perceived[74] and empirical[75]) in allowing smaller, upstream patent holders to control bargaining during collaborative arrangements with downstream innovators. Finally, in theory, there is nothing to prohibit upstream patent holders from allowing multiple downstream innovators from pursuing multiple research paths.[76]

The amount of upstream research conducted by the Australian medical biotechnology industry has risen steadily.[77] Many Australian research institutions and companies supply upstream technology to both Australian and overseas users of that technology.[78] Extracting maximum value for that technology presents challenges,[79] and this suggests that providing Australian inventors with bargaining power through broad initial patents is important. The industry has consistently highlighted the importance of intellectual property protection in recouping research and development expenditure on upstream research, and in attracting investment funding.[80] The government has highlighted the role that commercialisation plays in the development of a sustainable industry.[81]

Nevertheless, follow-on innovators may have difficulty gaining access to necessary upstream technologies and products in certain circumstances. It is submitted that while providing incentives for upstream biomedical invention is important, there are grounds for concern that the current patent system provides excessive protection to

---

[74] Rai suggests that collaborative arrangements are more likely to flourish given that many upstream patents are concentrated in small biotechnology companies, primarily because potential downstream innovators are likely to be less risk-averse than they would be were the rights concentrated in large companies; ibid, 830.

[75] See, eg, Josh Lerner and Alexander Tsai, *Do Equity Financing Cycles Matter? Evidence from Biotechnology Alliances* National Bureau of Economic Research, Working Paper No 7464, (2000) 20-21.

[76] The argument that multiple research paths are necessary to fully exploit the potential of a particular invention is one that may be particularly pertinent in the medical biotechnology area; See further below, 3.3.4.2.

[77] See above, 1.6.2.

[78] Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, (Nicol and Nielsen Study), 110-114. See also Australian Law Reform Commission, Parliament of Australia, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99 (2004) (ALRC Report), 525-530.

[79] See Nicol and Nielsen Study, above n78, 111-114. See also the discussion above 1.6.

[80] See, eg, ibid, 76-80, 82-86.

[81] See above, 1.3.

upstream inventors at the expense of downstream innovation.[82] There are a number of reasons that taken together, suggest this might be the case, and these relate generally to:

- the vast numbers of upstream medical biotechnology patents being granted;[83]
- the fact that many participants in the medical biotechnology industry are specialised and have limited research capabilities;[84] and
- the fact that licences to conduct follow-on research will usually be conducted 'ex post', and are therefore more prone to bargaining breakdown.[85]

A number of other factors may also contribute to the likelihood that access to licences may be refused.[86]

3.3.4.1 *THE EXPLOSION IN UPSTREAM PATENTS*

As indicated in Chapter 1, there has been an explosion in biomedical patenting.[87] This may be indicative that there is reason for concern in relation to the ability to conduct intermediate and downstream research and development. The generation of huge amounts of genomic information and proliferation of patents over this upstream information and the information-based tools used to generate it has resulted in challenges for how the intellectual property system can optimally reward inventors in the medical biotechnology industry.[88] Information technology-based research tools have been developed and become marketable.[89] It has been suggested that this information explosion has led to a change in focus from information possession to information management, a shift that the traditional intellectual property system is ill-equipped to handle.[90] Shifts in the markets for biomedical information and products also mean that the market cannot be characterised as a simple linear model.[91]

---

[82] A number of commentators have argued, therefore, that it is important to maintain adequate incentives for follow-on innovators; see, eg, Scherer, above n13; Barton, above n9; Rai, above n73. See also Long, Patents and Cumulative Innovation, above n33, 238-246.

[83] Below, 3.3.4.1.

[84] Below, 3.3.4.2.

[85] Below, 3.3.4.3.

[86] Below, 3.3.4.4.

[87] Above, 1.7.

[88] See Long, Patents and Cumulative Innovation, above n33, 229, 233, 236-7.

[89] Ibid, 234-5.

[90] Ibid, 236-237. See also Rebecca Eisenberg, 'Re-examining the Role of Patents in Appropriating the Value of DNA Sequences' (2000) 49 *Emory Law Journal* 783; Organisation for Economic Co-operation and Development (OECD), *Genetic Inventions, Intellectual Property Rights and Licensing*

Relying on a simple linear model, Scherer provides a description of options available to offset the effects of resource allocation distortions that can arise from broad upstream patents.[92] Scherer's focus is on ensuring that follow-on invention is able to proceed. However, Scherer points out that this analysis may be too simplistic given that many patented technologies are frequently precursors to biopharmaceutical innovation.[93] Thus, any one of these prior innovators can control whether subsequent innovation takes place by blocking that research.

3.3.4.2 *RESEARCH CAPABILITIES AND FOLLOW-ON INNOVATION*

A major justification cited in support of strengthening incentives for follow-on innovators is that it is desirable to have a variety of innovators pursuing follow-on innovation.[94] Participants operating in different industry sectors have different capabilities, and it has been suggested that the skills required for basic research giving rise to initial innovations often differ considerably to those required for follow-on activities and commercialisation.[95] In addition, it is unlikely that an initial innovator will foresee all of the possible opportunities stemming from their invention.[96] Even if they do, they are unlikely to have the resources to develop all of these prospects themselves,[97] or be able to adequately identify and coordinate the development of these prospects by follow-on inventors.

Practices: Evidence and Policies, (Berlin: OECD, 2002) <http://www.oecd.org/dataoecd/42/21/2491084.pdf> at 18 November 2003 (the OECD Report), where concern is expressed that challenges at the interface of biotechnology and information technology are likely, because companies will be forced to use a variety of intellectual property which may give rise to new access issues; at 80.

[91] Long, Patents and Cumulative Innovation, above n33, 233-234. This is primarily because there is a need to access a diverse range of technologies in order to conduct research in a particular area.

[92] Scherer, above n13, 1361-1364. Including the narrow interpretation of existing and future genome claims (particularly the utility requirement), the application of the doctrine of equivalents and reverse doctrine of equivalents rules, the exclusion of research conducted solely for research purposes, and the reduction of the effects of multiple patents through the imposition of a system of mandatory arbitration for patent holders and follow-on inventors.

[93] Scherer, above n13, 1361-1364.

[94] See, especially, Scherer, above n13, 1362; Barton, above n9, 545-55; Rai, above n73, 823, 831. Of course, as Merges and Nelson have shown, this issue is not peculiar to the medical biotechnology industry, but is evident across a variety of industries; see Merges and Nelson, above n9. In particular, the structure of the medical biotechnology industry has parallels in the semiconductor industry.

[95] See Scherer, above n13, 1362.

[96] See, especially, Barton, above n9, 455. Gene sequence patents, for example, have a number of potential applications, these being: tools for diagnostic tests, research tools, gene therapy and the production of therapeutic proteins to be used as medicines; Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper*, (2002) (Nuffield Discussion Paper), 47-8.

[97] See Scherer, above n13, 1362.

The long process from research to development means that it is desirable to have many researchers pursuing research paths, because frequently an initial innovator will be unable to see the many research paths that could be undertaken in respect of one initial invention. Different approaches to solving a research problem may have social value that could not have been foreseen at the outset.

3.3.4.3 *'EX ANTE' VERSUS 'EX POST' CONTRACTING IN BIOMEDICAL RESEARCH*

Another important factor is that it may be difficult in biomedical research to conduct successful bargaining and thus ensure follow-on development. Ideally, ex ante bargaining would ensure that follow-on innovators are identified and coordinated.[98] However, there are a number of reasons why licensing negotiations will frequently be conducted ex post in biomedical research:

- researchers may continue to conduct non-infringing research despite the presence of a patent in an area. They may to prefer to defer licence negotiations until they have a commercial technology or product with which to bargain, so that some of the uncertainty is removed from negotiations;[99]
- uncertainty as to the value of a follow-on invention may be particularly high when the invention is only speculative.[100] The rapid pace of invention in the medical biotechnology area is conducive to uncertainty in aspects of valuation. Similarly, the relative values of initial and follow-on inventions may be difficult to ascertain ex ante;[101]
- in any event, a follow-on inventor is unlikely to approach an initial patent holder to negotiate prior to investing sufficient resources toward understanding the implications of their invention.[102] In this case, they may be reluctant to risk misappropriation of their invention by the initial innovator;[103]
- an improvement may be the result of an independent insight in which case the inventor may not be aware of existing patents in an area;

---

[98] See the discussion above, 3.3.3.

[99] Note that the likelihood of this outcome may be bolstered by the ALRC's proposed research exemption. A researcher conducting research on an invention would be entitled under the exemption to conduct research without licence even where a commercial outcome is likely. The ability to do so may mean that some researchers postpone licensing negotiations until a commercial outcome is reached; see further above, 2.5.1.3.

[100] See Lemley, above n54, 1053.

[101] See also Scherer, above n13, 1362.

[102] Barton, above n9, 453. See also above n55.

[103] See Lemley, above n54, 1051.

- where there is risk that a follow-on inventor may become a competitor, socially beneficial licensing may be foregone in favour of private self-interest.[104] This is less likely to be an issue where the initial invention constitutes a basic invention with little or no commercial application; and
- attracting investment in research is not an easy process. In many cases follow-on innovators will have insufficient resources to negotiate for an ex ante licence prior to the development and commercialisation of their follow-on product.

It has been argued that if licensing negotiations are conducted ex post, or after the expenditure of research and development funds, there may be a serious risk of a bargaining holdup.[105] One basis for this argument is that because licensing negotiations are likely to take place ex-post, follow-on innovators must take the risk of unsuccessful negotiations into account in making investment decisions. This factor may cause them to exercise caution in investing in research. It is submitted that this argument strongly indicates that stronger support for follow-on innovators is necessary to ensure that follow-on research is able to proceed.[106]

Further, a patent holder may refuse to licence, or may choose to license on an exclusive basis.[107] In some cases, licensing negotiations may be governed by non-economic or strategic motivations, with the result that a licence may be refused on irrational grounds. This may particularly be the case where a patent or suite of patents, give(s) a patent holder a significant amount of power in a market:[108] Ex post licensing has the potential to be more difficult where an initial patent is broad but encompasses a range of possible research applications. In this case, the patent holder may prefer an exclusive licensing arrangement, or vertical integration and retention of the technology.

The ability to reach agreements (generally ex ante) is an undeniably important factor in arguments for concentration of research efforts through broad upstream patents. These arguments may stem from a belief that broad, initial patents stimulate

---

[104] See Federal Trade Commission Report, above n19, ch 2, 24, and the panellists cited therein.

[105] See Barton, above n9, 453. The issue of bargaining breakdowns in biomedical research is discussed further below, 3.4.

[106] See also Barton, above n9, 453.

[107] There might be a number of grounds on which a licence may be refused. In some cases, economic efficiency grounds may dictate a particular licensing outcome. These considerations are discussed further below, 8.3.3, 8.3.4.

[108] The concept of patents and market power will be discussed in detail in the context of s 46 of the *Trade Practices Act* 1974 (Cth), below, 8.2.

innovation, or from analysis in line with the prospect theory, that the prospect of coordinating future research justifies the grant of a broad patent.[109] However, it may be on this ground that these arguments are most vulnerable. Difficulties in negotiating ex post licences are likely to be exacerbated in medical biotechnology due to the many technologies frequently required to conduct follow-on research, and the potential for a vast number of these technologies to impact on many downstream research applications.

3.3.4.4 *OTHER RELEVANT FACTORS*

The factors discussed above provide compelling arguments for strengthening incentives for follow-on researchers in biomedical research. The long pre-commercial phase involved in most biomedical research also means that many follow-on products will constitute new applications rather than improvements that compete with the initial product.[110] An inability on the part of follow-on researchers to conclude bargains with initial innovators may therefore result in products or technologies in new markets not being developed. This issue is developed further in Chapter 5 and succeeding chapters. In particular, it will be argued that refusals to license may become problematic where the development of new products in separate downstream markets is affected.

John Barton advances a number of additional factors as supportive of greater rights for follow-on researchers:[111]

- the issue of patents as an incentive for research, which Barton contends is ambiguous except perhaps in relation to the pharmaceutical industry;[112]
- the fact that much initial research is basic and often this has been (and is) benefited more through direct funding than by patent grant;

---

[109] It was argued in Chapter 2 that the incentive-inducement theory provides the strongest justification for patent protection in biomedical research; above, 2.2.3.5. However, the prospect theory may be useful where the ability to control subsequent development is an integral part of the incentive to innovate. Arguments in relation to negotiating licences are applicable regardless of whether one relies on the incentive-inducement theory, or the prospect theory.

[110] Rai, above n73, her n4 points out that the cumulative nature of biopharmaceutical research can be differentiated from cumulative innovation in other industries. In many industries, the second generation improvement competes in the same end product market as the first generation product. In contrast, most second generation improvements within the context of the biopharmaceutical industry occur in the pre-commercial stage prior to the development of a marketable product such as a drug.

[111] Barton, above n9, 453-454.

[112] In Chapter 2, some empirical evidence in relation to patenting as an incentive for research was discussed in the context of the innovation-inducement theory as a justification for patents. See above, 2.2.2.1.

- the fact that there is a greater risk of anti-competitive behaviour with respect to initial patents. Broad patents may restrict follow-on research, and patents on research tools may prevent the development of subsequent (perhaps non-infringing) therapeutic products; and
- the fact that broad initial patents may mean that entry by later firms into the industry may be restricted or deterred as new generations of products are developed;[113]

The first factor is certainly contentious, although there is some indication that patents have become an increasingly important tool for attracting investment in biomedical research.[114] In Australia, the limited capital capabilities of most medical biotechnology companies render them heavily dependent on patent protection.[115]

3.3.4.5 *FOLLOW-ON INNOVATION AND BIOMEDICAL RESEARCH IN AUSTRALIA*

Dependence on patent protection by Australian medical biotechnology companies means that adequate protection for initial inventors should be assured. It is submitted, therefore, that this consideration must always be borne in mind when contemplating policy development in this area. Nonetheless, this does not mean that the other factors discussed in the preceding section have no relevance in the Australian context.

Although Australian research institutions and companies have been heavily involved in basic research to date, a majority of upstream biomedical patents in Australia are owned by non-Australians.[116] Therefore those Australian companies involved in intermediate and downstream research and development may have to negotiate access to patented technologies and materials necessary for follow-on research, with upstream inventors located offshore. In addition, many Australia researchers and companies that own upstream biomedical patents, license those patents on an exclusive basis.[117] If technologies are exclusively licensed, particularly to overseas

---

[113] A useful example to consider is that of cox-2 technology, discussed in Appendix 2. A broad patent over this technology may deter researchers in a variety of future research applications. See also John P Walsh, Ashish Arora and Wesley M Cohen 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in Wesley M Cohen and Stephen A Merrill (eds.), Patents in the Knowledge-Based Economy (2003), 50, 28.

[114] See above, 2.2.2.1.

[115] See Biotechnology Australia, Commonwealth of Australia, ALRC Report, above n78, 440-441, Nicol and Nielsen Study, above n78, 81-92.

[116] See above, 1.7.

[117] Empirical evidence on the incidence of exclusive licensing of upstream biomedical technologies will be considered in further detail below, 4.4.3.

companies, this will invariably mean that access to those technologies by other follow-on inventors is restricted. This will have implications for Australian researchers conducting downstream research, because the technologies available for licence will be limited.

Further, at some point, many upstream inventors will of necessity become follow-on inventors as opportunities for upstream research diminish. While there are plentiful research opportunities at present, research fields are becoming more cluttered as proprietary positions are sought and asserted. Genomics companies have diversified, and Australian inventors currently operating at the upstream end of the research spectrum may find that they need to adopt a similar course. Accordingly, mechanisms for gaining access to upstream inventions should be available in the event that recourse to them becomes necessary. The manner in which the industry is likely to evolve should be borne in mind when considering policy development.

3.3.4.6 *MECHANISMS FOR REGULATING FOLLOW-ON RESEARCH*

If it is necessary to ensure adequate incentives for follow-on innovators, and to maintain a competitive environment for follow-on inventions, it is necessary to consider how this might be done. In terms of regulation, four methods that have been alluded to are:

- restricting the grant of patents or the scope of rights granted to initial inventors;
- providing a statutory research exemption from infringement for research;
- compelling licensing through a compulsory licensing scheme; or
- utilising competition law to maintain a level of competitiveness in intermediate and downstream markets.

As discussed in Chapter 2, the first three options have been explored in Australia at some length, and it has been argued that there are problems relying on them to ensure that researchers have the ability to conduct intermediate and downstream research. This thesis will concentrate on the fourth option, and examine a specific circumstance in which competition law may operate to compel licensing and foster follow-on innovation. Specifically, it will consider the issue of refusals to license patents. Although competition law will not operate to prevent every negative impact on innovation, there may be circumstances in which competition law should intervene to prevent a patent holder refusing to license and so hindering follow-on innovation. An important consideration is to find ways to bolster rights for downstream innovators, without impinging on incentives for upstream innovation.

In some instances where follow-on innovators bargain with initial patent holders, bargaining breakdowns may occur because various factors make it difficult for the parties to reach agreement. In others, a party to the transaction may possess a greater degree of bargaining power than other parties. In this case, this party may be able to exert influence on the innovative process and in so doing have some effect on downstream levels of competitiveness. In some cases, the need to negotiate numerous licences may make it difficult for a follow-on innovator to gain access to the technologies necessary to conduct their research. The next section will consider the types of bargaining breakdowns that may be problematic in medical biotechnology research.

3.4 CATEGORISING BARGAINING BREAKDOWNS

The necessity to contract for the exchange of rights brings with it the risk that breakdowns will occur during the course of contractual bargaining. These breakdowns may result in a failure to access patents that would allow research to proceed. These issues may be particularly acute for the Australian medical biotechnology industry. As has been discussed, patents have value not only as a potential form of revenue,[118] but also to enable research to be conducted.[119] An inability to effectively license-out technology by Australian research institutions and companies will result in a failure by them to capitalise on the commercial value of their research. If, however, they are unable to effectively license-in technology, they may experience difficulty conducting further research which may have implications for product development. It is this second issue with which this thesis is concerned, although the two are heavily interrelated.

The complex issues surrounding possible bargaining breakdowns in respect of intellectual property protected biotechnological inventions have only recently been recognised in Australia, although there has been some deliberation on these issues in overseas jurisdictions. Chapter 4 outlines the empirical studies that have been conducted in other jurisdictions.[120] A particular study that explored this issue in considerable depth is a study of the US biomedical industry by John Walsh, Ashish

---

[118] Licensing-out patented technology or products is one method of realising revenue on a patent. In this and subsequent chapters, references to 'licensing-in' and licensing-out' will be made. Licensing-in refers to the situation where a party licenses a product or technology patented by another party for use in research and commercialisation activities. Licensing-out refers to the situation where a patentee provides another party with the right to exploit a patent in research and commercialisation activities.

[119] Through licensing-in technology necessary to conduct follow-on research.

[120] Below, 4.2.1.

Arora and Wesley Cohen.[121] Walsh, Arora and Cohen examined two forms of bargaining breakdown that have been identified as having the specific potential to arise in the medical biotechnology area: restrictions on access to single patented products or technologies, and anti-commons issues. The results of this study have been extensively relied upon. In Australia, the Nicol-Nielsen study has investigated these issues.[122] The ALRC also gave consideration to possible policy responses to evidence of bargaining breakdowns.[123] This section considers the issue of bargaining breakdowns in biomedical research in the context of these two issues.

3.4.1 Restrictions on Access

One of the two issues explored by Walsh, Arora and Cohen was whether the assertion of patents over foundational upstream discoveries is having the effect of undermining the advance of biomedical research.[124] A notable feature of biomedical research is that complex research paths are required to fully exploit the potential of broad upstream inventions.[125] Where access to a patent required for downstream research is restricted, there may be a detrimental effect on subsequent downstream development. Given that the essence of a patent right is the right to exclude others, there will invariably be some "routine under-use" in any well functioning patent system, and this may simply be a cost we pay for the operation of a patent system that otherwise benefits society.[126]

But where inventions over which access is restricted comprise foundational discoveries which themselves require further development in order to produce consumer products, there is may be some consequent effect on downstream development. One of the main justifications for the patent system is the invention-inducement theory, and as has been discussed, patenting may well be important to stimulate upstream biomedical innovation. The assertion of patents and exclusionary licensing practices may nonetheless have a negative impact on downstream innovation. The move from public dissemination of research results which in

---

[121] Walsh, Arora and Cohen, above n113. See also John P Walsh, Ashish Arora and Wesley M Cohen, 'Working Through the Patent Problem', 299 *Science* (2003): 1021.

[122] Nicol and Nielsen Study, above n78, especially Results Chapters 4 and 5. Results of this study relevant to the issues in this thesis will be discussed below, 4.4.

[123] ALRC Report, above n78, especially chs 23-27.

[124] Walsh and Others, above n113, 296-297.

[125] Rai, above n73, 831. This makes the prospect theory of patents particularly applicable in the biotechnology area; see Dan L Burk and Mark A Lemley, 'Biotechnology's Uncertainty Principle' (2004) 54 *Case Western Reserve Law Review* 691, 722-728.

[126] Heller and Eisenberg, above n10, 699; Rebecca S Eisenberg, 'Patenting Research Tools and the Law' in National Research Council (NRC), *Intellectual property and Research Tools in Molecular Biology* (1997) 6, 9-10.

themselves constitute important research inputs, to more prolific patenting of research tools sets up the main precondition for the concern that intermediate and downstream research may be impeded.[127]

Two further preconditions may exacerbate the problem. *First*, broad interpretation of claims on upstream foundational discoveries may extend the reach of upstream patents and deter downstream innovators from researching in what they perceive to be a broad area of research. *Secondly*, reach-through claims to future inventions (for example, a right to a compound that acts on a patented target even though the compound itself is not described in the patent claims) could deter subsequent innovation. This will of course depend on how broadly the original patent claim is interpreted, and even if patent offices continue to interpret claims narrowly, courts are not precluded from construing them more broadly.[128] This uncertainty may act to inhibit research in an area where researchers are concerned about how a patent claim may be interpreted.

Of the many examples of patented inventions that are likely to constitute important foundational discoveries, prominent examples include recombinant DNA technology, PCR and Taq polymerase, embryonic stem cells, and genes and proteins that may potentially be important in terms of therapeutic applications.[129] Walsh and Others suggest that there are two considerations when looking at this question:[130]

- how key the invention or research tool is to subsequent innovation, and how broad a range of subsequent inventions might depend on the initial invention; and
- is the invention rivalrous, or rival-in-use.[131] If one researcher uses such a tool, there will be less incentive for a competing researcher to use it because their profits will be eroded. On the other hand, some research tools are non-

[127] Walsh, Arora and Cohen, above n113, 296. The authors rely on their interview data to establish that there has been a surge in upstream patenting. Anecdotal data from company and academic scientists suggested there has been an increase in defensive patenting and in university patenting.

[128] See ibid, 296-297.

[129] See further Appendix 2.

[130] Walsh and Others, above n113, 332-334.

[131] See above n11. The example given by Walsh and Others is that of two compounds that block a receptor that is specific to a therapeutic approach to a disease. The discovery of one would decrease the profit of the other from use of its compound; ibid, 332.

rivalrous and can be used by a number of innovators with no erosion of their profits.[132]

If an upstream invention is fundamental to primarily competing downstream research applications, Walsh and Others contend that access to it is more likely to be restricted in some way, often through exclusivity in licensing. Exclusive exploitation of an invention will entail some social cost because the party exploiting the invention will not have the means to pursue every application.[133] While this is certainly true, Walsh, and Others point out that there may also be some social cost where patented technologies are widely licensed to many users. In this case, it may be less likely that access will be restricted completely, but perhaps more likely that terms such as reach-through rights to future inventions will be imposed. Their view is that it is nonetheless important in any case to consider the biological system being dealt with to determine whether there may be multiple ways of approaching a particular research issue. This will be one factor to consider in examining the impact of restricted access. In addition, the breadth with which patents are interpreted will determine the extent of research activities affected by those rights.[134]

Promoting access to mitigate the social cost associated with restricted access to an invention must however be balanced against the risk that the incentive to develop the invention in the first place will be lessened.[135] This balance needs to be borne in mind whenever a consideration of these issues is undertaken.

3.4.2 TRAGEDY OF THE ANTI-COMMONS

An anti-commons may arise where no party has an effective privilege of use over all the rights necessary to conduct research to develop a resource.[136] Where this is the case, parties must reach agreements with the various owners of the rights to enable them to aggregate the rights they require access to. They may, however, have difficulty reaching agreement.[137] If there were no impediments to successful bargaining, rights would be traded and resources effectively utilised.[138] But where

---

[132] Walsh, Arora and Cohen give examples in biomedical research as PCR, microarrays and combinatorial libraries; ibid, 332. Another prominent example would be recombinant DNA technology.

[133] Ibid, 333-334.

[134] Ibid, 334-335.

[135] See ibid, 333-334.

[136] See Michael A Heller, 'The Tragedy of the Anticommons: Property in the Transition from Marx to Markets' (1998) 111 *Harvard Law Review* 621, 668-669.

[137] See ibid, 676-677.

[138] See Coase, above n56.

agreement with a number of rights holders is required, prohibitive transaction costs may lead parties to decide that exchanging rights is not worthwhile.[139] A socially optimal level of consumption of the resource may not be achieved, resulting in a 'tragedy of the anti-commons' or under-use of the resource.[140]

A complex patent landscape necessitates bargaining to allow the utilisation of patented products, methods and technologies at various stages of the research and development path.[141] For some time, there has been concern that this proliferation of intellectual property over research inputs may present a daunting obstacle to successful bargaining in biomedical research.

The notion of an anti-commons in biomedical research was first advanced by Michael Heller and Rebecca Eisenberg. They assert that there are two ways in which a government may inadvertently create an anti-commons problem: through the creation of numerous overlapping property rights over potential products or resources, or through the use of reach–through licence agreements leading to licence stacking.[142] In their view, the explosion of patent grants within the industry, and the increasing prevalence of restrictive licensing practices mean that an anti-commons is inevitable.[143]

Heller and Eisenberg consider that there are several reasons why it is unlikely that the biomedical industry will overcome an anticommons without legal intervention. First, transaction costs of bargains within this industry are particularly high. Secondly, different sectors of the industry may find reaching agreement difficult. Finally, upstream researchers may overvalue their patented inventions making the development of downstream products less worthwhile. Thus, the preconditions for an

---

[139] See Heller and Eisenberg, above n10; Heller, above n136; Eisenberg, above n28. The reasons for breakdown in negotiations within industries reliant on cumulative innovation will vary from industry to industry. For an empirical examination of this issue see Merges and Nelson, above n9, 843-844.

[140] Heller, above n136, 677.

[141] As has been discussed, the importance of bargaining for the transfer of rights is highlighted by much of the economic literature dealing with cumulative innovation and the optimal allocation of intellectual property, as recommendations on allocations are often predicated on the likelihood of successful bargaining taking place.

[142] Terms claiming reach-through rights in patent licence agreements give a patent holder rights to downstream uses of a licensed invention, and they may give rights to royalties over future inventions, rights to intellectual property over future inventions, or exclusive licences over future inventions; see Heller and Eisenberg, above n10, 699. For a consideration of the competition issues surrounding reach-through terms in biomedical patent licensing agreements, see Jane Nielsen, 'Reach-Through Rights in Biomedical Patent Licensing: A Comparative Analysis of their Anti-Competitive Reach' (2004) 32 *Federal Law Review* 169.

[143] Heller and Eisenberg, above n10, 699-700.

anti-commons in biomedicine exist, and it is unlikely that the market will right itself unassisted.[144] Existing empirical evidence on the topic is divided. For example, Walsh and Others found little evidence of an anti-commons in biomedical research, but a report by an NIH Working Group suggests that increasing difficulties negotiating agreements over research tools is clear evidence that the conditions for an anti-commons persist.

3.4.3 Strategic Patenting Strategies

One matter worthy of comment is the tendency by companies in particular industries to amass large patent portfolios in the hope of dissuading competitors from entering or remaining in a market, or to bolster the company's bargaining position. [145] These offensive-patenting strategies might incorporate patents designed to bolster market power, and the patent holder may or may not intend using those patents.[146] The effect may be single patent holders or oligopolists[147] being in a position to preclude entry into particular markets in which they operate. They may increase the likelihood of bargaining breakdowns occurring as they increase the chance that licences will need to be obtained by industry participants in order for research to proceed. The biotechnology industry is one in which this patent landscape could conceivably emerge, as industry participants rush to secure patent protection and in so doing, fence in their intellectual property positions.[148]

---

[144] Ibid, 700-701. See also Eisenberg, above n28, 231-248. In addition, Eisenberg contends that different agents within organisations have different agendas, for example, scientists and technology transfer personnel within universities are generally at odds in what they are aiming to achieve; at 239-242.

[145] See the discussion regarding 'mutual-assured-destruction' strategies in Federal Trade Commission Report, above n19, ch 2, 30-31.

[146] Ibid, ch 2, 34-35. Indeed, patents may be obtained for the sole purpose of keeping rivals from entering the field rather than for the purposes of self-exploitation or licensing; at ch 2, 34.

[147] See John H Barton, 'Antitrust Treatment of Oligopolies with Mutually Blocking Patent Portfolios' (2002) 69 *Antitrust Law Journal* 851. Although a number of antitrust issues with regard to the behaviour of oligopolies emerge, it is only the issue of refusals to license by members of oligopoly groups with which this thesis is indirectly concerned.

[148] See the comments on the possible evolution of 'mutual-assured-destruction' strategies in relation to the biotechnology industry by John Barton in Transcript of Proceedings, *Federal Trade Commission Hearings into Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, (February 26 2002), [150]. Barton discusses the adoption of these strategies in relation to the semiconductor industry, and comments that a similar scenario could be envisaged for the financial services and biotechnology industries.

3.5 OVERCOMING BARGAINING BREAKDOWNS

The literature suggests that there may be a number of methods employed to overcome bargaining breakdowns, whether these breakdowns constitute restricted access to a single patent, or anti-commons.[149] In some instances, industry participants may employ methods of overcoming bargaining breakdown. For example, licensing, where successful, is an important method of securing access to patented products and technologies. Some methods, such as strategic patenting through the accumulation of large patent portfolios, may assist particular industry participants in ensuring freedom to operate, but are likely to result in a more cluttered patent landscape and increasingly complex conditions under which licensing arrangements must be negotiated.[150]

Where licences have not or cannot be negotiated, the research area may be one in which it is possible to invent around a particular patent or group of patents. Finally, collective rights organisations such as cross-licensing arrangements or patent pools may develop voluntarily in response to an anti-commons situation or where industry participants hold mutually blocking patents.[151] Other solutions such as patent clearinghouses and open source patents are also being discussed in the literature.[152]

In other instances, government authorities may impose regulated solutions on an industry or sector of an industry. For example, in anticipation of an adverse effect on innovation, patent standards may be modified to make it more difficult to obtain a

---

[149] The discussion that follows does not comprehensively discuss all of the methods of overcoming bargaining breakdowns. For a more detailed discussion, see, eg, Federal Trade Commission Report, above n19, ch 2, especially 21-25, 30-32.

[150] Ibid, ch 2, 30-32.

[151] It should be pointed out that in the US, the term, "blocking patents" has a specific legal meaning. Blocking patents occur where one patent holder holds a broad patent over an invention (the dominant patent) and another patent holder holds a narrower patent over an improvement to that invention, or a new invention (the subservient patent); See Merges and Nelson, above n9, 860-861, and their n96, which discusses the intuition behind the grant of blocking patents. The holder of the subservient patent would require a licence from the holder of the dominant patent in order to practice their invention, and the holder of the dominant patent would be precluded from exploiting the improvement without a licence. In most cases, once an improvement is developed and commercialised, a licence from the holder of a pioneering patent that blocks the improver from practising the improvement, would be required.

[152] See, eg, Richard C Atkinson, Roger N Beachy, Gordon Conway, France A Cordova, Marye Anne Fox, Karen A Holbrook, Daniel F Klessig, Richard L McCormick, Peter M McPherson, Hunter R Rawlings, Rips Rapson, Larry N Vanderhoef, John D Wiley, Charles E Young, 'Public Sector Collaboration for Agricultural IP Management' 301 *Science* (2003): 174; Sara Boettinger and Dan L Burk, 'Open Source Patenting (2004) 1 *Journal of International Biotechnology Law* 221; Yochai Benkler 'Commons-Based Strategies and the Problems of Patents' 305 *Science* (2004): 1110.

patent.[153] Competition law is another method of overcoming bargaining breakdowns and aiding the process of dissemination. Similarly statutory patent pools may mandate the consolidation and dissemination of patents. Regulated solutions may assist where it is unlikely that bargaining breakdowns will be resolved by industry participants.

For example, a number of commentators have been strong advocates of allowing industries to evolve to the point where private patent pooling arrangements are entered into, because they may be more tailored to particular industries and workable in practice than statutory schemes designed to deal with high transaction costs.[154] At the same time, other commentators have been pessimistic about the likelihood of emergence of collective rights organisations within the biotechnology industry.[155] Particular methods of overcoming or mitigating bargaining breakdowns may be more likely to assist in the resolution of bargaining breakdowns in some industries than in others. This thesis considers the appropriateness of competition law in condemning refusals to license patents in the biomedical industry.[156]

3.6 CONCLUSION

This chapter has demonstrated that important policy questions arise in industries where there is a risk of patents hindering follow-on innovation. Maintaining an innovative environment and facilitating follow-on research are critical concerns. Patents granted too early in the research process, or patents that are too broad, may damage follow-on innovation and future competition.[157] The concentration of patents also enables a patent holder to exert a degree of control over future generations of invention. It is concluded, therefore, that in a cumulative industry such as medical biotechnology, adequate incentives for follow-on researchers should be ensured.

---

[153] On the difficulty in modifying patent law standards to ensure their industry specificity, see, eg, Michael A Carrier, 'Unravelling the Patent-Antitrust Paradox' (2002) 150 *University of Pennsylvania Law Review* 761. See however, Dan L Burk and Mark A Lemley, 'Policy Levers in Patent Law' (2003) 89 *Virginia Law Review* 1575.

[154] See particularly Robert P Merges, 'Contracting into Liability Rules: Intellectual property and Collective Rights Organizations', (1996) 84 California Law Review 1293. See also United States Patent and Trademark Office, Patent Pools: A Solution to the Problem of Access in Biotechnology Patents? (2000), 8; Organisation for Economic Co-operation and Development, Genetic Inventions, Intellectual property and Licensing Practices: Evidence and Policies (2002), 67.

[155] See, eg, Heller and Eisenberg, above n10; Arti K Rai, 'Regulating Scientific Research: Intellectual Property Rights and the Norms of Science' (1999) 94 *Northwestern University Law Review* 77, especially 132-5; Scherer above n13, 1363.

[156] In this respect, the main issue for the purposes of the thesis is restrictions on access to single patents. An explanation of the anticommons issue was provided however, because access to a number of patents may be restricted, and this may render an anticommons situation likely.

[157] Barton, above n9, 455.

The first three chapters of this thesis have examined a number of issues relevant to the biomedical research environment. The cumulative nature of biomedical innovation, coupled with the structure of the industry and high levels of patenting within the industry, suggests that bargaining breakdown is prone to occur. The question that this thesis generally addresses is the role of competition law in regulating exclusionary licensing practices. This raises complex issues in relation to the interaction between intellectual property and competition law, and the point at which competition law should step in to control the use of intellectual property. Thus, the question entails consideration of the circumstances in which competition law should intervene to reduce levels of concentration in a particular market, and to remedy bargaining breakdown. The central issue is whether competition law is an appropriate mechanism to improve the bargaining position of follow-on innovators.

This thesis proposes that competition law should be considered as a means of facilitating access to patents over other forms of regulation. Changes to patent standards will not affect the considerable number of medical biotechnology patents granted to date. Making provision for exclusion from infringement for research purposes under the *Patents Act* 1990 is also unlikely to significantly alter the amount of research that may be conducted on a patented invention. Similarly, the compulsory licensing provisions, despite providing the basis for a viable alternative to competition law, are relatively cumbersome and have not been tested. There are advantages to dealing with restrictive patent licensing under the *Trade Practices Act* 1974 (Cth) (*TPA*) given the established body of jurisprudence that has evolved under the *TPA*, and the ability of competition law to take account of dynamic efficiencies in focusing on dissemination.

This thesis considers the most fundamental form of bargaining breakdown, that of refusals to license patents. It considers this issue in respect of medical biotechnology, an industry characterised by cumulative innovation. By refusing to license a patent, a patent holder can use that patent to preclude entry into either the market in which the patent holder is operating, or into more intermediate or downstream markets. Refusals to license intellectual property may take a number of forms in that they may be:[158]

- unilateral or individual;
- concerted, in that they involve agreements by competitors designed to restrain trade; or

[158] Herbert Hovenkamp, Mark A Lemley and Mark D Janis, *IP And Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2002) vol I, 13-4.

- conditional whereby an intellectual property owner enters into an agreement with a licensee containing unilaterally imposed terms or conditions.

It is important to distinguish between each form of refusal to license. While similar issues arise in relation to these three forms of refusal to license, competition law treatment of them differs considerably. Consideration of the issue in this thesis will be restricted to the first form of refusal to license, that of unilateral refusals to license. A unilateral refusal to license may also be constructive, that is, a license may be offered to a potential licensee, on terms that are so unreasonable that the offer to license amounts to a constructive refusal to license.

Prior to considering the legal position surrounding refusals to license intellectual property, the following chapter will consider empirical evidence of exclusionary licensing practices within the biomedical industry, since this will be an important consideration in determining the role competition law should play in facilitating follow-on research.

CHAPTER 4

THE AUSTRALIAN EXPERIENCE: AN EMPIRICAL ASSESSMENT OF RESTRICTIVE LICENSING PRACTICES WITHN THE AUSTRALIAN MEDICAL BIOTECHNOLOGY INDUSTRY

4.1 INTRODUCTION

As the preceding chapters have indicated, there is significant theoretical evidence of the potential for restrictive licensing in the medical biotechnology industry. This potential arises from the structure of the industry, the vast number of biomedical inventions that are patented, and the cumulative nature of biomedical research. Patent protection is an important asset to participants in all sectors of the industry. While many industry participants emphasise the importance of patent protection as an inducement to innovation, there is no doubt that the dissemination of upstream biomedical inventions is crucial to follow-on innovation. Licensing is an important tool to enable the widespread distribution of inventions so that follow-on innovation is facilitated.[1] This is the case regardless of the basis on which the initial patent grant is justified.[2]

Until recently, however, there has been a lack of empirical work investigating whether this potential is eventuating in practice, and evidence cited in support of concerns about research hold-ups has centred mainly on anecdotal discussion. This chapter considers the major empirical studies that have been conducted in this area. These studies have not concentrated on patenting levels, but have focused on the effects of patent licensing within biomedical research. Data relevant to the incidence of breakdowns in licensing begins to allow an assessment of how patent law and competition law interact.

It is argued within this chapter that there does not seem to be sufficient evidence to draw conclusive inference in relation to restrictive licensing practices within the industry, and that significantly more work in this area needs to be done. But the evidence does produce some indicative effects. There have been a number of studies conducted in the US and the EU.[3] The Nicol and Nielsen study, in which the author was involved, was conducted with particular reference to Australia.[4] This study was

---

[1] For a discussion on licensing as a form of exploitation of a patent, see above 2.5.

[2] Whether the invention-inducement theory or prospect theory is advanced as a justification for the grant of an initial patent, in an industry where research is cumulative, licensing is an important manner in which follow-on innovation may be facilitated. As discussed above, 3.3.3, 3.3.4, there are a number of reasons in theory why initial innovators in biomedicine may not freely license their inventions.

[3] See below, 4.2.

[4] Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, (Nicol and Nielsen Study) The Nicol and Nielsen Study considered medical biotechnology patenting and technology transfer practices within Australia. The study was undertaken jointly with Dr Dianne Nicol, and the resulting report was co-authored with Dr Nicol. The author and Dr Nicol contributed to all

the first comprehensive empirical work conducted in Australia examining issues associated with patent licensing. One of the issues investigated during the course of the study, was that of restricted access to patents necessary for biomedical research.[5]

Particular challenges facing the Australian industry make these issues very relevant. To recap, these challenges relate to:

- the need for Australian companies to seek foreign investment and enter into alliance activity with international companies; and
- the fact that most Australian patents falling into the biotechnology category are owned by foreign companies, necessitating the need for Australian companies to negotiate access deals with these companies.[6]

The impact of gene patenting and licensing on the development of the Australian biotechnology industry has not yet been assessed, although there is now some recognition of the need for examination of these issues. The Nicol and Nielsen study was conducted with the distinct challenges facing the Australian industry in mind.

The Australian Law Reform Commission (ALRC) also considered this issue, and recently released their Final Report which considered a range of important issues associated with gene patenting and licensing practices, including practices that may have some adverse effect on innovation within the industry.[7] Though the Nicol and Nielsen study was heavily cited by the ALRC, the ALRC Report resulted in limited recommendations. A central conclusion from the Nicol and Nielsen study was that although there was considerable potential for restrictive licensing within Australian biomedical research, there is limited evidence of these practices to date.[8] This is not to say they will not eventuate in time, but at present, research hold-ups appear to be minimal.

---

aspects of the study equally. See also Dianne Nicol and Jane Nielsen 'Australian Medical Biotechnology: Navigating a Complex Patent Landscape' (2005) *European Intellectual Property Review* (forthcoming).

[5] Results Chapter 5 of the study considered evidence relevant to whether an anticommons has developed in respect of biomedical research in Australia; Nicol and Nielsen Study, above n4, Results Chapter 5. This thesis will not consider the issues relevant to anticommons, for example, mounting transaction costs and reach-through rights.

[6] See generally, 1.7.

[7] Australian Law Reform Commission, Parliament of Australia, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99 (2004) (ALRC Report).

[8] A primary reason for undertaking the study was consideration of the issues raised in this thesis, although the study was very broad and encompassed a considerable number of other issues.

The data presented in this chapter will demonstrate that there is considerable evidence that Australian industry participants are managing to find solutions where access to patents necessary for research and development is refused, or where a researcher formed the view that a licence would be refused. In the few instances where licences are being refused, changes in research direction were reported to accommodate these. Nevertheless, the evidence does not account for instances where licences were not requested because it was perceived they would not be available, nor does it necessarily negate the potential for future research hold-ups due to refusals to license patents.

4.2 RELEVANT STUDIES IN OTHER JURISDICTIONS

A number of studies have been conducted in overseas jurisdictions in order to ascertain whether patents are having an adverse effect on levels of innovation within the medical biotechnology industry.[9] These studies will be considered in two categories, empirical studies, and those that have been primarily evidence-based and have been conducted on the basis of meetings or public hearings.

4.2.1 EMPIRICAL STUDIES

4.2.1.1 *UNITED STATES STUDIES*

(i) The United States National Institutes of Health Working Group on Research Tools

The United States National Institutes of Health established a Working Group on Research Tools to investigate access issues encountered by NIH funded investigators, and to investigate possible responses to any issues that arose. The inquiry was conducted through a series of interviews, and in 1998 the Working Group presented a Report detailing their findings and recommendations.[10] At the same time they released a set of guidelines for the transfer of research tools[11] within NIH funded research,

[9] This section discusses a number of the main studies conducted in relation to this issue. It does not discuss all studies that may have been carried out, but concentrates on those that have received more attention in the literature. These studies have considered a broad range of issues. The studies will be generally outlined in this section, and references made, where relevant, to the results of these studies during the remainder of the chapter.

[10] National Institutes of Health, *Report of the National Institutes of Health Working Group on Research Tools* (1998), <http://www.nih.gov./news/researchtools/index.htm> at 3 October 2002 (NIH Report).

[11] Note that the term 'research tool' is subject to varying interpretations, and different explanations of the term are discussed below, 4.3.1.

acceptance of which has been somewhat guarded.[12] The Working Group's inquiry had limited scope in that it was restricted to issues associated with access to research tools in transactions involving NIH grantees. At the same time, they recognised the issues they canvassed had broader application which were beyond the charge of the Working Group. The Working Group interviewed bench scientists, university technology transfer professionals, and personnel from private companies.

(ii) John Walsh, Ashish Arora and Wesley Cohen

John Walsh, Ashish Arora and Wesley Cohen were commissioned by the United States National Academies of Sciences to research licensing breakdowns within the medical biotechnology industry in the United States.[13] Walsh, Arora and Cohen set out to investigate two related questions: *first*, whether there was any evidence of an anti-commons effect within the industry and on academic research, and *secondly*, whether there were any restrictions on access to patents over inventions or research tools that are foundational to future research. As Walsh, Arora and Cohen point out, these issues have occurred in a number of industries.[14]

The methodology employed by Walsh, Arora and Cohen entailed interviewing respondents within various sectors of the industry. Seventy interviews were conducted with respondents from biotechnology and pharmaceutical companies, universities, law firms, government and trade associations.[15] Questions asked during interviews were aimed at exploring the issues outlined above.[16] The questions also focused on how negotiations over intellectual property rights have changed over time, and strategies employed by researchers and companies to overcome any challenges brought about by intellectual property.[17]

---

[12] National Institutes of Health (NIH), *Basic Guidelines for the Transfer of Research Tools To and From Recipients of NIH Funds*, Appendix A, NIH Report, above n10 (NIH Guidelines).

[13] John P Walsh, Ashish Arora and Wesley M Cohen 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in Wesley M Cohen and Stephen A Merrill (eds.), *Patents in the Knowledge-Based Economy* (2003) 287 (Walsh Cohen and Arora); see also John P Walsh, Ashish Arora and Wesley M Cohen, 'Working Through the Patent Problem', 299 *Science* (2003): 1021.

[14] Walsh, Arora and Cohen, above n13, 291-292.

[15] Ibid, 292-293. See their Table 1, 293 for a breakdown of respondents by organisation and occupation.

[16] Ibid.

[17] Ibid.

4.2.1.2 *THE GERMAN STUDY*

On behalf of the Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, and the German Federal Ministry of Education and Research, Joseph Straus, Henrik Holzapfel and Matthias Lindenmeir conducted a similar study.[18] The authors conducted approximately 25 interviews with a view to identifying trends and developments within the German biotechnology and pharmaceutical industries. A broad range of issues were canvassed, including the nature of collaborations within the industry, the availability of licensing, the effect of patenting on publication, infringement of genetic inventions, the quality of patent documents and the necessity for special protection for particular genetic inventions.[19]

4.2.1.3 *THE UNITED KINGDOM STUDY*

A study conducted by the Intellectual Property Institute (IPI) on behalf of the UK Department of Trade and Industry was undertaken to consider the effect of the implementation of the EU Directive for the Legal Protection of Biotechnological Inventions, on the UK bioscience sector.[20] Specifically, the study considered whether concerns about the effect of patents for genetic sequences, were founded. The main aims of the study were to gather empirical evidence on the effect of gene patents on access to genetic information, and the commercial exploitation of biotechnology.[21] The study methodology involved statistical analysis of data on gene patents, interviews with all participants from all sectors of the industry, and an on-line survey of participants in the UK biotechnology sector.[22] An extensive report was released in May 2004.

4.2.1.4 *OTHER EMPIRICAL STUDIES*

Another study investigating the differences in levels of DNA patenting and licensing within the various industry sectors has also been conducted,[23] while the effect of patents on the provision of clinical services was considered in a number of related

---

[18] Joseph Straus, Henrik Holzapfel and Matthias Lindenmeir, *Empirical Survey on Genetic Invention and Patent Law*, unpublished report (2002) (copy on file with author) (the German Study).

[19] A summary of the results is contained at I-II in The German Study, ibid.

[20] Intellectual Property Institute, *Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice* (2004) (The UK Study).

[21] Ibid, 5.

[22] For details of the study methodology see ibid, 19.

[23] Michelle R Henry, Mildred K Cho, Meredith A Weaver and Jon F Merz, 'DNA Patenting and Licensing' (2002) 297 *Science* 1279.

studies.[24] Some empirical evidence has also been collected in other studies. For example, the authors of a study considering the effect of Canadian agricultural biotechnology patent policy on the enhancement of social welfare, conducted a survey of research institutions in Canada, the US and Australia.[25]

4.2.1.5 *General Findings of the Empirical Studies*

The empirical studies detailed have been generally positive about the operation of the biomedical industry given high levels of patent activity within the industry, with few adverse results on downstream commercialisation being reported. The authors of some reports have, however, warned that the potential for hold-ups in innovation due to restrictive licensing practices remains.[26] For example, in their study of the United States industry, Walsh, Arora and Cohen were cautiously optimistic about limitations on access. They warned that although research in broad therapeutic areas has not been blocked to date, this may be through a combination of luck and institutional response, and the potential to impede progress in a broad research area still exists.[27] To some extent, the same potential exists for the Australian industry.

This concern extends to licensing of publicly funded research.[28] The provision of services in the diagnostics sector seems to be a matter for apprehension among industry participants, with Merz and Colleagues reporting widespread concern amongst their respondents that restrictive licensing practices with respect to patents covering genetic diseases were having a negative impact on the provision, quality and cost of genetic diagnostic services.[29]

---

[24] Jon F Merz, Antigone G Kriss, Debra DG Leonard and Mildred K Cho, 'Diagnostic Testing Fails the Test' 415 *Nature* (2002): 577. See also Mildred K Cho and Jon F Merz, 'Letter to Nature' 390 *Nature* (1997): 221; Mildred K Cho, 'Impact of Patents on Provision of Clinical Genetic Testing Services' (2002) (Paper Presented at *OECD Workshop on Genetic Inventions, Intellectual Property Rights and Licensing Practices* Berlin, January 24, 2002).

[25] Dan Dierker and Peter Phillips, 'The Search For the Holy Grail? Maximising Social Welfare Under Canadian Biotechnology Patent Policy' (2003) 6 *IP Strategy Today* 45.

[26] For example, Walsh, Arora and Cohen found few adverse effects on downstream development, but stated that the potential for research to be impeded remains; Walsh, Arora and Cohen, above n13, 335.

[27] Ibid, 335. See also the German Study, above n18, 9-11.

[28] See especially Henry, Cho, Weaver and Merz, above n23, NIH Report above n10.

[29] Merz, Kriss, Leonard and Cho, above n24. A central conclusion of this study was that exclusive licensing had led to the monopolisation of clinical testing services.

4.2.2 OFFICIAL REPORTS

4.2.2.1 *UNITED KINGDOM*

The Nuffield Council on Bioethics also released a discussion paper on the ethics of patenting DNA after extensively consulting core stakeholders within the United Kingdom industry.[30] This included an examination of issues concerned with restricted access to patents, including restrictions that prevent or hinder the development of new or improved medicines and treatments, and the obstruction of free exchange of materials and technologies due to the enforcement of patent rights.

4.2.2.2 *OECD*

Concern over the patenting of gene sequences and other products of biological systems prompted the Organisation for Economic Co-operation and Development (OECD) to hold a workshop investigating the impact of patenting and licensing practices on access to genetic technologies, with over 100 invited speakers and participants reviewing empirical evidence on these issues.[31] Draft Guidelines for the Licensing of Genetic Inventions were recently released for comment.[32] The OECD has indicated an intention to present revised guidelines for endorsement to the OECD in late 2005/early 2006.[33]

4.2.2.3 *UNITED STATES*

(i) United States Federal Trade Commission

The US Federal Trade Commission and Department of Justice held a set of hearings that aimed to investigate the complex issues surrounding intellectual property and competition law.[34] The hearings involved over 300 expert participants and invited

---

[30] Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper*, Discussion Paper (2002) (Nuffield Discussion Paper).

[31] See Organisation for Economic Co-operation and Development (OECD), *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies*, (2002) (the OECD Report).

[32] Organisation for Economic Cooperation and Development (OECD), *Draft Guidelines for the Licensing of Genetic Inventions*, (1 February 2005) <http://www.oecd.org/document> at 22 June 2005.

[33] See ibid.

[34] The first report from those hearings has been released; Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) (Federal Trade Commission Report).

public submissions.[35] As part of those hearings, a number of the issues surrounding access to intellectual property protected assets in general, and biotechnology patents in particular, came under scrutiny. These issues were considered in the context of competition law, and are given more detailed consideration throughout this thesis.

(ii) The United States National Academies of Science

The United States National Academies of Science held a workshop on intellectual property rights and the dissemination of research tools in molecular biology. The workshop heard from a variety of participants within the various sectors of the industry, and a summary of the workshop was subsequently collated and published.[36]

4.2.2.4 *AUSTRALIA*

The Australian Law Reform Commission (ALRC) received a reference in 2002 to investigate issues relevant to the patenting of genes, including the impact of gene patenting and licensing practices on research and commercialisation. The ALRC's Report, *Genes and Ingenuity: Gene Patenting and Human Health*, was released in June 2004.[37] During the course of its inquiry, the ALRC received submissions and consulted widely with relevant stakeholders. It also considered empirical and evidence-based studies from Australia, and from other jurisdictions. References to the ALRC Report will be made throughout this chapter.

4.2.2.5 *COMPARISON OF FINDINGS*

As with the empirical studies, the official reports have highlighted the main concern in relation to patents on biomedical inventions[38] as being access to diagnostic clinical testing.[39] Moreover, some reports recognised that the potential for negative effects on research remains depending on the interpretation of patent claims and the manner in which patents over genetic technologies are exploited.[40]

---

[35] See 'FTC Issues Report on How to Promote Innovation Through Balancing Competition Law with Patent Law and Policy' *Press Release* (28 October 2003) <http://www.ftc.gov/opa/2003/10/cpreport.htm> at 5 May 2004.

[36] National Research Council (NRC), *Intellectual Property Rights and Research Tools in Molecular Biology* (1997) (the NRC Report).

[37] ALRC Report, above n7.

[38] Note that a number of the empirical and evidence-based studies only considered issues relating to the patenting of genetic sequences; see The UK Study, above n20; Nuffield Discussion Paper, above n30; ibid.

[39] See OECD Report, above n31, 68-72; Nuffield Discussion Paper, above n30, 50-54.

[40] See especially OECD Report, above n31; Nuffield Discussion Paper, above n30.

4.3 Restrictions On Access To Research Tools in Medical Biotechnology

The official reports and empirical studies discussed in the preceding section have generally found limited evidence of bargaining breakdown within the biomedical industry. In this respect, these studies are aligned with the Nicol and Nielsen study. A considerable number of patented upstream biotechnology inventions are requisite to follow-on research. In some instances, research tools will be critical to follow-on research. This section clarifies how biomedical research tools are defined for the purposes of this thesis, before providing a guide as to how research tools or technologies are classified for the purposes of the empirical evidence presented in this chapter.

4.3.1 'Research Tools' in Biomedical Research

There is no universally agreed definition of a 'research tool'. As indicated in Chapter 1 of this thesis, in general terms biotechnology research tools are the technological developments and products that enable subsequent lines of biotechnology research to be pursued.[41] Defining the term beyond this is, however, difficult. A narrow definition of the term would limit research tools to those technologies that are traditionally understood to comprise methodologies employed in research laboratories for identifying potential drugs.[42] Notable examples are recombinant DNA technology, PCR taq polymerase, and genes and receptors.

A broad definition would encompass virtually all upstream and intermediate technologies that primarily constitute inputs into further research and are not in themselves 'end products' in the sense of products that will be available to consumers.[43] As well as the 'foundational' tools that would be encompassed in a narrow definition, examples of tools that would be included in a broad definition might include genomics databases, combinatorial libraries, clones and transgenic mice.[44] As Eisenberg points out, one resolution of this divergence in definitions has

---

[41] See above 1.4.2.

[42] See OECD Report, above n31, 50.

[43] Even so, a research tool may be classed as fairly downstream; an example given by Rai of a research tool that may be useful for downstream research, is a gene sequence used in testing for a particular genetic disease that does not open up other pathways of research. As Rai points out, this may not be clear at the outset. A patent holder may not be aware, for example, what disease pathways particular genes encoding receptors or enzymes code for. It is therefore difficult to envisage that a patent holder could investigate all possible disease pathways; Arti K Rai 'Genome Patents: A Case Study in Patenting Research Tools' 77 *Academic Medicine* (2002): 1369, 1368-1372.

[44] Ibid.

been the adoption of differing definitions of research tools by various industry and public sector representatives, so that many participants make a concerted effort to avoid defining their institution's product as a 'research tool'.[45]

The definition adopted for the purposes of this thesis is a broad definition, so that any research input constitutes a research tool. This is the general definition employed in many of the studies that have been conducted in the area.[46] It is recognised, however, that many research institutions and companies have patents over many research tools that they would class as important products in themselves.

4.3.2 CATEGORISING RESEARCH TOOLS

Restricting access to a particular patented invention may result in follow-on innovation being slowed, delayed, or blocked entirely.[47] Technologies necessary for biomedical research fall into a number of different categories, and relevant factors to consider are the nature of the patented technology in question, and whether the person seeking access to the patented technology is in a competitive relationship with the patent holder. The categories into which research tools fall may be generally described as follows:

1. technology that is being used by the patent holder and another researcher to conduct similar research, and one researcher subsequently finds the technology is already patented (for example, where a lead compound being used for development of the same drug by competing researchers is covered by patent);
2. patented technology useful for a range of follow-on uses, the products of which may ultimately compete (for example where a lead compound is being used for research into two different drugs that may ultimately compete with one another); and
3. patented technology that is useful for a range of non-competing, follow-on uses (PCR is a prime example).

---

[45] Rebecca S Eisenberg, 'Bargaining Over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?' in Rochelle C Dreyfuss, Diane L Zimmerman and Harry First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001) 223, 228-229.

[46] See, eg, Walsh, Arora and Cohen, above n13, especially 332-333; Nuffield, above n30, 47, NIH Report, above n10, 3-4.

[47] Discussed above 3.3.

Essentially, technologies that fall into categories two and three will be primarily non rivalrous, although clearly some technologies falling into category two will be rivalrous.[48] The instances of restricted access, which are of primary concern, fall into categories two and three. It is in these instances that there may be significant social cost associated with restricting access. It is socially desirable, for example, that patented inventions that fit into category three be widely disseminated. In this way, broad innovation will be promoted and society will benefit through the introduction of a variety of new products.

On the other hand, society accepts that there will be some reduction in competition associated with the patent system,[49] and is accordingly less concerned with restricted access to patented inventions that fall into category one. In order to encourage innovation, patents give an exclusive right to exploit an invention for a limited period.[50] This necessarily entails some reduction in competition, but the benefit to consumers is likely to outweigh the cost of one competitor being unable to develop the invention. Although there may be a cost disadvantage where competing researchers are precluded from developing competing products, there is unlikely to be a reduction in products available to consumers.

The second category is more problematic, and the desirability of promoting access becomes more equivocal. Broad access may be desirable because the potential of the invention is more likely to be maximised through having a variety of innovators exploiting the invention, particularly where it is unclear whether resulting products will compete. Walsh, Arora and Cohen cite the examples of Geron's exclusive licence for human embryonic stem cell technology and Myriad's diagnostic test licensing as having a dampening effect on research.[51] Clearly, the scope of the patent claims will become an important issue, because this will determine the breadth of follow-on research affected by the patent.

---

[48] The ultimate question considered in this thesis is the role competition law should play in regulating refusals to license medical biotechnology patents. The reason for attempting to categorise technologies when considering issues of refusals to license, is to assist in determining whether the intervention of competition law is required in some instances but not others, for example, in respect of non-rivalrous technology but not rivalrous technology.

[49] This is a cost of the patent bargain; see above, 2.2.

[50] See section dealing with incentive-inducement theory, above, 2.2.2.1.

[51] Walsh, Arora and Cohen, above n13, 333. Details of these patented technologies are provided in Appendix 2 of this thesis.

Although it is not always clear which category a particular patented invention is likely to fit into, this distinction has been borne in mind when considering whether the data obtained gives any insight into whether or not participants in the Australian biotechnology industry are having difficulties accessing patented upstream products or technologies that are required to enable them to conduct research. It is recognised, however, that some research tools are more fundamental to follow-on research than others.

4.3.3 PATENTED RESEARCH TOOLS

A number of the studies discussed in this chapter gave consideration to a number of foundational biomedical patents to which access has been restricted, in investigating the general effects of restrictive licensing. In the United States, for example, the preconditions for restricted access to patents certainly appear to exist, because a number of important, broad-ranging research tools are patented.[52] In some cases, these research tools can be used for a range of follow-on research activities. As a result of this, access to crucial patents may be blocked, and an array of follow-on research activities precluded at the expense of innovation. Many patented technologies that have been classed as 'foundational' to downstream research share common characteristics. The most notable characteristics are that:

- in some cases (but not all), the patents in question resulted from publicly funded research, or the research of public research institutions;[53]
- a number of the patents involved method claims as well as product claims;
- in the case of a number of these patented technologies, the full value or potential of the patent was not known at the time that patent was lodged;
- the patents are generally very broad and have the potential to impede research in the area or competing research to some degree;
- the patents have often been exclusively licensed.

A number of important research tools have been widely disseminated. The best example is probably recombinant DNA technology, patented by the Board of Trustees

[52] See John H Barton, 'Patent Scope in Biotechnology' (1995) 26 *International Review of Industrial Property and Competition Law* 605. See also Michael Heller and Rebecca S Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' 280 *Science* (1998): 698 (Heller and Eisenberg); Walsh, Arora and Cohen, above n13; See also Rai above n43.

[53] As indicated in Chapter 1, a trend in Australia and international jurisdictions is that many research tools that may previously have been freely disseminated are now being patented; see above, 1.4.

of Stanford University.[54] Recombinant DNA technology represents the cornerstone of modern molecular biology, and although very broad, the patents were widely licensed on a non-exclusive basis for low fees.[55]

Nevertheless, the manner in which many of these patented technologies have been exploited or enforced has been problematic. These examples provide some indication of the potential for research to be obstructed where patents are granted prior to the full scope of the claimed invention being known. Where these patents are not made available to other researchers, there may inevitably be some negative impact on innovation.[56] A difficult policy issue is to determine how much distortion to allocative efficiency is acceptable, and whether there should be some restriction on the freedom of a patent holder to license an invention as it sees fit.

An aspect of the Nicol and Nielsen study was to investigate the proprietary status of a number of these research tools in Australia.[57] This research revealed that a number of these fundamental patents have been patented overseas, but have not been patented in Australia.[58] It is submitted a reasonable assumption that may be drawn from this is that this is also likely to be the case in respect of other patents over biomedical research tools or inputs.

The fact that many of these technologies are not patented in Australia has implications for Australian researchers. The fact that many of these research tools are not patented

---

[54] Comprising United States Patent and Trademark Office (USPTO) Patent No US4 237 224 (granted in 1980) and Patent No US4 740 470 (granted in 1988). This technology does not appear to have been patented in Australia.

[55] For further discussion see, eg, the NRC Report, above n36, 40-42. The patents have now expired.

[56] Note that where patented inventions are made available, but on restrictive terms, this may also impact negatively on innovation. Patent holders may impose restrictive terms in patent licences to protect their proprietary position. For example, an initial patent may not be worth much in itself, but it may yield a follow-on invention of considerable value. A patent holder may therefore impose a term claiming rights to future inventions in order to ensure they achieve an adequate return on their investment. Consideration of these issues is outside the scope of this thesis, but see, eg, Jane Nielsen, 'Reach-Through Rights in Biomedical Patent Licensing: A Comparative Analysis of their Anti-Competitive Reach' (2004) 32 *Federal Law Review* 169.

[57] Undertaking a comprehensive search of Australian Patent Office's databases is a very costly and time-consuming process, and the on-line databases are difficult to navigate. Conducting searches of the on-line databases available yields results that are not guaranteed by Australian Patent Office to be accurate. On-line searching has been relied on in undertaking searches of the technologies discussed below given the inherent difficulties of conducting more thorough searches. It is therefore possible to state that no record would appear to exist in respect of a particular product or technology, but not possible to claim that these results are completely reliable.

[58] See Nicol and Nielsen Study, above n4, 41-49. A summary of a number of foundational patented technologies in provided in Appendix 2 of this thesis. This summary describes these technologies and their patent status in Australia.

in Australia is not entirely surprising given that Australia is not a large market in comparison with the major markets of the world.[59] Many more patents in the biotechnology category are granted in the US and Europe than in Australia. Given the high cost of filing and maintaining patents, inventors are likely to patent and market inventions in a limited number of jurisdictions.

4.3.3.1 *USE OF UNPATENTED FOUNDATIONAL RESEARCH TOOLS IN AUSTRALIA*

There may be some implications of the fact that these technologies are not patented for Australian researchers. There is no doubt that a considerable number of these research tools are important to Australian researchers. Research tools that are not patented in Australia can be used for research and development in Australia without fear of liability for infringement. Whether any commercial products of research using these research tools can be exported into markets where they are patented depends on the jurisdiction in question.

Governments in many major markets have prohibited such a practice.[60] For example, in the United States, the importation of intellectual property protected products, produced offshore without the consent of the owner of the technology is not allowed. However, the recent court decision of *Bayer AG v Housey Pharmaceuticals*[61] cast some doubt of the ability of these provisions to protect patent holders where a drug is developed offshore using a patented method. This litigation involved the Method of Screening patents discussed above, and the relevant provision in US patent law prohibiting importation for the purpose of sale or use, of a product made by a process patented in the United States.[62] The matter was decided on appeal as follows:

- the Housey patents are restricted to research methods and do not extend to manufacturing methods;

---

[59] See further ibid, 80-81.

[60] The essential issue here is the composition of provisions in national intellectual property legislation for parallel importation, which is the practice of importing products developed offshore (in a jurisdiction where the technology is not protected by patent) using the patented technology. While some jurisdictions allow parallel importation, most developed countries prohibit the practice. Detailed discussion of parallel importation is outside the scope of this thesis, but see further, Jane Nielsen and Dianne Nicol, 'Pharmaceuticals and Patents: The Conundrum of Access and Incentive' (2002) 13 *Australian Intellectual Property Review* 21.

[61] *Bayer AG v Housey Pharmaceuticals, Inc* 169 F. Supp. 2d 328 (D. Del. 2001); *Bayer AG v Housey Pharmaceuticals, Inc* 228 F. Supp 2d 467 (D. Del 2002); *Bayer AG v Housey Pharmaceuticals Inc* 340 F.3d 1367 App NO –2-1598 (Fed Cir 2003).

[62] *Patent Act* 35 USC § 271(g) (1952).

- the relevant provision applies only to patented manufacturing processes and not to research processes; and
- the importation of products produced using those research methods in other jurisdictions will not constitute infringement of the United States patents.

As a result, a drug developed in Australia using a research method patented in the US could be lawfully imported into the US and would not infringe the patent. This may, to some extent, place participants in the Australian industry at an advantage over participants in other jurisdictions. The precedent afforded by the Housey litigation is limited and applies only to patented research methods used to produce drugs. There are many situations involving the use of patented processes and products where it would not operate, for example, therapeutic applications developed using patented research methods. Further, protection would not extend to other major markets. In the European Union for example, it is unlikely that importation of products produced offshore using patented methods would be allowed.[63]

Many Australian researchers and companies operate on a multinational basis, and the use of products or processes over which patents are held elsewhere may be viewed negatively. Many are involved in collaborative arrangements with foreign companies and researchers, and may be reluctant to jeopardise these arrangements. Although Australian researchers and companies may make use of these foundational discoveries in their research without fear of infringement, any commercial benefits from doing so are likely to be limited.

4.3.3.2 *ENFORCEMENT OF PATENTED RESEARCH TOOLS*

A number of these foundational research tools are patented in Australia. There is no doubt that other important methods and technologies which will be required for biomedical research are also patented in Australia. The patent landscape is becoming increasingly complicated, and many upstream inventions have now been patented. In addition, it may be that research being conducted by the Australian industry will be seen as increasingly threatening as Australian companies and institutes gain an international presence. Although it would appear that patent rights have not been enforced as vigorously in Australia as they have in other jurisdictions, this is something that seems certain to change. Both overseas and Australian companies are starting to take a more aggressive approach to enforcement. A good example of this is

[63] For a more detailed discussion on applications of the principle of exhaustion of rights see Nielsen and Nicol, Pharmaceutical Patents and Developing Countries: The Conundrum of Access and Incentive' above n60, 35-36.

the stance taken by GTG in relation to their junk DNA patents.[64] GTG has also been exclusively licensed by Myriad Genetics to market and perform Myriad's patented testing procedures in Australia and New Zealand.[65] Of more direct concern for the purposes of this thesis are issues associated with an inability to gain access to upstream patents required in order to enable research to continue.

The issue of restricted access to patents is therefore an important issue for the Australian industry. Even though a considerable amount of upstream research is conducted by the Australian industry, respondents in all of the sectors investigated in the Nicol and Nielsen study, frequently require access to upstream patents. Even upstream researchers may need to access patents over particular research tools that are crucial to their research, as few upstream researchers are in the position of having developed and patented every research tool they may need to conduct their research.

4.4 Refusals to License Medical Biotechnology Patents in Australia: An Analysis of the Evidence

This section builds on the empirical studies discussed above by considering in some detail the Australian-based Nicol and Nielsen study. The primary issue addressed in this section is the occurrence of practices that act to limit access to medical biotechnology patents necessary to conduct research.[66] Specifically, it details evidence obtained in relation to refusals to license patents, and a number of associated issues.[67] This discussion relies on the three categories of technology identified earlier in this chapter,[68] and in doing so attempts to determine whether the technology in question is

[64] See the explanation of patents relating to Intron Sequence Analysis in Appendix 2.

[65] For details see <http://www.gtg.com.au/index_general.asp?menuid=080.030> at 24 June 2005).

[66] Note that the evidence presented in this chapter is discrete from evidence relating to the anticommons issue.

[67] The data obtained during the course of the study was obtained through a series of three surveys, (sent to biotechnology and pharmaceutical companies, research institutions and diagnostic institutions respectively) and around 40 semi-structured interviews of respondents from all industry sectors. A detailed study methodology is contained in Appendix 1. The study also covered data relevant to a number of restrictive licensing practices not considered for the purposes of this thesis, including costs and delays in patent licence negotiations, and restrictive terms and conditions contained in patent licences. See further Nicol and Nielsen Study, above n4, 156-168.

[68] As noted above, 4.3.2, the categories are:

> 1. technology that is being used by the patent holder and another researcher to conduct similar research, and one researcher subsequently finds the technology is already patented (for example, where a lead compound being used for development of the same drug by competing researchers is covered by patent);

rivalrous or non-rivalrous. In this context, evidence relevant to the following are considered:

- the existence of blocking patents in the industry;
- whether licences are being refused;
- the effect and frequency of exclusive licensing; and
- failure to exploit patents.

It should be noted that the ALRC in their recent inquiry into gene patenting in Australia, addressed many of these issues and gathered evidence through submissions, results obtained from its submissions and consultations are reported in its report *Gene Patenting and Human Health*, to be comparable to the results that are presented below. This chapter concludes by considering methods being utilised by industry participants to gain access to patents to which access is required.

4.4.1 BLOCKING PATENTS

As stated in Chapter 3, the blocking patents doctrine in the US has a specific legal meaning, and somewhat limited application.[69] During the course of this study, the term 'blocking patents' was used in a broader sense, as including any patents that blocked access to technology required for research.[70] In the company survey, respondents were asked whether their company had ever been required to change its research program because a patent blocked access to key research tools or materials. This question was intended to include situations where research to develop improvements was stymied in that it was perceived that a licence to a patent might not be granted. It essentially sought to determine whether any respondents had taken steps to avoid a blocking patent situation.

4.4.1.1 *EVIDENCE OF BLOCKING PATENTS*

Nine respondents to this question reported that they had changed their research program, (18 percent) and as would be expected, several of these respondents indicated that existing patents heavily influenced their research programs, with one

---

2. patented technology useful for a range of follow-on uses, the products of which may ultimately compete (for example where a lead compound is being used for research into two different drugs that may ultimately compete with one another); and

3. patented technology that is useful for a range of non-competing, follow-on uses.

[69] See above, 3.5.

[70] Note that this is also the definition of blocking patents employed by the ALRC in their report; see ALRC Report, above n7, 447, especially n42, and in the UK Study; see The UK Study, above n20, 15.

other commenting that only slight changes in the scope of their research were required to avoid infringing existing patents.[71] One indicated that they left the field completely if they were unable to work with patent holders to enable them to access necessary patents. Another four respondents provided comments that indicated they had come across patents that would potentially impact on their research programs. The survey did not go on to ask how the companies' research programs had changed, however this issue was explored in more depth in the interviews.

Of the 18 diagnostic institutions surveyed, only one reported access to patents necessary to conduct research being blocked (five percent). The patents in question were the BRCA1 and BRCA2 patents. Four of the 21 research institutions surveyed reported having to change their research program because a patent blocked access, (19 percent) and their responses were qualified. It may be that this figure was fairly insignificant because research institutions are less concerned about proceeding without a licence given that they rely on the existence of a practice-based research exemption.[72] It was not possible to discern from the survey results whether the research they were referring to was non-commercial in nature.

A significant number of interview respondents considered blocking patents to be a real issue within the industry. Many respondents commented that they could not see the value of companies obtaining patents purely for blocking or defensive purposes.[73] Having said this, 21 respondents to the company survey had applied for a patent for strategic reasons, that is, to allow them freedom to operate (43 percent). In most cases, that patent had been granted. It was not clear whether those particular patents were subsequently exploited or licensed-out, however many respondents who participated in interviews either had patents that they did not currently exploit, or knew of companies who held patents they did not currently exploit. In many cases, these patents were not licensed or otherwise transferred, although this may have been for a number of reasons.[74] In a number of instances respondents held patents they had not exploited but subsequently let them lapse, and routinely undertook audits of the patents on their books to enable them to identify these patents.

---

[71] Note that two of these responses were received from non-biomedical companies. Both of these respondents described their activities as falling into the category of plant/animal research.

[72] Although as discussed, the status of this exemption is unclear; see above, 2.5.1.

[73] On defensive and strategic patenting strategies, see, above, 3.4.3; Organisation for Economic Cooperation and Development (OECD), *Patents and Innovation: Trends and Policy Challenges* (2004) 29.

[74] For example, the patents may have had limited commercial value, or may not have been marketable. There may be a number of difficulties associated with licensing or otherwise transferring technology out, and these may prevent licensing deals in some instances.

One patent attorney interviewed during the course of the study had encountered many instances of blocking patents in biotechnology due to the nature of the research process and the necessity for most follow-on researchers to use patented technology held by others. The solutions most commonly observed by this respondent were working carefully around the prior art or seeking a licence.[75] A significant number of respondents interviewed reported that they had avoided research in an area because they were aware that another company held a patent to which they required access, and they considered they would have difficulty gaining access to that patent.[76] In most cases, these respondents indicated that they were in a horizontal, competitive relationship with the patent holder. It was evident that a number of these were clear competing products cases as outlined in category one above. In some cases, however, it was less clear that this was the case and it was more likely that the patented technology fell into category two. Often the ultimate outcome of research was not known at the time that the research was undertaken.

Some respondents engaged in academic research reported having difficulties gaining access to necessary patents. It would appear that patent holders are becoming increasingly wary of infringement by academic researchers as the line between academic research and commercialisation becomes increasingly blurred.[77] Again, it appeared in a number of cases that the technology in question fell into category two, although the data does not permit a strong view on this. This clearly poses a problem if a single patent has broad applicability, and restricting access has the potential to block off whole areas of research that cannot be foreseen at the time the research is conducted. The question here is whether these patented inventions to which access was blocked, comprise foundational discoveries that are key to broad areas of subsequent research.

The result of these licensing practices is also, as one respondent pointed out, that the patent holder will lose ground by failing to allow anyone to work on their patents. There must be some social cost associated with this, as well as the strategic cost to the patent holder of falling behind.

---

[75] See also above 3.3.4.3.

[76] The UK Study found little evidence that gene sequence patents have created patent thickets, but found some difficulties in negotiating in-licences, particularly for research tools, did exist. These problems related primarily to negotiating terms in licence agreements; The UK Study, above n20, 69. The OECD reported that although a risk of patent thickets remains in biotechnology, this has not had a significant impact on innovation to date; OECD Report, above n31, 61-62. Patent thickets are most likely to give rise to an anticommons, but have the potential to deter research where access to single blocking patents is required.

[77] For discussion on the decreasing divide between basic and applied science, see above 1.4.3.

4.4.1.2 *OVERCOMING BLOCKING PATENTS*

Of the interview respondents who commented that they had encountered difficulties of some kind with patents blocking research, many of them said they had overcome these difficulties by changing the direction of their research so as to avoid infringing the patent(s). In some cases, these patents were owned by competitors and the problematic patents were patents over technology that would compete with any technology derived from the research program if it continued (category one). In this situation, although it is to be expected that being granted access to a competing patent is unlikely, one research institution respondent pointed out that a licence deal might even be attractive to a competitor if you have a skill set that they want.

Other respondents commented that they required licences to research inputs to enable them to proceed, and tended to avoid research areas (or subsequently change the direction of their research) unless they were relatively sure they could obtain a necessary licence. Successful licence agreements were often reached. In a considerable number of cases where a licence was required and the researcher approached the patent holder, respondents indicated that a successful licensing outcome was eventually negotiated. One licensing manager contended that 99.99 percent of licensing deals within the industry run smoothly, and only about 0.01 percent stand out as anomalies. His view was that research is blocked in very exceptional cases.

However, other respondents reported that in many instances they did not even try to negotiate a licence if they were of the view that the relevant patent holder would be unlikely to enter into negotiations with them. In a majority of cases, the patented technologies fell into category one, although a number clearly fell into category two.

Licensing was the main strategy by which access to patents could be negotiated. In the case of blocking patents, cross-licensing is a mechanism by which a blocking patents situation may be overcome. While only a small number of interview respondents had been involved in any cross-licensing activity, a significant number considered that cross-licences would become more common within the industry.

Some respondents (particularly where the technology to which they required access fell into category one) reported that inventing around was a strategy they had employed to enable them freedom to operate, while others redirected their research efforts to avoid infringing relevant patents.[78] Respondents from the pharmaceutical

[78] By redirecting their research efforts, these respondents essentially altered their research programs to avoid infringing existing patents.

sector were generally of the view that it is not possible to obtain broad patents that block research in the pharmaceutical industry because of the ability of researchers to invent around. It was evident that these pharmaceutical patents represent a clear case of patents that fall into category one.

Note also that the Australian *Patents Act* 1990 provides that a compulsory licence may be granted where an applicant seeks access to a patent and also a patent that blocks them from exploiting that patent, although as discussed in Chapter 2, the application of this provision is very limited and would not allow, for example, the holder of a subservient patent to obtain a compulsory licence to gain access to a dominant patent.[79]

4.4.2 REFUSALS TO LICENCE

Ernst & Young reported that 20 percent of the companies surveyed during their 1999 survey had abandoned a project because they were unable to gain a licence.[80] While it is not clear whether licences were actually requested and refused, this figure suggests that refusals to license may be a problem that is encountered frequently by Australian medical biotechnology companies. The results obtained in the Nicol and Nielsen study indicate, however, that refusals to license do not, as yet, appear to be a significant problem for the industry.

4.4.2.1 *THE SURVEY DATA*

Of the companies that responded to the company survey, six reported being refused a patent licence (12 percent). Two other respondents, although failing to indicate that they had encountered a refusal to license, would appear by implication to have done so.[81] The question was intended to elicit responses as to unilateral refusals to license, although it would appear in one case at least that the refusal was predicated on unreasonable terms. Of the six companies who were refused a licence, none reported being in a vertical relationship with the patent holder, and three reported being in a

[79] See above, 2.5.2. The 'reasonable requirements of the public' test may address this issue, although it was submitted during the course of the discussion on compulsory licensing that uncertainty over the application of this provision makes its utility dubious.

[80] Ernst & Young, *Australian Biotechnology Report* (1999) 35.

[81] Answers to later questions rested on the assumption that they had been refused a licence. Note that one of these respondents was engaged in plant/animal research rather than biomedical research, although the patent for which a licence was apparently refused was described as an active drug patent.

horizontal relationship.[82] Responses about the nature of the relationship between the parties were not received from the other three respondents.

Reasons for the refusal were given by three respondents: two reported that exclusive licences were granted to another party, and the other stated that they were in competition with the patent holder.[83] A majority of these companies were significant in terms of size as measured by number of employees and revenue, with most of the respondents reporting revenue in excess of AU$5 million. Three were internationally owned. All of the companies had a significant number of patents ranging from eight to "thousands". Respondents were also asked about the kind of patent for which a licence was refused. Four respondents provided this information,[84] with one answering research tool, two answering gene sequence,[85] and one answering active drug patent.[86] It was surmised from the information concerning relationships with the patent holder or exclusive licensee, that the 'active drug patent' fell into category one, however this is not altogether clear from the limited data available. Given the types of patents to which access was refused, it would appear in the remaining three instances that the patented technology fell into either category two or three.[87]

Of the research institutions that responded to the survey, only two reported that they had been refused a licence (nine percent), and only one of those institutions had had to abandon a particular area of research because of the refusal. None of the diagnostic institutions surveyed had encountered a refusal to license, probably due to the low level of research and licensing-in being undertaken within the diagnostics sector.

---

[82] The respondent referred to above at n81 also reported being in a horizontal relationship with the patent holder.

[83] One other respondent who did not provide an affirmative answer to the refusal to license question, cited unreasonable terms as a reason for a refusal to license – it is not clear whether there was a refusal or not, but it seems in any event that it was not a unilateral refusal to license.

[84] One other respondent who had not answered yes to the refusal to licence question, answered this question and said the patented technology was enabling technology. They also said the patentee was in a horizontal relationship with them.

[85] One of these was also described as diagnostic.

[86] It was not possible to glean from the results whether the patents were being exploited in any event by either the patentee or another licensee.

[87] This would depend on what definition of 'research tool' had been employed by the respondent who provided this answer, and the particular gene sequences in question. It is not possible to state definitely whether these technologies were rivalrous or non-rivalrous.

4.4.2.2 *THE INTERVIEW DATA*

This perception that unilateral refusals to license are not a pervasive issue within the industry was reinforced by the interview data.[88] Most of the company and research institution respondents had not encountered outright refusals to license, although one managing director whose companies were involved in downstream development activities, had been refused licences by US companies on a number of occasions. His companies had only negotiated licence deals with US companies. He commented that many small to medium sized US companies had refused to license patents on the grounds that they would rather not risk losing a potential market. On the other hand, larger companies were more willing to license on the grounds that they were unlikely to enter that particular research area. This respondent's companies had not been offered licences on restrictive terms, but had only encountered outright refusals to licence. In the case of this respondent, the technology over which licences had been requested clearly fell into category two, as the companies in which he was involved were engaged in the business of value-adding to upstream and intermediate technologies.

This account appeared to be somewhat isolated. Another respondent engaged in downstream development activities reported that there had been an occasion where a research tool patent holder did not want to license them, but ultimately licensed their partner, effectively solving any problems created by the refusal. One university technology transfer officer stated that they had been refused licences but generally the problem was that terms were unacceptable. Some respondents complained that owners of research tool patents, while willing to license, unreasonably demanded reach-through royalties. Another respondent from a large pharmaceutical company agreed that refusals to license do happen, but considered that most deals that don't work out are probably unsuccessful primarily due to the low probability of success rather than other aspects.

One interpretation of this data is probably that refusals to license were not encountered because often it did not get to the stage that licences were requested. Many respondents acknowledged this. In this case, it could be argued that there may be instances where research areas are being avoided if there is a fear that a licence to a requisite research input is unlikely to be granted.[89] Many researchers and company

---

[88] Cf Ernst & Young, above n80, 35, where it is reported that 20% of their respondents reported abandoning a project due to an inability to obtain a licence.

[89] This may align the results of the study more closely with the figure obtained by Ernst & Young from their survey results; see above n88.

respondents stated that they avoided particular areas of research if competitors held patents, or if it looked as though obtaining a licence necessary to enable them to conduct research might prove to be too problematic. In some cases technology to which access was required clearly fell into category one, but in other cases it is likely that the patented invention fell into category two. For example, a respondent from a large pharmaceutical company stated that if it was clear the patent holder would not give a licence over a target, they tended not to pursue it. They had a large number of targets to choose from, so abandoning targets because they could not obtain the necessary licences to continue research was not hugely problematic.

To summarise, in line with the survey results a few interview respondents expressed frustration at difficulties in licensing-in enabling technologies, but these were greatly outnumbered by the number of respondents who had not experienced any problems. An alternative reading of the data is that respondents had available to them many rich technological opportunities and were not concerned if they perceived that they would be unable to obtain licences on occasion.

Patented research tools were also frequently used without licences, particularly by universities where it was unlikely or unclear whether or not a commercial product would result. It was conceded by a number of company respondents that it would be impossible to know what every lab or company was doing, so policing use of research tool patents is extremely difficult. A patent attorney interviewed agreed that research tool patents are very difficult to enforce, particularly at present when many research tool patents are owned by multinational companies.

4.4.2.3 *Reasons for Refusals To License*

Similarly, most respondents engaged in licensing-out their technology (including research tools) appeared to hold the view that it made good business sense to engage in fairly liberal licensing practices. This is not to say that exclusive licensing practices, or licensing-out on terms that may be problematic to one party, are not common within the industry. It seems clear that there are some parties with whom a patent holder would not contemplate a licence arrangement. Many respondents intimated this, and one respondent was more specific. Engaged in upstream research and development activities, this respondent gave three reasons why a requested licence might be refused:

- where the licence grant would conflict with their own business development, or with a licence granted to another party, particularly an exclusive licence;

- where the potential licensee was problematic in terms of finances or reputation within the market place; and
- where the intended application of the patented technology was unethical.

The first ground was undoubtedly the most common ground on which a licence would be refused, and this is in line with the survey results. It is to be expected that when a patent holder has a product patent, they are likely to refuse to license their own competitors or license two parties in competition. Again, patented inventions falling into category one are unlikely to be widely disseminated, and this may entail some social cost. Consistent with the objectives of the patent system, some degree of exclusion is to be expected.

In contrast, in situations where the products developed constitute broadly applicable foundational discoveries, failing to license broadly may have some consequent effect on downstream research. The same respondent also pointed out that in circumstances where "...we may have given a licence for gene therapy to treat breast cancer, and someone else wants it for all cancers", a licence would also likely be refused. Although there could clearly be a conflict for an exclusive licensee in such a case, it would certainly be questionable whether a company engaged in researching gene therapy for breast cancer competed with a company engaged in researching gene therapy for all cancers. This is more likely to be an instance that fits into category two or three,[90] and is more problematic in terms of restricted access.[91] It is difficult to say with any precision how frequently such a scenario might arise.

A consideration then, that has major bearing on whether patent holders are willing to license others, is the technology in question. Whether the technology is core to the activities of the patent holder will be an important variable. Patent holders will be understandably reluctant to license inventions that fall into category one, and in some instances category two. It became evident during the course of interviews that patent holders are more likely to license non-core technologies, and this may result in patent holders being willing to license technology falling into categories one and two. Where they were not licensed, in many cases it would appear that the inventions were being

[90] Depending on likely research outcomes.

[91] Note that a patent holder may license to a number of licensees, permitting each to undertake different uses or exploit in different territories. In this sense, a licence will be exclusive in terms of a particular field of use or territory, but the arrangement might not be quite so restrictive as an exclusive licence that is not so confined.

exploited in any event, although respondents did report inventions not being exploited.[92]

Broadly applicable research tools (falling into category three) are more likely to be widely licensed because this is a method of maximising revenue on them. Permitting others to use some enabling technologies is unlikely to impact significantly on the competitive advantage a patent holder or licensee may have. During interviews, there were no reported instances of licences to technology falling into category three being refused.

Submissions to the ALRC's inquiry into gene patenting indicated that refusals to license are not really problematic for the Australian industry.[93] Walsh, Arora and Cohen reached a similar conclusion in respect of the US industry:[94] in particular their respondents complained of restrictions on the use of targets.[95] In considering a number of examples, however, their conclusion was that it was only in a number of limited instances that access to a target was completely restricted or limited, and in most cases the target was being exploited by at least one party. It should be remembered, however, that there might be some social cost or impact on innovation, when few parties are working on solving one problem.[96] This is most likely to be an issue in respect of technology falling into categories two and three.

4.4.3 EXCLUSIVITY

4.4.3.1 *THE EFFECT OF EXCLUSIVITY ON RESEARCH*

It should again be emphasised that exclusivity is the cornerstone of the patent system. Exclusivity is part of the patent bargain, and the price society pays for the disclosure of invention. Without monopoly rights, the patent system would cease to function. The aim of this discussion, therefore, is to consider whether there are instances in which exclusive licensing practices are likely to hinder innovation in that use of an invention will be restricted.[97] An exclusive licensing arrangement means that other

---

[92] See below, 4.4.4.

[93] ALRC Report, above n7, 528.

[94] See also the German Study above n18, 7.

[95] Walsh, Arora and Cohen, above n13, 310-14.

[96] See Robert P Merges and Richard R Nelson, 'On the Complex Economics of Patent Scope' (1990) 90 *Columbia Law Review* 839, who argue that innovation will be best served by a variety of innovators working on improvements, rather than relying on the patent holder to coordinate development of subsequent innovation through licensing.

[97] As Rai and Eisenberg have pointed out, '[e]xclusive licences on research tools with potentially broad applications threaten to throttle scientific progress by limiting the number of players in a developing

parties will be refused licences, and it is in this context that this data is presented.[98] It is unlikely that public benefit considerations play a major role in market dealings between a licensor and a licensee. Again, the category into which technology will fall will be important, in that ideally non-exclusive licensing of inventions falling into category three (and often category two) will take place.

Data obtained revealed that while many patent holders initially aim to disseminate their technology widely, licensing decisions are often driven by revenue considerations. Respondents frequently expressed a desire to non-exclusively license their technologies where a number of licensees had been identified.[99] But in many cases in order to extract the best bargain they were required to license on an exclusive basis. Pharmaceutical companies in particular, demand exclusivity, particularly in relation to drug targets. Where licensing decisions are dictated to some extent by the bargaining power of the respective parties, licences may be granted to fewer licensees than would be considered to be socially optimal. This is particularly the case where a potentially non-rivalrous invention may not be licensed to its full capacity, and other non-competing uses of an invention may be precluded.

4.4.3.2 *EXCLUSIVE LICENSING IN PRACTICE*

Exclusivity can take a number of forms including geographical exclusivity, exclusivity for a limited period, or field-specific exclusivity. Licensing on an exclusive basis is commonplace within the industry. Of the 22 respondents to the company survey who had requested licences, 16 of those respondents had entered into licences on an exclusive basis (73 percent of respondents who had licensed-in, 33 percent of total respondents).[100] Ten parties had licensed-in on a non-exclusive basis, and five reported having both kinds of agreements. Two parties failed to provide details of the kind of arrangements entered into.

---

field.'; Arti K Rai and Rebecca S Eisenberg, Bayh-Dole Reform and the Progress of Biomedicine, (2003) 66 *Law and Contemporary Problems* 289, 301.

[98] As such, the competition law implications of terms in contracts providing for exclusive licensing arrangements will not be considered in this thesis.

[99] This was the case in respect of technologies falling into all three categories, but particularly in respect of category two and three technologies.

[100] All but two provided details of the kinds of arrangements entered into. Ten parties had licensed-in on a non-exclusive basis (one of these was involved in plant/animal research), and five reported having both kinds of agreements (again, one of these was involved in plant/animal research).

Sixteen of the 22 respondents who had licensed-out patents provided details of the kinds of licensing-out agreements they had entered into.[101] Twelve respondents had entered into exclusive licensing-out arrangements (54 percent of respondents who had licensed-out, 24 percent of total respondents). Only six respondents had entered into non-exclusive arrangements, and four reported both exclusive and non-exclusive deals.

Eight of the 12 research institution survey respondents who had requested licences had entered into non-exclusive licensing arrangements (67 percent of respondents who had licensed-in, 35 percent of total respondents), and three had entered into exclusive arrangements (25 percent of respondents who had licensed-in, 13 percent of total respondents). Thirteen research institutions had licensing-out arrangements, and 11 of these provided details of the type of arrangement. Seven said they had entered into exclusive arrangements, (54 percent of respondents with licensing-out arrangements, 33 percent of total respondents) and four said they had entered into both exclusive and non-exclusive arrangements (36 percent of respondents with licensing-out arrangements, 19 percent of total respondents). None said they had only entered into non-exclusive arrangements.

Of the three diagnostic facilities who had entered into licensing-in arrangements, one said they had entered into exclusive arrangements, and one non-exclusive. Only two respondents had licensing-out arrangements, and both of these were exclusive agreements.

Exclusive licensing appears to comprise a significant portion of licensing arrangements within the industry. This was confirmed by the interview data, which highlighted the role of exclusivity in licence agreements. The interview data also confirmed that whether a licence agreement is exclusive or non-exclusive will depend largely on a number of factors including:

- the nature of the invention being licensed;
- the negotiating power of the respective parties and their position in the drug or therapy development pipeline; and
- the nature and number of potential licensees.

[101] One party stated that their agreement had expired, two were in negotiations or planning to enter into an agreement, one party cited confidentiality and two did not know or did not provide an answer.

4.4.3.3 *THE NATURE OF THE INVENTION OR LICENSED PRODUCT*

Exclusive arrangements were viewed as appropriate where a licence was being sought with a particular commercial outcome or product in mind. Respondents also reported being reluctant to enter into non-exclusive arrangements where the price demanded was excessive. On the other hand, respondents were generally willing to expend significant amounts for exclusive licences.

A patent holder may exclusively license the whole subject matter of an invention, or a particular component of an invention. It is important to recall that specific fields of an invention may be separately licensed on different bases. The nature of the invention or the licensed component will be an important variable in licensing negotiations, as it will determine to some extent whether an exclusive or non-exclusive licensing deal will be more lucrative. As explained by a respondent involved in a biotechnology commercialisation company:

> Whether to licence exclusively or non-exclusively depends on the project. For example, when working with animal models most licences will be non-exclusive, devices will be exclusive. The type of licence depends on the type of technology and what you want to licence; service, compound, device etc. Each has its own quirky nature.[102]

Gene targets may be licensed either exclusively or non-exclusively depending on how wide any potential applications of the gene are. A gene patent may have a number of applications and one particular application or function (such as a diagnostic or therapeutic application) may be exclusively licensed, and others non-exclusively licensed. That is, a licence over a gene patent may not be totally exclusive, but may be field specific. Such arrangements were reported to exist by a significant number of respondents from both research institutions and companies.

A number of respondents confirmed that product based inventions (or components of inventions) are often exclusively licensed, while broadly applicable technology-based inventions are generally licensed on a non-exclusive basis. Platform technologies, assays, reagents such as monoclonal antibodies, and diagnostic tools for example, are generally licensed on a non-exclusive basis, while compounds and other drug targets, and particular applications of gene patents are often licensed exclusively. In short,

[102] Many of the foundational research tools discussed in Appendix 2 were exclusively licensed, which in many cases hindered the pace of research and development in a particular field. It is desirable that non-rivalrous technologies be non-exclusively licensed, as exclusive licensing of these technologies is likely to be detrimental to downstream product development.

technologies falling into category one are generally exclusively licensed, while broadly applicable technologies falling into category three are more likely to be non-exclusively licensed. Category two is more problematic, and it would appear that technologies falling into this category were in some instances licensed on a fairly limited basis. This was due in part to the fact that products resulting from the licence deal might compete with products developed by the patent holder. The factors discussed below also played some part.

Respondents also reported being more willing to exclusively license-out where the patented technology was not core to their activities. A number of respondents exclusively licensed-in technology in order to shore up their patent portfolios, recognising that they were far more likely to be granted an exclusive licence where the patent holder had no intention of using the patented technology. Under these circumstances, the generally held view was that although they may not want to use the technology, this was unlikely to be of concern to a patent holder who was unlikely to use the technology and realise any value on it themselves. It will be argued in later chapters that it may be appropriate to apply competition law where a patent holder refuses to license a patent and development of a product in a separate, downstream market is precluded. This data would tend to suggest that there is some evidence that patents are being exclusively licensed-in but not exploited, and this may have implications where access to that patent is sought to enable the conduct of research and development activities.

4.4.3.4 *The Negotiating Power Of The Parties And Their Position In The Development Pipeline*

Many company respondents said that they insisted on exclusive licences from university or biotech start-ups, while some generally bargained for assignments, exclusive licences and non-exclusive licences in that order. Many respondents agreed that an assignment was optimal but frequently they were forced to settle on less than a full assignment of rights. Respondents from universities, for example, stated that in licensing-out their technology or products, a non-exclusive licence would in many circumstances be desirable. However, a large number of research opportunities are available for licence, and in order to achieve a satisfactory licensing outcome many respondents said they were forced to accept that their product would need to be licensed-out on an exclusive basis or not at all.[103] Many respondents at various stages

[103] See also Henry, Cho, Weaver and Merz, above n23. This study found that in the US, non-profit organisations are far more likely to grant exclusive licences. Sixty-eight percent of licences granted by non-profit respondents were exclusive compared with 27 percent of licences granted by private firms.

in the development pipeline had licensing arrangements with large multinational firms, and agreed that there was often little choice but to license exclusively.

In some instances, respondents said they were forced to non-exclusively license their patents where they were being infringed, or risk a challenge to the validity of their patents that they could ill afford to defend.

4.4.3.5 *POTENTIAL LICENSEES*

The licensing decisions of many companies are dictated to some extent by their identification of potential licensees. For example, if only one or two companies would potentially be interested in the intellectual property, they would realise more benefit by licensing-out on an exclusive basis. Where there are a number of researchers operating in an area, one respondent involved in upstream research and development activities stated that they tried to license non-exclusively to extract more value from the intellectual property. Indeed, where this was the case, an exclusive licence would not be desirable unless the potential licensee had a significant share of the relevant market. Thus, identification of the markets to be serviced is an important part of any licensing decision.

Of course, the factor mentioned previously will come into play here; the ability of patent holders to enter into non-exclusive licensing-out arrangements where there are a number of licensees available, may be hindered to some extent by who the licensees are and what arrangements they are prepared to enter into. For example, though many respondents said they would probably license-out on a non-exclusive basis if they had a choice, they admitted their choice of licensing arrangement was dictated to some extent by the demands of licensees, who often insisted on exclusivity.

An interesting comparison can be drawn with the device sector of the industry, with one respondent from a company engaged in developing devices explaining that they non-exclusively license to competitors on a regular basis, and in fact competitors are likely to be the only parties interested in licensing their technology. In many cases, these deals involve cross-licensing which seems to be common within device companies.

The authors recognised there could be several reasons for this: the exclusive licensing mandate of the *Bayh-Dole Act* 35 USC §299 (1980); a desire by universities to reduce licensing expenses; a perception that universities are more likely than their industry counterparts to licence targets for drug discovery; and the fact that private companies may generate different types of invention to non-profit institutions.

At the downstream end of the research and development spectrum, respondents from pharmaceutical companies stated that they insisted on exclusive licences for compounds used as drug targets. Other respondents involved in downstream product development activities confirmed that they would only license-in products on an exclusive basis on the grounds that they could not afford to invest in research and development of a product under the threat of competition. Most licensees involved in licensing-in product based inventions from research institutions sought exclusive licences, and were reluctant to enter into agreements on any other basis. Price is obviously a consideration here, as products licensed on a non-exclusive basis will always be available at lower cost.

With reference to research tool (involving non-rivalrous technology) patents, a number of respondents who could be characterised as operating at the downstream end of the development continuum, predictably expressed a desire for non-exclusive licences for all broadly applicable research tools.[104] The Cohen-Boyer patent for recombinant DNA technology was mentioned by a number of respondents as a kind of ideal to be sought after in relation to licensing research tool patents. Exclusive licensing of research targets was more likely to be tolerated.[105] Indeed, these inventions are more likely to fall within category one.

By contrast, one respondent was involved in the bioinformatics sector. This respondent could think of only one or two examples of exclusive licensing deals involving software within the sector, and spoke of the sector maintaining an ethos of free, unrestricted access, and licensing occurring on a non-exclusive basis.[106]

4.4.4 Failure To Exploit Patents

Interview respondents were questioned about patents they held but did not exploit. As reported above, a number of respondents stated they could not see the sense in retaining patents but not exploiting them. At the same time, many respondents either held patents they did not exploit, knew of patents that were being held but not exploited, or speculated that this was certain to be the case.[107] Some respondents suggested that larger companies might employ the strategy of patenting in order to

---

[104] One respondent from a large pharmaceutical company stated that they would like to see guidelines for the licensing of research tools in line with the Guidelines released by the NIH. However, these guidelines have had a limited impact on the actual dissemination of patents over research tools; see above n12 and accompanying text.

[105] See also Henry, Cho, Weaver and Merz, above n23.

[106] Software is generally licensed for use as enabling technology. Note that proprietary databases have for the most part been licensed exclusively or semi-exclusively.

[107] In some cases these patents had been obtained by licensing-in.

exclude competitors from areas of research they considered they might enter at some stage. The position seems to be that many respondents we spoke to employ a defensive patenting strategy and in effect "fence in" their intellectual property position by obtaining families of patents.[108] One respondent commented on the degree of "over-patenting" evident at all levels of the industry.

One survey question sought to ascertain the levels of strategic and defensive patenting taking place in the industry. Survey respondents were asked whether they had ever applied for a patent for strategic reasons. This may include patents applied for where there was no intention to exploit a patent. Twenty-one of the 49 company respondents said that they had (43 percent). This figure is not surprising given available data about the high levels of patenting within the industry: strategic patenting and licensing strategies are crucial in order to ensure freedom to operate. It is likely that at least some of these respondents obtained patents for defensive reasons in that they did not wish to exploit them. Strategic and defensive patenting would appear to be far more prevalent within the company sector than other sectors. Only five of the research institutions surveyed said that they had applied for a patent for strategic reasons (22 percent), while one diagnostic facility answered this question in the affirmative (five percent). Given the high cost of obtaining patent protection and the limited resources of many research institutions and diagnostic facilities, these figures are not surprising.

Most interview respondents engaged in patenting agreed that they patented very broadly. A number of respondents reported that their companies had patents (or licences) on their books that they did not exploit. Their research options were so rich that they had many patents they just didn't have the resources to exploit themselves. Gene validation targets, for example, are being generated at a rapid pace. In addition to this, some respondents reported that they had identified technology they did not wish to see exploited, and paid the patent holder to effectively sit the intellectual property on a shelf and not seek licensing opportunities.

In some instances where patent holders did not exploit patents, they resolved this non-exploitation by either letting the patents lapse or licensing them out. Often, however licensing opportunities were not sought, nor available. In the case of many academic institutions, potential licensees had so many research opportunities, that many patents were not taken up and exploited. Marketing technology and products to overseas companies is difficult. If a potential licensee approached the patent holder, often this led to some sort of negotiated arrangement. If not, often the patents stayed on the

[108] See Dierker and Phillips, above n25, 45-62.

books of the patent holder. It may be the case in this instance that these patents were not worth working in any case in the sense that a commercial outcome was unlikely. Alternatively, it is possible that they were potential investors were simply not aware of the patents, or that the patent holders did not actively seek licensing opportunities.

One respondent considered that in many cases there is a lack of effort on the part of patent holders to license-out their technology. Alternatively, he suggested that research institutions in particular, file patent applications fairly indiscriminately due to pressure to generate income. A trade association representative, who criticised the tendency of research institutions to patent inventions without a commercial outcome in mind, shared this view.

A number of respondents commented that they could not see the point of obtaining patents (or licences) and not exploiting them. Maintaining patents in this instance was a waste of valuable funds, and their view was that they could not afford licence fees unless they intended exploiting the licensed technology. The main value of a patent was, to many respondents, a licence agreement or preferably, a number of licence agreements. Nevertheless, there was some divergence of views in respect of non-exploitation.

Some respondents continued to maintain patents they did not wish to currently exploit if there was a possibility they may subsequently become useful. One respondent involved in a technology transfer company suggested that the impetus behind many patent applications is a view on the part of a particular party that a patent may become valuable. This is particularly the case in research institutions where research takes priority and commercialisation retains a less critical role. Because of this there are many instances where patents are obtained and not exploited.

In some cases, licences may be obtained to products and technology but the licensee may refrain from exploiting the licences. One respondent from an upstream company stated that his company did not engage in much licensing-in. However, it would seek an exclusive licence where patents owned by other researchers and used for different purposes, created holes in their patent portfolio. This respondent indicated that licensing-in under these circumstances will usually be straightforward where the patent holder has no intention of exploiting the technology, or where the technology is not core to the organisation being approached. The patent may be a valuable and strategic addition to the licensee's patent portfolio, even if the licensee has no intention of exploiting the patent. Again, the implications of this practice may be that downstream research and development activities are precluded at the expense of one company's strategic proprietary position.

In summary, respondents who indicated that they had patents or licences they did not exploit, indicated that this was for two main reasons:

- they considered the technology may become useful at a later stage; or
- they wished to prevent someone else from exploiting the technology.

Aside from these motivations, few respondents maintained patents over technology they had no intention of exploiting. In general, respondents did not express concern that their technology would become obsolete, although respondents from the device and bioinformatics sectors of the industry specifically viewed this as a problem. Thus, concern at technology losing its value was not generally referred to as a motivation to license-out. The short life span of technology in the device sector prompted vigilant management of companies' patent portfolios. In the bioinformatics sector, the rapid pace of technology made intellectual property protection of dubious value.

Another university technology transfer officer had encountered negotiations for deals where the company was attempting to license to stop a product in the process of being developed by the university from being commercialised. Revocable licences are one way of safeguarding patents in which patent holders have a strong research interest by preventing licensees obtaining licences with no intention of exploiting them.

As outlined in Chapter 2, another safeguard exists in that the Australian *Patents Act* 1990 provides for the issue of compulsory licences for failure to exploit an invention. Specifically, an application for a compulsory licence can be made where the reasonable requirements of the public have not been satisfied, and the patent holder or their licensee has failed to provide a satisfactory explanation for failing to work the invention.[109]

Nevertheless, it seems that there are still some patents that are not exploited, and it may be that patent holders and licensees have no choice but to pursue the most commercially promising lines of research. There may, however, be some social cost where patents that may not lead to a commercially valuable outcome but are nonetheless relevant to some socially valuable research, are not exploited.

4.5 Overcoming Access Issues

There may be a number of options available to a researcher who finds that a particular research project is blocked by a patent held by another researcher.[110] A number of

[109] *Patents Act* 1990 (Cth) s133(2). See also above, 2.5.2.1.

[110] See above, 3.6.

these options have been alluded to during the course of this chapter. This section will briefly consider empirical evidence in relation to the efficacy of these options because this will be relevant to the role that competition law should be given. The options that will be discussed are:

- licensing patents;
- inventing around patents;
- infringing patents and relying on a research exemption; and
- challenging the validity of patents.

4.5.1 The Extent of Licensing Activity Within the Australian Industry

Perhaps the most obvious way to deal with patents that have the potential to restrict or prevent research and development is to enter into a licence agreement or some other collaborative arrangement. Although there is significant licensing activity within the Australian industry, it may be that at the present time, licensing is less widespread than it is in other jurisdictions. Other studies have found that licensing activity within the industry is extremely liberal.[111] Walsh Arora and Cohen, in particular, said that their respondents indicated that it is typically not that difficult to contract.[112] Many broadly applicable foundational patents are licensed non-exclusively, and there is a trend toward realising value from patents by licensing widely.[113] Data obtained in the Nicol and Nielsen study indicated that approximately half of the respondents were involved in licensing activity; most respondents who own patents reported licensing them out, and many respondents reported being able to licence-in technology to which they required access.[114] Although actual comparative figures from studies in other jurisdictions are not available, these studies give the impression of prolific licensing activity. The youth of the Australian industry may account for licensing figures being slightly low relative to other jurisdictions. Interview respondents were adamant that the Australian market is very active in terms of licensing, and licensing is an

[111] Walsh, Arora and Cohen, above n13, 322-3; The German Study, above n18, 6-7; The UK Study, above n20, 69.

[112] Walsh, Arora and Cohen, above n13, 322.

[113] Ibid, 323.

[114] Survey results revealed that 12 research institution respondents (52 percent) and 22 company respondents (45 percent) had engaged in licensing-in activities. Just three diagnostics institutions (18 percent 23 percent of diagnostic institutions conducting research) had licensed-in for research purposes. Most of the respondents who reported licensing-in activity had licensed in between one and four patents. Interview results were generally supportive of these figures. Note also that in their 1999 report, Ernst & Young found that half of the companies they surveyed were involved in licensing activity; Ernst & Young, above n80, 35.

important part of the business strategy of many intermediate Australian companies who seek to add value to technology they have licensed-in, before licensing it on.

Licence agreements with international companies and institutions are very important to the Australian industry, and indeed to the international industry as a whole.[115] Widespread collaborative activity was also reported, and this represented an important method of gaining access to technologies or products which were necessary to enable research to proceed. Respondents reported immense volumes of intellectual property deals per month within the global industry. However, licence deals are not always straightforward, and some difficulties in contracting effectively had been encountered by respondents to the study.[116] This may be a product of inequality in bargaining power and levels of experience between Australian researchers, and parties in jurisdictions where the industry is more established.

The ALRC made a similar finding, and to address these issues, recommended a number of measures aimed at facilitating more streamlined licensing-out and licensing-in arrangements.[117] In particular, Recommendation 22-2 recommended the development of non-binding 'model agreements and interpretive guidelines' for licensing, while Recommendation 22-3 recommended the consideration of additional industry initiatives to assist licensing practices. The ALRC considered that model agreements and guidelines developed in other jurisdictions could provide assistance in their development in Australia.[118]

A number of well-known examples where licensing-in patents has been problematic are outlined in Appendix 2. Licensing-in is unlikely to assist where the patents to which a researcher or company requires access are held by a competing researcher, or where the technology or product falls into category two and products that will be produced are likely to ultimately compete. In other words, rivalrous technologies are less likely to be licensed than non-rivalrous technologies.

---

[115] A vast majority of licensing-in deals were with foreign research institutions and companies, with in excess of 60 percent of licensing-in deals involving United States patent holders. Around 30 percent of licensing-in arrangements involved Australian research institutions and companies, with the remainder comprising mainly European Union, Canadian, Israeli and New Zealand patent holders. See also Dianne Nicol and Jane Nielsen 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 354-358.

[116] The ALRC made a similar finding, and to address these issues, recommended a number of measures aimed at facilitating more streamlined licensing-out and licensing-in arrangements; see ALRC Report, above n7, Recommendations 22-1, 22-2 and 22-3.

[117] Ibid.

[118] The ALRC referred specifically to the NIH Guidelines, above n12, and the OECD guidelines, above n32 (although the Draft Guidelines had not been issued at the time of the release of the ALRC Report); ALRC Report, above n7, 535-536.

4.5.2 INVENTING AROUND PATENTS

In ensuring freedom to operate, many respondents confirmed the need to make an evaluation of patents they need to access, and patents they need to work around. One respondent interviewed who was involved in downstream development activities, stated that reasonably skilled people can successfully negotiate where impediments to research exist, or find ways around those impediments. Inventing around problematic patents was reported to be an important strategy employed by researchers in all sectors of the industry.[119] Walsh, Arora and Cohen suggested that the ability of researchers to invent around may prompt licensing on reasonable terms.[120] Several respondents disagreed that inventing around is a commonly employed tactic for avoiding infringement. One respondent whose company is involved in upstream research concerning specific mutations on particular genes stated that very specific knowledge about a patent would be required before it could successfully be invented around. Another whose company is involved in downstream research considered that inventing around may come perilously close to constituting infringement. This respondent did acknowledge considering relevant patents on a regular basis to ensure an awareness of the research activities of other researchers and companies in the area.

Nevertheless, about two thirds of all respondents we interviewed who were engaged in research stated that they frequently invented around patents. One respondent estimated that researchers probably spend 50 percent of their time inventing around, while another considered that researchers in his company spend around 90 percent of their time working out how to get around patents held by competitors. It is clear that the ability of researchers to invent around will depend on the field of research involved, specifically:

- how encumbered the area of research is;
- the breadth of the relevant patent(s); and
- the nature of the patented product or technology.

---

[119] Studies that have revealed patents to be of dubious value have indicated that the principal reason for the limited effectiveness of patents in some industries is the ability of competitors to invent around; see Wesley M Cohen, 'Empirical Studies of Innovative Activity' in P Stoneman (ed), *Handbook of the Economics of Innovations and Technological Change* (1995) 188, 228; Richard Levin, Alvin Klevorick, Richard Nelson and Sidney Winter, *Brookings Papers on Economic Activity: Microeconomics* (1987); Wesley Cohen, Richard Nelson and John Walsh, 'Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)', (Working Paper No 7552, National Bureau of Economic Research, 2000).

[120] Walsh, Arora and Cohen, above n13, 323-324.

4.5.2.1 *LEVEL OF ENCUMBRANCE*

Some areas are more heavily patented than others are. One respondent commented that it may be getting harder to invent around within the biotechnology industry because of the increasing number of patents. It would appear that one of the most heavily encumbered areas is stem cell research, and yet respondents still reported working around those areas covered by competitor patents.[121] This is probably a factor that will become more relevant as the patent landscape within the industry becomes more cluttered.

4.5.2.2 *PATENT BREADTH*

Inventing around is less problematic in some areas than others because patents are narrower and thus more susceptible to inventing around. Patent requirements have become more stringent in the United States with the result that patents are narrower and therefore easier to invent around.[122] Some of the earlier patents were considered by respondents to be a real problem. One respondent pointed out that patent attorneys are trying to draft claims more broadly to prevent inventing around. Also, one respondent acknowledged that they tried to patent very broadly, filing as many patents as they could on a compound to prevent inventing around. This assisted them in avoiding a blocking patents situation by securing an area of research.

4.5.2.3 *THE TECHNOLOGY OR PRODUCT*

Inventing around may be more technically and economically feasible in some research areas than other. Inventing around may be particularly difficult in the case of a very broad initial patent, or for example, where a research area is very densely patented.[123] It may also be difficult where the patented invention involves genetic material given that there will often be no alternative to the naturally-occurring sequence.[124] It may be that the evolving nature of technology in some research areas is conducive to inventing around. For example, one respondent from an upstream company considered that:

> Gene sequences are a special case. Most of the method patents have competing methods for almost anything: microarrays etc. There are half a dozen guys trying to

[121] See also the discussion on the WARF patents in Appendix 2.

[122] With the exception of device patents where it was considered by one respondent that the United States standard of examination was quite poor, and resultant patents were difficult to get around.

[123] See generally Federal Trade Commission Report, above n34, ch 2, 21-22.

[124] See, eg, Nuffield Discussion Paper, above n30, 50. Cf OECD Report, above n31, 22.

> push the processes and if anyone tries to corner the market it will go somewhere else. It was thought that patenting genes, SNPs would corner the market. But now look at gene expression, messenger RNA expression, which are not captured by the patents, interference RNA, etc. these are all competing technologies. It is such a creative process, I have no concerns that anything could block for very long. In the end others will find ways around the things that people are trying to block. Next year is not even relevant. People do sometimes try to block but in every case they have failed.

At the furthest downstream end of the drug development pipeline, a respondent from a small pharmaceutical company noted that they considered that there were few patents in the pharmaceutical industry that could not be invented around. As one respondent from an intermediate company noted, it is often possible to get around patents held by others by moving down the synthetic pathway, changing processes, or inventing around. Again, patent claims in some areas are necessarily narrower than in other areas. For example, narrow process patents may be easy to get around, while promoters are one kind of technology that some respondents considered to be impossible to invent around.

Although inventing around may be possible, it is questionable whether it will result in all lost opportunities being recovered. Other studies have suggested that a single patent (or even group of patents) is unlikely to entirely inhibit research in a particular area. This is because, for example, a patent over a single protein is unlikely to prevent research into a particular disease given that many diseases are complex and there are often '...multiple approaches to the metabolic pathways.'[125] This is borne out by the interview data in the Australian study that makes it clear that few researchers or companies are forced to cease research entirely, although there may be some social cost associated with research being redirected to avoid infringement. This will depend again on the technology in question.

There is likely to be little social cost in the simple case of a researcher inventing around to avoid infringing a competitor's patents. Indeed, society is more likely to benefit in such a scenario. There may however, be some social cost where, for example, a patent over technology that is useful for research into the development of different but competing products is enforced. In many instances the data did not allow this distinction to be made, although it appeared that some cases at least fell into the latter category.

---

[125] Walsh, Arora and Cohen, above n13, 42. See also The UK Study, above n20, 69-70.

4.5.3 INFRINGEMENT AND RELIANCE ON A RESEARCH EXEMPTION

It became apparent during the course of conducting interviews that a significant amount of patent infringement is engaged in by industry participants. Some of this infringement appeared to be unintentional, and occurred primarily due to impediments in searching the prior art. In other cases, respondents indicated that they would infringe patents they considered to be invalid. A number of respondents indicated that they might proceed with research despite the existence of a patent that may block that research, and await notification from the patent holder that they had infringed the patent. Upon receiving notification, these respondents indicated that they would attempt to negotiate a licence. In a significant number of cases, respondents who adopted the strategy of infringing patents were company respondents. These respondents indicated that infringement is often difficult to detect and this contributed in some way toward the practice of infringing patents. This is particularly the case in relation to broadly applicable research tool patents: tracking infringement by competitors is far more straightforward than following the activities of a multitude of users of non-rivalrous technology.

These results accorded with results obtained by Walsh, Arora and Cohen, who concluded that infringement constitutes a practical 'working solution' in instances where access to a patent is in some way restricted.[126] It would appear, however, that infringement is not as pervasive a practice within the Australian industry as Walsh, Arora and Cohen found it to be within the US industry. This may in part be due to the fact that fewer fundamental research tools are protected by patent in Australia. The German Study concluded that some infringement in making and using research tools does occur, but this was primarily because few companies interviewed had reached the stage of commercialisation.[127]

Walsh, Arora and Cohen also found that infringement within the university environment is rife, and that infringement proceedings are unlikely to be instituted against research institutions.[128] They reported that not only do many research institutions rely on the research exemption, but few company respondents could see the value in pursuing university researchers due to the unfavourable publicity this would generate.[129]

---

[126] Walsh, Arora and Cohen, above n13, 324-328. See also The German Study, above n18, 10-11.

[127] The German Study, above n18, 10.

[128] Walsh, Arora and Cohen, above n13, 324-327.

[129] Ibid, 325-327. See also The German Study, above n18, 11.

The results obtained in the Australian study support this to an extent,[130] but many research institution respondents indicted that they would be unlikely to adopt this approach because their government sponsors prefer to adopt a more risk-averse strategy to intellectual property management. Commercial outcomes of many projects conducted by research institutions in Australia tend to be managed by technology transfer companies or companies aligned with the research institution. Many of the intellectual property issues (including infringement issues) that arise as a result of a project becoming commercial in nature tend, therefore, to be managed by commercial sponsors.

At the same time, the practice-based research exemption appears to remain an important vehicle within the research institution environment, with many research institution respondents reporting that they rely heavily on the exemption, and many patent holders acknowledging that they respect the existence of an exemption. The ALRC's proposed research exemption would not cover downstream, commercial uses of an invention, with the result that it would probably be relied upon to a lesser extent as a commercial outcome becomes likely. In any event, the commercial uses to which many upstream inventions using patented research tools are put would necessitate a license to use those patented technologies.

4.5.4 Challenging the Validity of Patents

The validity of patents may be challenged through either revocation proceedings or opposition proceedings, both available under the *Patents Act* 1990.[131] Revocation proceedings are pursued very infrequently, and few matters are actually litigated. Virtually every respondent who addressed the issue of revocation agreed that the main reason why challenges to validity were unlikely to be mounted was the considerable cost involved. As such, revocation proceedings are often not a viable option, particularly for research institutions and small companies. The threat of revocation may, however, be used as a bargaining tool in licence negotiations.

---

[130] See the discussion on the research exemption, above, 2.5.1. The ALRC received a number of submissions highlighting the importance of the research exemption to the research community and supporting the adoption of a new, explicit research exemption; see ALRC Report, above n7, 328-329. A number of submissions raised concerns that the exemption proposed by the ALRC would not adequately protect the research community; at 330-333. While many submissions received by ACIP considered an experimental use exemption to be an inherent aspect of the patent system, several submissions disagreed and considered there to be policy justification for such an exemption; Advisory Council on Intellectual Property, *Patents and Experimental Use*: Options Paper (2004); 25-26.

[131] See above at 2.4.

Opposition proceedings are instituted more frequently by Australian researchers and companies, although respondents were somewhat divided on the value of opposition proceedings. Some respondents considered opposition proceedings to be necessary whenever their proprietary position is threatened, and one respondent commented on their effectiveness in foreclosing progress in research by, particularly, research institutions and small companies. Others perceived little value in opposing patents, due to the cost involved and the risk that they could assist the patent holder in refining their claims.

As a result, it would appear that a majority of researchers are unlikely to test the validity of patents that may threaten their research, although revocation and opposition remain an important tactical tool in licensing negotiations. This can be contrasted with the situation in the US: Walsh, Arora and Cohen found that challenging patents was a strategy engaged to deal with an anticommons or restricted access situation, although their respondents commented on the significant costs involved in taking this course.[132]

4.6 CONCLUSION

The overseas studies considered in this chapter contained limited consideration of whether refusals to license, the primary issue considered in this thesis, were problematic in biomedical research. Nevertheless, they gave detailed consideration to whether or not restrictive licensing practices were being engaged in by patent holders. A number of the issues dealt with by these studies are relevant to refusals to license. This is because a number of restrictive licensing practices, for example, exclusive licensing and defensive patenting, may result in the non-availability of licences necessary to conduct downstream research. It is possible to say, therefore, that evidence from these studies is comparable to and consistent with data obtained in the Nicol and Nielsen study.

At this stage, it is difficult to gauge the extent of restrictive licensing given the somewhat limited empirical evidence available, and further empirical work that delves further into these issues is required. There is certainly evidence of exclusionary practices within the Australian and international industries, but it must be remembered that the essence of a patent right is the right to exclude others. Given this, it is not surprising that few respondents complain of restrictions on free access to patented

[132] Walsh, Cohen and Arora, above n13, 324, 332.

technologies and products. This is despite the fact that there are a significant number of patents within the industry that block research to some extent.

Data from the Nicol and Nielsen study is consistent with other international studies in demonstrating that there has been some limited evidence of refusals to license patents within the industry. The technology to which access is restricted needs to be considered. Few respondents complained about access to technology being restricted where that technology fell into category one. They accepted this as a necessary element of the patent system, and given (generally speaking) their support of the patent system, were content to bear this cost.

It also became evident that a majority of technologies falling into category three have been widely disseminated, although it is possible to conclude tentatively from the evidence that there may be exceptions. This finding has been reported in all of the empirical studies discussed in this chapter. Category two technology presents more difficulties in that there may have been some instances where access was refused. The data does not divulge whether the technology was nonetheless being exploited, which would, to a degree, lessen the social cost that restricted access entails.

However, it is probably fair to say that few respondents were concerned at the long-term effects of restricted access, and in most cases research was able to proceed albeit in a modified fashion. In a number of instances respondents indicated that their research continued, but the modification of research meant that various lines of research which could have led to promising results were not pursued.[133] Of course, it is difficult to gauge the effects of exclusionary practices without knowing where particular lines of research are likely to lead. Further work in this area that examines the longer-term effects of exclusionary licensing practices such as refusals to license would be useful. Data that systematically tracks particular patented technologies in respect of which licences have been refused would assist in drawing firmer conclusions about the effects of these restrictive licensing practices on downstream innovation and competition within the industry.

Access issues are alleviated to some extent by rapid technological advance within the industry which makes it more likely that alternatives to foundational inventions will be developed. Walsh, Arora and Cohen concluded that future problems resulting from exclusionary licensing practices in the United States could not be ruled out, and called

[133] As reported above, data obtained by Ernst & Young would seem to indicate that abandonment of promising research is relatively common within the Australian industry; see Ernst & Young, above n80, 35.

for continued vigilance to defend open science.[134] Data from the Nicol and Nielsen study endorses this finding.

Importantly, there is a significant upstream component to the Australian industry. Policy responses to restrictive licensing practices need to balance the benefits of improved access against possible reductions in incentives to upstream patent holders. Encouraging innovation remains a key concern, and the issue is how ensure that follow-on research proceeds without impacting on the ability of upstream or initial inventors to recoup their investment. The data also suggested that downstream users of technology may seek to license-in technology to assert a proprietary position. In this case, they may seek licences to patents they do not intend to ultimately exploit. Balancing the needs of downstream users who require access to technology against incentives to upstream users is a delicate exercise. The following chapter examines the interplay between intellectual property and competition law, and the role of competition law in promoting innovation. It then analyses the manner in which competition law should evaluate refusals to license intellectual property.

[134] Walsh, Cohen and Arora, above n13, 335.

CHAPTER 5

THE APPLICATION OF COMPETITION LAW TO DEALINGS IN INTELLECTUAL PROPERTY

5.1 INTRODUCTION

Preceding chapters have established the structure of biomedical research and the medical biotechnology industry, discussing the extent of government support for the industry evident in Australia. Chapter 4, via the empirical work undertaken, considered whether there are problems being encountered within the industry in relation to refusals to license patents. It can now be said that although there is limited evidence of refusals to license patents, there is sufficient evidence of practices such as exclusive licensing and defensive patenting to permit a conclusion that the potential for refusals to license exists. Patent law is a dense, and sometimes difficult to navigate area of law. The patent system is unlikely to address the potential for restrictive licensing practices such as refusals to license. Consequently, there may be scope for these issues to be addressed through competition law.

The complex interaction between intellectual property and competition law does, however, render this a difficult task. There is a need to preserve incentives to innovate, particularly in an industry such as medical biotechnology that is dependent on patent protection. The extent to which competition law should impinge on patent privileges raises seemingly intractable issues. It is an objective of this chapter to consider the role of each body of law in maximising incentives to innovate within the context of a cumulative, high technology industry such as medical biotechnology. This chapter attempts to provide a method of dealing with the particular issue of refusals to license, by applying reasoning from the broader context of the intellectual property/competition law interface. Although attempts to settle the conflict between intellectual property and competition law have been made, there is no universally agreed method of dealing with the interface.

The chapter begins by discussing the regulation of competition in Australia, and how intellectual property transactions are dealt with under this legislative regime. Given the influence of competition regimes in other jurisdictions on the development of the Australian legislation and competition law jurisprudence, reference is made to the evolution of relevant competition law provisions in the United States and Europe. Following from this discussion, the chapter attempts to balance the theoretical underpinnings of these two areas of law and to reach some conclusion on whether there is an optimal manner in which competition law should be framed to deal with intellectual property transactions, specifically refusals to license patents. Finally, a framework for dealing with refusals to license patents is proposed to resolve this seeming impasse, although it will be concluded that the framework should be applied with a sufficient degree of flexibility to allow courts the freedom to impose

competition law restraints depending on the individual circumstances of a particular case.

5.2 COMPETITION LAW TREATMENT OF INTELLECTUAL PROPERTY IN AUSTRALIA

Competition law in Australia is regulated primarily by the *Trade Practices Act* 1974 (Cth) (the *TPA*). This section briefly discusses provisions of the *TPA* relevant to the regulation of anti-competitive conduct contained in Part IV of that Act, before considering how intellectual property dealings are treated under the *TPA*. A limited exemption for some forms of dealings under intellectual property statutes is provided in s 51(3) of the *TPA*. This section analyses a number of reviews that have considered the desirability of maintaining this exemption, and considers whether refusals to license should receive special treatment under Part IV.

5.2.1 THE REGULATION OF COMPETITION IN AUSTRALIA THROUGH THE *TRADE PRACTICES ACT* 1974 (CTH)

Section 2 of the *TPA* states that 'The object of this Act is to enhance the welfare of Australians through the promotion of competition and fair trading and provision for consumer protection.'[1] Clearly, it follows that one of the policy objectives behind the *TPA* is the enhancement of public welfare through the prohibition of anti-competitive conduct. Part IV of the *TPA* proscribes certain forms of conduct by companies based on an assessment of whether or not that conduct is anti-competitive and comprises the following provisions:

- sections 45(2)(a)(ii) and 45(2)(b)(ii)[2] which regulate collusive conduct between competitors (contracts, arrangements or understandings) that substantially lessens competition;
- section 46 which prohibits a company with a substantial degree of market power from taking advantage of that market power by eliminating or substantially damaging a competitor, preventing the entry of potential competitors into a market, or deterring or preventing a party from engaging in competitive conduct;

[1] This provision was inserted into the *Trade Practices Act* 1974 (Cth) as a result of the *Competition Policy Reform Act* 1995 (Cth).

[2] These provisions will be referred to as 'section 45'.

- section 47 which regulates exclusive dealing;[3] where that exclusive dealing has the purpose or effect of substantially lessening competition in a market;[4]
- section 48 which prohibits resale price maintenance, or the practice or specifying the minimum price at which goods must be resold; and
- section 50, which prohibits mergers or acquisitions that would have the effect or likely effect of substantially lessening competition in a substantial market for goods or services.

Of these provisions, s 46 will be the only provision considered in detail in this thesis. A number of the Part IV provisions have the potential to interplay with intellectual property dealing where anti-competitive terms are imposed in licence agreements.[5] In that refusals to license intellectual property generally constitute unilateral conduct, this thesis will only consider the anti-competitive implications of refusals to license in the context of s 46. Refusals to license may have the potential to contravene s 45 where exclusive licensing limits the use of particular intellectual property privileges by other parties.[6] However, s 46 will be the focus of analysis, and its elements will be considered in detail in Chapter 6.

The following section considers s 51(3) of the *TPA*, which provides a limited exemption from a number of the Part IV provisions for certain conditions in licensing agreements. As will become apparent, s 51(3) does not exempt conduct that might breach s 46. Therefore, unilateral refusals to license patents will not fall within the exemption. Despite the fact that refusals to license are not exempted by s 51(3), the

---

[3] Exclusive dealing should not be confused with exclusive licensing. Exclusive dealing is the practice of supplying goods and services on certain conditions, for example, that goods will not be acquired from a competitor of the supplier.

[4] Note that the practice of third line forcing, which is the practice of supplying goods on the basis that goods be accepted from a third party, is illegal on a per se basis, although a proposed amendment to the *Trade Practices Act* 1974 (Cth) will mean that third line forcing will be subject to a substantial lessening of competition test; see the Trade Practices Legislation Amendment Bill (No 1) (2005), Sch 7, Pt 1. This amendment arose as a result of a recommendation of the *Trade Practices Act* Review Committee, Parliament of Australia, *Trade Practices Act Review* (2003), 131. For general discussion on the recommendations of the *Trade Practices Act* Review Committee, see, for example, Lynden Griggs, 'Small Business and the Operation of the *Trade Practices Act* – Another Review, Another Election, and the Battle Lines Between Big and Small Business are Once Again Redrawn!' (2004) 11 *Competition and Consumer Law Journal* 348.

[5] See, for example, Trade Practices Commission, *Application of the Trade Practices Act to Intellectual Property*, Background Paper (1991) (TPC Background Paper), 21-30.

[6] In any case, it may be that s 46 will catch exclusive licensing arrangements where they have the potential to be anti-competitive in that an exclusive licensing arrangement gives rise to combined market power. An amendment to s 46 has been proposed that will allow a court to take into account any market power a corporation possesses by virtue of contracts, arrangements or understandings with others; see further below, 6.3.5.

exemption will be considered in further detail for two reasons. *First*, consideration of exemption from Australian competition law for particular intellectual property transactions is an important factor in analysing the broader policy question of whether or not competition law should provide special treatment for intellectual property dealings.[7] *Secondly*, a recent review of the exemption recommended that s 51(3) be amended to encompass conditional refusals to license intellectual property,[8] and the implications of this recommendation are also relevant to the policy debate over intellectual property and competition law.

5.2.2 THE APPLICATION OF THE *TRADE PRACTICES ACT* TO INTELLECTUAL PROPERTY[9]

Having an intellectual property privilege will not necessarily protect the holder from the provisions dealing with anti-competitive conduct in Part IV of the *TPA*. It is specifically provided that the *TPA* applies generally to intellectual property transactions.[10] There is, however, a limited exemption to this blanket application of Part IV to intellectual property transactions contained in s 51(3) of the *TPA*.[11]

5.2.2.1 *SECTION 51(3) OF THE TRADE PRACTICES ACT*

Section 51(3) relevantly provides that:[12]

> (3) A contravention of a provision of this Part other than section 46, 46A or 48 shall not be taken to have been committed by reason of:

---

[7] For this reason, consideration will also be given to the general treatment of intellectual property dealings in other jurisdictions, notably the US and EU.

[8] See Intellectual Property and Competition Review Committee, Parliament of Australia, *Review of Intellectual Property Legislation Under the Competition Principles Agreement: Final Report* (2002) (IPCRC Report).

[9] See generally Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99, (2004), (ALRC Report), Geoff Adams and Dan McLennan, 'Intellectual Property Licensing and Part IV of the *Trade Practices Act*: Are the *TPA's* Pro-Competitive Provisions Anti-IP Commercialisation?' (2002) 51 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 10, Richard Hoad, 'Compulsory Licensing of Patents: Balancing Innovation and Competition' (2003) 54 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 28; Charles Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition' (2002) 30 *Federal Law Review* 97; Jason Fung, 'The Case of an Awkward Interface – Patents v Competition' (1998) 21(3) *University of New Sounth Wales Law Journal* 757; Warren Pengilley, 'Patents and Trade Practices – Competition Policies in Conflict?' (1977) 5 *Australian Business Law Review* 172.

[10] *Trade Practices Act* 1974 (Cth), s 51(1)(i).

[11] The term 'exemption' will be used in the context of s 51(3), although the sub-section is cast in the form of an 'exception'.

[12] Section 51(3) also applies to registered designs, copyright and EL rights within the meaning of the *Circuit Layouts Act* 1989 (Cth).

(a) The imposing of , or giving effect to, a condition of:

(i) A licence granted by the proprietor, licensee or owner of a patent, ... or by a person who has applied for the registration of a patent ...; or

(ii) An assignment of a patent, ... or of a right to apply for a patent ...'

to the extent that the condition relates to:

(iii) the invention to which the patent or application for a patent relates or articles made by the use of that invention; ...

If a condition in a patent licence is not exempted by s 51(3), it does not necessarily follow that it is anti-competitive. It simply means that it will not automatically attract the exemption. Sections 46 and 48 are explicitly stated to fall outside the exemption. Unilateral refusals to license patents will be dealt with under s 46, thus refusals to license intellectual property will not fall within the exemption. It will become evident that misuse of market power (in its respective legislative embodiments)[13] is the main area in which recent overseas litigation focusing on the interaction between intellectual property and competition law has been concentrated.[14]

Section 51(3) has rarely been relied on, and there has been debate over its relevance and how much certainty it provides to owners of intellectual property in conducting transactions for the exchange of IP rights.[15] It is not clear what conduct is exempted by s 51(3) in that the term 'relates to' is ambiguous.[16] In the only decision that dealt with how s 51(3) should be interpreted, Mason J stated that the exemption in s 51(3) will not apply where a condition in a licence seeks to obtain an advantage collateral to

[13] Two relevant international counterparts of s 46, these being section 2(a) of the *Sherman Act* 1890 and Article 82 of the *Treaty Establishing the European Community* [2002] OJ C 325/65, will be discussed below 5.4. Relevant case law in relation to these provisions and refusals to license intellectual property will be discussed in Chapter 7.

[14] See Carolyn Oddie and Patrick Eyers, 'Erosion of Rights – or Redressing the Balance: Competition Challenges to Intellectual Property Rights' (2004) 12 *Trade Practices Law Journal* 6, 14.

[15] The provision has been subjected to a number of reviews. These reviews will be discussed in more detail below, 5.2.2.2, but see especially IPCRC Report, above n8, 202-216; National Competition Council, Parliament of Australia, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999) (NCC Report) 149-246.

[16] See TPC Background Paper, above n5, 12-13.

the subject matter of the invention or in other words, to extend the scope of the intellectual property.[17]

This decision has been used to support differing interpretations of s 51(3).[18] A broad interpretation of 'relates to' would exempt almost any condition.[19] A narrow interpretation would require the condition to relate directly to the intellectual property in which case a vast majority of terms would fail to be exempted.[20] An intermediate view may see s 51(3) exempting conditions that increase the market power held by a holder of intellectual property beyond that granted.[21] In any case, s 51(3) provides little guidance as to the basis on which particular conditions are likely to fall within the exemption.

The original objectives of s 51(3) are unclear, and it was concluded by the National Competition Council (NCC) in their inquiry into the exemption that s 51(3) was probably enacted to prevent a perceived clash between intellectual property law and competition law.[22] The NCC also considered that the section may assist in identifying whether licensing conditions that are likely to have the effect of subdividing intellectual property are anti-competitive, and may provide intellectual property owners with greater certainty in which to undertake licensing or assignment of intellectual property.[23] In the NCC's view, this greater certainty can help reduce the costs associated with compliance with competition laws and encourage more licensing activity.[24]

5.2.2.2 *SECTION 51(3) REVIEWED*

In 1993, a report released by the Hilmer Committee of Inquiry (the Hilmer Committee) set out a number of recommendations aimed at facilitating an effective, uniform national competition policy.[25] In 1995, a National Competition Policy was implemented via the *Competition Principles Agreement* (*CPA*), which requires the

---

[17] *Transfield* v *Arlo* (1980) 30 ALR 201. The implications of this decision are discussed ibid, 12-13.

[18] See the discussion in IPCRC Report, above n8, 207.

[19] Ibid.

[20] Ibid.

[21] Ibid. This interpretation was also adopted by the TPC; see TPC Background Paper, above n5, 13.

[22] NCC Report, above n15, 160-164, 166. The NCC considered that this objective was no longer relevant because they concluded that there was no clash between these two bodies of law.

[23] NCC Report, above n15, especially 165-167.

[24] Ibid.

[25] Independent Committee of Inquiry into Competition Policy in Australia, Parliament of Australia, *National Competition Policy* (1993), xxi-xxxix (Hilmer Committee Report).

Commonwealth, States and Territories of Australia to implement competition policy taking into account matters such as the promotion of efficiency, competitiveness of Australian businesses and benefit to consumers.[26] An important component of the *CPA* was that governments in Australia review the anticompetitive effects of existing legislation, subject to the principle that:

> (a) the benefits of the restriction to the community as a whole outweigh the costs; and
>
> (b) the objectives of the legislation can only be achieved by restricting competition.[27]

The Hilmer Committee identified s 51(3) as a provision that required independent review, stating that it saw force in arguments for reform of the exemption, and for matters that fell within its purview to be dealt with under the *TPA*'s authorisation procedure.[28] This culminated in the recent reviews[29] of section 51(3) by the NCC in 1999,[30] and the Intellectual Property and Competition Review Committee (IPCRC) in 2002.[31] The Australian Law Reform Commission (ALRC) also considered the application of s 51(3) to genetic technologies as part of its recent inquiry.[32]

---

[26] *Competition Principles Agreement*, cl 1(3). The *Competition Principles Agreement* is contained in National Competition Council, Parliament of Australia, *Compendium of National Competition Policy Agreements* (1997), a series of agreements that combined, form the National Competition Policy. For more detailed discussion see Charles Lawson, 'Patent Privileges and the National Competition Council Policy – Patent Scope and Allocation?' (2005) 33 *Australian Business Law Review* 7.

[27] *Competition Principles Agreement*, above n26, cl 5(1). The *Competition Principles Agreement* also provided in cl 5(5) that proposals for new legislation be subject to the same principle.

[28] Hilmer Committee Report, above n25, 150-151. Section 88 of the *Trade Practices Act* 1974 (Cth) provides that authorisation and notification may be granted by the Australian Competition and Consumer Commission (ACCC) for conduct that would otherwise substantially lessen competition. The authorisation provisions do not apply to s 46, but authorisation given for conduct that would contravene s 46 in addition to a provision to which the authorisation provisions relate, will render that conduct lawful under s 46. For further discussion, see Stephen G Corones, Competition Law in Australia (3rd ed, 2004), [3.70], [8.205]. A number of amendments to the *Trade Practices Act* 1974 (Cth) which would expedite the authorisation process were proposed by the *Trade Practices Act* Review Committee, and those amendments have been incorporated into the Trade Practices Legislation Amendment Bill (No 1) (2005). See *Trade Practices Act Review* Committee, above n4, 112-114; Trade Practices Legislation Amendment Bill (No 1) (2005), above n4.

[29] For criticism of the manner in which reviews relating to patent privileges have been conducted under the *Competition Principles Agreement*, see Lawson, above n26.

[30] See NCC Report, above n15.

[31] See IPCRC Report, above n8.

[32] ALRC Report, above n9. Note also that the Trade Practices Act Review Committee also made mention of the exemption, but declined to make a detailed assessment of the provision on the grounds that the matter fell outside its terms of reference, and that a current Federal Court case was considering the matter; Trade Practices Act Review Committee, above n4, 86.

(i) The National Competition Council Report

The NCC interpreted its task under its Terms of Reference to be '... whether, and if so, how, Part IV of the TPA should regulate licensing and assignment of intellectual property rights.'[33] The NCC expressed the view that intellectual property privileges and general property rights share similar attributes,[34] so that intellectual property rights are 'neither particularly free from scrutiny under the antitrust laws, nor particularly suspect under them'.[35] It considered that there was no inherent conflict between intellectual property and competition laws.[36]

The NCC engaged in a process of weighing the costs and benefits of the exemption,[37] and focused on the certainty that s 51(3) provides to parties engaged in licensing as the main justification for ultimately recommending the retention of s 51(3).[38] However, the NCC recommended amendment to s 51(3) on the basis that the exemption as currently drafted did exempt some anti-competitive conduct. Consequently they recommended that the exemption be retained, but that s 51(3) be amended to remove horizontal dealings and price and quantity restrictions from its scope.[39] The recommendations resulting from the review remain under consideration by the Government,[40] and the recommendations made by the NCC were required to be considered by the IPCRC in its subsequent review of s 51(3).[41]

---

[33] NCC Report, above n15, 3. For criticism of the manner in which the NCC interpreted its Terms of Reference (and arguably limited the scope of its review), see Lawson, above n26, 12.

[34] NCC Report, above n15, 149.

[35] Ibid, 160.

[36] Ibid, 163. The NCC also recognised that there was no exemption such as that contained in s 51(3) in the legislation of overseas jurisdictions; ibid, 186-192.

[37] Ibid, 193-209, 221-231.

[38] Ibid, 220. Note that in its interim report, the NCC had recommended abolishing the provision entirely on a number of grounds, including uncertainty over the operation of the exemption, the lack of an exemption in other jurisdictions and the minor effect that repealing the exemption would be likely to have on investment in innovation; see National Competition Council, Parliament of Australia, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974*, Draft Report, (1998), 6, 96, 196-200. For further discussion, see Lawson, above n26, 13-14.

[39] NCC Report, above n15, 241-245. The NCC also recommended that the exemption be extended to include rights conferred under the *Plant Breeder's Rights Act* 1994 (Cth), and that the ACCC issue guidelines on the operation of s 51(3); see NCC Report, above n15, 221-223.

[40] National Competition Council, *National Competition Council Legislation Review Compendium* (4th ed, 2002), 31.

[41] The IPCRC was only required by its Terms of Reference to have regard to the conclusions and recommendations contained in the NCC Report; see IPCRC Report, above n8, 217.

(ii) The Intellectual Property and Competition Review Committee Report

The IPCRC stated that caution should be exercised in any change to the law that impacts on the ability of intellectual property holders to contract effectively, even where others are excluded from utilising the rights, because the ability to contract for the exchange of intellectual property assists in the efficient dispersion of intellectual property.[42] It considered that repeal of the section would create uncertainty with possible negative impacts on licensing activity, and that in the event of repeal Part IV provisions may catch currently exempted and socially beneficial licence conditions.[43] Despite this, the IPCRC considered that it is important to ensure that holders of intellectual property do not go beyond the scope of market power conferred by that intellectual property.[44] The IPCRC considered this concern to be particularly important in a jurisdiction such as Australia where intellectual property protection is relatively strong.[45] The Committee's view was that s 51(3) did not achieve an adequate balance.

The IPCRC therefore recommended a number of changes to s 51(3) to improve its efficacy. They recommended repealing and replacing s 51(3) with an amended version of the sub-section with the main amendments being that:[46]

- the new s 51(3) would apply to all of the Part IV provisions including s 46;
- the 'imposing of conditions in a licence, or the inclusion of conditions in a contract, arrangement or understanding, should also clearly mean the refusal by the owner of an [intellectual property] right to enter into a licence, contract, arrangement or understanding.';[47]

---

[42] Ibid, 210-11.

[43] Ibid, 210-211.

[44] Ibid, 211.

[45] Ibid, 211.

[46] Ibid, 213. The IPCRC recommended that s 51(3) be replaced with an amended sub-section that would ensure that:

> a contravention of Part IV of the *Trade Practices Act*, or of s 4D of that Act, shall not be taken to have been committed by reason of the imposing of conditions in a licence, or the inclusion of conditions in a contract, arrangement or understanding, that relate to the subject matter of that intellectual property statute, so long as those conditions do not result, or are not likely to result, in a substantial lessening of competition.

Ibid, 215. The IPCRC also recommended the expansion of s 51(3) to apply to all intellectual property statutes; at 215.

[47] The purpose of this recommendation was to protect a licensor in the absence of a completed contract; ibid, 213.

- dealings falling within the exemption in s 51(3) would be subject to an effects-based, or substantial lessening of competition test.[48]

In addition, the IPCRC recommended that the body charged with monitoring anti-competitive conduct, the Australian Competition and Consumer Commission (ACCC), issue guidelines to clarify when s 51(3) is likely to apply to particular terms and conditions.

(iii) The Implications of the Intellectual Property and Competition Review Committee Recommendations

The IPCRC's approach generally represented an adoption of the 'scope of the grant' approach,[49] which may in itself present difficulties in interpretation.[50] There is no doubt that difficulties inherent in s 51(3) would remain despite the IPCRC's proposed amendments. It is not clear how the test proposed by the IPCRC distinguishes between market power stemming directly from intellectual property, and market power that is beyond the scope of the right.[51] Moreover, while the 'substantial lessening of competition' test would conceivably be workable once augmented by guidelines,[52] the much-criticised 'relates-to' test would be retained along with uncertainty as to its interpretation.[53] It is submitted that the meaning of this phrase may, to some degree, be clarified as a result of the amendments to s 51(3). The phrase is likely to be given a wider interpretation given that terms that relate *directly* to the intellectual property statute would never involve a substantial lessening of competition. This tends to support the argument that a broader interpretation of 'relates to' would be adopted.

Equally, a broad interpretation would tend to exempt a large number of conditions from the operation of relevant Part IV provisions. This implication of adopting a very

---

[48] This requirement has been referred to as a 'substantial lessening of competition override'; Ian Eagles and Louise Longdin, 'Competition in Information and Computer Technology Markets: Intellectual Property Licensing and Section 51(3) of the *Trade Practices Act* 1974' (2003) 3 *Queensland University Journal of Technology Law and Justice Journal* 28, 33.

[49] This approach derives from the US 'inherency doctrine', and essentially it stipulates that intellectual property should be subject to competition law when its use goes beyond the scope of the right. See generally ibid, 32-36; Michael A Carrier, 'Unraveling the Patent-Antitrust Paradox' (2002) 150 *University of Pennsylvania Law Review* 761, 788-791.

[50] See Eagles and Longdin, above n48, 32-36. See also NCC Report, above n15, 190; Carrier, above n49, 788-791.

[51] See Eagles and Longdin, above n48, 34.

[52] Although Adams and McLennan argue that conditions in intellectual property licences are unlikely, for the most part, to substantially lessen competition; Adams and McLennan, above n9, 19-20.

[53] See Eagles and Longdin, above n48, 33-34.

wide view of s 51(3) may lead the judiciary to adopt a more cautious approach in interpreting s 51(3). In addition, an amended s 51(3) would still fail to provide any definitive guidance as to which particular conditions would be exempted by s 51(3), although guidelines would presumably offer some clarification depending on the form those guidelines took.

In considering the exemption contained in s 51(3), the IPCRC pointed out that it were constrained by the current Part IV provisions, and that comment on these provisions was outside the scope of its reference.[54] Nonetheless, the Committee would appear to have had some difficulty with the structure of Part IV and the adverse effects that were likely to be experienced by intellectual property holders on the basis of this structure. They indicated that their recommendations were necessarily restricted by the content of Part IV, which they claimed was enacted during an era of greater economic regulation.[55] Had it not been so constrained, (or had the Part IV provisions been differently constituted) it is possible the IPCRC would have made a very different set of recommendations. Indeed, it has been speculated that the retention of a statutorily based exemption may have been unnecessary had the Committee been content with the make-up of Part IV.[56]

There is undoubtedly a challenge in achieving a balance between allowing the exercise of intellectual property and ensuring that holders of intellectual property are not able to use those rights anti-competitively.[57] The need to maximise business certainty identified by the IPCRC must be offset against competing concerns, such as the effects of licensing on dynamic efficiencies associated with licensing intellectual property.[58] The recommendations of the IPCRC were an attempt to address these concerns in light of the constraints identified by the Committee.[59]

---

[54] IPCRC, above n8, 210. For criticism of this interpretation by the IPCRC of their Terms of Reference, see Lawson, above n26, 17-19.

[55] IPCRC, above n8 210. See also Eagles and Longdin, above n48, 29, 46. For criticism see Lawson, above n26, 18-19.

[56] Eagles and Longdin, above n48 34-36. The exemption means that intellectual property rights in Australia are treated differently to other forms of property rights, a principle which is at odds with the position in other jurisdictions. Because the constitution of Part IV of the *Trade Practices Act* 1974 (Cth) and the tests contained within many of the Part IV provisions are problematic, (and this is attested to by the degree of review undertaken in respect of Part IV since the enactment of the *Trade Practices Act* 1974 (Cth)), the Committee may have felt compelled to retain some degree of protection for intellectual property rights over and above that assigned to other property rights; at 34-36.

[57] IPCRC, above n8, 212.

[58] Organisation for Economic Co-operation and Development (1989) *Competition Policy and Intellectual Property Rights*, 15.

[59] Cf Lawson, above n26 18-19.

Nevertheless, the IPCRC's recommendation that conditional refusals to license be exempted by the s 51(3) exemption, may lead to unilateral refusals to license being structured so that they are covered by the exemption. In this sense, this recommendation amounts to a broadening of the exemption in relation to refusals to license.

(iv) The Government Response to the Intellectual Property and Competition Review Committee Report

As stated above, the Government is still considering its response to the NCC Report. It has, however, responded to the IPCRC Report and partly accepted the recommendations of the IPCRC. The Government Response indicates that the operation of s 51(3) will be expanded so that s 51(3) applies to all intellectual property statutes, but the remaining recommendations were accepted in limited form.[60] Specifically, it declined to expand the operation of s 51(3) to apply to all of the Part IV provisions, with the result that the exemption still will not apply to s 46. The Government did accept that the sub-section would apply to the per se provisions in Part IV, subject to a substantial lessening of competition test,[61] and that guidelines would be issued by the ACCC to assist in the operation of s 51(3). The Government indicated that these guidelines should:[62]

- outline when intellectual property licensing and assignment conditions might be exempted under s 51(3);
- outline when intellectual property licensing and assignment conditions might breach Part IV of the TPA through application of a substantial lessening of competition test; and
- indicate when conduct that is likely to breach Part IV of the TPA might be authorised.

As Eagles and Longdin point out, the government have, in laying down these stipulations, presented the ACCC with three quite distinct tasks.[63] In formulating guidelines that fulfil these tasks, the ACCC has a number of methodologies at its disposal. Regardless of which methodology is employed, the ACCC will face a

---

[60] Commonwealth of Australia, *Government Response to Intellectual Property and Competition Review Recommendations*, Information Package (Government Response) <http://www.ipaustralia.gov.au/pdfs/general/response1.PDF> at 31 May 2004.

[61] Including the per se prohibitions contained in ss 45, 45A, 47 and 4D.

[62] Government Response, above n60.

[63] Eagles and Longdin, above n48, 37.

number of issues in formulating a coherent policy for intellectual property dealings, and addressing each of the tasks assigned to it by the Government.[64]

The Government's response has been criticised due to the fact that it watered down the recommendations of the IPCRC.[65] The operation of s 51(3) is unlikely to alter dramatically,[66] although it will be less effective than the exemption proposed by the IPCRC.[67] The 'relates to' test will be retained, and it is this test that is arguably the most problematic element of s 51(3). In addition, the continued exclusion of certain provisions, including s 46, from the operation of s 51(3) appears to be arbitrary.

(i) The Recommendations of the Australian Law Reform Commission

Section 51(3)

Despite receiving a number of submissions questioning the utility of these modified amendments, the ALRC declined to recommend specific amendment to s 51(3) in their report *Genes and Ingenuity*, but did support amendment in line with the Government response to the IPCRC Report.[68] The ALRC was limited in respect of recommendations it could make, because its Terms of Reference were limited to issues associated with gene patenting.[69] Licensing is an important component of the medical biotechnology industry, and licensing arrangements involving gene patents are common. It is probably fair to say that little consideration is currently given to any protection provided under s 51(3) to parties to licensing arrangements. While an amended exemption in line with this recommendation is unlikely to provide any more certainty to patent holders than the section as currently drafted provides, the ALRC also made a further recommendation in relation to the issue of Guidelines which may provide significantly more clarity.

---

[64] These issues are discussed at length by Eagles and Longdin, ibid, 37-40.

[65] See ibid, 36-37.

[66] It has been suggested that the IPCRC has 'perhaps come closest ...' to achieving a 'clear dividing line between proper and acceptable exercise of intellectual property rights on the on the hand, and improper and unacceptable exercise of intellectual property rights on the other ...' Nevertheless, it may be that the exemption in s 51(3) has been retained because it has been 'seems to have been ineffectual and to have done no harm.'; Justice Kevin Lindgren, 'The Interface Between Intellectual Property and Antitrust: Some Current Issues in Australia' (2005) 16 *Australian Intellectual Property Journal* 76, 93.

[67] Eagles and Longdin, above n48, 36-37. The ACCC has indicated its view that the proposed amendments will significantly broaden the applicability of Part IV to licensing terms and conditions; Australian Competition and Consumer Commission, *Submission to Australian Law Reform Commission, Intellectual Property Rights over Genetic Materials and Genetic and Related Technologies – Gene Patenting and Human Health Issues Paper* (2003) 6, 8-9.

[68] ALRC Report, above n9, 576.

[69] Ibid, 7-8.

Recommendation 24-2 recommended that the ACCC issue guidelines to clarify the relationship between intellectual property and Part IV, addressing in particular:

(a) when the licensing or assignment of intellectual property might be exempted under s 51(3) or might breach Part IV; and

(b) when conduct that would otherwise breach Part IV might be authorised under Part VII of the *Trade Practices Act*.[70]

The ACCC had indicated to the ALRC in a submission responding to the that it intended issuing and implementing such guidelines subsequent to the amendment of s 51(3).[71] While these recommendations were generally in line with the IPCRC's recommendations, the ALRC went further and recommended that

> The guidelines should extend to the exploitation of intellectual property rights in genetic materials and technologies, including patent pools and cross-licensing.[72]

At present, holders of patents in the area of genetic technologies have limited guidance available as to when conduct in which they engage is potentially anti-competitive. Guidelines will therefore assist in elucidating when s 51(3) is likely to provide an exemption for patent holders from the reach of Part IV. They will hopefully also provide some guidance in relation to other issues identified by the ALRC, including the issue of refusals to license patents.

At the date of writing, legislation to amend s 51(3) had not been introduced into Parliament, and the provision remains in its current form. The Government has foreshadowed amendments in line with its response to the IPCRC Report upon the availability of an appropriate legislative vehicle.[73]

---

[70] Ibid, 576.

[71] Australian Competition and Consumer Commission, *Submission to Australian Law Reform Commission, Intellectual Property Rights over Genetic Materials and Genetic and Related Technologies – Gene Patenting and Human Health: Discussion Paper DP 68*, (2004), 3.

[72] ALRC Report, above n9 576.

[73] See Department of Treasury and Finance, Parliament of Australia, *Commonwealth Regulatory Plan* (2005) <http://www.treasury.gov.au/documents/936/RTF/_Toc107982889> at 16 August 2005, 9.

The Australian Law Reform Commission's Recommendations on the Role of the Australian Competition and Consumer Commission

The ALRC also highlighted its concern with the role of the ACCC in monitoring and enforcement. Despite acknowledging the difficulty of being cognisant of specific patent transactions,[74] the ALRC, in Recommendation 24-3, recommended that:

> As the need arises, the ACCC should review the conduct of firms dealing with genetic materials and technologies protected by intellectual property rights, to determine whether their conduct is anti-competitive ...[75]

Recommendation 24-4 recommended that government health departments and other stakeholders avail themselves of complaint procedures available under the *TPA* to alert the ACCC to conduct that may breach Part IV and 'have an adverse impact on medical research or the cost-effective provision of healthcare'.[76]

The ALRC accepted the ACCC's submission that it is a complaints-driven regulator.[77] In the absence of specific complaints, it is difficult to see how this role envisaged for the ACCC will have practical utility. The commercial nature of most transactions involving patents makes regulation difficult. Nevertheless, advocating an 'oversight' role for the ACCC in intellectual property dealings may go some way toward eliminating potentially anti-competitive conduct. As the ACCC itself pointed out in its submission, whether or not this area becomes an enforcement priority depends on whether it perceives there to be public interest in increased investigation.[78]

5.2.2.3 *Refusals To License Intellectual Property*

Where a refusal to license is predicated on conditions that may be considered to be unreasonable, s 51(3) may operate. Of course, this all depends on how an amended s 51(3) is interpreted, and the form taken by ACCC guidelines. Unilateral refusals to license patents will fall outside the ambit of s 51(3). They will continue to be subject to the tests contained within the misuse of market power provision, s 46, and the application of this provision to refusals to license patents will be considered in detail in subsequent chapters.[79]

---

[74] Ibid, 576-579.

[75] Ibid, 580.

[76] Ibid, 580.

[77] Ibid, 578-579 (para 24.98).

[78] Australian Competition and Consumer Commission, above n71, 4.

[79] See below, particularly Chapters 6 and 8.

5.3 THE AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY

The Agreement on Trade Related Aspects of Intellectual Property (TRIPS)[80] was discussed in Chapter 2 in respect of requirements for intellectual property protection.[81] Despite making extensive provision for uniformity in respect of intellectual property protection by WTO Members, TRIPS contains few provisions dealing with the interaction between intellectual property law and competition law. Article 8(2) contains the principle that member states may take appropriate measures, where needed, 'to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology'. Article 8(2) does not operate to impose an obligation on member states to counter the abuse of intellectual property, and provides no substantive legal clarity as to its application.[82]

In relation to contractual licences, article 40(1) provides:

> Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

Article 40(2) allows member states to make provision in national legislation specifying 'licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. ...' Article 40(2) also allows member states to 'adopt appropriate measures to prevent or control such practices ...'.

Article 40 contains scant guidance as to the identification or treatment of anti-competitive abuses of intellectual property through licensing practices or conditions.[83]

---

[80] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C of the Marrakesh *Agreement Establishing the World Trade Organization*, [1995] ATS 12 (entered into force 15 April 1994).

[81] See above, 2.2.3.

[82] See Andreas Heinemenn, 'Antitust Law of Intellectual Property in the TRIPs Agreement of the World Trade Organization' in Friedrick-Karl Beier and Gerhard Schricker (eds) *From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights* (1996) 239, 241-243.

[83] See Wolfgang Fikentscher, 'Historical Origins and Opportunities for Development of an International Competition Law in the TRIPs Agreement of the World Trade Organization (WTO) and Beyond' in Friedrick-Karl Beier and Gerhard Schricker (eds) *From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights* (1996) 226, 234-238; ibid, 239. Article 40(2) does contain a limited number of examples of categories of licensing practices and conditions that may be anti-competitive, although it is clear that these examples are not exclusive.

Again, the adoption of measures provided for in Article 40 is optional.[84] Article 40 does not apply to unilateral conduct that might constitute a misuse of market power, given that it occurs 'outside a licensing context ...'.[85] As a result, member states are afforded virtually unfettered discretion in regulating the intellectual property/competition law interface, which has resulted in a divergence of approaches to this important enforcement issue.[86] Issues relating to misuse of market power, in particular, are given very little consideration in TRIPS.

As discussed above, Article 31 of TRIPs contains provisions allowing member states to provide for the issue of compulsory licences in appropriate circumstances, although the list of circumstances provided in TRIPs is not exhaustive. One of the grounds specified is anti-competitive practices, although again, no further guidance is given as to what may constitute an anti-competitive practice.[87] Article 31 contains requirements that must be adhered to before a compulsory licence will be granted to an applicant. In summary, an applicant must have:

- made efforts to obtain authorization from the right holder to use the right on reasonable commercial terms and conditions;[88]

---

[84] Heinemenn, above n82, 245.

[85] See Pedro Roffe, 'Control of Anti-Competitive Practices in Contractual Licences Under the TRIPs Agreement' in Carlos M Correa and Abdulqawi A Yusuf (eds), *Intellectual Property and International Trade: The TRIPs Agreement* (1998) 261, 283.

[86] On the role of TRIPS in specifying international standards in respect of the intellectual property/competition law interface, see generally Herbert Hovenkamp, Mark A Lemley and Mark D Janis, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2002), (Hovenkamp, Lemley and Janis) vol II, ch 40. There have been a number of attempts by the United Nations, the OECD and the WTO to develop international standards in respect of this issue. A group of scholars also released a Draft International Antitrust Code (the Munich Code) contained as a supplement to 64 *Antitrust & Trade Register* (BNA) (1993). While this thesis will not undertake disussion of the development of international standards, Hovenkamp, Lemley and Janis identify the importance of this issue, and comment on these attempts; at ch 40, Lemley and Janis acknowledge the difficulties that have been experienced in dealing with these issues on an international basis, and conclude that '[i]n view of the largely discouraging history of international antitrust legislation, it may be more realistic to look to the development of a body of national common law on intellectual property/antitrust that is gradually prodded towards harmonization by WTO-level decisions on competition aspects of the TRIPS agreement.'; at vol II, [40.40]. See also Eleanor M Fox, 'Toward World Antitrust and Market Access' (1997) 91 *American University Journal of International Law and Policy* 1; Eleanor M Fox, 'Trade, Competition and Intellectual Property – TRIPS and its International Counterparts' (1996) 29 *Vanderbilt Journal of Transnational Law* 481; Jerome H Reichman, 'Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement' (1995) 29 *International Lawyer* 345; Susan K Sell, *Power and Ideas: North-South Politics of Intellectual Property and Antitrust* (1998).

[87] Heinemenn, above n82, 239, 244.

[88] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C of the Marrakesh *Agreement Establishing the World Trade Organization*, [1995] ATS 12 (entered into force 15 April 1994) art 31(b).

- those efforts have not been successful within a reasonable period of time;[89] and
- any use applied for must be authorised predominantly for the supply of the domestic market in which the use has been authorised.[90]

These conditions may be disregarded where a court or tribunal has made a determination that a practice or condition is anti-competitive. This indicates the importance of the protection of competition.[91]

Therefore, although TRIPS contains strict requirements for the provision of intellectual property protection, considerable discretion is left to Member States in regulating intellectual property through compulsory licensing, and particularly through competition law. The next section considers competition law treatment of intellectual property transactions in the US and EU.

5.4 Competition Law and Intellectual Property in International Jurisdictions

Whereas the *TPA* contains a statutory exemption from the operation of some competition law provisions for dealings in intellectual property, the US and European competition law regimes adopt quite different methods of indicating whether particular intellectual property dealings should be subject to the operation of their respective competition laws. The following sections will discuss basic principles of United States (US) and European Union (EU) competition law as applied to intellectual property transactions. They contain an examination of provisions relevant to refusals to license intellectual property,[92] in addition to more general discussion of the intellectual property/competition law interface in each of these jurisdictions. The purpose of this discussion is to allow some comparison of the manner in which the interface is regulated in each jurisdiction, as a conduit to examining how the issue of refusals to license should be treated in the Australian context.[93]

---

[89] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C of the Marrakesh *Agreement Establishing the World Trade Organization*, [1995] ATS 12 (entered into force 15 April 1994) art 31(b).

[90] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C of the Marrakesh *Agreement Establishing the World Trade Organization*, [1995] ATS 12 (entered into force 15 April 1994) art 31(f).

[91] Heinemann, above n82, 244.

[92] Although there are important differences between these terms and s 46, these provisions collectively will be referred to as 'misuse of market power provisions'. See further below, 7.1.

[93] As such, the following sections do not contain comprehensive treatment of relevant provisions of US and EU law.

5.4.1 THE UNITED STATES

Several statutes regulate US antitrust law,[94] which is enforced by the Antitrust Division of the Department of Justice (DOJ), and the Federal Trade Commission (FTC). Most relevant for the purposes of this thesis is the *Sherman Act* 1890 (the *Sherman Act*),[95] which prohibits contracts, combinations and conspiracies in restraint of trade.[96] Section 2 of the *Sherman Act* is the US counterpart of s 46 and provides that:

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony ...

5.4.1.1 *THE ELEMENTS OF SECTION 2 OF THE SHERMAN ACT*

The first element that must be proved in establishing a contravention of section 2 is that the defendant possesses monopoly power.[97] A rule of reason analysis is employed.[98] In addressing the issue of monopoly power, markets are defined in terms of their product and geographic dimensions.[99] Once monopoly power has been established, it must also be proved that the monopolist has engaged in an 'exclusionary practice', examples of which have developed as a result of the case law.[100] In the case of leveraging monopoly power from one market to another, it has

---

[94] A discussion of these statutes is contained in Alan Gutterman, *Innovation and Competition Policy* (1997) 71-74. The most relevant for the purposes of this thesis is the *Sherman Act* 15 USC (1890).

[95] *Sherman Act* 15 USC (1890).

[96] *Sherman Act* 15 USC §§ 1-2 (1890).

[97] The amount of market power required to constitute monopoly power will vary, but will generally be measured using three methods: market share, profit margins and constraints on pricing. The choice of method will depend on the facts of a particular case. Various cases have provided guidelines on the degree of power required to establish monopoly power. See, for example, Keith N Hylton, *Antitrust Law: Economic Theory and Common Law Evolution* (2003) Cambridge University Press, Cambridge, 230-243. See also generally Phillip E Areeda and Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and their Application* (2nd ed, 2002) (Areeda and Hovenkamp) chs 5 and 6.

[98] A rule of reason analysis allows a factual analysis in a particular case, and considers whether any justification for a restraint or anti-competitive practice exists; see *National Society of Professional Engineers v US* 435 US 679 (1978) 692.

[99] See the discussion in Areeda and Hovenkamp, above n97, vol 2A, [530-565].

[100] See ibid vol 3, [600-617].

been argued that modern case law imports a requirement that there be a specific intent to monopolise.[101]

It is well established that dealings in intellectual property are subject to the provisions of the antitrust statutes, including the provisions of the *Sherman Act*.[102] The achievement of monopoly power solely as a result of an advantage such as a legal licence will usually provide a defence to the attainment of monopoly power, but not to unlawful exclusionary practices engaged in by the monopolist.[103]

Although this provision is the US equivalent of s 46 of the *TPA*, clearly, there are some important differences between the two provisions. Most notably, s 2 requires monopolisation, whereas s 46 requires only that a corporation possess a substantial degree of market power.[104]

5.4.1.2 *THE US GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY RIGHTS*

US regulators and courts have a long history of regulating the interface between intellectual property and competition law.[105] Over the course of this regulation, the two bodies of law have 'traded ascendancy',[106] with intellectual property being subjected to tight scrutiny by antitrust enforcement agencies during the 1930s and 1940s, and again during the 1970s.[107] Since the early 1980s, US antitrust regulators

---

[101] Hylton, above n97, especially 202-206 discussing relevant case law. Significant discussion could be devoted to the history of section 2 and its elements. Note that while it is not intended to discuss the elements of section 2 or this case law in detail, US cases dealing with refusals to license and consequent leveraging issues will be discussed below in Chapter 7.

[102] Early Supreme Court decisions include *United States v Standard Sanitary Manufacturing Co* 226 US 20 (1912) and *Motion Pictures Patents Co v Universal Film Manufacturing Co* 243 US 502 (1917). Note that these cases marked the advent of two legal constructs in relation to the intellectual property/antitrust interface. The first was a view that an intellectual property right confers a monopoly on the holder of that right, and the second was that intellectual property and antitrust occupied two separate spheres of law; see Willard K Tom and Joshua A Newberg, 'Antitrust and Intellectual Property: From Separate Spheres to Unified Field' (1997) 66 *Antitrust Law Journal* 167, especially 170-173.

[103] Areeda and Hovenkamp, above n97, vol 3, [617].

[104] Although it might be argued that s 46 has been interpreted to require a degree of market power akin to monopoly power; see below, 6.3.5.

[105] See Hovenkamp, Lemley and Janis, above n86, vol I, [1.14].

[106] Ibid, [1-15]; Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) (Federal Trade Commission Report), Chapter 1, 14-15.

[107] FTC Report, above n106 Chapter 1, 15-18; Hovenkamp, Lemley and Janis, above n86, vol I, [1.15 – 1.17].

have adopted a more permissive approach toward patent law in line with the view that intellectual property and antitrust share a common goal.[108]

This changing view has been shaped by a number of factors,[109] including the creation of the Court of Appeals for the Federal Circuit[110] stronger standards of patentability,[111] and changing views toward the validity and importance of intellectual property (particularly patent) protection.[112] Developments in economic thinking also influenced antitrust theory.[113] The precedence of one particular body of law over the other has been shaped largely by political and economic factors.[114]

In the US, the treatment of terms and conditions in intellectual property licensing agreements is dealt with by Guidelines for the Licensing of Intellectual Property Rights ('The US Licensing Guidelines'), jointly produced in 1995 by the US Department of Justice and Federal Trade Commission ('The Agencies').[115]

---

[108] See, eg, Tom and Newburg; above n102; James B Kobak Jr, 'Running the Gauntlet: Antitrust and Intellectual Property Pitfalls on the Two Sides of the Atlantic' (1996) 64 *Antitrust Law Journal* 341, 345-346. On political influences on intellectual property policy, see, for example, Susan K Sell, *Private Power, Public Law: The Globalisation of Intellectual Property Rights* (2003); Peter Drahos, 'BITs and BIPs – Bilateralism in Intellectual Property' (2001) 4 *Journal of World Intellectual Property* 791; Peter Drahos and John Braithwaite, *Information Feudalism* (2002) especially ch 1.

[109] See, eg, Robert M Merges and John F Duffy, *Patent Law and Policy: Cases and Materials* (3rd ed, 2002) 11; Kobak, above n108, 347-350.

[110] One result of the establishment of the CAFC has been an increase in findings of patent validity; see, for example, John R Allison and Mark A Lemley, 'Empirical Evidence on the Validity of Litigated Patents' (1998) 26 *AIPLA Quarterly Journal* 185.

[111] See generally above, 2.4.

[112] Note that the development of the doctrine of patent misuse has occurred in tandem with these developments. It is not proposed that this doctrine be considered, although there is considerable overlap between this doctrine and certain antitrust principles. For further discussion on the role of this doctrine, see, eg, Hovenkamp, Lemley and Janis, above n86, vol I, [1.3c].

[113] Federal Trade Commission Report, above n106, Chapter 1, 22-23. More specifically, Chicago School thinking came to the fore during the 1970s and 1980s, which resulted in more lenient treatment of intellectual property, and a more laissez-faire view of regulation generally; Federal Trade Commission Report, above n106, Chapter 1, 22-23.

[114] Hovenkamp, Lemley and Janis, above n86, vol I, [1.15-1.17].

[115] US Department of Justice and the Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property*, (1995) (US Licensing Guidelines) <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm> at 27 October 2003.

The Guidelines state the regulatory policy of the US Department of Justice and the Federal Trade Commission, as is indicated by the following statement (see Guideline 1.0):

> These Guidelines state the antitrust enforcement policy of the US Department of Justice and the Federal Trade Commission (individually, "the Agency," and collectively, "the Agencies") with respect to the licensing of intellectual property protected by patent, copyright, and trade secret law, and of know-how. By stating their general policy, the Agencies hope to assist those who need to predict whether the Agencies will challenge a practice as anticompetitive. However, these Guidelines cannot remove judgment and discretion in antitrust law enforcement.

Heightened interest by the antitrust authorities in relation to the intellectual property/antitrust intersection has led some to suggest that antitrust may experience a period of revival in relation to its regulation of intellectual property transactions.[116] Concern about the vigour with which intellectual property is presently able to be asserted is typified by the following statement by former Federal Trade Commission Chairman, Robert Pitofsky:

> Traditionally, cases at the intersection between intellectual property and antitrust laws have been analyzed by examining the impact on economic incentives and balancing them against anticompetitive effects. ... An approach that starts from the point of view that a patent holder does not have to sell or license to anyone, and proceeds from that unchallenged assumption to the rule that it therefore can condition its sales or licenses in any way it sees fit ... would be an unwise and unfortunate departure from the traditional approach in this area. I question whether there is a reason to believe any such interpretation is necessary to encourage the innovation process.[117]

The Guidelines are outcome directed in that they consider the impact of particular restrictions on economic efficiency and competition.[118] The Guidelines are based on three premises:

- for the purpose of antitrust, intellectual property is comparable to any other form of property;
- intellectual property is not presumed to create market power; and
- intellectual property licensing allows firms to combine complementary factors of production and is generally pro-competitive.[119]

In relation to the first premise, the Agencies apply antirust to intellectual property in the same way it applies to other forms of property, taking into account the *particular*

> Moreover, the standards set forth in these Guidelines must be applied in unforeseeable circumstances. Each case will be evaluated in light of its own facts, and these Guidelines will be applied reasonably and flexibly.

[116] See, eg, Hovenkamp, Lemley and Janis, above n86, [1.17]; remarks of FTC Commissioner Mary L Azcuenaga, 'The Intersection of Antitrust and Intellectual Property: Adaptations, Aphorisms and Advancing the Debate' (1996) <http://www.ftc.gov/speeches/azcuenaga/alis.htm> at 16 December 2004.

[117] Robert Pitofsky, 'Challenges of the New Economy: Issues at the Intersection of Antitrust and Intellectual Property' (2001) 68 *Antitrust Law Journal* 913, 923-924.

[118] See Eagles and Longdin, above n48, 38.

[119] US Licensing Guidelines, § 2.0.

characteristics of intellectual property.[120] The Guidelines recognise that while many licensing arrangements are welfare-enhancing and pro-competitive, antitrust concerns may still arise. To this end the Agencies will focus on the actual effects of an arrangement, not its formal terms.[121] Restrictions in licensing arrangements will usually be evaluated on a rule of reason analysis, in that any anti-competitive effects will be weighed against any pro-competitive effects that arise.[122] Restraints that are clearly anti-competitive will be per se unlawful,[123] and the Guidelines also allow an antitrust 'safety zone' to encourage licensing activity. The safety zone will apply where:

- the restraint is not facially anti-competitive; and
- the licensor and its licensees collectively account for no more than twenty percent of each relevant market significantly affected by the restraint.[124]

If market share data is unavailable, the Agencies will assess whether or not there are four or more independently controlled technologies that are substitutable for the technologies controlled by the parties at comparable cost, or whether or not there are four or more independently controlled entities that have the capacity and incentive to engage in research and development activities that are a close substitute for those of the parties to the licensing agreement.[125]

---

[120] In stating that intellectual property is comparable to any other form of property, the Guidelines provide the following qualification:

> The Agencies apply the same general antitrust principles to conduct involving intellectual property that they apply to conduct involving any other form of tangible or intangible property. That is not to say that intellectual property is in all respects the same as any other form of property. Intellectual property has important characteristics, such as ease of misappropriation, that distinguish it from many other forms of property. There characteristics can be taken into account by standard antitrust analysis, however, and do not require the application of fundamentally different principles; ibid, § 2.1

A footnote to this guideline then provides that:

> As with other forms of property, the power to exclude others from the use of intellectual property may vary substantially, depending on the nature of the property and its status under federal or state law. The greater or lesser legal power of an owner to exclude others is also taken into account by standard antitrust analysis.

[121] US Licensing Guidelines, § 3.1.

[122] Ibid, §§ 3.4, 4.2.

[123] Ibid, § 3.4.

[124] Ibid, § 4.3.

[125] Ibid.

Licensing is generally viewed as pro-competitive, and a licensor's freedom to deal with their intellectual property will generally only be fettered by the following limitations:

- where restrictions in a licensing agreement relate to non-patented products or processes; or
- where the restrictions harm competition between companies who may have been actual or likely potential competitors in the absence of an agreement.[126]

The Agencies may analyse the competition effects of agreements in respect of technology or innovation markets. A technology market consists of the intellectual property that is licensed or its close substitutes.[127] A technology market analysis will be used when rights to intellectual property are marketed separately from the products in which they are used.[128] An innovation market is a market in new or improved goods and services. An innovation market analysis may be used where a licensing arrangement may adversely affect competition to develop new or improved goods or processes, and the effects on innovation cannot be adequately addressed through the analysis of goods or technology markets.[129]

5.4.1.3 *Refusals to License Intellectual Property Rights Under the US Guidelines*

Contentions that unreasonable terms contained in licence agreements are anti-competitive will be dealt with under the principles just discussed. In respect of outright refusals to licences intellectual property, the Guidelines provide that a holder of intellectual property is under no general obligation as a result of attaining market power through intellectual property, to license the use of that intellectual property to others.[130] This principle does, however, contain the following proviso:

> As in other antitrust contexts, however, market power could be illegally acquired or maintained, or, even if lawfully acquired and maintained, would be relevant to the

[126] See ibid, §§ 3.1, 3.3, 4.1. In practice, this will not apply to companies in a horizontal competitive relationship.

[127] Ibid, § 3.2.2. A technology market analysis will be used when rights to intellectual property are marketed separately from the products in which they are used.

[128] Ibid, § 3.2.2.

[129] Ibid, § 3.2.3. Innovation market analysis may be used in conjunction with goods or technology market analysis.

[130] Ibid, § 2.2.

> ability of an intellectual property owner to harm competition through unreasonable conduct in connection with such property.[131]

US courts both prior and subsequent to the development of the US Licensing Guidelines have consistently declined to recognise a general duty to license.[132] It has been contended, however, that the proviso cited above leaves courts with the possibility of invoking the essential facilities doctrine in relation to intellectual property.[133] US case law in relation to refusals to license intellectual property will be considered in Chapter 7.

5.4.2 THE EUROPEAN UNION

The *Treaty Establishing the European Community*[134] contains provisions regulating anti-competitive conduct within the European Union (EU).[135] Article 81[136] prohibits practices, decisions or agreements 'which have as their object or effect the prevention, restriction or distortion of competition within the EU'. Article 82[137] prohibits the abuse of a position of dominant market power, and is the EU equivalent of s 46:[138]

> Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States.
>
> Such abuse may, in particular, consist in:

---

[131] Ibid, § 2.2.

[132] These cases are discussed below, 7.2.1.2.

[133] Kobak, above n108, 354.

[134] *Treaty Establishing the European Community* [2002] OJ C 325/65.

[135] For a useful discussion on the EC Institutions and the enforcement of competition law by the European Commission and Courts, see Valentine Korah, *An Introductory Guide to EC Competition Law and Practice* (7th ed, 1997) 17-25. Note that competition law is primarily enforced by the European Commission, and appeals are heard by the Court of First Instance (CFI), and the European Court of Justice (ECJ). The European Court of Justice gives single judgments with no dissents, and may or may not follow the preliminary opinion given by one of the Advocate Generals of the Court. The Advocate Generals are appointed by Member States and provide an opinion on which the judges of the Court of Justice may rely. The fact that dissenting judgments and separate opinions are not allowed has been criticised; see, for example, at 19-20.

[136] Formerly Article 85.

[137] Formerly Article 86. In the following chapters, earlier cases that consider Article 86 instead of Article 82, will refer to Article 86. Thus, these references are intended to refer to the same provision.

[138] As to the aim of Article 82 in the protection of competition see Richard Whish, *Competition Law* (4th ed, 2001) 149-150; Sarah A Turnbull, 'Barriers to Entry, Article 86 EC and the Abuse of a Dominant Position: An Economic Critique of European Community Competition Law' (1996) 17(2) *European Competition Law Review* 96.

(a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;

(b) limiting production, markets or technical development to the prejudice of consumers;

(c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;

(d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

The European Court of Justice has stated that there are a number of elements to be satisfied in proving a breach of Article 82:[139]

> [F]or the prohibition under Article 86 [now Article 82] to apply, it is ... necessary that three elements shall be present together: the existence of a dominant position, the abuse of this position, and the possibility that trade between member-States may be affected thereby.[140]

5.4.2.1 *THE ELEMENTS OF ARTICLE 82*

Thus, although attaining a position of dominance is not in itself unlawful, a market participant with dominance must take care not to abuse that position.[141] The first step in determining the issue of dominance is to define the relevant market, and the second is to consider whether or not the undertaking is dominant in that market. The European Commission and Courts approach the question of market definition by considering the relevant product market[142] and then the relevant geographic market.[143]

---

[139] Note that the operation of Article 82 is in the process of being revised: see Phillip Lowe, *Speech Delivered by Phillip Lowe at the Fordham Corporate Law Institute Thritieth Annual Conference on International Antitrust Law and Policy Conference*, Washington, 23 October 2003 <http://europa.eu.int/comm/competition/speeches/text/sp2003_040_en.pdf> at 17 November 2004.

See also Brian Sher, 'The Last of the Steam-Powered Trains: Modernising Article 82' (2004) 25(5) *European Competition Law Review* 243.

[140] *Parke, Davis & Co v Proble, Centrafarm and Others* (1968) CMLR 47, 59.

[141] See Steven D Anderman, *EC Competition Law and Intellectual Property Rights: The Regulation of Innovation* (1998), 147.

[142] 'A relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable, by reason of the products' characteristics, their prices and their intended use'; Case 6/72 *Europemballage Corp and Continental Can Co Inc v European Commission* [1973] CMLR 199, [32]. Both demand side and supply side substitutability are considered using a test similar to the SSNIP test, although demand side substitutability has been more rigorously considered; see *Commission Notice on the Definition of the Relevant Market for the Purposes of Community*

The Commission is in the practice of defining markets somewhat narrowly with the result that very small undertakings may in fact be found to be dominant[144].

A dominant position is defined as

> [A] position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of its consumers.[145]

The test for dominance therefore requires consideration of whether effective competition is being prevented, (in line with the concept of market power advanced by economists) and whether an undertaking is able to behave independently.[146] In practice, a finding on dominance will be made after consideration of a number of relevant factors that have evolved as a result of the case law.[147]

The concepts of abuse detailed in Article 82 are not exhaustive, and the provision has been interpreted to incorporate a wide range of conduct.[148] Article 82 has been interpreted by the ECJ to apply to anti-competitive conduct in addition to exploitative behaviour, or in other words, to conduct that damages the structure of markets in which a dominant firm has weakened competition.[149] The third element, that of an effect on trade, will be satisfied where certain conduct brings about an alteration in the structure of competition in the relevant market.[150]

Competition Law, OJ C 372 on 9/12/1997; and see Anderman, *EC Competition Law and Intellectual Property Rights*, above n141, 151-153.

[143] See *Commission Notice on the Definition of the Relevant Market for the Purposes of Community Competition Law*, above n142. See also the discussion in Korah, Introductory Guide, above n135, 79-88.

[144] See especially Anderman, *EC Competition Law and Intellectual Property Rights*, above n141, 157-160, Whish, above n138, 165-166.

[145] *United Brands v Commission* [1978] 1 CMLR 429, [65] (Judgment).

[146] See Whish, above n138, 152-153.

[147] See the discussions of these factors ibid 153-163; Korah, above n135, 89-92.

[148] See, eg, Whish, above n138, 176-184; Korah, above n135, 97-121.

[149] See especially *Michelin v Commission* [1983] ECR 3462, [70]. See also Anderman, *EC Competition Law and Intellectual Property Rights*, above n141, 181-182.

[150] *Commercial Solvents v Commission* Cases 6/73 and 7/73 [1974] 1 CMLR 309.

Dealings in intellectual property are subject to Article 82.[151] In addition to Article 82, the competition laws of individual Member States are set out in national competition legislation.

5.4.2.2 *EU Competition Law Regulation of Intellectual Property Dealings*

Although the US has been described as the 'historically more activist antitrust side of the Atlantic ...',[152] the interface between intellectual property and competition law was, until recently fairly tightly regulated in the EU. In some respects antitrust became less accommodating of intellectual property during the latter decades of the twentieth century.[153] Intellectual property has traditionally been dealt with nationally by member states, and intellectual property privileges came to be perceived as barriers to entry that had the potential to inhibit the development of a common market.[154] This led to somewhat cautious attitudes toward regulation of intellectual property dealings, which have recently, to some extent, been relaxed.[155]

The intellectual property/competition law interface in European law during this time was generally governed by the existence, exercise dichotomy,[156] whereby determinations by the European Court of Justice indicated that the court took the view that while the existence of intellectual property was a national matter, the exercise of that right could be examined by the European Court of Justice. The distinction arose from comments made by the European Court of Justice in *Consten and Grundig v Commission*,[157] although the dichotomy has proved unworkable[158] in more recent cases and to a large extent been dispensed with.[159] Instead, the European Commission and

---

[151] See generally Anderman, *EC Competition Law and Intellectual Property Rights*, above n141, 148-150.

[152] Kobak, above n108, 342.

[153] See generally Valentine Korah, 'The Interface Between Intellectual Property and Antitrust: The European Experience' (2002) 69 *Antitrust Law Journal* 801; Kobak, above n108, 346-347. See also the discussion in Chapter 7 dealing with EU case law on refusals to license.

[154] Korah, above n135, 803. See also Valentine Korah, 'Patents and Antitrust' (1997) 4 *Intellectual Property Quarterly* 395, 400.

[155] Korah, above n135, 803-807. Although, as Korah points out, there were exceptions to this trend, in general intellectual property dealings were analysed ex post so that any efficiencies associated with investment in research and development were disregarded; at 803-804.

[156] See, eg, Korah, above n135, 217-218.

[157] *Consten and Grundig v Commission* [1966] ECR 299, 345 (Cases 56/64 and 58/64).

[158] Indeed, the origins of the dichotomy in the *Treaty Establishing the European Community* [2002] OJ C 325/65 have been questioned; see Thomas C Vinje, 'The Final Word on *Magill*: The Judgment of the ECJ' (1995) 17(6) *European Intellectual Property Review* 297, 299-301.

[159] See, eg, ibid, 299-301.

Courts have adopted a more 'circumstances-based approach to dealing with disputes concerning the exercise of intellectual property.[160]

(i) Block Exemptions

As discussed, provisions within The Treaty on European Union regulate anti-competitive conduct within the European Union.[161] There are a number of Group Exemptions contained in regulations that exempt certain conduct from particular provisions, generally where the conduct is deemed to be in the public interest. These exemptions are in the nature of practice-oriented guidelines in that they specify whether or not particular conduct is likely to be permitted, or contravene competition law prohibitions.

In order to qualify for the exemption, the conduct must satisfy the criteria under the regulations: if these criteria are satisfied the conduct is automatically exempted. Most relevant to date has been Regulation (EC) No 240/96 (31 January 1996) (no longer in force).[162] This exemption was aimed primarily at facilitating the dissemination of technology, and it operated on a narrow basis. In essence, the exemption only applied to exempt conduct where it was considered highly unlikely to be anti-competitive.[163] The benefits of the exemption could be withdrawn where the effects of the exempted agreement were incompatible with Article 81(3) of the Treaty.[164]

(ii) The New EU Competition Regime

As of 1 May 2004, the EU adopted a new competition law regime. The main aims of the reform of the competition system are generally to:

- enhance enforcement activities;
- increase certainty to businesses;
- adopt greater reliance on economic analysis;
- improve merger control; and

---

[160] Ibid, 301.

[161] See above, 5.4.2.

[162] *Commission Regulation (EC) 240/96 on the Application of Article 81(3) of the Treaty to Certain Categories of Technology Transfer Agreements*, [1996] OJ L 31/2 (*Regulation 240/96*). Article 81(3) provided a limited exemption from the application of Article 81. Article 82 contains no corresponding exemption.

[163] See NCC Report, above n15, 189.

[164] *Regulation 240/96*, above n140, Article 7. Although use of the withdrawal power has been very limited, the threat of its use has been utilised to induce parties to change their conduct; see Anderman, *EC Competition Law and Intellectual Property Rights*, above n141, 85.

- undertake internal reforms to enhance adoption and implementation of the preceding measures.[165]

The substantive prohibitions contained in Articles 81 and 82 will remain unchanged.

Regulation 240/96 was due to expire in 2006, and in 2001 the Commission adopted a mid-term review report of this Regulation.[166] Submissions were invited in relation to the TTBE Mid-Term Report, and the operation of Regulation 240/96. This procedure was aimed at evaluating the effectiveness of Regulation 240/96 over the duration of its operation. The Report was critical of the way in which technology transfer agreements are evaluated under Regulation 240/96. In particular, it found that the Regulation focuses more on the form of the agreement than on the actual effects of the market. In addition to analysing the policy approach on which the Regulation is based, the Report found that:[167]

- the Regulation is too prescriptive which may discourage efficient transactions and hamper dissemination of new technologies;
- the rules under the Regulation require simplification and clarification;
- a number of restraints under the Regulation are presumed illegal or excluded from the operation of the Regulation without good economic justification;
- by concentrating on the form of the agreement, the benefit of the block exemption is extended to a number of situations which should not always be exempted (the example of exclusive licensing is given);
- the Regulation makes insufficient distinction between competitors and non-competitors.

---

[165] See Mario Monti, 'EU Competition Policy After May 2004', *Paper presented at the Fordham Annual Conference on International Antitrust Law and Policy, New York,* (2003) <http://europa.eu.int/comm/competition/speeches/index_speeches_by_the_commissioner.html> at 31 May 2004.

[166] *Commission Evaluation Report on the Transfer of Technology Block Exemption Regulation No 240/96: Technology Transfer Agreements Under Article 81,* COM (2001) 786, (Mid-Term Report).

[167] See ibid.; See also Kirtikumar Mehta and Luc Peeperkorn, 'Licensing of Intellectual Property Under EU Competition Rules: The Review of the Technology Transfer Block Exemption Regulation' *Statement to the FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, Washington, (2002) <http://www.ftc.gov/opp/intellect/020522mehtadoc.pdf> at 12 March 2004.

See also Summary of Submissions on TTBE Review Report, Annex 1, <http://europa.eu.int/comm/competition/antitrust/technology_transfer/summary_of_comments.pdf> at 20 January 2004.

The outcome of the review has been the drafting of a revised Regulation.[168] As of 1 May 2004, Regulation 240/96 ceased to be operative, and the Commission of the European Communities adopted a new exemption for technology transfer agreements.[169] The Commission has also issued draft guidelines aimed at providing explanation and guidance as to the operation of the Revised TTBE, and the application of Article 81 to licensing agreements that fall outside the scope of the Revised TTBE.[170] Major changes to the current system are:[171]

- the Revised TTBE treats agreements between competitors fundamentally differently from agreements between non-competitors; and
- a less formalistic approach to determining the effects of technology licensing agreements. Treatment of licence agreements will depend largely on the market share of the parties.[172] Where market share falls below the requisite level, the parties to an agreement will be able to take advantage of a 'safe harbour'. A number of licensing restrictions are classified as 'hardcore' restrictions and prohibited. Outside the safe harbour, the TTBE Guidelines employ a more economic analysis in explaining how Article 81 will apply in individual cases.

---

[168] See *Commission Regulation (EC) 772/2004 of 27 April 2004 on the Application of Article 81(3) of the Treaty to Categories of Technology Transfer Agreements* [2004] OJ L 123/11 (Revised TTBE) and *Guidelines on the Application of Article 81 of the EC Treaty to Technology Transfer Agreements* [2004] OJ C 101/02 (TTBE Guidelines). See also 'Commission Proposes New Safe Harbour for the Licensing of Patents and Know-How', *EU Press Release*, (2003) <http://www.juridicum.su.se/jurweb/utbildning/master/master_of_european_intellectual_property_law/Commissionpressroom.pdf> at 31 May 2004.

Article 249 (ex art 189) provides that the Revised TTBE 'shall be binding in its entirety and directly applicable in all Member States.'

[169] See Revised TTBE, above n168.

[170] TTBE Guidelines, above n168.

[171] See Revised TTBE and TTBE Guidelines, above n168; Monti, above n165, 4; Valentine Korah, 'Draft Block Exemption for Technology Transfer' (2004) 25(5) *European Competition Law Review* 247; David Hull and Amy Toro, 'Reform of the Technology Licensing Rules' (2004) *The European Antitrust Review*, 34; John Ratliff, Axel Gutermuth and Rajeshree Bhojnani, 'European Commission Proposes New Competition Rules for Technology Licensing', (2003) <http://www.wilmer.com/files/tbl_s29Publications/FileUpload5665/2904/News_215243279180219011515101300.pdf> at 31 May 2004.

[172] Parties who are competitors will not benefit from the block exemption if their combined market share exceeds 20 per cent. Parties who are not competitors will not benefit from the block exemption if their individual market share exceeds 30 per cent. Note that this analysis applies to product markets only, and special rules apply to technology markets.

5.4.2.3 *REFUSALS TO LICENSE INTELLECTUAL PROPERTY*

Although there has been a good deal of focus on when particular conduct will be exempted from the scope of Article 81, there is no exemption in respect of conduct that may fall foul of Article 82. Instead, dealings that may be in breach of Article 82 will simply be subject to the requirements of that provision, and evaluated according to whether or not the requirements of that provision are made out.[173] Given this, unilateral refusals to license intellectual property will simply be dealt with under the case law principles formulated in respect of Article 82. This body of case law will be considered in Chapter 7, but the following comments are worth bearing in mind:

- for holders of intellectual property, there is a real risk (as a result of a tendency toward narrow market definition by the Commission) that markets will be defined narrowly under Article 82 with the result that a finding of dominance or *de facto* monopoly becomes more likely;[174]
- an intellectual property holder may be accorded particular rights in one market, but those rights might not extend to other secondary markets;[175] and
- because the issue of abuse is intricately linked to the question of dominance, a finding that a greater degree of dominance exists may have some impact on the standard of conduct required in assessing whether conduct is abusive.[176]

5.4.3 SUMMARY

It is evident from the foregoing discussion that refusals to license intellectual property within each jurisdiction discussed are dealt with on a case-by-case basis, and are not subject to any exemption from competition law. Indeed, there is no legislatively-based exemption from competition law for intellectual property dealings in the US.[177]

---

[173] See below 7.3.

[174] Anderman, *EC Competition Law and Intellectual Property Rights*, above n141, 159-160.

[175] Ibid, 187-188.

[176] Ibid, 168-169.

[177] Interestingly, the NCC recognised that the lack of an exemption for licensing conditions in other jurisdictions did not appear to have harmed investment in research. The NCC also found that there were a number of other grounds on which retention of the exemption in s 51(3) was questionable, including uncertainty over the operation of s 51(3), the relatively minor consideration competition law would receive in decisions about investing in innovation, and the global nature of licensing which throws into question the need for favourable treatment in a particular jurisdiction; NCC Report, above n15, 196-200. The NCC failed to directly address these matters in recommending retention of the exemption.

Instead, the US Licensing Guidelines do no more than provide an indication of the enforcement policy of US regulators.[178]

The exemption contained in section 51(3) of the *TPA* fails to exempt refusals to license intellectual property. The IPCRC recommended specific amendment to s 51(3) to specifically incorporate conditional refusals to license intellectual property. It is submitted that this recommendation might be open to question on the grounds that there may be limited evidence to justify such an exemption. Depending on the particular view taken of the role of competition law in regulating intellectual property transactions, such expansion may not be desirable. Moreover, the fact that the issue is dealt with on an individual basis in other jurisdictions is highly relevant. It is aligned with the position taken in the Government Response, which was to continue to treat conditional refusals to license contrary to s 46 as falling outside the scope of the exemption.

The next section considers the interaction between intellectual property and competition law, and argues that there is some doubt that an exemption from competition law for intellectual property transactions is warranted at all. For this reason, it is submitted that it is entirely appropriate that refusals to license are not exempted, and are dealt with on a case-by-case basis. It does, however, attempt to set out a general framework to guide regulation in this area, in line with the theoretical effect of refusals to license and the empirical evidence presented in Chapter 4.

5.5 The Interaction of Intellectual Property and Competition Law

5.5.1 Reconciling Aims

As articulated in Chapter 2, one of the central justifications for patent law is the provision to inventors of a temporary, exclusive right to exploit an invention in order to encourage innovation.[179] Despite some disagreement over whether intellectual property laws (and in particular patent laws) are necessary to stimulate innovation,[180] they have been accepted as an integral component of the legislative framework for the

[178] In contrast, both Australia and the EU exempt certain intellectual property dealings from breaching particular competition law provisions, although their operation and effect vary considerably. The Commission has also issued Guidelines indicating regulatory policy in implementing the Revised TTBE, and ACCC Guidelines in relation to s 51(3) would have a similar effect.

[179] See further above, Chapter 2.2.

[180] See the discussion above, 2.2.2.1.

promotion of innovation in all WTO countries.[181] Competition law, on the other hand, prohibits certain anti-competitive behaviour by corporations, and places limitations on the use of market power.[182] The effect that intellectual property may have on follow-on innovation has already been discussed,[183] and it is the potential for intellectual property to impact negatively on the innovative process that raises competition law issues.

Intellectual property inevitably imposes allocative costs on the public through restricting competition in goods and services,[184] and intellectual property laws can only be justified if the costs of limiting access to innovative ideas can be sufficiently offset by an appropriate level of innovation and dissemination.[185] Intellectual property laws clearly recognise the value of competition in that intellectual property protection is limited in scope, duration and effect,[186] and applies to some subject matter but not others. At the same time, competition laws defer to intellectual property laws to some degree in allowing innovators a limited monopoly to exclusively exploit a privilege. Viewed simplistically, intellectual property law and competition law are in conflict.[187]

The dominant paradigm, both in Australia[188] and internationally,[189] is that intellectual property law and competition law essentially share the same goal, and that is to

---

[181] TRIPs was very much a negotiated outcome between WTO member states, and some WTO countries agreed to adopt the standards imposed by TRIPs in exchange for other beneficial trade outcomes. In this respect, a number of concessions to particular countries were made, and this reflects that there are a number of TRIPs signatories, particularly developing countries, who may question whether strong intellectual property standards necessarily promote innovation; see generally Sell, *Private Power, Public Law*, above n108.

[182] See Hovenkamp, Lemley and Janis, above n86, vol I, [1.5].

[183] Above, 3.3.

[184] See Nancy T Gallini and Michael J Trebilcock, 'Intellectual Property Rights and Competition Policy: A Framework for the Analysis of Economic and Legal Issues' in Robert D Anderson and Nancy T Gallini, *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (1998) 17, 17-18.

[185] See Hovenkamp, Lemley and Janis, above n86, vol I, [1.9 – 1.13].

[186] See Hovenkamp, Lemley and Janis, above n86, vol I, [1.10]; Gallini and Trebilcock, above n184, 17-18.

[187] The literature on this topic is extensive. For a brief overview of the issues associated with the patent law/competition interface, see, eg, Organisation for Economic Cooperation and Development (OECD), *Competition Policy and Intellectual Property Rights* (1998) background note. Many of the other references cited in this chapter also provide useful discussion.

[188] IPCRC Report, above n8, 209-214; NCC Report, above n15, 160-164. See also Philip Tucker, 'Refusal to License Intellectual Property Rights and Misuse of Market Power – Where is the Line in the Sand?' (1999) 10 *Australian Intellectual Property Journal* 78, 78-79; TPC Background Paper, above n5, 8-10, especially 9; Pengilley, above n9; 174-176.

[189] See, eg, the discussion in FTC Report, above n106 ,ch 1, 7-9; Hovenkamp, Lemley and Janis, above n86, vol I, [1.9]-[1.13]; Gutterman, above n94, 11-12; Gallini and Trebilcock, above n184, 18; OECD,

benefit consumers by encouraging innovation and enhancing economic efficiency within markets. Intellectual property laws encourage innovation and the development of new products, and encourage competitors to compete with existing participants using more efficient means. Competition laws seek to impact on prices, output and market structure and in doing so, to promote rivalry and consequently innovation. Accordingly, both seek to maximise long-term dynamic efficiencies through the encouragement of innovation.

5.5.2 DIVERGING APPROACHES TO COMPLEMENTARY AIMS

This congruence between the two bodies of law is not, however, absolute, and there are instances where tension continues to exist between them. This tension stems in part from the manner in which intellectual property laws and competition laws set out to achieve their (albeit complementary) aims:

> An essential difference ... in the achievement of pro-competitive effects between competition law and intellectual property law lies in their temporal character: competition law strives to maintain a consistently competitive market whilst intellectual property law is content to allow mild distortions in market conditions to realise long term benefits. Thus, despite the common goal, intellectual property law's mode of achieving market efficiencies is antithetical to competition law's view of acceptable behaviour.[190]

Although intellectual property laws and competition law both have as their objective the promotion of innovation and long-term dynamic efficiencies, there may be cases in which it is not clear how innovation may best be served: through the provision of intellectual property, which inevitably leads to short-term market distortions, or through competition laws which monitor competition on a perpetual basis.[191] Finding the balance will invariably be problematic in some instances.[192]

In an economic sense, intellectual property restricts access by others in order to provide the holder of the legislated privilege with a social advantage (the right to

---

Competition Policy and Intellectual Property Rights (1998), above n187, 7; Tom and Newberg, above n102; Carrier, above n49, 766. See also the US Licensing Guidelines, § 1.0.

[190] Tucker, above n188, 79. See also Federal Trade Commission Report, above n106, ch 1, 8-14; Maureen O'Rourke, 'Striking a Delicate Balance: Intellectual Property, Antitrust, Contract and Standardisation in the Computer Industry' (1998) 12 *Harvard Journal of Law and Technology* 1, 31.

[191] Tucker, above n188, 79-80. See also Hovenkamp, Lemley and Janis, above n86, vol I, [1.3b]; Carrier, above n49, 766-771.

[192] See Anderman, *EC Competition Law and Intellectual Property Rights*, above n141, 5-7; OECD, above n187, 7.

exclude others). The difficult question for competition law is when the privilege restricts access more than necessary to secure that social advantage.[193] The broad issue addressed in this thesis is when competition law should be implemented to optimise follow-on innovation and to facilitate long-term dynamic efficiency, with specific reference to medical biotechnology. This may necessarily involve some trade-off in short and long-term efficiencies.

5.5.3 FINDING THE BALANCE

As indicated in previous sections of this chapter, to the extent that intellectual property laws and competition laws can be reconciled, competition laws in many jurisdictions defer to some degree to dealings in intellectual property. Competition law and policy in many jurisdictions, including Australia, contains some guidance as to the treatment to be afforded to intellectual property transactions. Policy in the area may be guided by different considerations in different jurisdictions,[194] and in relation to various issues and industries.

5.5.3.1 *GENERAL PRINCIPLES AND POLICY DEBATE*

There are many difficulties inherent in enacting an optimal competition policy for dealing with issues arising in relation to intellectual property licensing. While a framework for competition policy in relation to intellectual property is desirable,[195] determining the specifics of such a framework is fraught with difficulty. This difficulty stems from variance in views on the principles that should guide competition policy in respect of intellectual property. Gallini and Trebilcock point out that competition policy may have a number of effects on the social surplus amounting from innovation through the provision of:

- ex ante incentives to innovate or undertake research and development;
- ex post incentives to disseminate technologies and products; and
- price competition in markets where the new technologies and products are utilised.[196]

---

[193] See William M Landes and Richard A Posner, *The Economic Structure of Intellectual Property Law* (2003) 374-375.

[194] Indeed, this may be the case in relation to competition policy generally, although the issues are somewhat amplified when the difficult case of intellectual property is raised.

[195] Gallini and Trebilcock, above n184, 22-27. See also Tom and Newberg, above n102; Louis Kaplow, 'The Patent-Antitrust Intersection: A Reappraisal' (1984) 97 *Harvard Law Review* 1813.

[196] Gallini and Trebilcock, above n184, 21-22.

Gallini and Trebilcock suggest that the second and third effects should guide competition policy in relation to intellectual property.[197] Accordingly, they contend that the following principles should guide the application of competition law analysis to intellectual property law:[198]

> [Principle 1] There should not be a presumption that an intellectual property right creates market power.[199]
>
> [Principle 2] Competition policy should acknowledge the basic rights granted under patent law.
>
> [Principle 3] A licensing restriction should be permitted if it is not anticompetitive relative to the outcome that would result if the licence were proscribed; otherwise, an evaluation of the potential efficiency effects of the restriction on the pricing and diffusion of the intellectual property should be made.

These principles formed part of the executive summary of the OECD's Report on *Competition Policy and Intellectual Property Rights*.[200] Although participants of the roundtable that led to the report gave unqualified support for the first principle,[201] the position was far more equivocal in relation to the second and third principles.[202] In particular, the second principle was considered by roundtable members to be 'most in need of elaboration and possible qualification.'[203] This highlights the difficulty inherent in balancing the two bodies of law. Disagreement over this principle really underscores the debate as to which body of law should take precedence, and whether competition law should treat intellectual property as inherently different from other forms of property. It is submitted that while intellectual property does have unique characteristics that should be borne in mind in competition law analysis, this should not preclude

---

[197] Ibid, 22, 24-26.

[198] Ibid, 22.

[199] Many commentators assert that intellectual property will confer market power only in rare cases; see, for example, Edmund W Kitch, 'Elementary and Persistent Errors in the Economic Analysis of Intellectual Property' (2000) 53 *Vanderbilt Law Review* 1727, 1729-1739; Landes and Posner, above n193, 374-375. While this is certainly true, in rare cases a patent may confer market power. An accumulation of intellectual property rights could also operate to confer market power.

[200] OECD, above n187, 8-9

[201] The issue of patents and market power will be discussed below, 8.2.2.

[202] OECD, above n187, 8-9.

[203] Ibid, 9. See also FTC Report, above n106, where it was concluded that while antitrust policy should take patent policy into account in promoting long-term consumer welfare, it is equally important that competition policy concerns be considered by those responsible for implementing patent law and policy; ch 6, especially 1-9.

competition law being applied in the same manner as it is to other forms of property.[204]

A closely related issue is whether competition law should be concerned with the existence of intellectual property,[205] or merely its exercise. It is probably fair to say that the currently populist view is that:

> antitrust will be concerned not with the legitimate exercise of an intellectual property right granted by the government, but with efforts to *expand* the scope of that right,[206] either to new products, or temporally, or by conditioning access to the right on restrictions of competition. Efficient wealth maximization requires that a line be drawn between conduct that is permissible and that which is impermissible.[207]

The fundamental question is whether it is the task of intellectual property laws or competition laws to define the boundaries or scope of the legislated privilege, and therefore the legitimate exercise of intellectual property.

---

[204] Competition regulators certainly do not agree with the second principle proposed by Gallini and Trebilcock. The US Antitrust Guidelines provide an obvious example; see above, n120. The position of the ACCC is also worth considering. Despite the exemption contained in s 51(3) of the *Trade Practices Act* 1974 (Cth), the ACCC has consistently asserted that intellectual property should be treated in the same manner as other contracts, arrangements and understandings, subject to the authorisation and notification procedures; see Australian Competition and Consumer Commission, *Submission to the Intellectual Property and Competition Review Committee*, (1999), 16-17. See also Hilmer Committee Report, above n25, 150-151.

[205] Although there may be issues associated with the grant of a patent, these being (1) whether the patent is warranted, and (2) whether the patent (or whether a group of patents taken in combination) confers market power. The first issue is addressed by patent law, but the second is not. It has been recommended that the Patent Office be cognisant of the detrimental effects of granting patents that confer market power; FTC Report, above n106, ch 1, 9-12, 37-38.

[206] This approach essentially embodies the scope of grant doctrine. This doctrine has been criticised on the grounds that it defers overly to patent holders at the expense of competition law; see Carrier, above n49, 788-791.

[207] See Hovenkamp, Lemley and Janis, above n86, vol I, [1.3b]. See also Gutterman, above n94, 12, and note the following comment by Melamed and Stoeppelwerth, who explain that the notion of anti-competitive conduct can be articulated as follows:

[T]here appears to be an emerging consensus in both the economics literature and judicial decisions that anticompetitive conduct is conduct that serves no legitimate purpose, or is itself unprofitable, and is undertaken in order to exclude or weaken competitors in anticipation of increased market power and resulting supracompetitive recoupment. ... both the antitrust laws and the intellectual property laws distinguish between earning monopoly profits, which property owners are entitled to do, and sacrificing profits in order to create additional power; A Douglas Melamed and Ali M Stoeppelwerth, 'The CSU Case: Facts, Formalism and the Intersection of Antitrust and Intellectual Property' (2002) 10 *George Mason Law Review* 407, 418-419.

In other words, conduct will be deemed exclusionary if it lacks a valid efficiency justification; at 12.

5.5.3.2 *COMPETITION TREATMENT OF INTELLECTUAL PROPERTY*

There are costs associated with exempting a greater range of conduct from the operation of competition laws: stronger incentives by way of intellectual property protection do not necessarily equate with social benefit.[208] One outcome of stronger intellectual property protection is decreased price competition.[209] Immunity from competition may also operate to reduce incentives to innovate where patent holders hold a position of dominance in a market.[210] At the same time, intellectual property can grant significant power to an innovator, and the boundaries of intellectual property can in some circumstances be more difficult to determine than those of tangible property.[211] These factors would tend to militate against overly broad deference to intellectual property laws by competition law.[212]

On the other hand, business certainty and dissemination are the primary benefits of a broad exemption.[213] Allocative efficiency is likely to be increased as a result of confidence in the legality of intellectual property dealings.[214] Intellectual property possesses unique characteristics such as its significant social benefit and its ease of appropriability that tend to support stronger rights for intellectual property holders.[215] The necessity to combine complementary assets offers further support.[216]

Some commentators have attempted to provide some method of measuring the benefit to the patentee with the loss to society of a particular licensing restriction.[217] These

---

[208] FTC Report, above n106, ch 1, 14.

[209] Ibid.

[210] See Tom and Newberg, above n102, 199-200.

[211] Richard J Gilbert and Willard K Tom, 'Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later' (2001) 69 *Antitrust Law Journal* 43, 83-86.

[212] James Langenfeld, 'Intellectual Property and Antitrust: Steps Toward Striking a Balance' (2001) *Case Western Reserve Law Review* 91, 94-97.

[213] See, eg, NCC Report, above n15, 193-199.

[214] Willard K Tom and Joshua K Newberg, 'US Enforcement Approaches to the Antitrust-Intellectual Property Interface' in Robert T Anderson and Nancy T Gallini (eds) *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (1998), 343, 359.

[215] These arguments are summarised in Langenfield, above n212, 93-94. See also OECD, above n187, 8.

[216] Langenfeld, above n212, 93; IPCRC Report, above n8, 210.

[217] See, especially, William Baxter, 'Legal Restrictions on Exploitation of the Patent Monopoly: An Economic Analysis' (1966) 76 *Yale Law Journal* 267; Ward Bowman Jr, *Patent and Antitrust Law: A Legal and Economic Appraisal* (1973); Kaplow, above n195; Mark R Patterson, 'When is Property Intellectual? The Leveraging Problem?' (2000) 73 *South California Law Review* 1133; Carrier, above n49. Kaplow, for example, sought to develop a formula that 'examines the ratio between the reward the patentee receives when permitted to use a particular restrictive practice and the monopoly loss that results from such exploitation of the patent; Kaplow, above n195, 1816.

attempts are subject to some criticism in that the process of measurement presents difficulties. They also apply to licensing restrictions, and do not apply to refusals to license patents. This issue therefore continues to present challenges to policy makers.

The bounds that competition law places on dealings in intellectual property are important not just because they determine the outcome of matters that may be litigated, but also because they influence the manner in which practitioners advise parties, and the manner in which parties behave in negotiations.[218] For example, a patent holder who knows there are likely to be very few circumstances in which a refusal to license that patent would be successfully litigated, will be more confident in refusing a licence and asserting that position. A party who is likely to be refused a licence is more likely to seek a licence and instigate legal proceedings if they are aware that the matter could be determined in their favour.

It is submitted that competition law should play a role in monitoring the use of intellectual property, but that it should be employed carefully.[219] Policy design and implementation in this area should take account of the important role that intellectual property plays in stimulating innovation, and of the desirability of the dissemination of those rights.[220] In line with this, intellectual property laws should be capable of being amended to remedy perceived weaknesses in their operation; competition law should not step in to intervene on a frequent basis where these laws are viewed as deficient.[221] Arguments supporting this approach have been made in respect of the information goods market given that these markets are characterised by:[222]

- monopoly power in a fewer number of industry participants;
- patterns of progressive concentration; and

---

[218] Steve Anderman, 'The Aftermath of *Magill*' in Eric Barendt, *The Yearbook of Media and Entertainment Law* (1996) vol 2, 235, 244 ('[C]ompetitors will be encouraged in their negotiations with rightholders, their complaints to the Commission, and possibly their litigation in Member State Courts'). See also the discussion in John Temple Lang, 'European Community Antitrust Law: Innovation Markets and High Technology Industries' (1997) 20 *Fordham International Law Journal* 717, 812-816.

[219] See also Jill McKeough, 'Is Intellectual Property Different or are all Unhappy Monopolists Similar?' (2003) 26 *University of New South Wales Law Journal* 289.

[220] See also, Anderman, *EC Competition Law and Intellectual Property Rights*, above n141, 5-6.

[221] Alessandra Narciso, '*IMS Health* or the Question Whether Intellectual Property Still Deserves a Specific Approach in a Free Market Economy' (2003) 4 *Intellectual Property Quarterly* 445, 452.

[222] See generally ibid, 450-451; John H Barton, 'Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation' (1997) 65 *Antitrust Law Journal* 449; Carl Shapiro, *Competition Policy in the Information Economy* (1999), paper obtained from author's website <http://faculty.haas.berkeley.edu/shapiro/comppolicy.pdf> at 15 November 2004, 4-6.

- oligopolistic markets with a shrinking number of significant competitors.

Similar issues arise in respect of medical biotechnology, and these new market structures depart from conventional market structures for tangible goods.[223] Calls for changes to the copyright system have been made in circumstances where copyright is extending to information-based goods in order to clarify the extent of protection in this industry and reduce the number of instances where protection is broad and dubious.[224] Similar considerations have also driven recommendations for amendments to patent laws, particularly in relation to biotechnology patents.

Viewed this way, competition law does have an important role to play in curbing the anticompetitive practices of patent holders. Many patents in medical biotechnology are strong, and there have been a number of changes to patent law standards in all jurisdictions to ensure that this is the case. Given this, there should be some mechanism to ensure that these strong rights are not exercised in an anti-competitive manner. This is particularly the case where those rights impose broad protection over a number of uses. In relation to high-technology industries such as medical biotechnology, the matter is perhaps succinctly put by one US commentator in discussing the difficulty in determining the appropriate limits antitrust should place on intellectual property:

> From an antitrust perspective, the dynamic quality of innovation and intellectual property, its capacity to change and revitalise industries, has its negative or dark side as well as it positive or bright side. The dark side is that control of the innovation process or its fruits – whether in the form of a computer operating system, a biotech tool, or anything else, could lead to control over vast areas of industrial or commercial endeavour. Though largely intangible, resources such as these can be seen as every bit as strategic as the [tangible assets] of the past with which antitrust and its essential facilities and monopolisation principles have always so uneasily struggled.[225]

Although it is arguable that competition law should intervene in intellectual property dealings only rarely, there are circumstances in which intervention may be desirable. Granting immunity to patent holders precludes this possibility. It is difficult to lay down definitive rules as to when competition law may usefully play a part, and it may

---

[223] See the discussion above, 1.5.

[224] Narciso, above n221. See generally Kobak, James Kobak Jr, 'Intellectual Property, Competition Law and Hidden Choices Between Original and Sequential Innovation' (1998) 3 *Virginia Journal of Law and Technology*, 6, particularly, 41-44.

[225] Kobak, above n108, 350-351.

be that a case-by-case assessment is the most appropriate method of proceeding. There are, however, some basic rules that may be put in place to deal with particular issues. The remainder of this chapter will be devoted to examining the appropriate role for competition policy in promoting innovation, and to establishing some guidelines for treatment of refusals to license intellectual property.

5.5.4 THE ROLE OF COMPETITION POLICY IN FOSTERING INNOVATION

In Chapter 1, some economic studies considering the impact of competitive as opposed to concentrated market structures in fostering innovation were considered.[226] These studies have yielded contradictory results, and the most reasonable conclusion would appear to be that the optimal level of competition within a market would depend on the particular industry in question. Factors such as the manner in which innovation proceeds[227] and the degree of technological opportunity available in an industry will have a bearing on whether or not a competitive market structure is conducive to innovation in that industry. 'Competitive' in the economic sense, should be taken to mean the efficient exploitation of an economy's resources. It will not necessarily mean a greater number of participants competing in a particular economic market.[228]

There is an issue as to what role competition policy has in attempting to influence the rate of innovation within an industry by policing licensing arrangements. Should competition law be proactively involved in policing intellectual property dealings, and if so to what extent should it be involved? Would it be most beneficial if regulatory authorities employed an interventionist approach, or should competition law, in effect be a 'backstop' to curb only very extreme exercises of intellectual property at the instigation of competitors?

The extent to which consideration of the research and development effects of licensing restrictions should be taken into account is problematic given the inconclusive nature of economic evidence examining the link between competition policy and innovation.[229] In light of this tenuous link, Gallini and Trebilcock propose a limited examination of the research and development effects of licensing restrictions

---

[226] Above, 1.8.2.

[227] See above, 1.8.2.2.

[228] See Landes and Posner, above n193. 379.

[229] Gallini and Trebilcock, above n184, 23-26. See also the discussion by Marina Lao, 'Unilateral Refusals to Sell or License Intellectual Property and the Antitrust Duty to Deal' (1999) 9 *Cornell Journal of Law and Public Policy* 193, 213-218. See further above, 1.8.2.2.

by competition authorities.[230] The principles espoused by them in forming a framework for the treatment of intellectual property dealings by competition law reflect this, by concentrating on the pricing and diffusion aspects of a licensing restriction. Yet the evidence in respect of whether concentrated market structures are conducive to innovation is equally unsettled, and it is therefore unclear whether one body of law should take precedence over the other in encouraging innovation. For this reason, consideration of innovative effects may be entirely relevant to a competition analysis of a particular intellectual property licensing practice.

Commentators generally advocate that consideration of research and development be given, in one of three ways:[231]

- competition policy should be coordinated with patent policy to provide adequate incentives for research;
- restrictions that reduce innovation in future markets for products and processes should be prohibited by competition law; or
- competition law should be concerned with the allocative effects of licensing on diffusion and pricing of technologies and products, not on encouraging research and development.

While the first approach recommends that research and development considerations be explicitly taken into account by competition policy, the other approaches propose a more subtle consideration of the effect of a particular licence or licensing restriction on innovation. The views of various commentators reflect these varying policy choices.[232] Gallini and Trebilcock take the view that patent policy and competition policy have discrete roles to play. Not surprisingly, they advocate that on a general basis, the third approach be taken. The third approach is concerned with the allocative effects of a contract on diffusion and pricing:

> the task of patent policy is to define those rights which encourage innovation (in terms of duration and protection from imitation); the task of competition policy is to prevent the anticompetitive transfer and use of technology while respecting the basic exclusive rights as laid out by patent law. Indeed, this policy will affect the

---

[230] Gallini and Trebilcock, above n184, 25-26.

[231] These approaches are summarised ibid, 24-25.

[232] An advocate of the first approach, for example, is Robert Merges; see Robert P Merges, 'Antitrust Review of Patent Acquisitions: Property Rights, Firm Boundaries, and Organisation' in Robert D Anderson and Nancy T Gallini (eds) *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (1998) 111.

> innovator's overall return, and therefore the incentive to innovate in the first place, but the decision to allow the licence will be based on the *ex post* incentive to license, not on the *ex ante* incentives to innovate.[233]

Gallini and Trebilcock acknowledge that all three approaches may be appropriate in different circumstances depending on the market involved and the technological conditions. The issue addressed in this thesis centers on determining how competition policy should provide for follow-on innovation. In this respect competition law is an important tool to facilitate dissemination of technology and regulate prices. Further, patent law has some mechanisms to counter excessive rights given to upstream innovators where those rights are overly broad. For example, patents may be challenged and overly broad patents are unlikely to withstand such challenge.[234]

However, this does not mean that competition law should not be cognisant of ensuring adequate provision of incentives for research and development. Competition law has long been considered to be an important tool in the promotion of innovation.[235] In Australia, it would appear the process of reform being implemented under the National Competition Policy demonstrates that competition law is being recognised as an increasingly important element of an innovative and dynamically efficient economy.[236]

It is submitted that competition policy has a direct role to play in maintaining a competitive environment for follow-on innovators in intermediate and downstream medical biotechnology markets.[237] At the same time, it must retain sufficient flexibility to account for the myriad markets and technologies to which it must be

---

[233] Gallini and Trebilcock, above n184, 25.

[234] Of course, of greater concern than broad single patents, may be accumulations of patents, the assertion of which may operate to foreclose research in a particular area.

[235] This is a commonly recognised goal of competition law. See, for example, FTC Report, above n106, ch 1; David M Hart 'Antitrust and Technological Innovation in the US: Ideas, Institutions, Decisions, and Impacts, 1890-2000' (2001) 30 *Research Policy* 923; Pitofsky, above n117. See generally Carrier above n49.

[236] See *Competition Principles Agreement*, above n26. The Productivity Commission recently conducted a review of the National Competition Policy. The Review identified 'support for technological innovation' as an important reform that had yet to be addressed; See Productivity Commission, Parliament of Australia, *Review of National Policy Reforms*, Inquiry Report No 33 (2005) 368. The Review identified the need to 'continue to pursue reform opportunities across the economy ...', and stated that another important matter for policy attention was 'ensuring that there are cost-effective mechanisms in place to address market failures in technological innovation, including appropriate intellectual property protection'; at 360, 369. See also Lawson, above n26.

[237] See also Federal Trade Commission Report, above n106, ch 2, 36, where it was concluded while patent policy and competition have important roles to play in promoting innovation, neither is solely capable of fostering innovation. Therefore, the two must work in tandem.

applied. Any competition law analysis in areas of high technology such as biotechnology (which is itself a diverse industry) must be capable of accommodating different considerations in respect of different segments of the industry. In light of this, a focus on the impact of particular licensing arrangements on innovation may be appropriate in certain circumstances.

5.5.5 COMPETITION POLICY AND REFUSALS TO LICENSE INTELLECTUAL PROPERTY

The right of a holder of intellectual property to refuse to license that right is one of the most problematic questions that has arisen in the recent literature dealing with the intellectual property/competition law interface. The issue is a fundamental one that exemplifies the difficulty of the intellectual property/competition law interface. Different commentators take different views on the interface, and essentially, these approaches fall into one of two categories:

- the antitrust-immunity approach, whereby holders of intellectual property are given complete immunity from antitrust laws. Under this approach, holders of intellectual property would be entitled to refuse to license any party on any basis; and
- an approach that attempts to balance the immunity granted by intellectual property laws with the effects of competition intervention. Under this approach, intellectual property holders would not be granted carte blanche immunity, but under exceptional circumstances, may be compelled to license their intellectual property.[238]

As will become evident from the discussion in Chapter 7, various courts in the EU and the US have taken different approaches to determining the issue of refusals to license. While some have adopted the first approach, others have advocated the limited intrusion of competition law into the right of an intellectual property holder to refuse to license.[239] This has invariably led to controversy.

---

[238] These approaches are usefully summarised in Sergio Baches Opi, 'The Application of the Essential Facilities Doctrine to Intellectual Property Licensing in the European Union and the United States: Are Intellectual Property Rights Still Sacrosanct?' (2001) 11 *Fordham Intellectual Property, Media and Entertainment Law Journal* 409, 443-451.

[239] The first approach has, as its genesis, Chicago school economics while the second is predicated on mainstream economics. As discussed above, 1.8, US antitrust administration is entering a post-Chicago phase, with a return to mainstream theory evident in many facets of their operation; see, for example James Kobak Jr, 'Intellectual Property, Competition Law and Hidden Choices Between Original and Sequential Innovation' (1998) 3 *Virginia Journal of Law and Technology*, 6, 19-22.

The views of commentators mirror these approaches.[240] Gallini and Trebilcock, for example, support the second approach. They support the general right of a patent holder to exclusively exploit that patent and refuse to license others because this right is consistent with patent law and the second principle of the framework outlined above.[241] At the same time, they acknowledge there could be circumstances where it is desirable to compel licensing.[242]

Despite these criticisms, it will be argued in the following chapters that the right of a patentee to refuse to license a patent should not be unfettered, and that a patent holder should be subject to competition law for a refusal to license. Despite the difficulties in determining the exact bounds of a patent holder's right to refuse to license, it is submitted that the antitrust-immunity approach is overly simplistic and ignores the negative effects refusals to license may sometimes have on diffusion of technology. These considerations are particularly pertinent in medical biotechnology where most refusals to license are likely to occur in the context of a vertical relationship where access to potentially non-rivalrous technology is sought.

As foreshadowed during the course of this chapter, it is submitted that a refusal to license a patent should be subject to the reach of competition law. There is some doubt as to whether an exemption for any form of intellectual property dealing from competition law necessarily promotes efficiency, but the focus of this thesis is on refusals to license. Therefore, it is submitted that it is entirely appropriate that refusals to license be subject to the misuse of market power provisions in each of the jurisdictions discussed.

A strong basis for this assertion is that refusals to license intellectual property have never been exempt from s 46 of the *TPA*. Despite this, there is limited empirical evidence to date of refusals to license in medical biotechnology, an industry in which it would be expected that refusals to license might be an issue for downstream researchers and companies. Further, there have been no litigated refusals to license, which may be indicative that refusals to license are not unduly hindering research. Of course, it may also indicate perceived deficiencies with s 46, an issue that will be explored further in Chapters 6 and 8.[243]

---

[240] Relevant viewpoints will be discussed in Chapters 7 and 8.

[241] Gallini and Trebilcock, above n184, 41.

[242] Ibid, 42.

[243] Particularly relevant is the fact that there have been a number of cases litigated in both the US and the EU. It is difficult to say why this may be the case, but it may be due to lower rates of litigation generally in Australia. It may also be due to the fact that considerably more upstream research has

At the same time, it is recognised that there will be few instances in practice where a refusal to license intellectual property contravenes competition law. This is because in most cases, a legitimate business justification[244] will operate to exonerate the conduct.[245] It will be argued in Chapter 8, however, that there may be some circumstances where it is difficult to establish that a refusal to license is predicated on efficiency grounds. This will particularly be the case where the holder of a legislated privilege seeks to expand the scope of the privilege, or extend it into a discrete market not covered by the privilege.

Accordingly, the following framework should guide policy makers and courts, and will form the basis for argument in subsequent chapters of this thesis:

[1]	Generally speaking, a refusal to license intellectual property will not contravene competition law.
[2]	A refusal to license will, however, become examinable under competition law where the refusal is for the purpose of (i) expanding the scope of the intellectual property or (ii) extending market power into another distinct market not covered by the intellectual property.[246]
[3]	Where a refusal becomes examinable under [2](ii), the refusal should be examinable whether or not the holder of the intellectual property is currently exploiting the separate market,[247] and the reservation of another market for its own (actual or potential) use should not necessarily allow it to foreclose competition by others.

Because of its focus on downstream innovation, this framework is particularly relevant to a cumulative industry such as medical biotechnology, where there is

---

traditionally been conducted in Australia, as is exemplified by an industry such as medical biotechnology. These issues will be examined in more detail below; see especially 8.1.

[244] See further below, 6.4.1, 8.3.

[245] In addition, the additional elements of each of the misuse of market power provisions must also be established.

[246] See also Adams and McLennan, above n9, 16-17. Abraham I van Melle, 'Refusals to License Intellectual Property Rights: The Impact of *RTE v EC Commission* (*Magill*) on Australian and New Zealand Competition Law' (1997) 25 *Australian Business Law Review* 4, 14-16.

[247] Cf Tucker, above n188, 86.

potential for follow-on research to be impeded.[248] The third limb of the framework is proposed precisely because many upstream biotechnology patents may be useful for a number of downstream uses, some of which may indirectly compete. The framework is, however, generalisable to dealings in other forms of intellectual property.[249] At the same time, it is recognised that patent protection has special characteristics that mean that refusals to license patents may have greater anti-competitive implications.[250] Copyright protection provides a case in point.[251] *First*, the statutory requirements for obtaining patent protection are higher and unlike copyright protection, patent protection will only be granted after a process of examination. *Secondly*, a patent monopoly grants a more complete monopoly than copyright protection, and unlike copyright protection, precludes independent invention.[252] In high-technology industries this may operate to limit researchers operating in a particular field. Following from this, it may be more difficult to substitute a patented invention than to substitute a copyrighted work.[253]

Use of the framework can also be tailored to take into account characteristics peculiar to specific industries. It is submitted that competition law is well equipped to focus on inter-industry differences, given that it evolves largely on the basis of case law.[254] Policy forms an integral part of competition law jurisprudence.[255] Recent

---

[248] Indeed, the primary concern in medical biotechnology is likely to be the situation where a patent holder seeks to prevent research in a downstream market.

[249] Of course, there are important differences between the various forms of intellectual property, and the anti-competitive implications of refusals to license patents may be greater than refusals to license other forms of intellectual property. See further below,

[250] See also van Melle, above n246, 25-27.

[251] Many of the comparative cases that will be discussed in Chapter 7 involved copyrighted works. In contrast, few have involved patented inventions. The applicability of principles from these cases to refusals to license patents will be discussed further below, 7.2.4, 7.3.4.

[252] This is despite the fact that the period of patent protection at 20 years is shorter than the period of copyright protection at 70.

[253] See, eg, Robert J Hoerner, 'The Antitrust Significance of a Patent's Exclusionary Power' (1992) 60 *Antitrust Law Journal* 867.

[254] As stated in respect of US antitrust law in the FTC Report, '[t]hat antitrust law develops largely through case law gives it the flexibility to incorporate the goals of patent law into the antitrust analysis of conduct with respect to patents' FTC Report, above n106, ch 6, 1. A similar claim can be made in relation to Australian competition law.

[255] Burk and Lemley make a related argument in relation to patent law, arguing that the use by courts of 'policy levers' that tailor the application of a uniform patent system to particular industries in order to take account of industry-specific or invention-related variations, is desirable; Dan L Burk and Mark A Lemley, 'Policy Levers in Patent Law' (2003) 89 *Virginia Law Review* 1575. The application of policy levers in different industries has resulted in the development of some industry specific rules in industries such as pharmaceuticals, biotechnology and software; at 1675-1695. Burk and Lemley assert that the setting of rigid or 'bright-line' rules by the legislature in areas where levels of innovation are at stake, is inappropriate; Ibid. They acknowledge that this argument may be contentious. There is debate

jurisprudence in relation to s 46 of the *TPA*, for example, has been characterised by the adoption of increasingly restrictive interpretations of the elements of s 46. A distinct policy basis for decision-making would be preferable to ad hoc decision making.[256] The adoption of flexibility in the application of s 46 combined with the proposed framework would ensure that Australian competition law regulators and courts have at their disposal appropriate tools for the regulation of refusals to license intellectual property.

It should be emphasised, therefore, that rigid adherence to the above framework is not proposed. Because it has been argued that refusals to license be dealt with on a case-by-case basis, the framework should be applied with a degree of flexibility. Refusals to license patents (and indeed other forms of intellectual property) may be predicated on a number of grounds, and it is difficult to decree a definitive test that takes account of all circumstances.[257] The framework is therefore proposed on the grounds that it provides an adaptable guide for regulators and courts in assessing when a refusal to license should receive more detailed consideration.

In the Australian context, the proposed framework would be in line with the law relating to refusals to supply tangible property.[258] It is partly a reflection of the position taken by the former TPC in their Background Paper on Misuse of Market Power,[259] that s 46 may be infringed where '... a corporation with a substantial degree of market power seeks to obtain an advantage greater than that conferred by the relevant statute or seeks to extend the monopoly conferred by the relevant statute into markets other than those protected by the statute.' The logical implication from this is

---

in the economics literature over the advisability of setting bright-line rules as opposed to allowing judges to apply flexible standards, and scholarly argument in favour of judicial minimalism over judicial precedent incorporating policy choices; at 1668-1670 and the references cited therein. Nevertheless, they contend that informed policy making in the area of patent law is preferable to forced adherence to strict rules; at 1670.

[256] See further below, 6.3, 6.4.

[257] See generally Carrier, above n49.

[258] See also Van Melle, above n246, 16. In this respect, Corones submits that on the basis of a seminal Australian refusal to deal case, *Queensland Wire Industries Pty Ltd v The Broken Hill Proprietary Company Ltd* (1989) 167 CLR 177, 'Just as BHP was condemned for extending its market power from one market to another, an owner of intellectual property rights is likely to be condemned for seeking to extend its monopoly into markets other than those covered by the relevant statute granting those rights', Stephen G Corones, 'Reconciling Intellectual Property Rights and Competition Law: The *Magill* TV Guide Case' (1992) *Australian Business Law Review* 265, 269. As will become apparent from the discussion in the following chapters, however, based on recent judicial determinations on s 46, this is by no means 'likely'.

[259] Trade Practices Commission (1990) *Misuse of Market Power*, Background Paper, 35.

that there should be some mechanism for ensuring that competition in downstream markets is not adversely affected by upstream intellectual property.

To some extent, this framework applies an approach that considers the scope of the patent grant. Carrier has criticised[260] the application of rules that apply a 'scope of the grant' approach, or that focus on whether intellectual property affects multiple markets.[261] In relation to the scope of the grant approach, Carrier points out that the primary criticism of this approach is its elevation of patent law over competition law. Further, it fails to account for inter-industry differences, and results in difficult questions regarding patent scope.[262] In relation to tests that question whether a separate market is affected by the conduct of the holder of an intellectual property privilege, Carrier alleges there are difficulties. These relate to problems in defining markets, and in accounting for differences between markets.[263]

It is submitted that the flexibility inherent in the framework proposed would overcome many of these difficulties. Application of the framework is intended to be flexible, on the basis that refusals to license are dealt with on an individual basis. In this respect, many of the issues that Carrier raises could be addressed. It would leave the way open for courts to apply competition law over patent law if appropriate. It would also allow courts to tailor decisions to account for variations in industry characteristics, and to consider whether the application of competition law would be likely to enhance welfare through increased innovation.[264] Although the framework makes reference to the scope of the grant test, it is not solely dictated by it and leaves sufficient room for conduct to be found to be anti-competitive in other circumstances.[265] Further, as a matter of practical reality, there are likely to be very

---

[260] In an attempt to overcome difficulties inherent in current approaches to determining when a licensing restriction will be anti-competitive, Carrier proposes a test that focuses on innovation, inter-industry characteristics and behaviour. It applies a series of presumptions and rebuttals; see generally Carrier, above n49. Carrier acknowledges that the test may be criticised on the basis that it is difficult to apply, and contends that economic studies on the role of innovation within particular industries should assist courts in applying the test; Ibid, 841-844. This may be open to question on the grounds that these studies have offered inconclusive evidence; see above, 2.2.2.1.

[261] In this sense, Carrier is referring to tests that challenge activity in a market outside that contemplated by the intellectual property; ibid 791. Note that Carrier's test applies to licensing restrictions generally, and not simply to refusals to license.

[262] Ibid, 788-791.

[263] Ibid, 791-793.

[264] Courts in the EU, for example, have already indicated a willingness to take into account the characteristics of particular forms of intellectual property under consideration; see further below, 7.3.1.

[265] Indeed, it will be argued that there are few circumstances where a refusal to license a patent in a primary medical biotechnology market is anti-competitive. The only scenario might be where a patent holder obtains and uses a patent for defensive purposes. In refusing to license an innovator in a

few instances where a refusal to license a patent in an upstream market inhibits innovation,[266] and few matters that fall within this category are litigated. Defining markets is often an arduous undertaking, and this is unlikely to be resolved by avoiding the question of whether innovation in a downstream market is affected.

5.6 CONCLUSION

Section 51(3) of the *TPA* exempts certain restrictive conditions in intellectual property licence agreements from a number of the provisions in Part IV condemning anti-competitive conduct. This exemption is somewhat unique, in that it differs from the treatment of restrictive conditions in the other jurisdictions discussed, the US and EU. It is also limited in its scope in that it does not apply to certain Part IV provisions, notably s 46, and it does not (and will not as a result of amendment) encompass refusals to license intellectual property.

There are fundamental questions as to whether any exemption from competition law for intellectual property is warranted, and answers to these questions were sought by the Hilmer Committee but remain unanswered by subsequent reviews addressing the issue. The lack of exemption in other jurisdictions, especially the US, raises doubts as to whether removal of the exemption would dramatically impact on levels of innovation within Australia. Certainly the failure to provide an exemption in respect of refusals to license patents would not appear to have resulted in high levels of litigation or to have had an overly detrimental impact on investment in innovation or levels of innovative activity in medical biotechnology. Indeed, the industry has taken on a similar structure in each of the jurisdictions discussed in this thesis.

It is appropriate, therefore, that refusals to license continue to be subject to the rules governing anti-competitive conduct, and be assessed on an individual basis. There is, however, scope for clarifying the treatment to be given to refusals to licence and the circumstances most likely to give rise to anti-competitive concerns. The framework outlined in this chapter aims to provide some clarification of these circumstances. It is not an attempt to provide a precise indicator of when a refusal to license will contravene s 46, but it does provide a flexible guide as to when a refusal to license should receive further consideration as a possible misuse of market power.

---

downstream market, a patent holder may seek to expand the scope of a patent privilege; see further below, 8.3.3, 8.3.4.

[266] See further below, 8.3.2, 8.3.3.

CHAPTER 6

ATTACKING A REFUSAL TO LICENSE: SECTION 46(1) OF THE TRADE PRACTICES ACT 1974 (CTH)

6.1 INTRODUCTION

If patent law has deficiencies in fulfilling its role of promoting innovation, there is a question as to what the role of competition law is in filling that gap. Chapter 5 presented a framework designed to assist policy makers, regulators and courts in determining when a unilateral and unconditional refusal to license is likely to be anti-competitive. Section 46 is the provision most likely to be invoked where it is alleged a unilateral refusal to license a patent is predicated on anti-competitive grounds. Section 46 is one of the shortest, most cryptic sections contained in Part IV of the *Trade Practices Act* 1974 (Cth) (the *TPA*). Its elements have been interpreted extensively but restrictively in a number of recent Australian High Court decisions.

This chapter will consider s 46(1) of the *TPA*. The policy objectives and elements of s 46 will be explained, and High Court jurisprudence and government responses to that jurisprudence will be analysed in detail. This analysis will demonstrate that particular elements of s 46 have been narrowly interpreted. A very literal approach to analysis of s 46 has been taken, with the result that s 46 is likely to apply in very limited circumstances, most likely where a corporation is monopolistic or near-monopolistic and has engaged in clearly predatory behaviour. This chapter does not attempt to apply s 46 to refusals to license patents. That task is undertaken in Chapter 8. Given the complexities of recent High Court elucidations of s 46, this Chapter analyses the manner in which the elements of s 46 have been interpreted for the purposes of discussion in Chapter 8 on how s 46 is likely to apply to refusals to license in medical biotechnology.

Section 46(1) of the *TPA* contains a prohibition against the misuse of market power by corporations with a substantial degree of power in a market. The section provides as follows:

> A corporation that has a substantial degree of power in a market shall not take advantage of that power for the purpose of –
>
> (a) eliminating or substantially damaging a competitor of the corporation or of a body corporate that is related to the corporation in that or any other market;
>
> (b) preventing the entry of a person into that or any other market; or
>
> (c) deterring or preventing a person from engaging in competitive conduct in that or any other market.

Exclusionary conduct by a corporation with substantial market power will only be caught by s 46(1) where that market power leads to the exclusionary conduct.[1] A corporation may possess market power, and utilise economic efficiencies harming competitors in the process. This conduct will not be penalised under s 46(1) unless all of the elements of that section are established. The elements that must be proved in order to establish a contravention of s 46(1) are:

- a corporation must possess substantial market power;
- it must take advantage of that market power; and
- the taking advantage of market power must be engaged in for one of the proscribed anti-competitive purposes referred to in s 46(1).

As will become evident, the courts have laid down stringent requirements in relation to the section and have established a high threshold for satisfaction of the elements of s 46. Before considering in detail the elements of s 46(1), the policy objectives behind s 46(1) will be briefly discussed. These policy objectives are reflected in the approaches that have been taken by various courts in analysing the elements of s 46, and account to some degree for divergences in opinions as to how s 46 should be construed. Critically, the policy objectives will reflect in the approaches likely to be taken in determining the balance between intellectual property and competition law.

6.2 Policy Objectives Behind Section 46(1)[2]

The policy objective behind the *TPA* generally is to enhance public welfare by prohibiting anti-competitive conduct.[3] In addition to the somewhat ambiguous wording of s 2, the focus in the purpose provisions on the protection of individual competitors has given rise to some confusion as to the policy objectives of s 46.[4]

---

[1] Conduct will not be caught where it results in a corporation that did not possess market power, attaining that market power. In other words, a crucial element of s 46(1) is that the corporation possess market power at the time the conduct alleged to breach s 46(1) is engaged in; *Boral Besser Masonry Limited (now Boral Masonry Ltd) v Australian Competition & Consumer Commission* (2003) 195 ALR 609. See also Geoff Edwards, 'The Hole in the Section 46 Net: The *Boral* Case, Recoupment Analysis, the Problem of Predation and What to do About it' (2003) 31 *Australian Business Law Review* 151.

[2] A comprehensive discussion of the issues inherent in discerning the policy objectives of s 46 is contained in Stephen Corones, 'Section 46 of the *Trade Practices Act*: *Boral*, the Dawson Committee and the Protection of Small Business' (2003) 31 *Australian Business Law Review* 210.

[3] See s 2, *TPA*. The objects and policy objectives of the *TPA* are discussed further, above 5.2.1.

[4] Stephen Corones, 'The Characterisation of Conduct under Section 46 of the Trade Practices Act' (2002) 30 *Australian Business Law Review* 409, 410-411; Warren Pengilley, 'Misuse of Market Power in Australia: Are the Tests Now Those of Fairness, Efficiency or Business Justification?' (2001) 8 *Canterbury Law Review* 70. In relation to the purpose provisions, see further below, 6.5.

Section 46 itself contains no explicit statement of the policy behind the section.[5] Accordingly, there has been some debate over whether the section is intended to protect small business, or the interests of consumers and the competitive process.[6]

Although the view that s 46 operates to protect individual (usually small and medium-sized) competitors has gained some limited judicial support,[7] recent High Court jurisprudence has firmly established that the primary policy objective of s 46 is that of protecting consumers through the promotion of a competitive environment and the advancement of economic efficiency.[8] Arguably the purpose provisions can be reconciled with this aim of s 46 if the view is taken that consumer welfare is maximised through a competitive market which results in goods and services being provided to consumers as cheaply and efficiently as possible.[9] This assists in explaining the composition of the purpose provisions, in that these provisions are aimed at promoting a *competitive environment* in a market for goods and services.

Arguably, however, this interpretation of s 46 places its focus outside the sphere of conduct it was intended to regulate. Concern has been expressed that s 46 fails to give any protection to small and medium-sized entities who are subjected to the market power of large, powerful corporations.[10] This will have implications where a small company alleges that a refusal to license a patent by a large, vertically-integrated

---

[5] At the time the amended s 46 was inserted into the Trade Practices Act, the Attorney-General stated in the Second Reading Speech that '... an effective provision controlling misuse of market power is most important to ensure that small business are given a measure of protection from the predatory actions of powerful competitors.'; *House of Representatives Debates*, Trade Practices Revision Bill, 19 March 1986 (Cth), 1626.

[6] See, eg, Corones, The Characterisation of Conduct, above n4, 410-411; Corones, Protection of Small Business, above n2; Frank Zumbo, 'The *Boral* Case: Has the High Court Done Justice to s 46?' (2003) 11 *Trade Practices Law Journal* 199.

[7] Corones, Protection of Small Business, above n2, 211-215 provides a discussion of these decisions. See especially, *Pont Data Australia Pty Ltd v ASX Operations Pty Ltd* (1990) 21 FCR 385 upheld on appeal, *ASX Operations Pty Ltd v Pont Data Australia Pty Ltd* (1991) 27 FCR 460; *Taprobane Tours v Singapore Airlines Ltd* (1990) 96 ALR 405; *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 37-38 (Kirby J in dissent); *Australian Competition and Consumer Commission v Boral Ltd* (2001) 106 FCR 328, 390 (Merkel J); *Rural Press Ltd v ACCC* (2003) 78 ALJR 274, 296 (Kirby J in dissent).

[8] *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 191 (Mason CJ and Wilson J), 194 (Deane J); *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 13 (Gleeson CJ, Gummow, Hayne and Callinan JJ); *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 625 (Gleeson CJ and Callinan J), 640 (Gaudron, Gummow and Hayne JJ). Corones suggests that while the second view of s 46 is now firmly entrenched, there is still some support for the first view, with the result that the matter cannot be considered to be finally settled; Corones, Protection of Small Business, above n2, 226.

[9] Brenda Marshall, 'The Relevance of a Legitimate Business Rationale Under Section 46 of the *Trade Practices Act*' (2003) 8 *Deakin Law Review* 49, 61.

[10] Zumbo, The *Boral* Case: Has the High Court Done Justice to s 46, above n6.

company is anti-competitive. The focus of courts in construing s 46 will be on whether there is some consequent impact on competition within the relevant market, not on protection of the company requesting a licence.

In addition, it has been argued that the lack of clearly stated policy objectives in s 46 leads to difficulty in characterising conduct as anti-competitive or legitimate.[11] Section 46 has undergone a number of reviews,[12] the most recent of these being the review conducted by the Trade Practices Review Committee (the Dawson Committee), which provided its report in early 2003,[13] and the report of the Senate Economics References Committee (the Senate Committee) released in early 2004.[14] Despite increasing concern regarding the efficacy of s 46 in protecting small businesses, the Dawson Committee endorsed the view of s 46 espoused in *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd (Queensland Wire)*,[15] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd (Melway)*[16] and *Australian Competition and Consumer Commission v Boral Ltd (Boral)*,[17] and recommended that s 46 remain in its current form without amendment.[18]

---

[11] Corones, The Characterisation of Conduct, above n4, 410-411.

[12] Note that few of these reviews have resulted in amendment to s 46. Indeed, the most recent changes to s 46 were those made in 1986 in the Trade Practices Revision Bill. These arose as a result of proposals contained in Commonwealth of Australia, *Trade Practices Act: Proposals for Change* (1984) which explored recommendations made by the Trade Practices Consultative Committee, *Small Business and the Trade Practices Act*, December 1979 (AGPS, Canberra 1979).

[13] Trade Practices Review Committee, *Review of the Competition Provisions of the Trade Practices Act* (January 2003) (The Dawson Committee Report). The Report is available at:

<http://www.tpareview.treasury.gov.au/content/report.asp> (at 15 July 2004).

[14] Senate Economics References Committee, Parliament of Australia, *The Effectiveness of the Trade Practices Act 1974 in Protecting Small Business*, (2004) (Senate Committee Report).

[15] *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177. *Queensland Wire* involved a refusal by BHP to supply 'Y-bar', a component of 'star picket' fence posts, to a competitor of BHP's subsidiary, which was supplied with the product. Queensland Wire was successful in the High Court.

[16] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1. *Melway* involved the termination of a distributorship arrangement by Melway, a publisher of street directories, and the appointment of another. A subsequent refusal to supply that distributor was justified by Melway on the basis of adherence to a long-standing distribution system. The High Court found that Melway did not contravene s 46.

[17] *Australian Competition and Consumer Commission v Boral Ltd* (2001) 106 FCR 328. *Boral* involved an allegation of predatory pricing in respect of concrete masonry products. Boral was successful before the High Court. The Report was released prior to the High Court's determination in *Boral*, and the Dawson Committee was asked to re-examine s 46 issues in light of this decision. The substance of the Dawson Committee Report remained unchanged as a result of these further deliberations.

[18] See Dawson Committee Report, above n13, Chapter Three.

Continuing concern as to the effectiveness of the *Trade Practices Act* in protecting small business prompted the inquiry by the Senate Committee and the subsequent release of the Senate Committee Report.[19] The Senate Committee Report highlighted the contrasting views within business, regulatory and academic circles as to the role of s 46 and its utility in fulfilling this role. Diverging conclusions were reached by the Senate Committee, comprised of Labor and Democrat senators on the one hand, and the Government Senators on the other.[20] For the most part, the Government accepted the recommendations of the Government Senators in advocating few substantive amendments to s 46.[21]

Thus, the focus of courts in interpreting s 46 is on the competitive process rather than the protection of individual competitors, although as recognised in the Senate Committee Report, competition requires competitors, and the retention of a certain number of competitors in a market is necessary in order to maintain competitiveness in a market.[22]

It is submitted that this policy aim of s 46 is the correct one – s 46 should be aimed at protecting the competitive process rather than promoting or entrenching the position of individual participants in a market.[23] But even if this is accepted, the standards that have been set in relation to each of the s 46 elements are prohibitive, and will mean the elements will be established in only a very few cases.[24] Indeed, s 46 has been successfully invoked only rarely. Difficulty in establishing the elements of s 46 is

---

[19] Senate Committee Report, above n14. The Senate Committee relied heavily on the submission of the ACCC in reaching and framing its recommendations; see Australian Competition and Consumer Commission, *Submission to the Senate Economics References Committee Inquiry into the Effectiveness of the Trade Practices Act 1974 in Protecting Small Business*, (2003).

[20] Government Senators, *Government Senators' Report* in Senate Economics References Committee, Parliament of Australia, *The Effectiveness of the Trade Practices Act 1974 in Protecting Small Business*, (2004), 81 (Government Senators' Report). Specific recommendations by the Senate Committee and Government Senators will be considered in the context of each element.

[21] Commonwealth of Australia, *Australian Government Response to the Senate Inquiry into the Effectiveness of the* Trade Practices Act *1974 in Protecting Small Business* (Government Response to Senate Committee Report). See also Lynden Griggs, 'Small Business and the Operation of the *Trade Practices Act* – Another Review, Another Election, and the Battle Lines Between Big and Small Business are Once Again Redrawn!' (2004) 11 *Competition and Consumer Law Journal* 348.

[22] Senate Committee Report, above n14, [1.18]-[1.26]. See also Government Senators' Report, above n20, 81-82.

[23] See also the interesting comments in Justice Robert Shenton French, 'Competition Law – Covering a Multitude of Sins' (2004) 12 *Competition and Consumer Law Journal* 125, 136-139.

[24] An empirical study of s 46 cases from the commencement of the *TPA* until 2003 discerned that of the 33 cases which have proceeded to final judgment in either the Federal Court or High Court, contraventions have been established in just four cases; Alexandra Merrett, 'The Court Speaks for Itself: What Australian Decisions Say About Assessing Market Power for the Purposes of s 46 of the TPA' (2004) 11 *Competition and Consumer Law Journal* 330, especially 221-332, Annexure 1.

likely to be exacerbated where an alleged misuse of market power involves the use of patents. Chapter 8 will demonstrate that a party alleging that a refusal to license a patent contravenes s 46 will have additional hurdles above those faced by general litigants alleging a breach of s 46. Accordingly, there must be some doubt as to whether s 46 fulfils its role of defending the competitive process.

The elements of s 46 will now be evaluated in turn. As this analysis will reveal, recent High Court jurisprudence has focused on the first two elements, that is, the substantial market power standard and the 'take advantage' test.

6.3 SUBSTANTIAL MARKET POWER

A corporation must possess a substantial degree of market power before s 46 will come into play. This test was introduced into s 46 by virtue of the *Trade Practices Revision Act* 1986 (Cth). These amendments significantly altered the composition of the misuse of market power provision in the *TPA*. Prior to the amendments, s 46 required that a corporation be in a position substantially to control a market, with the result that the section effectively applied only to monopolists or those with overwhelming dominance in a market.[25] The Attorney-General stated in his Second Reading Speech that:

> The amendments proposed ... are designed to make s 46 much more effective. The test for the application of the section is to be reduced from that of a corporation being in a position substantially to control a market to a test of whether a corporation has a substantial degree of market power. As well as monopolists, s 46 will now apply to major participants in an oligopolistic market and in some cases, to a leading firm in a less concentrated market.[26]

As will become apparent, this attempt to increase the effectiveness or reach of s 46 would appear to have met with limited success. The concept of substantial degree of market power will now be examined in greater detail.

---

[25] *House of Representatives Debates*, Trade Practices Revision Bill, 19 March 1986 (Cth), 1626, 1626. Recourse to extrinsic materials such as Explanatory Memoranda and Second Reading Speeches may be had by virtue of the *Acts Interpretation Act* 1901(Cth), section 15AB where a statutory provision is '... ambiguous or obscure', or where the ordinary meaning conveyed by provision '... leads to a result that is manifestly absurd or is unreasonable.'

[26] *House of Representatives Debates*, Trade Practices Revision Bill, 19 March 1986 (Cth), 1626, 1626.

6.3.1 THE SUBSTANTIAL MARKET POWER THRESHOLD

The threshold test in establishing a contravention of s 46 is market power. The High Court recently confirmed that the appropriate starting point in any analysis of s 46 liability is an assessment of market power. The Full Court of the Federal Court (the Full Court) in the recent cases of *Australian Competition and Consumer Commission v Boral Ltd*[27] (*Boral*) and *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd*[28] (*Melway*) proceeded directly from a finding of an exclusionary purpose, to a conclusion about taking advantage of market power.[29] For example, the Full Court in *Boral* viewed intent as being central to a finding of s 46 liability.[30]

The High Court majority in *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission*[31] (*Boral*) considered the Full Court to be in error in their primary focus on the purpose element. As Gleeson CJ and Callinan J commented:

> To a substantial extent, the reasoning of the Full Court appears to have been affected by an error of the same kind as was corrected by this Court in *Melway*. The Full Court began with the purpose of eliminating or damaging a competitor, and reasoned inferentially from that. The dangers involved in such a process have already been mentioned.[32]

The High Court majority in *Melway* had cautioned against such an approach, stating that '... there are cases in which it is dangerous to proceed too quickly from a finding about purpose to a conclusion about taking advantage. That is especially so when, in a context such as the present, the purpose as referred to in s 46 is relatively narrow.'[33] The High Court held that even if a finding about purpose has been made, it is

---

[27] *Australian Competition and Consumer Commission v Boral Ltd* (2001) 106 FCR 328.

[28] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (1999) ATPR 41-693.

[29] A similar approach was taken by Deane J in *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 197-198.

[30] See, eg, the judgment of Finkelstein J, *Australian Competition and Consumer Commission v Boral Ltd* (2001) 106 FCR 328, especially 397-398.

[31] *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609.

[32] *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 636 (Gleeson CJ and Callinan J). See also the judgments of Gaudron Gummow and Hayne JJ, 649 and McHugh J, 664.

[33] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 18 (Gleeson CJ, Gummow, Hayne and Callinan JJ).

necessary in every case to ask whether the conduct could have been engaged in, in a competitive market.[34]

An analysis that has purpose as its starting point may be flawed as conduct that may appear to be exclusionary may in fact be competitive. In this respect, anti-competitive exclusionary conduct and competitive rivalry that has the effect of enhancing economic efficiency and consumer welfare may be indistinguishable, highlighting the ambiguous nature of purpose.[35] As Gleeson CJ and Callinan J pointed out in *Boral*:[36]

> ...where the conduct alleged to contravene s 46 is competitive pricing, it is especially dangerous to proceed too quickly from a finding about purpose to a conclusion about taking advantage of market power. Indeed in such a case, a process of reasoning that commences with a finding of a purpose of eliminating or damaging a competitor, and then draws the inference that a firm with that objective must have, and be exercising, a substantial degree of power in a market, is likely to be flawed.

Thus, the preliminary inquiry where liability under s 46 is in issue is the possession of substantial market power, and an examination of market power must occur outside the context of the impugned behaviour.[37] This structural approach to market power analysis raises a temporal issue. If consideration of market power must take place before consideration of the impugned conduct, strategic conduct undertaken with the aim of creating the ability to engage in anti-competitive conduct cannot be considered in assessing market power.[38] Thus, in the case of an allegation of a refusal to license a patent, market power must be considered independently of that refusal to license. This would render it unlikely that a finding of market power would be made where a patent holder refuses to license to a company that would compete in the same market as the patent holder in the event that a licence were granted.

---

[34] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 48 (Gleeson CJ, Gummow, Hayne and Callinan JJ).

[35] Stephen G Corones, *Competition Law in Australia* (3rd ed, 2004) 344-345.

[36] *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 632 (Gleeson CJ and Callinan J). Although this comment was made in the context of predatory pricing, it is clear from the judgment of Gleeson CJ and Callinan J that it can be generalised.

[37] *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 634 (Gleeson CJ and Callinan J).

[38] Merrett, above n24, 341-342. See also Kirby J's dissenting judgment in *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 693-694.

6.3.2 WHAT IS A 'MARKET'?

In determining whether a corporation possesses substantial market power, the relevant market must be defined.[39] In doing so, a purposive approach will be adopted in that the purpose of the provision alleged to have been contravened will be borne in mind in determining the boundaries of the particular market in which the anti-competitive conduct is alleged to have taken place.[40] Focusing on a purposive approach will assist in correctly determining the appropriate functional market level, or whether the market in question comprises the upstream or downstream market segments, or some combination thereof.[41] Thus, there is no requirement in the legislation that markets be either narrowly or widely defined.[42] It also mirrors the approach taken in overseas jurisdictions, particularly the United States (US) and European Union (EU).[43] There are four requisite steps in a purposive analysis of market definition:[44]

> First: Start with a specification of the conduct claimed to be unlawful...
>
> Secondly: Study the precise terms governing breach, in light of the policy of the Act and remedy sought.
>
> Thirdly: Identify the firm(s) or division(s) of the firm(s) that undertake the conduct.

---

[39] Note however that defining a market and determining whether a defendant possesses substantial market power in that market are part of the same process and are separated to simplify and facilitate the market power analysis: defining the relevant market is a subsidiary inquiry to that of evaluating market power; see *Queensland Wire Industries Pty Ltd v Broken Hill Co Ltd* (1989) 167 CLR 177, 187-188 (Mason CJ and Wilson J).

[40] Neville R Norman and Philip L Williams, 'The Analysis of Market and Competition Under the *Trade Practices Act*: Towards the Resolution of Some Hitherto Unresolved Issues' (1983) 11 *Australian Business Law Review* 396, 400-401; Maureen Brunt, 'Market Definition Issues in Australian and New Zealand Trade Practices Litigation' (1990) 18 *Australian Business Law Review* 86. Indeed, market definition is, as Professor Brunt points out, a tool to facilitate further analysis; at 126-127. See also Geoff Edwards, 'From Super-League to the Super-Market? The Appropriate Emphasis in Market Definition' (1996) 4 *Competition and Consumer Law Journal* 220, 223; Lynden Griggs, 'A Teleological Approach to Market Definition – Has it Led to Single Product Market Definition?' (2002) 4 *University of Notre Dame Australia Law Review* 77, 78-79.

[41] Corones, *Competition Law in Australia*, above n35, 44-46; Griggs, A Teleological Approach, above n40, 81. But see generally the caution sounded in Rhonda L Smith and Jill E Walker, 'Australian Trade Practices and the Emerging Role of 'Commercial Reality' versus Substitution in Market Definition' (1997) 5 *Competition and Consumer Law Journal* 1, 3-4.

[42] As pointed out by Smith and Walker, above n41, 18.

[43] Griggs, A Teleological Approach, above n40, 78-79.

[44] See Brunt, above n40, 127.

Fourthly: Ascertain the effective market-place constraints upon the firm(s)' conduct through identifying the relevant market.

In other words, while substitutability retains an important role, commercial realism is infused into the process of market definition.[45]

The dangers of placing too heavy an emphasis on market definition have been stressed,[46] and some commentators have denounced the tendency in some judgments to employ an overly legalistic approach to market definition.[47] Ideally market definition should not occupy too much of a court's time, but should be treated as a contextual issue.[48]

6.3.2.1 *SUBSTITUTABILITY AND THE BOUNDARIES OF MARKETS*

'Market' is defined in s 4E of the *TPA* as:

> ... a market in Australia and, when used in relation to any goods or services, includes a market for those goods or services and other goods or services that are substitutable for, or otherwise competitive with, the first-mentioned goods or services.

This definition is based on the economic premises of demand and supply-side substitutability. A market will be defined to include products that are substitutable for the product in issue in a particular case. Substitutability is assessed using the SSNIP (small but significant and non-transitory increase in price) or price incentive test initially expounded in Australia in *Re Queensland Co-operative Milling Association Ltd v Defiance Holdings Ltd (Re QCMA)*,[49] which requires a consideration of the likely effect of an increase (generally five to 10 percent) in the price of the product in issue.[50] This assessment requires consideration of the likely effect of the price rise on

---

[45] Smith and Walker, above n41, especially 21.

[46] *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 187 (Mason CJ and Wilson J); Brunt, above n40, 126-7; Edwards, The Appropriate Emphasis in Market Definition, above n40, 157.

[47] See, eg, Robert Baxt, 'The Australian Concept of Market – How it Came to Be' in Megan Richardson and Philip Williams (eds), *The Law and the Market*, (1995) Federation Press, Sydney, 10, 27; Edwards, The Appropriate Emphasis in Market Definition, 221-222.

[48] Geoff A Edwards, 'Sub-Markets as Competition Law Markets: the Appropriate Approach to the Sub-market Concept in Market Definition' (1998) 6 *Competition and Consumer Law Journal* 156, 157.

[49] *Re Queensland Co-operative Milling Association Ltd v Defiance Holdings Ltd* (1976) 25 FLR 169, 190.

[50] The SSNIP test has been 'borrowed' from US jurisprudence, and has a number of limitations. Most notably, it is subject to the 'cellophane fallacy', which emerged after the United States decision of *United States v E I du Pont de Nemours & Co* 351 US 377 (1956). The cellophane fallacy refers to the difficulty in applying the SSNIP test in cases involving anti-competitive conduct other than mergers;

demand for substitutable products (the cross-elasticity of demand), as well as a consideration of the ability of the supplier of a product to produce alternative products using the same production facilities (the cross-elasticity of supply).[51] As the Trade Practices Tribunal stated in *Re Queensland Co-operative Milling Association Ltd v Defiance Holdings Ltd* (*Re QCMA*):[52]

> A market is the area of close competition between firms or, putting it a little differently, the field of rivalry between them... Within the bounds of a market there is substitution between one product and another, and between one source of supply and another, in response to changing prices. So a market is the field of actual and potential transactions between buyers and sellers amongst whom there can be strong substitution, at least in the long run, if given a sufficient price incentive... Whether such substitution is feasible or likely depends ultimately on customer attitudes, technology, distance and cost and price incentives.
>
> It is the possibilities of such substitution which sets the limits upon a firm's ability to 'give less and charge more'. Accordingly, in determining the outer boundaries of the market we ask a quite simple but fundamental question: If the firm were to 'give less and charge more' would there be, to put the matter colloquially, much of a reaction?

In practice, application of this test involves identification of the narrowest set of goods or services that are substitutable for the goods or services that are the subject of complaint.[53] Only close substitutes will be considered in examining the interchangeability (or cross-elasticity) of the product or service in issue with other

---

whereas it is appropriate in the case of mergers to measure the effect of a price rise on prevailing prices, in other cases of anti-competitive conduct, an accurate result requires measurement at competitive prices (which are likely to be lower) rather than prevailing prices; see, eg, John D Heydon, The Law Book Company Limited, *Trade Practices Law*, vol 1, [3.395]-[-+3.410]. Quantitative computation of hypothetical competitive prices is bound to be complicated by the cellophane fallacy; see, eg, Cento Veljanovski, 'The Economics of the Relevant Market in EC Competition Law' (1998) *International Review of Competition Law* 4, 8-9; Australian Competition and Consumer Commission, *Merger Guidelines* (Canberra 1999); Note that the SSNIP test is only applied in the United States in merger analysis. On the operation of the test in the US and its application in Australia, see Deidre L Hay, 'A Lesson from the US Hypothetical Monopolist about Market Definition Timeframes and Thresholds and the *QCMA* Test' (1998) 6 *Competition and Consumer Law Journal* 73.

[51] See *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 199 (Dawson J), 210 (Toohey J).

[52] *Re Queensland Co-operative Milling Association Ltd v Defiance Holdings Ltd* (1976) 25 FLR 169, 190. This passage was most recently approved by the High Court in *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 643 (Gleeson CJ and Callinan J). Gaudron, Gummow and Hayne JJ agreed with Gleeson CJ and Callinan J in relation to the issue of market definition, at 638.

[53] On evidence that may be relied upon in defining markets, see the detailed exposition in Caron Beaton-Wells, *Proof of Antitrust Markets in Australia* (2003).

products or services, and the fact that consumers will consider some products to be alternatives for others will not necessarily result in those products being substitutes in the sense that they constitute a single market.[54] In order to be a substitute, a product must be so closely related to another product that an alteration to the price of one product impacts on demand for (or supply of) the other. Substitutes should not be confused with complementary products.[55] The High Court majority in *Boral* recently confirmed the importance of employing a narrow approach to the question of substitutability.[56]

The relevance of the definition of market in s 4E to a 'market in Australia' should also be noted. As a result of this definition, the ACCC and relevant courts have jurisdiction to investigate contraventions of the *TPA* in Australia only.[57] There may be an issue, where licences are requested from overseas companies, as to whether a refusal to license occurs within the context of an Australian market. The remainder of this thesis will proceed on the basis that refusals to license a patent that are intended to be worked in Australia, will fall within the confines of the definition of market contained in the *TPA*.

6.3.2.2 *MARKET DIMENSIONS*

A market may have a number of dimensions. Substitutability is relevant in the context of determining the product bounds of a market, but it will also be applied in determining the geographical limits of a market, the functional dimension of a market,[58] and the time period over which substitution possibilities should be measured.

The primary consideration in the context of the geographical confines of a market will be the effect of an incentive price rise in one location, on a competitor in another location. If consumers can source substitutes from an alternative location, this will be

---

[54] *Arnotts Limited and Others v Trade Practices Commission* (1990) 24 FCR 313, 332.

[55] David K Round, 'Market Definition in Australian Antitrust: Time for a Changed Approach?' (1996) 9 *Corporate and Business Law Journal* 193, 221.

[56] *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 635 (Gleeson CJ and Callinan J), 638 (Gaudron, Gummow and Hayne JJ), 662-663 (McHugh J). The High Court accepted the judgment of the Full Federal Court on this point; see *Australian Competition and Consumer Commission v Boral Ltd* (2001) 106 FCR 328, 377 (Beaumont J), 408 (Finkelstein J).

[57] See Warren Pengilley, 'Patents and Trade Practices – Competition Policies in Conflict?' (1977) 5 *Australian Business Law Review* 172, 191-193, 201-202.

[58] Although its usefulness may be limited for identifying the functional dimensions of a market; see Smith and Walker, above n41, 20.

strong evidence these two locations comprise one market.[59] It is unlikely, however, that foreign imports will be included within a market, as Australian courts have been reluctant to define the scope of a market beyond Australia as a whole and in many cases the reach of a market will be defined on a considerably more conservative basis.[60]

It may also be necessary in a given case to determine the extent of a market on a functional level whereby various functional levels of an industry may constitute separate markets.[61] This may be particularly important in a cumulative industry such as the medical biotechnology industry where innovation occurs on a sequential basis, and trade in very upstream products with a number of potential applications occurs. Careful definition of the functional dimension of a market will be crucial in order to ensure that markets are not defined too broadly, thus distorting analysis of market power.

As detailed, the Trade Practices Tribunal in *Re QCMA* defined a market as '...the field of actual and potential transactions between buyers and sellers amongst whom there can be strong substitution, at least in the long run, if given a sufficient price incentive.'[62] This reference to 'the long run' connotes a temporal element in relation to the evaluation of substitution possibilities available to customers.[63] In other words, an assessment of the time required to redeploy existing capacity in response to a price incentive is an integral component of market definition.[64] Determination of a relevant time dimension will vary according to the particular facts of the case at hand.[65] Edwards suggests that:

---

[59] Although as Deane J observed in *Queensland Wire*, 'The outer limits (including geographic confines) of a particular market are likely to be blurred'; *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 196 (Deane J).

[60] See, eg, *Howard Smith Industries* (1991) ATPR (Com) 50-111.

[61] See, eg, *Davids Holdings Pty Ltd v A-G (Cth)* (1994) 49 FCR 211. See also Smith and Walker, above n41, 20-21.

[62] *Re Queensland Co-operative Milling Association Ltd v Defiance Holdings Ltd* (1976) 25 FLR 169, 190.

[63] *Re AGL Cooper Basin Natural Gas Supply Arrangements* (1997) ATPR 41-593, 44-210 quoting *Telecom Corporation of NZ Ltd v Commerce Commission* (1991) 3 NZ BLC 102 340, 102 363.

[64] Ibid.

[65] For example, a fairly long-term view of the market was taken in *Re AGL Cooper Basin Natural Gas Supply Arrangements* (1997) ATPR 41-593. In this case, the Trade Practices Tribunal acknowledged that there were 'three dated markets of interest: the market in 1986, the market today, and the market in "the future" ... perhaps ten or fifteen years hence'; at 44-210.

> The question of how long a period should be considered in market definition is a question how long a period of discretionary power we are willing to afford firms the ability to use. This is unlikely to be much more than a year, and may well be only a few months.[66]

In reality, temporal components of market definition are likely to vary with the facts of particular cases, and this aspect of market definition has been relatively unexplored by the Australian judiciary.[67] It may be, however, that longer time dimensions may be more appropriate in respect of innovative high technology industries where innovation is fast-paced,[68] or industries typified by long-tem contractual arrangements.[69] This will have implications for an industry such as medical biotechnology, where technological developments are proceeding at a rapid pace. Medical biotechnology is an industry in which long-term contractual arrangements are likely to be commonly encountered given the preponderance of patents over research products and processes.

6.3.2.3 *THE SUB-MARKET CONCEPT*

The sub-market concept has been recognised as being somewhat problematic in Australian trade practices law,[70] although the concept has not been dispensed with entirely. A sub-market is a smaller segment of a particular market.[71] While some have supported the use of sub-markets as an aid to analysing the functioning of a particular market,[72] others have cautioned against the use of sub-markets because sub-market analysis may displace analysis in respect of the market as a whole.[73] In reality, sub-

---

[66] Edwards, The Appropriate Emphasis in Market Definition, above n40, 235.

[67] Mitchell Landrigan, 'The Temporal Dimension of a Market: Illustrations from Case Law and the US Merger Guidelines' (1997) 5 *Trade Practices Law Journal* 242. See also Donald Robertson, 'Time and Risk: The Temporal Dimension of Competition Analysis and the Role of Long-term Contracts' (1998) 26 *Australian Business Law Review* 273, 296-297. Note, however, the relationship between the temporal dimension of market definition and the time period used for competition analysis; Rhonda L Smith and Rachel Trindade, 'It's Time: The Temporal Dimension of Competition Analysis' (2004) 12 *Competition and Consumer Law Journal* 142.

[68] Corones, *Competition Law in Australia*, above n35, 73. See also *Telecom Corporation of NZ Ltd v Commerce Commission* (1991) 3 NZ BLC 102 340, 102 365 - 102 366.

[69] Robertson, above n67, 288.

[70] In US antitrust law, a sub-market has been recognised as being an area of a product market that is capable of attracting liability independently of that market; see *Brown Shoe Co v US* (1962) 370 US 294, especially 325-6.

[71] *Re Queensland Co-operative Milling Association Ltd v Defiance Holdings Ltd* (1976) 25 FLR 169, 190-191; Brunt, above n40, 119.

[72] See, eg, Brunt, above n40, 117-119; Norman and Williams, above n40, 404-405; *Singapore Airlines Limited v Taprobane Tours WA Ltd* (1991) 33 FCR 158, 181 (French J).

[73] See, eg, Edwards, Sub-Markets as Competition Law Markets, above n48; Mitchell G Landrigan, 'The Delineation of Sub-Markets Under *TPA* Part IV' (1997) 5 *Competition and Consumer Law*

markets are likely to play a subsidiary role in market definition, and may be useful in '...pointing to a particular characteristic, a structural dimension, of the market, i.e. how the market works, once the market has been defined'.[74]

6.3.2.4 *SINGLE PRODUCT MARKETS*

It follows from a purposive approach to market definition that in some instances a single product or product brand may constitute a separate market.[75] Because market definition is necessary only to the extent that it contextualises the issues at the heart of the section at issue, whether or not a narrow or wide, or short-run or long-run market definition is relevant will vary with the circumstances of each case. Narrow market definition is not uncommon, and judgments that have insisted that s 4E requires consideration of the widest possible range of substitution possibilities regardless of the facts of the case at hand,[76] are potentially flawed.[77]

Accordingly, courts have been willing to find that a single product is capable of constituting a market in a number of cases.[78] The key issue will be that of

---

Journal 58, especially 70-71. Note that Edwards argues that if a sub-market can be identified, that sub-market should be identified as the relevant market, and the sub-market concept dispensed with. On the other hand, Landrigan argues that sub-market analysis may be useful, but that the Tribunal and courts should start from the basic proposition that a firm cannot exercise market power in a sub-market because a sub-market constitutes an area of intense competition. See also *ACCC v Universal Music Australia Pty Ltd* (2001) 115 FCR 442, 521 (Hill J). In this case Universal Music Australia Pty Ltd (Universal) and Warner Music Australia Pty Ltd (Warner) supplied compact discs in the Australian wholesale market, and each held a one-sixth share of the market. Retailers began to import copies of compact discs into Australia upon removal of parallel importation restrictions from the *Copyright Act* 1968 (Cth). Universal and Warner threatened to remove trading benefits and ceased trading with some retailers as a result. Both Universal and Warner were successful before the Full Court on the basis that they did not possess substantial market power; *Universal Music Australia Pty Ltd and Others v ACCC* (2003) 131 FCR 529.

[74] *ACCC v Universal Music Australia Pty Ltd* (2001) 115 FCR 442, 521 (Hill J). For an analysis of the cases in which sub-market analysis has been employed, see Landrigan, The Delineation of Sub-Markets; above n73; Baxt, above n47.

[75] Griggs, A Teleological Approach, above n40, 94-96; Edwards, Sub-markets as Competition Law Markets, above n48, 160-163.

[76] See, eg, *News Ltd v Australian Rugby League Pty Ltd* (1996) ATPR 41-466.

[77] See, eg, Griggs, A Teleological Approach, above n40, 77-84; Edwards, The Appropriate Emphasis in Market Definition, above n40, 226-230. Section 4E was inserted into the *TPA* in order to remedy the situation in *Top Performance Motors Pty Ltd v Ira Berk (Qld) Pty Ltd* (1975) ATPR 40-004, in which the market was confined to one make of car. There is nothing in the words of the section or in the report of the Swanson Committee which recommended the change, to support any particular view on market definition; see Trade Practices Review Committee (1976) *Report to the Minister for Business and Consumer Affairs*, [5.19-5.22].

[78] See, eg, *Mark Lyons Pty Ltd v Bursill Sportsgear Pty Ltd* (1987) ATPR 40-089; *Regents Pty Ltd v Subaru (Aust) Pty Ltd* (1998) 84 FCR 218 (*Regents Case*), 228 (RD Nicholson J). Corones points out that the facts of *Regents Case* would appear to contradict RD Nicholson J's assertion that in

substitutability.[79] It is submitted that the possibility of a single product being defined as a separate competition law market should not be discounted,[80] although the circumstances in which a single product will be a market in itself are likely to be limited.[81] Where, however, it is difficult to duplicate a particular product, that product may constitute a monopoly and should rightfully be defined as a market in itself. The same might apply for medical biotechnology products that are difficult to invent around, and are key to development in a research area.

6.3.2.5 *DOWNSTREAM OR SECONDARY MARKETS*

The Senate Committee noted in their Report that it seems unlikely as a result of the recent High Court decision in *Rural Press Ltd v Australian Competition and Consumer Commission (Rural Press)*[82] that a finding of market power in one market can lead to a finding that that market power has been taken advantage of in another market.[83] The Senate Committee considered that leveraging market power should be caught by s 46, and recommended legislative clarification of this matter.[84] This recommendation of the Senate Committee was endorsed by the Government Senators,[85] and the Government in its response to the Senate Committee Report.[86] This

appropriate circumstances, a market for an individual brand name product might exist, although these circumstances did not exist here; see Corones, *Competition Law in Australia*, above n35, 60-61.

[79] *Mark Lyons Pty Ltd v Bursill Sportsgear Pty Ltd* (1987) ATPR 40-089, 48,797, (Wilcox J).

[80] See Edwards, Sub-markets as Competition Law Markets, above n48, 160-163. Cf Baxt, above n47, 10.

[81] For commentary on the holding of Hill J at first instance in *ACCC v Universal Music Australia Pty Ltd* (2001) 115 FCR 442 that individual compact disc title were capable of constituting 'temporary monopolies', see Stephen G Corones, 'Temporary Monopolies and s 46 of the *Trade Practices Act*' (2002) 30 *ABLR* 246.

[82] *Rural Press Ltd v ACCC* (2003) 78 ALJR 274, 284 (Gummow, Hayne and Heydon JJ). The case involved a threat by Rural Press, a local newspaper publisher, against a rival publisher that began circulating in the area in which Rural Press circulated. Rural Press essentially threatened to establish a rival business in the other publisher's traditional circulation area unless it withdrew from the circulation area of Rural Press. Rural Press was successful in the High Court.

[83] Prior to the High Court's decision in *Rural Press*, it was generally understood as a result of the Federal Court's decision in *Victorian Egg Marketing Board v Parkwood Eggs Pty Ltd* (1978) ATPR 17 789 (*Parkwood Eggs*), that leveraging market power from one market into a second market would be caught by s 46. The Full Federal Court in *Rural Press* distinguished *Parkwood Eggs* (and declined to follow it in any case given that it was an interlocutory decision), holding that market power must be found to have been taken advantage of in the market in which substantial market power exists. The High Court observed these comments but failed to provide any further clarification of them; *Rural Press v ACCC* (2002) 118 FCR 236, 278.

[84] Senate Committee Report, above n14, Recommendation 5. This recommendation reads: 'The Committee recommends that s 46 be amended to state that a corporation which has a substantial degree of power in a market shall not take advantage of that power, *in that or any other market*, for any proscribed purpose in relation to that or any other market.'

[85] Government Senators' Report, above n20, 88

could have implications in cases of refusals to license intellectual property where innovation in a downstream or secondary market has the potential to be affected by market power in an upstream market.

It should also be noted that a market may exist where a product or service exists, even though there has been no trade to date in that product or service. As stated by Deane J in *Queensland Wire*:[87]

> [A] market can exist if there be the potential for close competition even though none in fact exists. A market will continue to exist even though dealings in it be temporarily dormant or suspended ... [and even if] there is no supplier of, nor trade in, ... goods at a given time – because for example, one party is unwilling to enter any transaction at the price or on the conditions set by the other.

The matter was most recently confirmed by the High Court in *NT Power Generation Pty Ltd v Power and Water Authority* (*NT Power*).[88] This has applicability to any case involving a refusal to supply, including a refusal to license a patent.[89]

6.3.3 The Concept of Market Power

It has been widely recognised that the concepts of competition and market power are heavily interrelated, and that there is an inverse relationship between the two.[90] The structural conditions of a market will be indicative of whether or not a corporation possesses market power, or whether competitive conditions prevail.[91] The Trade Practices Tribunal in *Re QCMA* highlighted the importance of considering structural indicators, in enunciating the following, seminal definition of competition:

> Competition expresses itself as rivalrous market behaviour ... In our view effective competition requires both that prices should be flexible, reflecting the forces of demand and supply, and that there should be independent rivalry in all dimensions of the price-product-service packages offered to consumers and customers.

---

[86] Government Response to the Senate Committee Report, above n21, 8.

[87] *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 196 (Deane J). See also Dawson J, 200 and Toohey J, 211-212.

[88] *NT Power Generation Pty Ltd v Power and Water Authority* (2004) 210 ALR 312, 341-342 (McHugh ACJ, Gummow, Callinan and Heydon JJ).

[89] See below, 8.2.1.2(b).

[90] Corones, *Competition Law in Australia*, above n35, 40. There is significant international literature dealing with this issue. Of most influence on Australian competition law has been Carl Kaysen and Donald F Turner, *Antitrust Policy* (1959).

[91] Kaysen and Turner, above n90, 73.

> Competition is a process rather than a situation. Nevertheless, whether firms compete is very much a matter of the structure of the markets in which they operate. The elements of market structure which we would stress as needing to be scanned in any case are these:
>
> (i) the number and size distribution of independent sellers, especially the degree of market concentration;
>
> (ii) the height of barriers to entry, that is the ease with which new firms may enter and secure a viable market;
>
> (iii) the extent to which the products of the industry are characterised by extreme product differentiation and sales promotion;
>
> (iv) the character of 'vertical relationships' with customers and with suppliers and the extent of vertical integration; and
>
> (v) the nature of any formal, stable and fundamental arrangements between firms which restrict their ability to function as independent entities.
>
> Of all these elements of market structure, no doubt the most important is (i), the condition of entry. For it is the ease with which firms may enter which establishes the possibilities of market concentration over time; and it is the threat of the entry of a new plant into a market which operates as the ultimate regulator of competitive conduct.[92]

Market power, on the other hand, is the antithesis of competition or the ability to '...raise prices and exclude entry.'[93] Market power may, however, be exhibited by practices unrelated to price and is therefore defined more broadly than simply the ability to raise prices in an unconstrained manner.[94] Accordingly,

---

[92] *Re Queensland Co-operative Milling Association Ltd v Defiance Holdings Ltd* (1976) 25 FLR 169, 188-189. These structural elements have been repeatedly applied by the courts in competition cases since *Re QCMA* in order to determine the level of competitiveness of a market; in relation to s 46, see, eg, *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177. The courts have adopted an essentially mainstream approach in relation to s 46, relying on a modified structure-conduct-performance approach; see the discussion in Corones, *Competition Law in Australia*, above n35, 32-34.

[93] *Re Queensland Co-operative Milling Association Ltd v Defiance Holdings Ltd* (1976) 25 FLR 169, 188.

[94] *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 200 (Dawson J); *Re Queensland Co-operative Milling Association Ltd v Defiance Holdings Ltd* (1976) 25 FLR 169, 188-189.

> A firm possesses market power when it can behave persistently in a manner different from the behaviour that a competitive market would enforce on a firm facing otherwise similar cost and demand conditions.[95]

Any constraints on market power inherent in the structure of the market must be considered in order to determine whether a corporation's actions are subject to these constraints. If they are, the market will generally be considered to be competitive. If the corporation is able to act in an unconstrained manner, it may be that the market power element contained in s 46(1) will be satisfied. This notion of market power is reflected in s 46(3);[96] in determining degree of market power, s 46(3) requires that regard be had to the extent to which the conduct of the corporation is constrained by the conduct of competitors or potential competitors, suppliers or customers within the market:

> In determining for the purposes of this section the degree of power that a body corporate or bodies corporate has or have in a market, the court shall have regard to the extent to which the conduct of the body corporate or of any of those bodies corporate in that market is constrained by the conduct of:
>
> (a) competitors, or potential competitors, of the body corporate or of any of those bodies corporate in that market; or
>
> (b) persons to whom or from whom the body corporate or any of those bodies corporate supplies or acquires goods or services in that market.

Thus, a number of matters may be relevant to the determination of market power including 'the number of competitors, their strength and size, the height of barriers to entry and the stability or volatility of demand ...'[97] As discussed in Chapter 1, barriers to entry are strong determinants of the level of competition within a market.[98] Indeed, barriers to entry have been identified under Australian competition law as being the

---

[95] Kaysen and Turner, above n90, quoted with approval in *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 200 (Dawson J). This passage has been quoted with approval in subsequent High Court decisions; see *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 21 (Gleeson CJ, Gummow, Hayne and Callinan JJ) and *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 664 (McHugh J).

[96] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 21 (Gleeson CJ, Gummow, Hayne and Callinan JJ).

[97] *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 643, (Gaudron, Gummow and Hayne JJ). See also above, 1.8.

[98] See the discussion on barriers to entry and their relevance to market structure and market power above, 1.8.1.

key indicator of market power and the presence or absence of competitive conditions.[99] A corporation may have a large market share, but this will not preclude entry by potential competitors in the absence of barriers to entry as Mason CJ and Wilson J observed in *Queensland Wire*:

> A large market share may well be evidence of market power ... but the ease with which competitors may enter the market must also be considered. It is only when for some reason it is not rational or possible for new entrants to participate in the market that a firm can have market power. There must be barriers to entry. ... Barriers to entry may be legal barriers – patent rights, exclusive government licences and tariffs for example. Barriers to entry may also be a result of large "economies of scale". Where the economies of scale in a market are such that the minimum size for an efficient firm is very large relative to the size of the market, it may be that potential competitors will be dissuaded from entering the market by the apprehension that only one firm would survive.[100]

It has now been recognised in Australia, however, that barriers to entry may be 'structural', or they may be 'strategic' in that they stem from the practices and policies of incumbent market participants.[101] Both should be considered in evaluating market power,[102] and it is important to bear in mind that not all barriers to entry may be socially undesirable.[103] The need to obtain an intellectual property licence may

---

[99] *Re Queensland Co-operative Milling Association Ltd v Defiance Holdings Ltd* (1976) 25 FLR 169, 188-189; *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 189-190 (Mason CJ and Wilson J); *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 27 (Gleeson CJ, Gummow, Hayne and Callinan JJ); *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 635 (Gleeson CJ and Callinan J).

[100] *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 189-190 (Mason CJ and Wilson J). See also *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 635, (Gleeson CJ and Callinan J).

[101] *Australian Competition and Consumer Commission v Boral Ltd* (2001) 106 FCR 328 per Finkelstein J. See also *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 673 (McHugh J), 690 (Kirby J). See also the discussion on barriers to entry in Corones, *Competition Law in Australia*, above n35, 20-32, 98-104. The Organisation for Economic Cooperation and Development (OECD) has also adopted an expansive definition of barriers to entry in line with Bain's work, and has categorised barriers to entry as being either structural or innocent (or economic), or strategic (or behavioural); Organisation for Economic Co-operation and Development, *Glossary of Industrial Organisation Economics and Competition Law* (undated), 13; Joseph Bain, *Barriers to New Competition: Their Character and Consequences in Manufacturing Industries* (1965).

[102] Corones, *Competition Law in Australia*, above n35, 104; Mark L Burton, David L Kaserman and John L Mayo, 'Modeling Entry and Barriers to Entry: A Test of Alternative Specifications', (1999) *The Antitrust Law Bulletin* 387, 387-388.

[103] F Michael Scherer and David Ross, *Industrial Market Structure and Economic Performance*, (3rd ed) (Houghton Mifflin Company, Boston, 1990), 361, their n27.

constitute a structural barrier to entry,[104] but rewards for innovation are an example of a socially advantageous barrier to entry.[105] The manner in which an intellectual property right is exercised may in some circumstances constitute a strategic barrier to entry. Australian courts, and the Tribunal and Commission have generally taken an intuitive (as opposed to an analytical economic) approach to assessing the significance of barriers to entry,[106] and arguably any assessment of the implications of conduct that may operate to deter entry should be undertaken over a reasonable period of time,[107] in order to ensure that market power operates on a persistent or long-term basis.[108]

Australian courts have maintained a generally structuralist approach to analysing market power.[109] The test that results from High Court jurisprudence would appear to be a series of cumulatively applied economic analyses that focus on:

(1) the ability of a corporation to raise its prices above competitive levels;

(2) the ability of a corporation to act persistently in a manner unconstrained by competition in circumstances of workable competition; and

(3) consideration of whether it is rational or possible for new entrants to enter the market.[110]

In considering the issue of market power, a court will give considerable weight to evidence that points to ease or difficulty of entry, and assess this in light of other relevant factors.[111]

---

[104] Corones, *Competition Law in Australia*, above n35, 98.

[105] Scherer and Ross, above n103, 361, their n27.

[106] Hood points out that the method adopted is generally to consider 'evidence of actual successful or failed entry attempts.'; Antra Hood, 'Barriers and Impediments to Entry in Australian Health Care Markets After *Stirling Harbour*, *Boral* and *Melway*' (2002) 20 *Australian Business Law Review* 6, 12. See also Corones, *Competition Law in Australia*, above n35, 104-106.

[107] Corones, *Competition Law in Australia*, above n35, 104-106. Corones suggests consideration of attempts at entry over a period of at least five years.

[108] See also *Universal Music Australia Pty Ltd v ACCC* (2003) 131 FCR 529, 565.

[109] Merrett points out that *Queensland Wire* was the first case in which clear tests for market power were defined, although market power was never in issue in that case. The *Queensland Wire* tests were applied in *Melway*, and further developed in *Boral*. An absence of competitive constraint became the key factor in the High Court's judgments in *Boral*, and the issue was frequently stated in absolute rather than relative terms. This would appear to preclude a finding of market power in cases of oligopoly; Merrett, above n24, 332-343.

[110] Ibid, especially 340. For examples of an application of this approach see Emmett J (dissenting) in *ACCC v Australian Safeway Stores Pty Ltd* (2003) 129 FCR 339, and the Full Court of the Federal Court in *Universal Music Australia Pty Ltd v ACCC* (2003) 201 ALR 636.

6.3.4 THE MEANING OF 'SUBSTANTIAL DEGREE' OF POWER IN A MARKET

As part of determining whether a corporation possesses market power, a court must analyse whether that market power is substantial. The term 'substantial' is not defined in the *Trade Practices Act*, and is a relative concept.[112] In assessing degree of market power, the Explanatory Memorandum accompanying the legislation that amended s 46(1) to its current form explains that 'substantial' is intended to signify 'large or weighty' or 'considerable, solid or big'.[113] The Trade Practices Commission adopted this meaning of 'substantial' in a Background Paper issued in 1990.[114]

Although clarifying to some extent the interpretation that should be given to the phrase 'substantial degree of power', the Explanatory Memorandum does not delineate with any precision, the circumstances in which a corporation is likely to possess a substantial degree of market power. Limited guidance is available by way of judicial interpretation of the term, with several different interpretations being placed on it.[115] While it is apparent from the Explanatory Memorandum and the Second

---

[111] For a useful discussion on various factors that may point to market power, see Heydon, above n50, [5-110-5-260].

[112] Explanatory Memorandum, Trade Practices Revision Bill 1986 (Cth), [40]. Lockhart and Gummow JJ observed that 'substantial degree of market power' operates on a relative basis, and that the difficulty lies not in its definition, but in the application of the concept to the circumstances of particular cases; *Eastern Express Pty Ltd v General Newspapers Pty Ltd* (1992) 35 FCR 43, 63 (Lockhart and Gummow JJ).

[113] Explanatory Memorandum, Trade Practices Revision Bill 1986 (Cth), [41]. Recourse to the Explanatory Memorandum is arguably justified, as the term is ambiguous and not subject to its ordinary meaning. As discussed above, the Attorney-General also indicated in his Second Reading Speech that the amended s 46(1) was intended to have a lower threshold for application than the previous provision which required that a corporation be in '...a position substantially to control a market.'; see above n26 and accompanying text.

[114] Trade Practices Commission, *Misuse of Market Power Background Paper* (1990), section E, [44].

[115] Contrast, eg, the definition provided by Dawson J in *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 200 (substantial market power constitutes 'the advantage which flows from monopoly or near monopoly'), with that provided by Wilcox J in *Eastern Express Pty Ltd v General Newspapers Pty Ltd* (1991) 30 FCR 385, 403-404 ('real or of substance and not insubstantial or nominal'). The term is likely to be given a more intermediate interpretation in line with the judgment of Lockhart and Gummow JJ in *Eastern Express Pty Limited v General Newspapers Pty Ltd* (1992) 35 FCR 43, 46, who observed that 'significant' in the context of s 46 means substantial or large. Their judgment in this respect was cited with approval by the Full Court of the Federal Court in *Universal Music Australia Pty Ltd v ACCC* (2003) 131 FCR 529.

Reading Speech that something less than monopoly power is required,[116] the extent of market power connoted by the term is unclear.[117]

6.3.5 THE CURRENT MARKET POWER STANDARD

The Explanatory Memorandum does provide some further assistance in relation to the approach to be taken in assessing market power, and in particular to the approach envisaged via the application of s 46(3).[118] It points out that s 46(3) reflects the approach of the European Court of Justice in three major decisions, and that these cases afford guidance as to how market power should be assessed pursuant to s 46(3).[119] In light of these decisions, an evaluation of whether a corporation possesses market power will focus on the market share, structural features and level of independence of a particular corporation, and also on other matters, such as the impact of competitors' market share and behaviour, and potential levels of competition.

Findings of substantial market power in s 46 cases have been relatively rare.[120] It has been contended that the High Court majority's decision in *Boral* has resulted in a reversion in the meaning of market power to monopoly or near monopoly.[121] The High Court in *Boral* required evidence of an absence of competitive conditions in establishing market power, and evidence pointing to competitive conditions (which will tend to be present even in oligopoly markets) will tend to preclude a finding that any corporation possesses market power. Zumbo suggests that in the absence of

---

[116] Explanatory Memorandum, Trade Practices Revision Bill 1986 (Cth), [35], [37]; *House of Representatives Debates*, Trade Practices Revision Bill, 19 March 1986 (Cth), 1626.

[117] Hay suggests that an assessment of whether a corporation possesses 'substantial' market power must hinge on market share; George A Hay, 'Market Power in Australasian Antitrust: an American Perspective' (1994) 1 Competition and Consumer Law Journal 215, 223-225.

[118] Explanatory Memorandum, Trade Practices Revision Bill 1986 (Cth).

[119] Explanatory Memorandum, Trade Practices Revision Bill 1986 (Cth), [46]. The cases referred to in the Explanatory Memorandum are *Europemballage and Continental Can v Commission* [1973] CMLR 199, *United Brands v Commission* [1978] 1 CMLR 429 and *Hoffman-La Roche v Commission* [1979] 3 CMLR 211. Note that Article 86 (now Article 82) of the Treaty of Rome requires a position of dominance in a market, which is stated in the Explanatory Memorandum to be greater than the threshold degree of market power required under s 46(1); at [46].

[120] Merrett points out that '... [T]he only findings of market power since 1987 will have occurred where the issue has been – in fact or in effect – conceded.', Merrett, above n24, 333, 343, Annexure 2. Indeed, Merrett's analysis indicates that there have been fewer findings of market power since the 1986 amendments than there had been prior to the amendments. The notable exception is the decision of the Full Federal Court in *ACCC v Australian Safeway Stores Pty Ltd* (2003) 129 FCR 339. Merrett suggested the decision of the Full Court was unlikely to escape a reversal by the High Court, Merrett, 343. Leave to appeal to the High Court was, however, refused; see below, n124.

[121] See the Senate Committee Report, above n14, [2.11]-[2.17]; Zumbo, The *Boral* Case: Has the High Court Done Justice to s 46, above n6.

collusion, an 'absence of competitive conditions' is likely to exist only in situations of monopoly, near monopoly or where a corporation is in a controlling or dominant position in a market.[122]

In considering the question of substantial market power, The Senate Committee concluded that amendment to s 46 was required in order to reinforce the Parliamentary intention behind the 1986 amendments, despite the fact that an appeal in the case of *ACCC v Australian Safeway Stores Pty Ltd* (*Safeway*)[123] case was pending to the High Court.[124] The Senate Committee consequently recommended that s 46 be amended to state that the threshold of "a substantial degree of power" is lower than the former threshold of substantial control.[125] They also recommended that a declaratory provision be included in s 46 outlining matters to be considered in determining the issue of substantial market power. Thus, the recommendation proposed by the Senate Committee was as follows:

1. the threshold of 'a substantial degree of power in a market' is lower than the former threshold of substantial control;

2. the substantial market power threshold does not require a corporation to have an absolute freedom from constraint – it is sufficient if the corporation is not constrained to a significant extent by competitors or suppliers;

---

[122] Zumbo, The *Boral* Case: Has the High Court Done Justice to s 46, above n6. See also Merrett, above n24, 343. Kirby J made a similar point in *Boral* when he stated that the operation of s 46 is now 'in effect, ... confined to monopolists and near monopolists. In substance, the notion of "control" of the market ... [has been] restored'; *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 689 (Kirby J).

[123] *ACCC v Australian Safeway Stores Pty Ltd* (2003) 129 FCR 339. The case involved a number of incidents where Safeway, a supermarket chain, deleted from their supermarkets products from particular bread bakers. The deletions occurred either to deter the bakers from supplying independent retailers, or to assist in negotiating satisfactory case deals for Safeway.

[124] The Senate Committee referred to a submission by the Law Council of Australia that denied that the test for substantial market power had been raised to one of dominance. The Law Council pointed to the decision of the Full Federal Court in *Safeway* where a corporation with 16 percent market share was found, on the basis of a number of factors, to have substantial market power, and contended that any amendment to s 46 should be deferred pending the outcome of the *Safeway* appeal; see the Senate Committee Report, above n14, [2.15]. Note that Safeway was found to have market power on a number of other grounds, including 'excess capacity' in the market, barriers to a participant of similar size entering the market and the fact that Safeway's actions resulted in one baker refusing to supply discounted bread to retail customers on a number of occasions; *ACCC v Australian Safeway Stores Pty Ltd* (2003) 129 FCR 339, [310-324]. Leave to appeal to the High Court in respect of a number of issues including that of market power, was recently refused; see <http://www.hcourt.gov.au/registry/slresults/10-09-04M.htm> at 8 August 2005.

[125] Senate Committee Report, above n14, Recommendation 1.

3. more than one corporation can have a substantial degree of power in a market;

4. evidence of a corporation's behaviour in the market is relevant to a determination of substantial market power.[126]

The Government Senators doubted the utility of the first proposal, but accepted that the remaining three proposals may be effective in clarifying the scope of s 46.[127] The Government disagreed that the judgments in *Boral* required a total absence of competitive constraint,[128] and declined to accept any aspect of this recommendation.[129] While they considered the second proposal would be likely to generate further complexity, the remaining proposals were rejected in that the Government considered them to be redundant.[130]

The Senate Committee also recommended that s 46 be amended to state that:

> in determining whether or not a corporation has a substantial degree of power in a market for the purpose of s 46(1), the court may have regard to whether the corporation has substantial financial power.
>
> 'Financial power' should be defined in terms of access to financial, technical and business resources.[131]

Again, the Government Senators were reluctant to interpose further requirements into s 46 that they considered to be unnecessary and that could result in an extension to the scope of s 46.[132] The Government endorsed the finding of the Government Senators.[133] The Government did, however partially accept a further recommendation by the Senate Committee in relation to the combined market power of separate entities. The Government agreed that s 46 should be amended to allow a court to 'take account of any market power the corporation has that results from contracts, arrangements or

---

[126] Ibid. This recommendation was based on a proposed recommendation by the ACCC; see the ACCC Submission, above n19, 19.

[127] Government Senators' Report, above n14, 85-86.

[128] The Government also pointed to the decision in *Safeway* in support of this contention; Government Response to the Senate Committee Report, above n21, 4.

[129] Ibid, 3-4.

[130] Ibid.

[131] Senate Committee Report, above n14, Recommendation 4.

[132] Government Senators' Report, above n20, 88.

[133] Government Response to the Senate Committee Report, above n21, 7.

understandings with others.'[134] This may be relevant where companies are institutions vertically integrate in order to shore up access to patents. In instances where this occurs, market power may be judged not on the basis of the power possessed by a single entity, but with respect to market power possessed as a result of licence arrangements with other parties.

6.3.6 SUMMARY

In determining questions of substantial market power under s 46, a court must initially discern the relevant market in which a corporation operates, and then determine whether that corporation possesses substantial market power in that market. In assessing market power, courts will consider the presence or absence of barriers to entry, and then take into account other relevant factors. Arguably, the High Court has interpreted the market power standard in a restrictive fashion, so that a finding of substantial market power will necessitate a complete absence of competitive conditions. Accordingly, the Full Federal Court's decision in *Safeway* should be considered to be an anomaly in the recent line of jurisprudence interpreting the market power standard. In that case, competitive conditions were present but a finding of market power was made on the basis of a number of relevant factors.[135]

Establishing substantial market power in respect of intellectual property ownership is difficult. It will be argued in Chapter 8 that on the basis of current, narrow interpretations of substantial market power, there are unlikely to be any circumstances where Australian courts would be likely to make a finding of market power in respect of the ownership of medical biotechnology patents. This is despite the fact that it has been recognised in Australia that intellectual property is capable of giving rise to market power.[136]

6.4 'TAKING ADVANTAGE' OF MARKET POWER

The second element of s 46 is that a corporation 'take advantage' of market power possessed in the relevant market. This element has also been subject to extensive interpretation by the High Court. Despite this, the precise meaning of the test contained within this element remains unclear.

---

[134] Ibid, 8 in response to Recommendation 6, Senate Committee Report. Recommendation 6 was slightly broader than the Government's preferred amendment, which essentially restates the law as established by Justice Lockhart in *Dowling v Dalgety Australia Limited and Others* (1992) 34 FCR 109.

[135] See above, n124.

[136] See below, 8.2.2.1.

6.4.1 THE HIGH COURT'S INTERPRETATION OF 'TAKE ADVANTAGE'

In *Queensland Wire* the High Court, by majority, held that the term 'take advantage of' in the context of s 46 simply means 'use' and is not to be interpreted in a pejorative sense.[137] In undertaking this objective assessment of whether a corporation has 'used' its market power, the majority[138] in *Queensland Wire* determined that it is necessary to consider whether the corporation would have been in a position to engage in the conduct in question in a competitive market.[139]

The correctness of this approach was affirmed[140] by the High Court majority in *Melway*,[141] who stated that it is necessary to consider whether the conduct would have been engaged in, in a market in which there is '... a sufficient level of competition to deny a substantial degree of power to any competitor in the market.'[142] In other words, a hypothetical inquiry must be undertaken in which a consideration of the impugned conduct under conditions of workable competition is required.[143] In so doing, the

---

[137] *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 190-191 (Mason CJ and Wilson J), 194 (Deane J), 202 (Dawson J, agreeing with Deane J), 213 (Toohey J).

[138] Deane J took a different approach in that he proceeded directly from a finding that BHP were refusing to supply for a proscribed purpose, to a conclusion that BHP were taking advantage of their market power; (Deane J), and see above, 6.3.1.

[139] *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 192 (Mason CJ and Wilson J), 197-198 (Deane J), 202 (Dawson J), 216 (Toohey J).

[140] It has been argued that *Melway* effectively goes beyond the High Court's judgment in *Queensland Wire*, in that *Queensland Wire* is not clear authority for an approach that asks whether the conduct 'would' have been engaged in under workably competitive conditions; see Daniel Clough, 'Misuse of Market Power – "Would" or "Could" in a Competitive Market?' (2001) 29 *Australian Business Law Review* 311, 335. Indeed, it was unclear after *Queensland Wire* whether the conditions under which the corporation's conduct had to be considered were perfectly competitive, or workably competitive conditions; at 335.

[141] The dissenting judge, Kirby J, held that the term 'take advantage of' simply means 'use', and stated that it is unnecessary to '... pose the hypothetical questions (sometimes difficult to resolve) as to whether such corporation could, or would, acting rationally, have engaged in the forbidden conduct if it were subject to effective competition.'; *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 43 (Kirby J). Kirby J retreated from this position to an extent in *Rural Press Ltd v ACCC* (2003) 78 ALJR 274, 301, in that he conceded that the expression means more than simply 'use'.

[142] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 23 (Gleeson CJ, Gummow, Hayne and Callinan JJ).

[143] In this respect, *Melway* expands on *Queensland Wire*; see Ray Steinwall, '*Melway* and Monopolisation – Some Observations on the High Court's Decision' (2001) 9 *Competition and Consumer Law Journal* 93, 98-99, 100. Zumbo contends that the High Court has placed inappropriate focus on the hypothetical enquiry as to whether the corporation would have engaged in the same conduct in the absence of market power at the expense of attention on the nature of the conduct, and whether or not market power would allow that conduct to be sustainable over a period of time; Zumbo, The *Boral* Case: Has the High Court Done Justice to s 46, above n6, 222. Cf Lynden Griggs and Samantha Hardy, '*ACCC v Boral* – the High Court Awaits Another Section 46 Case!' (2001) 9 *Trade Practices Law Journal* 201, 207-212

majority recognised that it is not appropriate to consider the likelihood of a corporation's conduct taking place in '...circumstances that are completely divorced from the reality of the market.'[144]

The High Court appears in effect, to have implicitly incorporated a 'business rationale'[145] justification into the 'take advantage' element.[146] If a corporation is able to demonstrate, through evidence, that the conduct would have been engaged in under workably competitive conditions on economic efficiency grounds,[147] this may provide a legitimate business explanation for the conduct which will negative the 'take advantage of' test, and exonerate the corporation from liability.[148] At the very least, the court will consider this evidence as an additional factor militating against a finding that the 'take advantage of' element has been established. If a decision to engage in a course of conduct can be supported on economically efficient grounds, there is no reason why the conduct should be labelled as being anti-competitive.[149] Accordingly, many commentators have applauded the High Court's inclusion of

---

[144] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 25 (Gleeson CJ, Gummow, Hayne and Callinan JJ). This confirms that a consideration of the conduct under conditions of workable, rather than perfect competition is required.

[145] It has been pointed out that there is likely to be little practical difference between the terms 'legitimate' and 'rational' as used to describe business 'justifications', 'explanations' and 'rationales'. Although varying combinations of these terms are evident in s 46 jurisprudence and academic commentary, they represent essentially the same concept; Marshall, above n9, 62.

[146] See also the High Court decision in *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 625 (Gleeson CJ and Callinan J). Cf Kirby J (in dissent) in *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 41, arguing that debates about proscribed as opposed to permissible conduct arise in relation to the identification of purpose, and not in characterising the acts as 'taking advantage'.

[147] Marshall, above n9, 63. Efficiency considerations were taken into account in relation to the take advantage element prior to *Melway*; see Michael O'Bryan, 'Section 46: Law or Economics' (1993) 1 *Competition and Consumer Law Journal* 64, 84; Frances Hanks and Philip L Williams, 'Implications of the Decision of the High Court in *Queensland Wire*' (1990) 17 *Melbourne University Law Review* 437, especially 445-446. Cf Lawson, who argues that the effect of *Melway* was to *introduce* the consideration of efficiency arguments, as a result of which the operation of s 46 was narrowed; Charles Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition' (2002) 30 *Federal Law Review* 97, 123-128.

[148] Corones, The Characterisation of Conduct, above n4, 414-420. Corones points out that there is no consensus in the Federal Court as to the relevance of rational business justifications to the 'take advantage of' test. Corones supports the inclusion of an explicit requirement that business justifications be taken into account in objectively considering this element; at 419-420.

[149] For detailed analyses of the economic bases for the decision in *Melway*, see, eg, Daniel Clough, 'Law and Economics of Vertical Restraints in Australia' (2001) 25 *Melbourne University Law Review* 20; Edwards, '*Melway* – a TCE Perspective' (2002) 10 *Trade Practices Law Journal* 77; Michael O'Bryan, above n147. See generally Karen Yeung, 'The Courtroom Economist in Australian Anti-trust Litigation: An Underutilised Resource?' (1992) *Australian Business Law Review* 461; Maureen Brunt, 'The Use of Economic Evidence in Antitrust Litigation: Australia' (1986) *Australian Business Law Review* 261.

efficiency considerations into s 46 analysis, although there has been some debate over whether these considerations are more appropriately taken into account in relation to the take advantage element, or the purpose element.[150]

The High Court's jurisprudence in relation to s 46 has generated an extensive body of commentary, based primarily on the lack of prospective certainty provided in relation to the 'take advantage' test.[151] Proponents of recent judicial pronouncements that have dealt with the 'taking advantage' test contend that these judgments provide businesses with a sufficient level of certainty to allow them to gauge whether or not anticipated behaviour is likely to contravene s 46.[152] Still other commentators have praised early High Court decisions on s 46, but lamented the application of the principles laid down in these cases by lower courts.[153]

The 'take advantage' test would appear to have been further modified in *Rural Press*, where the High Court (by majority) held that it may be possible to determine whether a corporation had taken advantage of its market power by considering whether it 'could' have acted in the way in which it acted in competitive conditions.[154] This change in focus arguably removes the requirement that a commercial explanation for

---

[150] A number of relevant articles are discussed in this section, and below, 6.5 Proscribed Purpose. Note that some commentators have cautioned against relying solely on economic efficiency as a determinant of liability in s 46 cases; see, eg, Peter Prince, '*Queensland Wire* and Efficiency – What Can Australia Learn From US and New Zealand Refusal to Deal Cases?' (1998) 5 *Competition and Consumer Law Journal* 237.

[151] See, eg, Warren Pengilley, 'Thirty Years of the *Trade Practices Act*: Some Thematic Conclusions' (2004) 12 *Competition and Consumer Law Journal* 1; Henry Ergas and Mitchell Landrigan, 'Not *Another* Article About Section 46 of the *Trade Practices Act*!' (2004) 32 *Australian Business Law Review* 415; David Meltz, '"Market Entry – See Adjoining Map": *Melway* and the Right Not to Supply' (2002) 10 *Trade Practices Law Journal* 96; Clough, above n140; Weeliem Seah, 'Fair Competition or Unfair Predation: Identifying the Misuse of Market Power Under Section 46' (2001) 9 *Trade Practices Law Journal* 236; Warren Pengilley, 'Misuse of Market Power: The Unbearable Uncertainties Facing Australian Management' (2000) 8 *Trade Practices Law Journal* 56; Richard Dammery 'Section 46 of the *Trade Practices Act*: The Need for Prospective Certainty' (1999) 6 *Competition and Consumer Law Journal* 246; Kathryn McMahon, 'Refusals to Supply by Corporations With Substantial Market Power' (1994) 22 *Australian Business Law Review* 7; Warren Pengilley, '*Queensland Wire* and its Progeny Decisions: How Competent are the Courts to Determine Supply Prices and Trading Conditions?' (1991) 21 *Western Australia Law Review* 225;

[152] Marshall, above n9; Rhonda Smith and David K Round, 'The Puberty Blues of Competition Analysis: Section 46' (2001) 9 *Competition and Consumer Law Journal* 189; Roger Featherston and Geoff Edwards, 'Recent Developments in Misuse of Market Power' (2000) 8 *Trade Practices Law Journal* 79; Brenda Marshall, 'Refusals to Supply Under Section 46 of the *Trade Practices Act*: Misuse of Market Power or Legitimate Business Conduct?' (1996) 8 *Bond Law Review* 182; Sandra Welsman, 'In *Queensland Wire*, The High Court has Provided an Elegant Backstop to "Use" of Market Power' (1995) *Competition and Consumer Law Journal* 189.

[153] See, eg, O'Bryan, above n147.

[154] *Rural Press Ltd v ACCC* (2003) 78 ALJR 274, 285-286, (Gummow, Hayne and Heydon JJ).

the conduct be provided in order to exonerate a corporation from s 46 liability, and places emphasis on physical capacity. This may have the effect of undermining the objectives of s 46 and removing economic considerations from analysis of the 'take advantage' test. Provided it can be established that a corporation could not have engaged in conduct in a workably competitive market, the take advantage test will not be satisfied. As the dissenting judge Justice Kirby observed:

> ...[T]here is a great difference between a test of *physical* possibility and one of *commercial* likelihood. There may be few forms of commercial conduct that are physically impossibly, with or without substantial market power. However, such a criterion affords no assistance in distinguishing conduct that involves "taking advantage of market power", in a way forbidden by s 46 of the Act, from that which does not (Kirby J's emphasis).[155]

This shift in emphasis from 'would' to 'could' is, however, one that has been evident in Federal Court and High Court judgments for some time since *Queensland Wire*.[156] Clough suggests that in the long-run and assuming economic rationality, what a corporation 'would' do in a perfectly competitive market will coincide with what that corporation 'could' do.[157] It is submitted that not only is perfect competition an inappropriate standard by which to measure a defendant's conduct,[158] it is not always reasonable to assume economic rationality. This is particularly the case in relation to bargaining for the exchange of patents, as outlined in Chapter 3.[159] For this reason, there will be implications if a court chooses to apply one test over another.[160]

As discussed below,[161] the Government Senators' Report addressed this point, and recommended that s 46 be amended to require specifically that courts consider, in relation to the 'take advantage' test, whether the corporation 'would' be likely to

---

[155] *Rural Press Ltd v ACCC* (2003) 78 ALJR 274, 301 (Kirby J). See also Australian Competition and Consumer Commission, *Inquiry into the Effectiveness of the Trade Practices Act 1974 in Protecting Small Business: Second Supplementary Submission to the Senate Economics References Committee*, 14 January 2004, Submission 30b, 4.

[156] See Clough, above n140.

[157] Ibid, 314.

[158] Indeed, the High Court has confirmed that it is inappropriate to consider the conduct of a defendant under perfectly competitive conditions; see above, n144 and accompanying text.

[159] See above, 3.3.3.

[160] Indeed, Clough points out that the distinction between the tests becomes important where conduct takes place in imperfect market conditions, or where the relevant time period is the short-run; Clough, above n140, 314-317.

[161] See below, 6.4.3.

engage in the conduct in question if it lacked a substantial degree of market power. The Government refused to endorse this recommendation.

The result is that it is unclear whether the High Court in *Rural Press* has overruled *Melway* on this point, or whether the High Court has used the terms 'would' and 'could' interchangeably. In *Rural Press*, the majority stated that:

> The Commission's criticism of the Full Federal Court for asking whether Rural Press and Bridge "could" engage in the same conduct in the absence of market power must be rejected. A majority of this Court in [*Melway*] adopted the same test in saying:
>
> > "Bearing in mind that the refusal to supply the respondent was only a manifestation of Melway's distributorship system, the real question was whether, without its market power, Melway could have maintained its distributorship system."
>
> The Commission did not demonstrate either that that did not mean what it said, or that what it said should be overruled.[162]

However, despite this use of the word 'could', the majority in *Melway* were clear that a 'would' approach should be taken when considering the action likely to be taken by a corporation under competitive conditions. The majority preferred the reasoning of the dissenting judge, Heerey J in the Full Court who explicitly adopted a 'would' approach.[163] Thus, the High Court majority held that:

> The only purpose of the hypothesis is to seek to test whether Melway has taken advantage of its degree of market power. It is one thing to compare what it has done with what it might be thought it would do if it lacked that power. It is a different thing to compare what it has done in circumstances that are completely divorced from the reality of the market.[164]

In expressly rejecting the 'could' approach proposed by the respondent,[165] the majority stated that:

---

[162] *Rural Press Ltd v ACCC* (2003) 78 ALJR 274, 285-286, (Gummow, Hayne and Heydon JJ) referring to *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 26 (Gleeson CJ, Gummow, Hayne and Callinan JJ) (full references omitted).

[163] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1 (1999) 90 FCR 128, 134-135.

[164] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 25 (Gleeson CJ, Gummow, Hayne and Callinan JJ).

[165] The respondent argued in its written submissions that 'the Appellant had a substantial degree of market power. Necessarily it took advantage of that power when it refused to supply the Respondent. What it may or may not have done, in a competitive market, was nothing to the point.'; *Melway*

> The argument denies that, where the case is one of refusal to supply, in determining whether a corporation is taking advantage of its power in the market, it can ever be relevant to consider how the corporation would have behaved without such power. However, such a proposition is directly contrary to the reasoning of four of the five members of the Court in *Queensland Wire*.[166]

Thus, the High Court clearly adopted an approach that asked whether the conduct would have been engaged in under workably competitive conditions.[167] The evidence in this case allowed the Court to answer this inquiry by considering actual evidence as to how Melway had behaved prior to attaining market power. The majority in *Rural Press* applied a 'could' test without undertaking a rigorous analysis of the approach of the High Court majority in *Melway*. With respect, it is not clear whether the High Court in *Rural Press* were aware of the implications of choosing one approach over the other. This is particularly perplexing given the constitution of the majority in each case.[168]

An examination of jurisprudence since *Queensland Wire*, however, indicates that courts would appear to have used the terms interchangeably,[169] or at least without evidence of a clear understanding of the implications of employing one test over the other.[170] Indeed since *Queensland Wire* (which is arguably not clear authority for either approach),[171] variously constituted federal courts have demonstrated a tendency to apply a 'could' approach to the resolution of the 'take advantage' test.[172] *Melway* clarified the position,[173] which must now be taken to be once again subject to uncertainty.[174]

Publishing Pty Ltd v Robert Hicks Pty Ltd (2001) 205 CLR 1, 27 (reported in judgment of Gleeson CJ, Gummow, Hayne and Callinan JJ).

[166] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 27 (Gleeson CJ, Gummow, Hayne and Callinan JJ).

[167] See also, Clough, above n140, 335-336. The High Court majority in *Rural Press* made no attempt to overrule *Melway* on the requirement that the conduct of the corporation be examined under workably competitive conditions.

[168] Gummow and Hayne JJ formed part of the majority in both *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1 and *Rural Press Ltd v ACCC* (2003) 78 ALJR 274.

[169] Law Council of Australia, *Supplementary Submission by the Trade Practices Committee of the Business Law Section of the Law Council of Australia to the Senate Economics References Committee*, 26 May 2004, Submission 18b, 8.

[170] See generally Clough, above n140.

[171] Ibid, 317-319.

[172] Ibid, 319-333.

[173] Ibid, 333-36.

[174] Cf Law Council of Australia, Supplementary Submission, above n169, 8.

It is submitted that the 'would' approach serves to base s 46 far more thoroughly in economic reasoning and commercial considerations. As Kirby J pointed out in *Rural Press*, a test grounded in physical possibility is contrary to the policy behind the *TPA* of protecting competition for the good of consumers.[175] Amendment is arguably necessary to shift the emphasis from what has become a formalistic interpretation of s 46 to a more transaction-based approach.[176] The 'could' approach invariably reduces the section's effectiveness by increasing the difficulty for plaintiffs to establish the counterfactual test under s 46.[177]

A 'could' test would mean that the circumstances in which s 46 applies are likely to be limited, as theoretically it is possible to engage in almost any form of conduct regardless of whether a corporation possesses market power. It has been argued that the High Court's latest interpretation of the 'take advantage' test may mean that s 46 will apply only to corporations with a minimum of near monopoly power; provided a corporation can demonstrate that conduct was possible without market power, the test will not be made out.[178]

If a 'could' approach is taken in relation to the take advantage test, the ability to consider efficiency considerations will be removed from the take advantage element because a 'could' test does not enquire into the economic legitimacy of conduct.[179] This may not be problematic if there is room for these considerations with regard to the purpose element.[180] It may also be appropriate where conduct is assessed on the basis of perfectly competitive conditions and a long-run analysis is applied.[181] However, under conditions of workable competition, the 'take advantage' test would

---

[175] *Rural Press Ltd v ACCC* (2003) 78 ALJR 274, 296, 300, 302 (Kirby J). Unless the 'could' approach is taken as effectively meaning 'would', which seems precluded by the majority judgment; see Warren Pengilley, '*Rural Press*: A Controversial High Court Decision on Misuse of Market Power and Other Issues' (2004) 19(10) *Australian and New Zealand Trade Practices Law Bulletin* 137, 145.

[176] See Pengilley, Thirty Years, above n151, 14-17;

[177] Ergas and Landrigan, above n151, 428.

[178] ACCC Submission to Senate Economics References Committee, above n19, 4. See also Frank Zumbo, 'The High Court's *Rural Press* Decision: The End of Section 46 as a Deterrent Against Abuses of Market Power?' (2004) 12 *Trade Practices Law Journal* 126.

[179] Clough, above n140, 314-315, 339. The decision also has other implications. First, it may insulate particular assets from consideration of market power, a result that seems manifestly unfair. It many also prevent conduct that protects market power from falling within the ambit of s 46; see Pengilley, *Rural Press*: A Controversial High Court Decision, above n175, 144.

[180] Clough, above n140, 338-340. Cf Marshall, above n9, 63. See further below, 6.5.1.

[181] See Clough, above n140, 314. See also Ergas and Landrigan who criticises the could test in that it 'invites speculation as to what behaviour may or may not be observed under particular market structures', Ergas and Landrigan, above n151, 416-417. Ergas and Landrigan also criticise the use of a perfectly competitive market standard; at 416-417.

never be satisfied and s 46 would be rendered otiose.[182] On the basis of *Melway*, the appropriate benchmark against which to measure conduct is that of workably competitive conditions, and the majority in *Rural Press* did not overrule this finding.

Thus, it is difficult to state with any precision the exact interpretation to be placed on s 46 with respect to the take advantage test, and this leaves doubt as to how efficiency or commercial considerations should be pleaded as exonerating factors. It is submitted that consideration of these factors is necessary in order to consider whether a competitive environment has constrained the conduct of a firm with market power. It is also entirely consistent with the policy objective of s 46, that is, protection of the competitive environment. Arguably, application of a 'could' test fails to incorporate this policy objective into the 'take advantage' test.[183]

The High Court has given a number of apparently conflicting judicial statements on the issue, and it is not clear which of these is likely to be preferred in future determinations. The section must be amended to clarify which approach applies.[184] At present, the position must be taken to be unclear, and there has been an over-emphasis by variously constituted courts on the semantics of the section[185] at the expense of consideration of the economic basis of conduct.

6.4.2 TAKING ADVANTAGE AND CAUSATION

The High Court majority's judgment in *Melway* also confirmed that, in satisfying the 'take advantage of' element, a causal link between market power and the conduct in issue must be made out.[186] The majority acknowledged (in obiter) that this causal connection may be established where the market power of the corporation 'materially facilitated' the conduct in question, even though it may have been possible to engage in the conduct without market power.[187] This test was also applied by the High Court

---

[182] See Clough, above n140, 314, 340.

[183] See also Ergas and Landrigan, above n151, 430.

[184] Pengilley supports legislative amendment to clarify which test applies; see Pengilley, Thirty Years, above n151, 13-14. See also Clough, above n140; Ergas and Landrigan, ibid, especially 430.

[185] See also Pengilley, Thirty Years, above n151, 13-14.

[186] *Natwest Australia Bank Ltd v Boral Gerrard Strapping Systems Pty Ltd* (1992) 111 ALR 631, 637 (French J). See also *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 21 (Gleeson CJ, Gummow, Hayne and Callinan JJ); *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 632 (Gleeson CJ and Callinan J); *Rural Press Ltd v ACCC* (2003) 78 ALJR 274, 286 (Gummow, Hayne and Heydon JJ).

[187] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 23 (Gleeson CJ, Gummow, Kirby, Hayne and Callinan JJ), applied by the Full Federal Court in Full Federal Court in *ACCC v Australian Safeway Stores Pty Ltd* (2003) 129 FCR 339. The High Court accepted that this test would

in *Rural Press*.[188] This low threshold has been criticised as reducing the amount of certainty that s 46 provides.[189] The test will be considered on a relative basis, as a result of which considerable variance in views is likely.[190]

As a result of the recent High Court decision in *Rural Press*, the Senate Committee recommended amendment to s 46 to clarify the elements of the 'take advantage' test as follows:

> 'In determining whether a corporation has taken advantage of its market power, the courts should consider whether:
>
> - the conduct of the corporation is materially facilitated by its substantial degree of market power;
> - the corporation engages in the conduct in reliance upon its substantial degree of market power;
> - the corporation would be likely to engage in the conduct if it lacked a substantial degree of market power; or
> - the conduct of the corporation is otherwise related to its substantial degree of market power.[191]

The Government Senators rejected the need for such amendment on the basis that the 'take advantage' test is not hindered by current judicial interpretation of the term,[192] and this rejection was endorsed in the Government Response.[193] As such, s 46 will not be amended in the near term, and the High Court's latest pronouncement on the 'take advantage' test will stand. It may be that the matter will be considered further in due course, and that a watching brief in respect of this issue will need to be maintained. Arguably, the High Court is unlikely to consider that the issue requires further

---

be satisfied where the market power 'made it easier for the corporation to act for the proscribed purpose than would otherwise be the case.'; *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 23.

[188] *Rural Press Ltd v ACCC* (2003) 78 ALJR 274, 286 (Gummow, Hayne and Heydon JJ).

[189] Marshall, above n9, 55. It has also been pointed out that it is somewhat paradoxical that satisfaction of the counterfactual test has been made more difficult while the standard of proof required for the 'taking advantage' test has been reduced; Ergas and Landrigan, above n151, 428.

[190] Corones, The Characterisation of Conduct above n4, 420. See also Ergas and Landrigan, above n151, 428.

[191] Senate Committee Report, above n14, [2.28]. See also Recommendation 2.

[192] Government Senators' Report, above n20, 86.

[193] Government Response to the Senate Committee Report, above n21, 5-6.

clarification,[194] and the High Court's refusal to allow special leave to appeal in the *Safeway* case may evidence this.[195]

6.4.3 SUMMARY

In considering the 'take advantage' element, Australian courts will seek to determine the answer to a counter-factual question, and will consider the likelihood of the impugned conduct occurring under workably competition conditions. What is not clear is whether the courts will apply a test asking whether the corporation 'would' have engaged in the conduct under competitive conditions, or whether a court will ask whether the corporation 'could' have engaged in the conduct under competitive conditions.

While the application of a particular test will have implications in proving that a corporation took advantage of market power in any alleged contravention of s 46, parties who are refused patent licences are likely to find it particularly difficult to make out this element. Upon the application of a 'would' test, efficiency considerations will operate to justify the conduct in most cases. The application of a 'could' test would, however, make it virtually impossible to establish a taking advantage of market power, even in the circumstances outlined in limbs [2] and [3] of the framework proposed in Chapter 5. Asking whether conduct was physically possible under competitive conditions will almost always yield a positive answer.[196]

6.5 PROSCRIBED PURPOSE

It is necessary under s 46 to establish that conduct has been engaged in for an anti-competitive purpose.[197] Purpose is an 'intention to achieve a result.'[198] Purpose will be examined objectively[199] in the absence of evidence that points to a subjective intent.[200]

---

[194] Zumbo, The High Court's *Rural Press* Decision, above n178, 127.

[195] See above n124. Although s 46 was considered in the *NT Power* case, this aspect of the 'taking advantage' element was not discussed; see *NT Power Generation Pty Ltd v Power and Water Authority* (2004) 210 ALR 312.

[196] Discussed further below, 8.3.

[197] Thus it is irrelevant whether or not the conduct had the effect intended; what is required to be proved is that the conduct was carried out for one of the purposes listed in s 46.

[198] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 18-19 (Gleeson CJ, Gummow, Kirby, Hayne and Callinan JJ) citing *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 214 (Toohey J).

[199] See Donald Robertson, 'The Primacy of "Purpose" in Competition Law – Part 1' (2001) 9 *Competition and Consumer Law Journal* 101, especially 121-122.

An anti-competitive purpose need not be the sole purpose for engaging in conduct; provided it is a substantial purpose this will be sufficient to satisfy the purpose element.[201]

6.5.1 THE PROSCRIBED PURPOSES

While ss 46(1)(b) and (c) deal with potential competition, s 46(1)(a) (eliminating or damaging a competitor) is aimed at damage to current competitors.[202] Section 46(1)(c) potentially has the widest reach of any of the proscribed purpose provisions, and does not appear to require that the corporation engaging in the proscribed conduct be in a directly competitive relationship with the party deterred or prevented from engaging in competitive conduct.[203]

The purpose provisions have been criticised on the basis that they are '... so widely drawn and ill-defined as to be unhelpful in drawing the distinction between competitive and predatory conduct.'[204] McMahon argues that the proscribed purposes, as formulated, attack competitive conduct.[205] She alleges that this has led to a failure in s 46 cases dealing with refusals to supply to establish a suitable framework for dealing with refusals to supply under the provision.[206]

A number of attempts have been made to introduce an 'effects' based test into s 46.[207] The introduction of an effects-based test was most recently considered and rejected by the Dawson Committee,[208] and the Senate Economics Committee.[209] A number of commentators support an effects-based test as an alternative to or substitute for the

---

[200] *General Newspapers Pty Ltd v Telstra Corporation* (1993) 45 FCR 164. Purpose may be objectively ascertained by inference from the conduct of the corporation or any other person, or from other relevant circumstances; *Trade Practices Act* 1974 (Cth), s 46(7). See also Zumbo, The *Boral* Case: Has the High Court Done Justice to s 46, above n6, 212-213; Explanatory Memorandum, Trade Practices Revision Bill 1986 (Cth).

[201] *Trade Practices Act*, 1974 (Cth), s 4F(1)(b). For criticism of the application of this test, see Corones, The Characterisation of Conduct, above n4, 412-413.

[202] Corones, *Competition Law in Australia*, above n35, 354-5-366 citing *Victorian Egg Marketing Board v Parkwood Eggs Pty Ltd* (1978) 33 FLR 294, 304 (Bowen CJ).

[203] Corones, *Competition Law in Australia*, above n35, 366.

[204] McMahon, above n151, 18.

[205] Ibid.

[206] Ibid, 19.

[207] A summary of these attempts is contained in Mitchell Landrigan, A Peters and J Soon, 'An Effects Test Under s 46 of the Trade Practices Act: Identifying the Real Effects' (2002) 9 *Competition and Consumer Law Journal* 258, 261-269. See also Corones, The Characterisation of Conduct, above n4, 411-413.

[208] Dawson Committee Report, above n13, 77-84.

[209] Senate Economics Report, above n14, 27-28.

current purpose-based test, primarily on the ground that the policy objective of s 46 (the protection of competition) is more readily achieved through examination of the effects of conduct on competition rather than on the purpose for which the corporation undertook the conduct.[210] Although establishing the third element under s 46 may be simplified by the introduction of an effects test, it is submitted that its introduction would only serve to intensify the concerns of McMahon expressed above, that legitimate, competitive conduct falls within the purview of the section. The existing purpose test may be far from satisfactory, but an effects test is likely to catch efficient conduct that may otherwise circumvent the operation of the section.

Post *Queensland Wire*, courts generally focused on purpose in assessing the legitimacy of conduct.[211] *Melway* shifted the emphasis back to the take advantage element. It is evident from the High Court's decision in *Melway* that the existence of a rational business explanation may operate to exculpate a corporation in terms of the 'take advantage' test. Consideration of business justifications did, however precede this decision, but they were taken into account, if at all, in relation to the purpose element.[212]

Clough suggests that the purpose test becomes more important if a 'could' test is employed in relation to the 'take advantage' element.[213] Because the application of a 'could' approach means that economic efficiency considerations will not be taken into account in relation to the 'take advantage' element, it will be necessary to take them into account under the purpose element. In contrast, a 'would' approach takes efficiency considerations into account under the 'take advantage' element, leaving questions as to how the purpose test should be characterised.[214]

Marshall has argued that business justifications are relevant to both elements,[215] although the fact that these elements raise different enquiries means that different justifications will be relevant to each element.[216] As discussed earlier,[217] Marshall

---

[210] See, eg, Corones, The Characterisation of Conduct, above n4, 411-413. An effects test would examine the likely effect of conduct on competition, rather than the purpose for which the corporation undertook the conduct.

[211] Clough, above n140, 319.

[212] Marshall, above n9, 62-62; ibid, 319.

[213] Clough, above n140, 338-340.

[214] Ibid.

[215] Cf Corones, The Characterisation of Conduct, above n4, 415 who argues that business justifications are relevant to the purpose element as opposed to the 'take advantage' test. See also McMahon, above n151, 32-35; Meltz, above n151, 108-109.

[216] Marshall, above n9, 63.

categorises those justifications that are relevant to 'taking advantage' as 'efficiency' justifications, but broadly classes those that are relevant to the purpose element as 'quality control/consumer welfare' and/or 'reputation/bottom line' considerations.[218] The court must examine the validity of any justification advanced on an objective basis, but subjective evidence may be relevant to the enquiry.[219] It is submitted that Marshall's conclusions on the irrelevance of efficiency considerations to the purpose element seem very reasonable in light of recent High Court jurisprudence.[220] If efficiency considerations are relevant to the 'take advantage' element, it is difficult to see how they can also be relevant to the purpose element. The justifications that Marshall proposes to be relevant to the purpose element would certainly seem to be concerned with disproving the pejorative element of s 46.

6.5.2 SUMMARY

In establishing the purpose element, one of the proscribed purposes must be a substantial purpose for the conduct. A justification along the lines of those proposed by Marshall will likely exonerate a defendant. There may be a number of justifications advanced to justify conduct, and particular justifications will also be relevant to refusals to license intellectual property. In particular, quality control considerations and the prevention of free riding may be accepted by Australian courts to justify an otherwise anti-competitive purpose. These justifications will be discussed further in Chapter 8.[221]

---

[217] See above, 6.4.1.

[218] Marshall, above n9, 63. See also Heydon, above n50, vol 1, [5-410].

[219] Brenda Marshall, 'The Resolution of Access Disputes Under Section 46 of the *Trade Practices Act*' (2003) 22(1) *University of Tasmania Law Review* 9, 37-38; Seah, above n151, 248.

[220] As such, Marshall summarises various justifications that may, where there is appropriate evidence, allow a corporation to disprove purpose as 'past unsatisfactory dealings with a customer, a customer's poor credit record, a lack of confidence in a customer's business ethics, a customer's inability to maintain accurate records or propensity to engage in deceptive advertising or unfair practices, concerns about the quality of a customer's after sales service or other matters affecting the commercial reputation of the supplier'; Marshall, above n219, 41-42.

[221] See below, 8.4.

6.6 THE ESSENTIAL FACILITIES DOCTRINE[222]

Section 46 provides an obvious mechanism to enable access to a competitor's service or facility necessary to conduct business. However, difficulties in establishing a contravention of s 46 led the Hilmer Committee to recommend the enactment of a national access regime within the context of the *TPA*.[223] As a result of its recommendations, Part IIIA of the *TPA* was enacted. Part IIIA contains a procedure through which competitors may seek access to infrastructure facilities.[224]

The use of intellectual property is specifically excluded from the scope of Part IIIA.[225] As such, a refusal to license intellectual property will not fall within the access provisions. In the next chapter, the development of essential facilities doctrines in US and EU jurisprudence will be discussed. Despite the limitations of these doctrines, there may be circumstances in which they may allow intellectual property to constitute an essential facility.[226] It is therefore necessary to consider whether there are any circumstances in which s 46[227] will continue to operate to enable access to services or facilities despite the existence of Part IIIA.

---

[222] The topic of essential facilities in Australia has been the subject of a considerable number of articles. A number of these articles are referered to in this section, although there is no attempt to be exhaustive in coverage of commentary on the topic. In addition to the articles cited in this section, see, eg, Ross H Patterson, 'Making Hilmer Clear: The Essential Facility Recommendation and the New Zealand Experience' (1994) 2 *Trade Practices Law Journal* 131; Rhonda Smith and Jill Walker, 'Part IIIA Efficiency and Functional Markets' (1998) 5 *Australian Journal of Corporate Law* 183; Warren Pengilley, 'The Privy Council Speaks on Essential Facilities Access in New Zealand: What are the Australasian Lessons?' (1995) 3 *Competition and Consumer Law Journal* 26.

[223] Independent Committee of Enquiry into Competition Policy in Australia, *National Competition Policy* (1993) (the Hilmer Report),s 266-268. The Hilmer Report cited a number of concerns in relying on the general competitive conduct rules, primarily citing difficulties in showing a proscribed purpose, and in courts determining the terms on which access should occur, at 243-244.

[224] Described in the Hilmer Report as 'electricity transmission grids, telecommunication networks, rail tracks, major pipelines, ports and airports'; Hilmer Report, above n223, 240. For consideration of the requirements of Part IIIA see, eg, Brenda Marshall and Rachel Mulheron, 'Declarations of Essential Services Under Part IIIA of the *Trade Practices Act*: A 'Discipline' on Access Reform' (2003) 31 *University of Western Australia Law Review* 226.

[225] See the definition of 'service' in *Trade Practices Act* 1974 (Cth), s 44B.

[226] Note that access regimes in relation to particular facilities have been introduced in the US and the EU. This was a factor in the Hilmer Committee's recommendations to enact a specific statutory regime rather than to continue to rely solely on s 46; Hilmer Report, above n223, 247.

[227] It was accepted by the Hilmer Committee that s 46 was potentially applicable to access disputes; ibid, 243.

A number of commentators have addressed this issue, and come to varying conclusions. In relation to the applicability of s 46 to essential facility disputes subsequent to the enactment of Part IIIA, Pengilley posited three possible positions:[228]

- section 46 and Part IIIA are both applicable;
- the proposed access regime is a complete access code making s 46 inapplicable in cases where Part IIIA applies; and
- s 46 and Part IIIA are each applicable where they do not overlap.

It seems clear that s 46 will continue to play some role in access disputes, and a number of commentators have supported a continued role for s 46. Pengilley considered the first of the options outlined above to be the most likely,[229] while other commentators have envisaged more of a 'residual' role for s 46 (in line with either the second or third of Pengilley's scenarios).[230] That is, s 46 will continue to operate where Part IIIA does not apply, but will not operate where Part IIIA is predominant. The Hilmer Committee stated that facilities that are not nationally significant should continue to be dealt with under s 46. The only contentious point, therefore, was whether facilities that fell within Part IIIA could also be dealt with under Part IV.

In the recent case of *NT Power*,[231] the High Court put the matter beyond doubt, confirming that they did not view Part IIIA as precluding the operation of s 46, so that Part IIIA and s 46 play a parallel role.[232] In line with this, s 46 provides an alternative process to that provided for under Part IIIA. This also allows s 46 to be utilised where access to intellectual property is sought. As the majority in *NT Power* stated,

---

[228] Warren Pengilley, 'The National Competition Policy Draft Legislative Package: The Proposed Access Regime' (1995) 2 *Competition and Consumer Law Journal* 244, 251.

[229] Ibid. See also Michael O'Bryan, 'Access Pricing: Law Before Economics?' (1996) 4 *Competition and Consumer Law Journal* 20; Valentine Korah, 'Access to Essential Facilities Under the *Commerce Act* in the Light of Experience in Australia, the European Union and The United States' (2000) 31 *Victoria University of Wellington Law Review* 231, 233-242.

[230] See, eg, Alister Abadee, 'The Essential Facilities Doctrine and the National Access Regime: A Residual Role for Section 46 of the *Trade Practices Act*?' (1997) 5 *Trade Practices Law Journal* 27; Marshall, The Resolution of Access Disputes, above n219, 16-18. See also the Full Federal Court decision in *NT Power Generation Pty Ltd v Power and Water Authority* (2002) 122 FCR 399, particularly 404-405 (Lee J), 422 (Branson J). The essential facilities doctrine was also rejected in obiter comments by the Full Federal Court in *Queensland Wire*, although these comments were not commented on by the High Court; see *Queensland Wire Industries Pty Ltd v BHP Co Ltd* (1988) ATPR 40-841, 49,076–49,077.

[231] *NT Power Generation Pty Ltd v Power and Water Authority* (2004) 210 ALR 312.

[232] *NT Power Generation Pty Ltd v Power and Water Authority* (2004) 210 ALR 312, 333-335.

'provided the notoriously difficult task of satisfying the criteria of liability can be carried out, s 46 can be used to create access regimes ...'[233]

Without commenting on the efficacy of Part IIIA,[234] it is submitted that the High Court's ruling on this point is perfectly logical.[235] It is consistent with the Hilmer Committee's recommendations that claims under s 46 should be excluded upon declaration of a facility.[236] This recommendation does not contend that the choice between s 46 and a specific access regime be removed entirely,[237] merely that upon the invocation of Part IIIA, s 46 ceases to become applicable. Prior to this point, an applicant has a choice of avenues for seeking access. It is also consistent, as the High Court has pointed out, with the structure of the act given that s 44ZZNA which provides that Part IIIA is to have no effect on the operation of Part IV.[238]

The important point, however, for the purposes of this thesis, is that there is no doubt that s 46 will apply to facilities that do not fall within Part IIIA to enable access to be granted. Thus, s 46 provides a general access regime pursuant to which access to intellectual property may be sought.[239] Whether or not it proves to be an effective

---

[233] *NT Power Generation Pty Ltd v Power and Water Authority* (2004) 210 ALR 312, 334.

[234] See, eg, Abadee, above n230, 40-47; Daniel Clough, 'Economic Duplication and Access to Essential Facilities in Australia' (2000) 28 *Australian Business Law Review* 325; Warren Pengilley, 'Hilmer and "Essential Facilities"' (1994) 17 *University of New South Wales Law Journal* 1.

[235] Cf, eg, Nicole Calleja, 'Access to Essential Services – Have the Hilmer Reforms Been Successfully Implemented?' (2000) 8 *Trade Practices Law Journal* 206, especially 222.

[236] Hilmer Report, above n223, 260, 267.

[237] Cf Marshall, above n219, 16. Abadee also relies on the Explanatory Memorandum, *National Competition Policy Draft Legislative Package* (1994) [1-11] for his contention that Part IIIA precludes the operation of s 46 where it is applicable:

> ...[s 46] is proscriptive by nature ... By contrast, a legislative access regime would largely operate in a non-proscriptive manner, seeking to facilitate agreement between the parties ... and ... providing an arbitration mechanism to settle the issues in dispute. Such a regime should be able to deal with access disputes in a more timely manner than through court action for a purported contravention of s 46.

See Abadee, above n230, 38. See also Marshall, above n219, 16. It is submitted that it can equally be inferred from this passage that the role envisaged for s 46 would be that it would operate alongside Part IIIA, and that the comments on s 46 relate merely to the difficulty in establishing a contravention of s 46 rather than on the primacy of Part IIIA.

[238] *NT Power Generation Pty Ltd v Power and Water Authority* (2004) 210 ALR 312, 334.

[239] As noted by the ALRC, the *TPA* appears to permit compulsory licensing as a remedy for anti-competitive conduct. Section 87(1) of the *TPA* empowers a court to make such order as it thinks 'appropriate' to compensate a party for loss or damage suffered as a result of a breach of Part IV. Although it is not clear whether this would include an order for a compulsory licence, the grounds listed (in s 87(2)) are examples and are not exhaustive; see Australian Law Reform Commission, Parliament of Australia, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99 (2004) (ALRC Report), 621.

access regime depends on whether courts are willing to extend the ambit of an already restrictively interpreted provision, to intellectual property.

6.7 CONCLUSION

There are acknowledged problems with Part IV as a whole, and this has prompted numerous reviews of s 46. Despite these reviews, which have considered many of the Part IV provisions in great detail, it seems unlikely that major reform of the competition provisions will eventuate in the foreseeable future. The Intellectual Property and Competition Review Committee acknowledged that they were hamstrung to a degree in the recommendations they made, by the structure of the Part IV provisions and the problems inherent in them.[240] It is undeniably difficult to address the intellectual property/competition law balance until the imbalance between the policy objectives of Part IV and the manner in which Part IV achieves those objectives are resolved through legislative reform.

Section 46 provides a salient example. The recent spate of High Court cases and reviews of s 46, and the plethora of commentary that has resulted partly as a result of these processes, exemplify long-standing problems with the section. There has been a

---

An alternative basis for granting a compulsory licence would exist under s 80(5). Section 80 of the *Trade Practices Act* 1974 (Cth) empowers a court to make an order for an injunction for a contravention of, *inter alia*, Part IV. A court may draft an order in such terms as it determines to be appropriate (s 80(1)), and the power conferred by s 80 is broad; see generally John D Heydon, The Law Book Company Limited, *Trade Practices Law*, vol 2, [18.1010]. Section 80(5) gives a court the power to grant a mandatory injunction to do an act or thing; *A V Jennings Ltd v First Provincial Building Society Ltd* (1996) ATPR 41-494. Section 80(5) relevantly provides as follows:

> The power of the Court to grant an injunction requiring a person to do an act or thing may be exercised:
>
> (a) whether or not it appears to the Court that the person intends to refuse or fail again, or to continue to refuse of fail, to do that act or thing;
>
> (b) whether or not that person has previously refused or failed to do that act or thing; and
>
> (c) whether or not there is an imminent danger of substantial damage to any person if the first-mentioned person refuses or fails to do that act or thing.

References to persons include references to bodies corporate: *Acts Interpretation Act* 1901 (Cth), s 22(1)(a). The broad powers granted by s 80(5) would enable a court to make an order for a compulsory licence. It is acknowledged that difficulties would invariably arise in setting a commercial supply price, although consideration of this specific issue is outside the scope of this thesis. See generally Stephen G Corones 'Remedies Under the *Trade Practices Act* for Refusal to Supply' (1993) 10(3) *Australian Bar Review* 259.

[240] Intellectual Property and Competition Review Committee, Parliament of Australia, *Review of Intellectual Property Legislation Under the Competition Principles Agreement: Final Report* (2002) (IPCRC Report), 210. See also Ian Eagles and Louise Longdin, 'Competition in Information and Computer Technology Markets: Intellectual Property Licensing and Section 51(3) of the *Trade Practices Act* 1974' (2003) 3 *Queensland University Journal of Technology Law and Justice Journal* 28, 29.

marked lack of success in actions brought under s 46, and despite commendable efforts to develop economically sound tests in relation to s 46, it remains difficult at this point to discern clearly applicable principles from the major cases. Current doubt over the relevant tests to be applied in respect of s 46 mean these issues are likely to remain unresolved. In particular, there is some doubt as to what the current market power standard is, and the appropriate test to be applied in attempting to satisfy the 'take advantage' element. On the basis of recent reviews, s 46 will not undergo any significant amendment. This is not to say that amendment or clarification of the provision is not warranted, and this is explored further in Chapter 8.

Chapter 8 evaluates the likely impact of intellectual property dealings and in particular the probable treatment of refusals to license medical biotechnology patents, in terms of the current composition and interpretation of the section. Clear issues exist in relation to intellectual property dealings and s 46. Comparative case law discussed in Chapter 7 will be referred to during the course of this analysis. It will be concluded that there are unlikely to be any circumstances where a refusal to license a patent constitutes a misuse of market power pursuant to s 46.

In Chapter 5, it was stated that there are limited circumstances where a refusal to license a patent should be capable of falling within s 46. This formed the basis for the second and third limbs of the framework outlined in Chapter 5.[241] In Chapter 8, it will be argued that in even in these circumstances, Australian courts would be unlikely to find that the elements of s 46 are made out. The high threshold imposed in respect of the s 46 elements will be intensified when these elements are applied to a refusal to license a medical biotechnology patent. While this will be entirely appropriate in a majority of cases, it leaves no room for the small sub-set of refusals to license that could be classed as a misuse of market power, to receive adequate consideration under s 46.

---

[241] See above, 5.5.5. The second and third limbs provided that:

> [2] A refusal to license will, however, become examinable under competition law where the refusal is for the purpose of (i) expanding the scope of the intellectual property or (ii) extending market power into another distinct market not covered by the intellectual property.[241]
>
> [3] Where a refusal becomes examinable under [2](ii), the refusal should be examinable whether or not the holder of the intellectual property is currently exploiting the separate market,[241] and the reservation of another market for its own (actual or potential) use should not necessarily allow it to foreclose competition by others.

CHAPTER 7

REFUSALS TO LICENSE INTELLECTUAL PROPERTY: A COMPARATIVE ANALYSIS OF UNITED STATES AND EUROPEAN CASE LAW

7.1 INTRODUCTION

Having considered in detail s 46 of the *Trade Practices Act* 1974 (Cth) (TPA) and the key High Court cases interpreting that provision, this chapter attempts to draw themes from the comparative case law. United States (US) case law has conventionally received considerable attention by Australian courts in contemplation of competition law matters. This has particularly been the case in relation to s 46 and its US equivalent, section 2 of the *Sherman Act*.[1] The European Union (EU) legislative scheme is also of growing importance to Australia, and is giving rise to a growing body of case law.[2] The provision that is relevant to the issues discussed in this thesis is Article 82 of the *Treaty Establishing the European Community*.[3] The issue of refusals to license has been the subject of litigation on a number of occasions in both jurisdictions. This case law has resulted in a significant body of commentary. Australian courts have rejected a parochial approach that fails to consider case law from other jurisdictions. In particular, the cases that will be discussed in this chapter would be likely to be relied upon by Australian courts should the issue of refusals to license arise in relation to s 46. It is important to consider this growing body of case law given that there is no Australian case law to guide Australian courts.[4]

This chapter considers differences in treatment between the jurisdictions in which case law exists, and the relevance of these differences. At the outset it is important to note that the basic position in relation to licensing intellectual property is uniform across all three jurisdictions: there is no general duty to license intellectual property.

---

[1] *Sherman Act* 15 USC (1890).

[2] Space constraints mean that these discussions will necessarily be brief. The discussion that follows is intended to be an overview of international positions, sufficient to enable consideration of the implications of this jurisprudence for Australian policy.

[3] *Treaty Establishing the European Community* [2002] OJ C 325/65.

[4] Although there are two instances where the Australian Competition and Consumer Commission (ACCC) alleged that a refusal to license intellectual property constituted a misuse of market power. The first involved proceedings against the Commonwealth Bureau of Meteorology for refusing to supply copyrighted reports necessary for use in the downstream market for newspaper meteorological graphics. The second involved customer database information owned by Telstra, which may have been subject to copyright, and which was required for use in the downstream market for telephone directories. The first case settled, while in the second, Telstra provided court enforceable undertakings to the Commission. There is, therefore, no established precedent from either case. Although this is certainly not indicative of the position likely to be taken by courts, these requirements by the ACCC to give undertakings does demonstrate that there have been instances where upstream intellectual property has impacted had the potential to impact negatively on downstream markets. The matter has also been considered by the Trade Practices Commission in their 1991 Background Paper, although the guidance given is limited; see Trade Practices Commission (TPC) *Background Paper: Application of the Trade Practices Act to Intellectual Property* (1991) (TPC Background Paper), 15-18, 20-21.

This is consistent with the right of an intellectual property holder to exclude others. As will become evident, however, this principle is not absolute and is subject to some important exceptions. As a result of recent case law in the US and the EU, it has become evident that quite divergent approaches are being taken to antitrust regulation of refusals to license intellectual property within these jurisdictions, and the impact of this divergence has yet to be assessed.[5]

As Hovenkamp, Lemley and Janis point out, there are important distinctions between the provisions that are the subject of this chapter.[6] *First*, section 2 and Article 82 emanate from 'fundamentally different historical and political contexts ...'[7] Article 82, unlike section 2, is part of an attempt to harmonise and integrate the European economy.[8] *Secondly*, the structural and conceptual frameworks within which the respective laws operate differ considerably.[9] Nevertheless, the purpose of this chapter is to present an evaluation of cases that would be considered by Australian courts should the matter of refusals to license arise. It analyses two bodies of case law from the perspective of their relevance in the Australian context and is not an attempt to undertake a comparative analysis.

7.2 UNITED STATES JURISPRUDENCE[10]

The following section will discuss US jurisprudence dealing with refusals to license intellectual property. There are a significant number of cases that are potentially

---

[5] See James B Kobak Jr, 'Running the Gauntlet: Antitrust and Intellectual Property Pitfalls on the Two Sides of the Atlantic' (1996) 64 *Antitrust Law Journal* 341, especially 365.

[6] Herbert Hovenkamp, Mark A Lemley and Mark D Janis, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2002), (Hovenkamp Lemley and Janis), vol II, [45.3b].

[7] Ibid.

[8] Ibid.

[9] Ibid.

[10] There is a vast literature on this topic, and reference has been made to only a few of the many important articles relevant to the field. In addition to the articles cited during the course of this section, see, eg Jeffrey Mackie-Mason, 'What to do About Unilateral Refusals to License?' (2002) *Paper prepared for the DOJ/FTC Hearings, Washington DC*; Scott A Stempel and John F Terzaken, 'Casting a Long IP Shadow Over Antitrust Jurisprudence: The Federal Circuit's Expanding Jurisdictional Reach' (2002) 69 *Antitrust Law Journal* 711; Ronald S Katz and Adam J Safer, 'Should One Patent Court be Making Antitrust Law for the Whole Country?' (2002) 69 *Antitrust Law Journal* 687; J Venit and J Kallaugher, 'Essential Facilities: A Comparative Law Approach' [1994] *Fordham Law Institute* 315. The discussion in Herbert Hovenkamp, Mark A Lemley and Mark D Janis, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2002), (Hovenkamp Lemley and Janis), vol I, Chapter 13, was particularly useful, and references to this work are made throughout the following sections.

relevant. This section does not attempt to discuss all of this case law, but is limited to consideration of the leading cases.

7.2.1 UNITED STATES CASE LAW DEALING WITH REFUSALS TO LICENSE

As set out in Chapter 5, section 2 of the *Sherman Act* (1890)[11] is the provision that will apply to unilateral refusals to license intellectual property.[12] Section 2 applies to dealings in intellectual property.[13]

7.2.1.1 *THE BASIC POSITION*

It is a fundamental principle of US intellectual property law that a holder of intellectual property has no general duty to license, or to use its privilege at all.[14] Further, the *Patents Act*[15] provides that a patent owner will not be guilty of patent misuse by virtue of its refusal to use or license a patent.[16] In a number of cases concerning refusals to license intellectual property, US courts have stated, however, that intellectual property protection will not provide immunity from antitrust laws. Refusals to license have generally been dealt with through application of principles similar to those applied in refusal to deal cases. There exists a vast body of US case law dealing with refusals to deal, although application of systematic principles to these cases has arguably been lacking.[17] Glazer and Lipsky categorise US refusal to

---

[11] *Sherman Act* 15 USC (1890).

[12] To reiterate, *Sherman Act* 15 USC § 2 (1890) provides:

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony ...

The elements of § 2 were discussed above, 5.4.1.1.

[13] See, eg, *United States v Standard Sanitary Manufacturing Co* 226 US 20 (1912) and *Motion Pictures Patents Co v Universal Film Manufacturing Co* 243 US 502 (1917).

[14] The relevant authority in relation to patent law is *Continental Paper Bag v Eastern Paper Bag* 210 US 405 (1908). See also *Standard Oil Co v United States* 283 US 163 (1931). This principle is embodied in the US Department of Justice and the Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property*, (1995) (US Licensing Guidelines) <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm> at 27 October 2003, § 2.2.

[15] *Patent Act* 35 USC (1952).

[16] *Patent Act* 35 USC § 271(d)(4) (1952).

[17] For a useful analysis of the development of the refusal to deal doctrine, see, eg, Kenneth L Glazer and Abbott B Lipsky Jr, 'Unilateral Refusals to Deal Under Section 2 Of the *Sherman Act*' (1995) 63 *Antitrust Law Journal* 749.

deal cases generally into three main groups based on their objective competitive characteristics:[18]

- cases where a monopolist in a single, identified market refuses to deal;
- cases where a monopolist refuses to deal to gain or protect a monopoly in another market;[19] and
- cases where the monopolist refuses to deal with a party with which it does not compete.

Glazer and Lipsky provide this detailed examination in order to develop an analysis dependant on the particular characteristics of specific refusal to deal scenarios. Refusals to license intellectual property have traditionally fallen within the first and second groups. In relation to the first group, there have been some cases where intellectual property holders have refused to license technology to their competitors.[20] Glazer and Lipsky further refine the second group by dividing the cases into those that have involved vertically integrated markets, and those involving complementary markets. Cases where refusals to license have been alleged in vertical markets have typically fallen into the category of essential facility cases.[21] With respect to complementary markets, refusal to license cases can generally be grouped into refusals to share proprietary information with competing suppliers,[22] and cases involving aftermarkets for complementary products.[23]

---

[18] Ibid, especially 765-766. Glazer and Lipsky undertook this analysis by examining refusal to deal cases that had been decided by the courts.

[19] Note that 'leveraging' is recognised by some US courts as an independent violation of § 2 in that a violation may occur when a monopolist uses its position in one market to gain a competitive advantage (as opposed to a monopoly) in another market (eg, *Berkey Photo Inc v Eastman Kodak Co* F2d 263, 276 (2d Cir 1979). Other courts have been more reluctant to accept this expansive view of leveraging theory and require monopolisation in the second market. See Marina Lao, 'Unilateral Refusals to Sell or License Intellectual Property and the Antitrust Duty to Deal' (1999) 9 *Cornell Journal of Law and Public Policy* 193, fn 12, 198-209. Further, Lao points out that this matter is far from settled in the literature, with a number of notable Chicago school scholars questioning whether a monopolist can earn more than one monopoly rent; see, eg, Richard A Posner, *Antitrust Law: An Economic Perspective* (1976) 181-183. In turn, their position has been criticised by scholars who view monopoly leveraging as potentially anticompetitive, see eg, Louis Kaplow, 'Extension of Monopoly Power Through Leveraging' (1985) 85 *Columbia Law Review* 515.

[20] See, eg, *EI du Pont de Nemours & Co* (1980) aff'd 698 F2d 1377 (9th Cir) cert denied 464 US 955 (1983).

[21] These cases are discussed below, 7.2.3.

[22] For example, *Berkey Photo, Inc v Eastman Kodak Co* 603 F 2d 263 279-285 (2nd Cir 1979) cert denied, 444 US 1093 (1980); *BellSouth Advertising v Donnelley Information* 719 F Supp 1551 (SD Fla 1988) rev'd on other grounds, 999 F 2d 1436, 1566-1567 (11th Cir 1993).

[23] See, eg, *Image Technical Services Inc and Others v Eastman Kodak Co* 125 F 3d 1195 (9th Cir 1997), cert denied, 523 US 1094 (1998); *Data General Corporation and Data General Service Inc v*

This is not to say that refusals to license are not capable of falling into the third group. It could be envisaged, for example, that the holder of a patent right that constitutes an input into a number of downstream applications, may refuse to license downstream users because the patent holder wishes to reserve those downstream markets for its own use, or because an exclusive licence prevents the patent holder licensing to another downstream user. In general, however, these examples are not being encountered, or not being litigated. In addition there is no clear answer as to exactly when a refusal to license will fall foul of section 2. The following sections provide a brief overview of the primary US cases dealing with refusals to license intellectual property.

7.2.1.2 *THE CASE LAW – REFUSALS TO LICENSE INTELLECTUAL PROPERTY*[24]

Liability under section 2 of the *Sherman Act* will only arise where a refusal to deal 'extends, preserves, creates or threatens to create significant market power ... '.[25] Even under these circumstances, it will be difficult for a plaintiff to show that a refusal to license is anticompetitive given the general right of an intellectual property holder to deal with that privilege as they please. It has become clear that the refusal must extend the scope of the intellectual property in order to contravene section 2.[26]

There have been many cases dealing with refusals to deal with tangible property. Although a property owner may refuse to deal with a competitor that right is not unlimited. Section 2 may be violated where:

- the defendant acts with anticompetitive intent;
- there is no business reason for the refusal; or
- the property involved is an essential facility.[27]

A number of cases have considered refusals to license intellectual property. Various circuits have taken different approaches to the issue,[28] with the result that it is not

---

Grumman Systems Support Corporation 761 F Supp 185, 191-192 (D Mass 1991), aff'd in part and remanded, 36 F 3d 1147 (1st Cir 1994).

[24] The following discussion follows generally the format adopted by Hovenkamp, Lemley and Janis, above n6, and references to their work are made throughout the following sections where appropriate.

[25] Hovenkamp, Lemley and Janis, above n6, [13.23].

[26] Ibid, [13.23].

[27] See Ronald Myrick and Jonathon Gleklen, 'Antitrust Liability for the Exercise of Intellectual Property Rights Under US Law' (*Paper presented at a meeting of the International Association for the Protection of Intellectual Property*, Lisbon, 20 June 2002) <www.aippi.org/reports/Vortrag_Myrick.pdf> at 28 August 2005 (citations omitted).

clear what course the US Supreme Court would take were it required to consider the issue.[29] The following sections consider the leading cases in the area.[30]

(i) Intergraph Corporation v Intel Corporation[31]

Intergraph manufactured computer workstations. *Intergraph Corporation v Intel Corporation (Intergraph)* concerned a claim that Intel had discontinued supply to Intergraph of advance proprietary information, chips and technical support[32] in breach of section 2. The Federal Circuit heard the matter on appeal and held that there was no evidence of a section 2 violation in this case. Its decision was based on the grounds that Intel and Intergraph did not compete, and that Intel was justified in discontinuing preferential supply arrangements to Intergraph given that Intergraph had sued Intel.[33]

Nonetheless, the Court acknowledged that a refusal to deal could constitute a violation of section 2 where the refusal is directed against competition and its purpose is to 'create, maintain, or enlarge a monopoly'[34] and there was no valid business justification for the conduct.[35]

---

[28] US Federal Courts (Federal Trial Courts are also referred to as US District Courts) hear disputes that arise under US statutes. Appeals from the District Courts are heard by the US Courts of Appeals or Circuit Courts. At present, there are 11 regional Circuit Courts as well as the DC Circuit Court and the Federal Circuit. The Federal Circuit was specially created to hear patent and copyright appeals. Decisions from the US Circuit Courts are appealed to the Supreme Court, although the Supreme Court grants few petitions of certiorari. Thus, for the bulk of federal matters, the Circuit Courts are effectively courts of final resort.

[29] See Hovenkamp, Lemley and Janis, above n6, [13.28-13.29]. Note that the matter went before the Supreme Court before being remanded for trial. The Supreme Court did not have to consider the issue of Kodak's intellectual property, but commented that a manufacturer with 'inherent power' in one market is not immunised from the antitrust laws in another market, and that 'power gained through some natural and legal advantage such as a patent, copyright ... can give rise to liability if a seller exploits his dominant position in one market to expand his empire into the next.'; *Image Technical Services Inc v Eastman Kodak Co* 504 US, 451 (1992), n29.

[30] Note that there are a considerable number of relevant authorities however this section considers only the leading, recent judicial pronouncements in the area.

[31] *Intergraph Corporation v Intel Corporation* 195 F 3d 1346 (Fed Cir 1999) (hereafter *Intergraph*).

[32] Despite that fact that the case concerned products protected by intellectual property (proprietary information and patents) the court made no reference to this intellectual property and treated the case as a refusal to deal case. The District Court, on the other hand, expressly referred to Intel's patents, and concluded that Intel had 'no legitimate intellectual property basis with which it can refuse to supply ...': *Intergraph Corp v Intel Corp* 3 F Supp 2d 1255, 1279 (ND Ala 1998).

[33] *Intergraph Corporation v Intel Corporation* 195 F 3d 1346 (Fed Cir 1999), 1358-1359.

[34] *Intergraph Corporation v Intel Corporation* 195 F 3d 1346 (Fed Cir 1999), 1358.

[35] *Intergraph Corporation v Intel Corporation* 195 F 3d 1346 (Fed Cir 1999), 1358.

(ii) Data General Corporation and Data General Service Inc v Grumman Systems Support Corporation[36]

Data General Corporation and Data General Service Inc v Grumman Systems Support Corporation (*Data General*) This case involved a group of independent service organizations (ISOs) who argued that Data General had refused them access to copyrighted diagnostic software for use in repairing computer hardware. The ISOs argued that Data General was attempting to monopolise the market for service of its computer hardware. The ISOs used the software in any event and were sued for copyright infringement. The ISOs alleged that Data General had breached section 2.

The First Circuit held that the relevant inquiry was whether there was sufficient evidence to support a monopolisation claim.[37] It held that a refusal to license by a monopolist could support a monopolisation claim, but a desire on the part of a copyright holder to exclude others constituted a 'presumptively valid justification for any immediate harm to consumers.'[38] It was necessary to examine whether there was evidence to rebut the presumption in each case, and in this case there was no such evidence. The market for repair had not been significantly more competitive when Data General had supplied the ISOs. It was therefore impossible to conclude that Data General's former market practices satisfied demand under competitive conditions.[39] Data General's intent was not a relevant consideration.[40]

(iii) In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation[41]

In the case of *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* (*Xerox*), Xerox commenced a policy of refusing

---

[36] *Data General Corporation and Data General Service Inc v Grumman Systems Support Corporation* 761 F Supp 185, 191-192 (D Mass 1991), aff'd in part and remanded, 36 F 3d 1147 (1st Cir 1994).

[37] *Data General Corporation and Data General Service Inc v Grumman Systems Support Corporation* 761 F Supp 185, 191-192 (D Mass 1991), aff'd in part and remanded, 36 F 3d 1147 (1st Cir 1994), 1185-1186.

[38] *Data General Corporation and Data General Service Inc v Grumman Systems Support Corporation* 761 F Supp 185, 191-192 (D Mass 1991), aff'd in part and remanded, 36 F 3d 1147 (1st Cir 1994), 1187.

[39] *Data General Corporation and Data General Service Inc v Grumman Systems Support Corporation* 761 F Supp 185, 191-192 (D Mass 1991), aff'd in part and remanded, 36 F 3d 1147 (1st Cir 1994), 1188.

[40] *Data General Corporation and Data General Service Inc v Grumman Systems Support Corporation* 761 F Supp 185, 191-192 (D Mass 1991), aff'd in part and remanded, 36 F 3d 1147 (1st Cir 1994), 1188-1189.

[41] *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001).

supply of its patented copier parts to Independent Service Organisations (ISOs) and their customers, with the result that the business of servicing Xerox copiers was reserved to Xerox. Xerox counterclaimed for patent and copyright infringement,[42] arguing that it was under no duty to license the ISOs.

The Federal Circuit refused to impose liability on Xerox, holding that a patent holder was under no duty to license its patent except where:

- there was evidence of illegal tying;
- the patent was obtained by fraud;
- a lawsuit to enforce the patent was a sham; or

The ISOs argued that Xerox had sought to extend its patents beyond the scope of the statutory grant by attempting to control the market for service of its copiers in addition to the market for manufacture. The Court rejected this claim, holding that Xerox had not sought to illegally extend the scope of its patent protection beyond the statutory patent grant.[43] It observed that patents could cover more than one market, and the patent protection afforded to Xerox extended to the market for service.[44] The Court considered it unnecessary to consider Xerox's subjective motivation for refusing to license, and the result of their ruling was the creation of a per se rule of legality, with three very narrow exceptions.[45]

In relation to the copyrighted material, the Court endorsed the presumption created in *Data General*.[46] The Court refused to consider Xerox's subjective motivation for refusing to license in the absence of evidence that the copyrights were obtained by unlawful means or used to gain monopoly power beyond their statutory grant.[47]

---

[42] Xerox had copyright over its service drawings.

[43] *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001), 1327-1328.

[44] *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001), 1328.

[45] *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001), 1327.

[46] *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001), 1329.

[47] *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001), 1329.

(iv) Image Technical Services Inc and Others v Eastman Kodak Co[48]

The facts in *Image Technical Services Inc and Others v Eastman Kodak Co* (*Image Technical)* closely resembled those in *Xerox*, in that Kodak discontinued supply of photocopier parts to a number of ISOs. Kodak did not sue for patent or copyright infringement, but eventually defended the claim on the basis that its parts and software were protected by intellectual property.[49]

In finding against Kodak, the Ninth Circuit applied the rebuttable presumption laid down in *Data General*[50] (which had been restricted to copyright) to the refusal by Kodak to license its patented and copyrighted parts.'[51] They held that the presumption had been rebutted in this case on the grounds that:

- only a very small portion of Kodak's parts were actually patented;[52] and
- Kodak's intellectual property justifications were clearly not the genuine basis for the refusal to license.[53]

In considering the second ground, the Court looked to Kodak's intent in refusing to license, stating that

> [N]either the aims of intellectual property law, or the antitrust laws justify allowing a monopolist to rely upon a pretextual business justification to mask anticompetitive conduct.[54]

---

[48] *Image Technical Services Inc and Others v Eastman Kodak Co* 125 F 3d 1195 (9th Cir 1997), cert denied, 523 US 1094 (1998).

[49] Note that the matter went before the Supreme Court before being remanded for trial. The Supreme Court did not have to consider the issue of Kodak's intellectual property, but commented that a manufacturer with 'inherent power' in one market is not immunised from the antitrust laws in another market, and that 'power gained through some natural and legal advantage such as a patent, copyright ... can give rise to liability if a seller exploits his dominant position in one market to expand his empire into the next.'; *Image Technical Services Inc v Eastman Kodak Co* 504 US, 451 (1992), n29.

[50] To reiterate, the presumption applied in that case was that a desire on the part of a copyright holder to exclude others will constitute a presumptively valid business justification for harm to consumers. See above, 7.2.1.2(ii).

[51] *Image Technical Services Inc and Others v Eastman Kodak Co* 125 F 3d 1195 (9th Cir 1997), cert denied, 523 US 1094 (1998), 1219-1220.

[52] *Image Technical Services Inc and Others v Eastman Kodak Co* 125 F 3d 1195 (9th Cir 1997), cert denied, 523 US 1094 (1998), 1120.

[53] *Image Technical Services Inc and Others v Eastman Kodak Co* 125 F 3d 1195 (9th Cir 1997), cert denied, 523 US 1094 (1998), 1219-1220.

[54] *Image Technical Services Inc and Others v Eastman Kodak Co* 125 F 3d 1195 (9th Cir 1997), cert denied, 523 US 1094 (1998), 1219.

Thus, the Court considered intent to be a relevant factor in rebutting the presumption that ownership of intellectual property creates a presumptively valid justification for immediate harm to consumers. It would appear that the Court considered that findings such as the one it made would be rare in that they commented that they had 'serious concern' about the effect of claims such as this.[55]

(v) Subsequent Cases

It is worth noting two decisions subsequent to *Xerox*. The first, *United States v Microsoft Corporation* (*Microsoft*),[56] was not a unilateral refusal to deal case, but the DC Circuit made the following comment that would fail to exempt refusals to deal from antitrust liability:

> [Microsoft] claims an absolute and unfettered right to use its intellectual property as it wishes: "If intellectual property rights have been lawfully acquired," it says, then "their subsequent exercise cannot give rise to antitrust liability." ... That is no more correct than the proposition that use of one's personal property, such as a baseball bat, cannot give rise to tort liability.[57]

The other is a decision of the Supreme Court, *Holmes Group Inc v Vornado Air Circulation Systems Inc*,[58] where the Supreme Court held that the jurisdiction of the Federal Court is limited to cases involving patent claims, and does not extend to patent counterclaims to antitrust claims. This divests the Federal Circuit of exclusive jurisdiction over patent law matters,[59] and casts doubt on the jurisdiction of the Federal Court to determine issues such as those that arose in *Xerox* and *Intergraph*. Indeed, the Federal Circuit has begun transferring decision to the Circuit Courts on the basis of *Vornado*.[60] It also renders uncertain the precedential value of *Xerox* and *Intergraph*, and a recent decision of the Eleventh Circuit has stated that the decision only has persuasive authority.[61] The decision has been criticised[62] and has been the

---

[55] For a critique on the effect of *Image Technical Services Inc and Others v Eastman Kodak Co* 125 F 3d 1195 (9th Cir 1997), cert denied, 523 US 1094 (1998) see Michael H Kauffman, '*Image Technical Services Inc v Eastman Kodak Co*, Taking One Step Forward and Two Steps Back in Reconciling Intellectual Property Rights and Antitrust Liability' (1999) 34 *Wake Forest Law Review* 471.

[56] *United States v Microsoft Corporation* 253 F 3d 34 (DC Cir 2001).

[57] *United States v Microsoft Corporation* 253 F 3d 34 (DC Cir 2001), 63.

[58] *Holmes Group Inc v Vornado Air Circulation Systems Inc* 122 S Cr 1889 (2002).

[59] See, eg, Arti K Rai, 'Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform' (2003) 103 *Columbia Law Review* 1035, 1125.

[60] See, eg, *Telecom Technical Services Inc and Others v Rolm Company and Others* 388 F3d 820 (11th Cir 2004); *Medigene AG v Loyola University* 2002 WL 1478674 (Fed Cir June 27 2002)

[61] *Telecom Technical Services Inc and Others v Rolm Company and Others* 388 F3d 820 (11th Cir 2004), 826.

subject of a Congressional Hearing.[63] As yet, no legislation has been passed to overturn the decision.

(vi) Reconciling US Case Law

Hovenkamp, Lemley and Janis offer suggestions as to how these different approaches might be reconciled:[64]

- consider the decisions in light of the subtle differences presented by their individual factual scenarios. For example, Kodak's actions in *Image Technical* were clearly not motivated by a desire to protect their intellectual property, and the decision was probably intended to reflect this;
- analyse the rules laid down in the decisions in terms of the risks of error posed by the various rules. For example, a per se rule may provide business certainty but removes the ability to analyse individual cases on their facts with the risk that some possibly anti-competitive behaviour will be allowed. Choosing one rule over another necessarily involves weighing up various risks of error.[65]

Other commentators are more skeptical that the decisions can be reconciled, because the differences arose from fundamental variance in the manner in which the courts viewed the limitations of a patent grant.[66] While the Court in *Xerox* considered that patent protection extended to the market for service, the Court in *Image Technical* would appear to have considered the patent grant to be restricted to the market for

---

[62] Primary complaints are that the decision conflicts in Congressional intent in creating the Federal Circuit, and will result in decreased uniformity in hearing patent matters and 'forum shopping' by plaintiffs; see, eg, Elizabeth I Rogers, 'The Phoenix Precedents: The Unexpected Rebirth of Regional Circuit Jurisdiction Over Patent Appeals and the Need for a Considered Congressional Response' (2003) 16 *Harvard Journal of Law and Technology* 411; Larry D Thompson, 'Adrift on a Sea of Uncertainty: Preserving Uniformity in Patent Law Post-*Vornado* Through Deference to the Federal Circuit' (2004) 92 *Georgetown Law Journal* 523.

[63] Subcommittee on Courts, the Internet, and Intellectual Property, Committee on the Judiciary, US House of Representatives, One Hundredth Ninth Congress, *Holmes Group, The Federal Circuit and the State of Patent Appeals* (March 17 2005) Serial No 109-7 <http://judiciary.house.gov/Oversight.aspx?ID=117> at 9 August 2005.

[64] See Ibid, vol I, [13.29-13.30]. Hovenkamp, Lemley and Janis point out that the factual situations in each of the three cases did not give rise to truly unilateral refusals to deal in that they technically involved tying arrangements. The cases may have been decided differently had they involved purely unilateral refusals to license; at [13.30].

[65] See also A Douglas Melamed and Ali M Stoeppelwerth, 'The *CSU* Case: Facts, Formalism and the Intersection of Antitrust and Intellectual Property' (2002) 10 *George Mason Law Review* 407, 424.

[66] See, eg, Lao, above n19, 204. See also Michael A Carrier, 'Unravelling the Patent-Antitrust Paradox' (2002) 150 *University of Pennsylvania Law Review* 761.

parts.[67] Some commentators have questioned the correctness of the position in *Xerox*, on the basis of its breadth.[68]

7.2.2 SYNTHESIS AND SUMMARY OF THE US APPROACH TO REFUSALS TO LICENSE

Consideration of the cases discussed in the preceding section makes it evident that different courts in the US have laid down different tests to be applied in ascertaining whether a refusal to license intellectual property. While the First Circuit in *Data General* laid down a rebuttable presumption, the Federal Court in *Xerox* appears to have established a per se rule of legality for patents. The approach of the Ninth Circuit in *Image Technical* follows that in *Data General* to an extent, but is, in effect, an extended version of the *Data General* presumption in that it applies to patents as well as copyright, and allows consideration of a defendant's subjective intent.[69]

The holding in *Xerox* has garnered a considerable amount of support. Proponents of the rule argue that holders of intellectual property should be free to refuse to deal with any party.[70] Although the decision in *Xerox* is unlikely to be considered to be binding precedent at the present time due to the decision in *Vornado*,[71] Congressional amendment may result in its reinstatement as an authoritative precedent.[72] Further the decision remains persuasive authority.[73]

The decision in *Xerox* has many critics.[74] While it would appear that some agree in principle with the right of a holder of intellectual property to refuse to license in a

---

[67] See Lao, above n6, 204.

[68] See, eg, James Kobak Jr, 'The Federal Circuit as a Competition Law Court (2001) 83 *Journal of the Patent and Trademark Office Society* 527; Suzzette Rodriguez Hurley, 'Failing to Balance Patent Rights and Antitrust Concerns: The Federal Circuit's holding in *In re Independent Service Organisations Antitrust Litigation*' (2004) 13 *Federal Circuit Bar Journal* 475, 493-494; ibid, 205. Lao also questions its consistency with the statements of the Supreme Court in *Image Technical Services Inc v Eastman Kodak Co* 504 US, 451 (1992), n29.

[69] See Hovenkamp, Lemley and Janis, above n6, [13.28].

[70] See, eg, Jonathon I Gleklen, 'Per Se Legality For Unilateral Refusals to License IP is Correct as a Matter of Law and Policy' (2002) July, *The Antitrust Source* 1, <http://www.abanet.org/antitrust/source/> at 8 November 2004.

[71] *Holmes Group Inc v Vornado Air Circulation Systems Inc* 122 S Cr 1889 (2002).

[72] See above, n63 and accompanying text.

[73] See *Telecom Technical Services Inc and Others v Rolm Company and Others* 388 F3d 820 (11th Cir 2004).

[74] See, eg, Robert Pitofsky, 'Challenges of the New Economy: Issues at the Intersection of Antitrust and Intellectual Property' (2001) 68 *Antitrust Law Journal* 913; Nicolas Oettinger, '*Sherman Act* Violations: Refusal to License Intellectual Property: *In re Independent Service Organisation Antitrust Litigation* (2001) 16 *Berkley Technology Law Journal* 323; James B Gambrell, 'The Evolving Interplay of Patent Rights and Antitrust Restraints in the Federal Circuit' (2001) 9 *Texas Intellectual Property Law Journal*, 137.

narrow set of circumstances, many have argued[75] for exceptions,[76] particularly in cases where privileges are leveraged from one market into another in order to expand the scope of the privilege,[77] and cases of conditional refusals to license that seek to expand the scope of those privileges.[78] A number of commentators have also criticised the Court's treatment in *Xerox* of intellectual property as different to other forms of tangible property,[79] and the lack of sound economic analysis by the Court.[80]

In relation to the leveraging issue,[81] Gleklen argues that a patent gives the patent holder a right to leverage their patent into other markets, and the right to exploit a

---

[75] In response to these arguments see Jonathon Gleklen, 'Antitrust Liability for Unilateral Refusals to License Intellectual Property: *Xerox* and its Critics' (*Paper presented to the Department of Justice/Federal Trade Commission Hearings*, Washington DC, 1 May 2002) 5-15. A previous version of this paper was published at (2001) 2(1) *Antitrust and Intellectual Property* 11.

[76] The arguments advanced by parties on both sides of the debate are complex and focus on the relevant statutory scheme, principles of statutory construction and legislative history. While it is not necessary to examine these arguments in detail for the purposes of this thesis, they are usefully contrasted in Lao, above n19 and Gleklen, Per Se Legality for Unilateral Refusals to License Intellectual Property, above n70.

[77] See, eg, Lao, above n19; Mark R Patterson, 'When is Property Intellectual? The Leveraging Problem' (2000) 73 *South California Law Review* 1133.

[78] See, eg, Hovenkamp, Lemley and Janis, above n6, [13.31-13.32]; Jeffrey K Mackie-Mason, 'Antitrust Immunity for Refusals to Deal in (Intellectual) Property is a Slippery Slope' (2002), July, *The Antitrust Source* 1, <http://www.antitrustsource.com> at 1 November 2004.

This thesis does not deal directly with conditional refusals to deal, but does assert by virtue of limbs [2] and [3] of the framework proposed in 5.5.5 that attempts to expand the scope of intellectual property should be subject to competition law.

[79] See, eg, Melamed and Stoeppelwerth, above n65; Mackie-Mason, above n78. There are a number of limitations on the right of the owner of tangible property to refuse to deal; see above, 7.2.1.1. Melamed and Stoeppelwerth note that the effect of Xerox is to 'effectively immunise from antitrust liability a dominant firm's decision to deny rivals access to inputs or facilities they need, merely because those inputs or facilities contain patented or copyrighted materials, regardless of the competitive effect of the denial.'; Melamed and Stoeppelwerth, above n65, 409. Note that the competitive implications may be graver where access to inputs is denied to non-competitors.

[80] See, in particular, Kobak, above n5, 533-535, 539-541; Maureen O'Rourke, 'Striking a Delicate Balance: Intellectual Property, Antitrust, Contract and Standardisation in the Computer Industry' (1998) 12 *Harvard Journal of Law and Technology* 1, 31-35, Suzzette Rodriguez Hurley, 'Failing to Balance Patent Rights and Antitrust Concerns: The Federal Circuit's holding in *In re Independent Service Organisations Antitrust Litigation*' (2004) 13 *Federal Circuit Bar Journal* 475, 493-495; Peter M Boyle, Penelope M Lister and J Clayton Everett Jr, 'Antitrust Law at the Federal Circuit: Red Light or Green Light at the IP-Antitrust Intersection?' (2002) 69 *Antitrust Law Journal* 739. Specifically, the Federal Circuit is alleged to have failed to undertake sufficient analysis of the relevant market, the degree of market power, and the effect on the market of the refusal to license, see, especially, Maureen O'Rourke, 'Striking a Delicate Balance: Intellectual Property, Antitrust, Contract and Standardisation in the Computer Industry' (1998) 12 *Harvard Journal of Law and Technology* 1. It is difficult to see how factual analysis would be necessary upon application of a per se rule of legality, and this may assist in explaining this omission. The Court did, however, fail to provide a thorough economic evaluation of its rationale for implementing a per se rule.

[81] On the general requirements of establishing a leveraging claim, see Maurits Dolman, 'Restrictions on Innovation: An EU Antitrust Approach' (1998) 66 *Antitrust Law Journal* 455, 471-472.

patent may extend to more than one economic market because it is limited only by the claim language.[82] Accordingly, a broad scope of claims, read literally, could result in a number of antitrust markets being encompassed.[83] Enabling a patent holder to refuse to license these patents in these markets, regardless of whether they represent a crucial input, would be a legitimate exercise of the patented privilege.[84]

On the other hand, a particular economic monopoly, which is important for antitrust purposes, does not automatically follow from a patent monopoly.[85] Further, the patent right conveyed by statute is not intended to be unfettered. In the US, for example, there is no argument among commentators that tying arrangements should be (and are in fact) subject to antitrust scrutiny. If tying protected to unprotected patents falls outside the bounds of a patented right, it is submitted that leveraging a monopoly in one market into another secondary market is also capable of falling outside the patent holder's exclusive right. Indeed, leveraging and tying arrangements may have similar competitive outcomes,[86] and should be subject to similar antitrust standards.

Many commentators, despite advocating intellectual property as a presumptively valid business justification for refusing to license, recognise that there may be circumstances where holders of intellectual property seek to extend the scope of those privileges.[87] A rebuttable presumption would operate effectively in cases involving straightforward refusals to license. Intellectual property protection should not, however, provide an automatic justification for refusing to deal with another party where that refusal deals with property to which the intellectual property holder is not entitled by virtue of the privilege.[88] A rebuttable presumption should not protect a

---

[82] Gleklen, Antitrust Liability for Unilateral Refusals to License Intellectual Property, above n75, 7-8, discussing *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001), District Court decision, 1136, 1138. In addition, commentators such as Gleklen are not swayed by arguments in relation to footnote 29 of the *Kodak* decision; at 6-7 and see above, n49, n68.

[83] Gleklen, Antitrust Liability for Unilateral Refusals to License Intellectual Property, above n75, 7-8. Note that even some critics of the decision do not believe that the decision should be unfettered and should be subject to exceptions; see the discussion below, 7.2.1.2(vi).

[84] Ibid.

[85] Patterson, above n77, especially 1155-1156. Patterson points out that a defendant should be required to show that a patent is the source of its economic leveraging power; at 1156.

[86] Lao, above n19, especially 220.

[87] See also, Hovenkamp, Lemley and Janis, above n6, [13.31-13.32].

[88] Hovenkamp, Lemley and Janis point out that an important requirement in the application of the irrebuttable presumption is proof that the allegedly infringing use falls within the scope of the right, or does in fact infringe the right. This is more likely to be in issue in the case of copyright than patent law, because there are more limitations on a copyright holder than there are on a patent holder; ibid, [13.34-13.38].

patent holder, in circumstances where that patent holder, for example, simply refuses to license a party in a separate downstream market in which the patent holder does not operate.[89]

At the same time, considering evidence of subjective intent is bound to be problematic, in that it fails to take account of the competitive effects of a refusal to license. It is also likely to lead to evidentiary issues where allegations of 'pretext' are made,[90] and is illogical in that the effects of a desire to protect intellectual property are closely aligned with the effects of actions taken on the basis of a desire to eliminate competition.[91] In any event, it may be that the decision in *Image Technical* will be read narrowly so that evidence of intent will only be taken into account in cases where there is clear evidence (as there was in *Image Technical*) that a refusal to license was predicated on grounds other than intellectual property as asserted by the privilege holder.

Ultimately, very few claims are likely to be successfully upheld. Nevertheless, Melamed and Stoeppelwerth contend that there are compelling reasons for ensuring that an appropriate standard is in place for evaluating the legality of refusals to license. Specifically, they argue that a per se rule of legality is inappropriate because:

- some unilateral refusals to deal are in fact anticompetitive and damaging and warrant intervention by competition law;
- it is often difficult to distinguish between unilateral refusals to deal and other forms of exclusionary conduct. Implementing a per se rule is likely to encourage intellectual property holders to seek to exploit this fact;
- an immunity for intellectual property holders in the antitrust laws would be likely to distort business behaviour by discouraging licensing and undermining innovation; and
- a per se rule of legality ignores developments in US Supreme Court jurisprudence that base antitrust decisions on economic reasoning and fact-based analysis.[92]

---

[89] Note that there may be justifications for this conduct, and these are canvassed in more detail below, 8.3.4.1.

[90] Gleklen, Antitrust Liability for Unilateral Refusals to License Intellectual Property, above n75, 8.

[91] *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001), 1329; Kauffman, above n55, 523-524; Myrick and Gleklen, above n27, 30-31.

[92] Melamed and Stoeppelwerth, above n65, 423-425. See also Pitofsky, above n74.

Although it is not clear which of the approaches taken above would be likely to predominate were the Supreme Court required to consider the issue, the arguments advanced by critics of *Xerox* are certainly compelling. It was argued in Chapter 5 that the application of an antitrust-immunity approach in respect of this issue is inappropriate, because it ignores the fact that refusals to license may have anti-competitive implications.[93] They should, therefore, be subject to competition law. The governing factor in any assessment of a refusal to license by a patent holder that possesses the requisite degree of market power is whether that refusal to license is justified by efficiency considerations. A per se rule of legality with very narrowly defined exceptions leaves no room for this approach.

The framework presented in Chapter 5 is proposed on the basis that refusals to license be subject to competition law, and those refusals to license falling into limbs [2] and [3] be particularly subject to scrutiny. It is also intended that the framework be flexibly applied and refusals to license assessed on a case-by-case basis. Accordingly, limb [1] does not preclude closer inspection by regulators of a refusal to license in a primary market. Exceptional circumstances would, however, need to exist for such a refusal to license to contravene section 2 of the *Sherman Act*. US courts have generally taken a conservative view of refusals to license, and a finding of liability for a refusal to license falling within the second and third limbs would be rare. However, an approach that leaves *scope* for a finding of liability under limbs [2] and [3] of the framework is to be preferred.

While many refusals to deal are likely to escape antitrust scrutiny, it will often be the case that there is a fine line between legitimate and anticompetitive behaviour. The imposition of a blanket rule is therefore arguably inappropriate.[94] At the present time *Xerox* is unlikely to be followed, however, this may not be the case indefinitely.[95] It is submitted that the approach taken in *Data General* is to be preferred, and is more consistent with the framework. This approach could equally be applied to patents so that evidence that a patent holder was seeking to expand the scope of its privilege, or

---

[93] Above, 5.5.5.

[94] It may be that the decision in *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001) was intended to be, and will be interpreted to be, a narrowly operating rule that covers only purely unilateral refusals to license and does not operate in relation to other forms of conduct such as conditional refusals; see, eg, R Hewitt Pate, 'Refusals to Deal and Intellectual Property Rights' (2002) 10 *George Mason Law Review* 429; Boyle, Lister and Everett, above n80, 747-7484. Cf MacKie-Mason, above n10, especially 9. Even if this is the case, it is debatable whether or not a per se rule is appropriate.

[95] This will depend on whether Congress takes any action to overturn the result. See above, n63 and accompanying text.

refusing to license into a downstream market without any efficiency justification, would result in the rebuttal of the presumption of validity.[96]

It must also be borne in mind that different considerations do apply in respect of the various forms of intellectual property, as each confer different privileges and protection.[97] While copyright merely protects against the right to copy, patents provide a temporary monopoly and convey a far broader privilege. It is submitted that for this reason, they are likely to be accorded greater protection under competition law, and that US cases that have distinguished between the two regimes have invariably had these considerations in mind. Nevertheless, there could be circumstances where a refusal to license a patent has anti-competitive implications, and courts should take this into account.

7.2.3 ESSENTIAL FACILITIES

Hovenkamp, Lemley and Janis point out that the essential facilities doctrine is, in some respects, broader than the narrow refusal to deal claim.[98] While the remedy available for a refusal to deal would be limited to the specific act complained of by the competitor, an essential facilities claim provides a basis on which to seek an order that an intellectual property holder license all potential competitors.[99]

7.2.3.1 *THE DEVELOPMENT OF THE ESSENTIAL FACILITIES DOCTRINE IN THE US*

The essential facilities doctrine originated in the US in order to deal with cases where access to physical facilities and infrastructure were required in order to compete in a particular industry. It comprises a sub-set of the more general refusal to deal claims dealt with under section 2 of the *Sherman Act*, and as such is not an independent cause of action.[100] The doctrine has evolved via an extensive body of case law, which is too voluminous to discuss fully in this thesis. Instead, this section will simply seek to give a brief overview of the operation of the doctrine, and point to its import in terms of intellectual property.

---

[96] Nevertheless, the presumption is likely to result in findings of liability in fewer circumstances than would be likely under the framework, because the framework specifies general circumstances in which the scope of privileges conferred by intellectual property are likely to be expanded.

[97] This point was made in *Telecom Technical Services Inc and Others v Rolm Company and Others* 388 F3d 820 (11th Cir 2004), 826.

[98] Hovenkamp, Lemley and Janis, above n6, [12.22-13.23].

[99] Ibid.

[100] See the discussion in Robert Pitofsky, Donna Patterson and Jonathon Hooks, 'The Essential Facilities Doctrine Under US Antitrust Law' (2002) 70 *Antitrust Law Journal* 443, 446-447.

There are certain preconditions laid down in *MCI Communications Corp v AT&T Co*[101] that require satisfaction before the essential facilities doctrine will operate:

> (1) control of the essential facility by a monopolist; (2) a competitor's inability practically or reasonably to duplicate the essential facility; (3) the denial of the use of the facility to a competitor; and (4) the feasibility of providing the facility.[102]

A corollary to the fourth requirement is that a defence of legitimate business justification is also available to a defendant.[103] A plaintiff will need to show that more than mere inconvenience has been created by denial of access to the facility.[104] In addition, access to the facility must be indispensable in order to compete with the owner of the facility in a downstream market, and in most cases the facility will be an input of some kind necessary to produce a product in a downstream market in which the parties compete.[105] It would appear that competition must be foreclosed in a separate but related market before the doctrine will operate.[106] Vertical integration on the part of a monopolist is thus a cornerstone of the doctrine.

Commentators have endorsed the retention of these preconditions, and there is consensus even among advocates of the doctrine that strict conditions must govern its continuance.[107] Supporters of the doctrine assert that the courts have been far more willing to endorse it than most commentators, although only under the specific

---

[101] *MCI Communications Corp v AT&T Co* 708 F 2d 1081, 1132-1133 (7th Cir 1983), cert denied, 464 US 891 (1983).

[102] *MCI Communications Corp v AT&T Co* 708 F 2d 1081, 1132-1133 (7th Cir 1983), cert denied, 464 US 891 (1983).

[103] See *City of Anaheim v S Cal Edison Co* 955 F 2d 1373, 1379 (9th Cir 1992).

[104] *Alaska Airlines v United Airlines* 948 F 2d 536, 544-546 (9th Cir 1991).

[105] For example, the court in *MCI Communications Corp v AT&T Co* 708 F 2d 1081, 1132-1133 (7th Cir 1983), cert denied, 464 US 891 (1983) stated (at 1132) that:

> [A] monopolist's control of an essential facility (sometimes called a "bottleneck") can extend monopoly power from one stage of production to another, and from one market into another. Thus, the antitrust laws have imposed on firms controlling an essential facility the obligation to make the facility available on non-discriminatory terms.

Cf *Aspen Highlands Skiing Corp v Aspen Skiing Co* 738 F 2d 1509 (10th Cir 1984), which is the only clear authority supporting a contrary proposition; Paul D Marquardt and Mark Leddy, 'The Essential Facilities Doctrine and Intellectual Property: A Response to Pitofsky, Patterson and Hooks (2003) 70 *Antitrust Law Journal* 847, 854-855.

[106] See, especially, Phillip E Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* (2nd ed, 2002) [771(a)]; Hovenkamp, Lemley and Janis, above n6, [13.13]. Cf Pitofsky, Patterson and Hooks, above n100, 458-461. In response to this assertion by Pitofsky and Others, see Marquardt and Leddy, above n105, especially 855.

[107] See, eg, Mark A Lemley, 'Antitrust and the Internet Standardization Problem' (1996) 28 *Connecticut Law Review* 1041, 1085-1086.

conditions that govern its application in exceptional circumstances.[108] Many commentators, however, have argued for the abolition of the doctrine on the basis that it has evolved without clear limiting principles.'[109] The doctrine continues to operate but has been very narrowly construed by US courts.[110]

7.2.3.2 *THE ESSENTIAL FACILITIES DOCTRINE AND INTELLECTUAL PROPERTY*

Some commentators have supported the operation of the doctrine in cases involving intellectual property.[111] In a limited number of cases the doctrine has been argued in relation to intellectual property. For the most part, these attempts have been unsuccessful. Intellectual property privileges are unlikely to constitute an essential facility because they will rarely satisfy the requisite grounds from the *MCI Communications* case:[112]

- intellectual property privileges are unlikely in most cases to confer a monopoly, which is a necessary component of an essential facilities claim;
- a finding that intellectual property constitute a barrier to entry is unlikely to be made given that exclusion is the incentive provided by intellectual property;
- the holder of the intellectual property and the firm seeking access must compete in a downstream market; and
- in many cases, it is questionable whether intellectual property is essential for competition.

Although courts have not gone so far as to hold that intellectual property can never form the basis of an essential facilities claim,[113] no US court has explicitly held that

---

[108] Pitofsky, Patterson and Hooks, above n100.

[109] See, eg, Philip Areeda, 'Essential Facilities: An Epithet in Need of Limiting Principles' (1989) 58 *Antitrust Law Journal* 841, although see his n21 (noting that *MCI Communications Corp v AT&T Co* 708 F 2d 1081, 1132-1133 (7th Cir 1983), cert denied, 464 US 891 (1983) is probably correct in enforcing provision of an essential facility in some circumstances). See also Areeda and Hovenkamp, above n106, [771c].

[110] See, eg, the discussion in McCurdy, Gregory McCurdy, 'Intellectual Property and Competition: Does the Essential Facilities Doctrine Shed Any New Light?' (2003) 25(10) *European Intellectual Property Review* 472, 473-475.

[111] See, eg, Pitofsky, Patterson and Hooks, above n100, 452; Lao, above n19, especially 218 (noting that the refusal of a patent monopolist to deal with competitors in complementary markets would have the effect of eliminating competition and reducing innovation and consumer choice in those complementary markets).

[112] See generally Hovenkamp, Lemley and Janis, above n6, [13.18].

[113] Instead, courts have concluded that on the facts of the particular case in dispute the essential facilities doctrine was inapplicable. See, eg, *Data General Corp v Grumman Systems Support Corp* 761

intellectual property is essential.[114] Most claims that intellectual property constitutes essential facilities have been made on the basis that a privileged level of access to a particular competitor was discontinued.[115] This basically refutes any claim that a facility is essential for competition generally in a particular market. It is also conceivable that in many cases the holder of intellectual property will be able to successfully argue that the availability of some substitute for that privilege will defeat an argument that it constitutes an essential facility.[116]

Hovenkamp, Lemley and Janis suggest that claims that intellectual property privileges are essential facilities should be denied outright, although exceptions to this rule should be made where intellectual property is incidental to the control of a particular facility.[117] One commentator has suggested that it will only be established that intellectual property constitutes an essential facility where the holder of the intellectual property has gained control of a market that extends 'above and beyond the control that naturally flows from the exercise of the [intellectual property] rights themselves'[118] Further, it would need to be virtually impossible for competitors to attain any market share without the facility.[119] This may pave the way for

---

F Supp 185, 191-192 (D Mass 1991), aff'd in part and remanded, 36 F 3d 1147 (1st Cir 1994). Note that the court in this case concluded that if:

> [M]anufacturers of complex and innovative systems were required to share with competitors the development of accessories, because they had a possibly absolute advantage through producing the system, the incentives of copyright and patent laws would be severely undermined. Not only would the manufacturer, who is in the best position to create these accessories, have less incentive to do so, but also the impetus for competitors to reverse engineer and produce competing solutions would be reduced.

[114] See, eg, David L Aldridge Co v Microsoft Corp 995 F Supp 728, 751-756 (SD Tex 1998); Intergraph Corp v Intel Corp 195 F 3d 1346 (Fed Cir 1999). Note, however, BellSouth Advertising v Donnelley Information 719 F Supp 1551 (SD Fla 1988) rev'd on other grounds, 999 F 2d 1436, 1566-1567 (11th Cir 1993), where the district court held that the essential facilities doctrine was capable of applying to 'information wrongfully withheld', in this case, a copyrighted telephone directory.

[115] See, eg, Hovenkamp, Lemley and Janis, above n6, vol I, [13.3c]; *David L Aldridge Co v Microsoft Corp* 995 F Supp 728, 751-756 (SD Tex 1998); *Intergraph Corporation v Intel Corporation* 195 F 3d 1346 (Fed Cir 1999).

[116] Although arguably some patented medical biotechnology tools are difficult to substitute or invent around; see below, 7.2.4 Application of US Case Law to Refusals to License Medical Biotechnology Patents.

[117] Hovenkamp, Lemley and Janis, above n6, vol I, [13.18]-[13.22]. See also Abbott B Lipsky Jr and J Gregory Sidak, 'Essential Facilities' (1999) 51 *Stanford Law Review* 1187, 1193.

[118] McCurdy, above n110, 476 referring to the judgment in *Data General Corp v Grumman Systems Support Corp* 761 F Supp 185 (D Mass 1991), aff'd, 36 F 3d 1147 (1st Cir 1994). See also Hovenkamp, Lemley and Janis, above n6, [13.20.e]

[119] McCurdy, above n110, 477.

consideration of medical biotechnology patents as essentially facilities, although it is acknowledged that the possibility of the courts applying the doctrine to any form of intellectual property is remote. The restriction of the essential facilities doctrine to very exceptional cases has been supported by commentators, and finds support in the case law. It is very unlikely that a US court would apply the doctrine to a refusal to license intellectual property. This may operate to preclude a breach of section 2 where a patent holder refuses to license into a vertically integrated market. In this case, there must be some doubt as to whether liability under limbs [2](ii) and [3] of the framework could be established.

7.2.4 Application of US Case Law to Refusals to License Medical Biotechnology Patents

Issues at the intersection of intellectual property and antitrust have been widely discussed in relation to the information sector,[120] primarily in relation to copyrighted information technology (such as peripheral hardware and support systems) and software information. The biotechnology industry shares many of the characteristics of these industries. Both are characterised by a fast pace of technological innovation, a large number of market entrants at the initial stages of industry development, and efforts on the part of market participants to create and expand monopoly positions. Many of these efforts have not gone unrewarded, with progressive concentration being the hallmark of both industries.[121]

It would probably be fair to say, however, that the medical biotechnology industry offers smaller market participants a greater chance of continued innovative activity despite the presence of larger players on the market. Concentration has not necessarily precluded competition, although vertical integration is becoming increasingly common and is in fact desirable for many smaller companies and research institutions. There has also traditionally been a higher threshold for obtaining patent protection than copyright protection,[122] although with the vast numbers of patents being granted, patent protection appears to be increasingly attainable.

---

[120] See, eg, John H Barton, 'Paradigms of Intellectual Property/Competition Balances in the Information Sector' Organisation for Economic Cooperation and Development (OECD), *Competition Policy and Intellectual Property Rights* (1998), 295; O'Rourke, above n80. Note also the examples cited in the European context below, 7.3.4.

[121] In relation to information industries see, eg, Alessandra Narciso, '*IMS Health* or the Question Whether Intellectual Property Still Deserves a Specific Approach in a Free Market Economy' (2003) 4 *Intellectual Property Quarterly* 445, especially 450-451.

[122] Copyright protection is also conferred without a requirement that it be applied for, whereas as discussed earlier, obtaining patent protection involves a rigorous process of application and examination.

In comparison, there is surprisingly little discussion in the context of the medical biotechnology sector. This may be due to the fact that issues in relation to the information sector have been in existence for longer, and have been litigated, or that they have not yet been recognised in relation to medical biotechnology. It may also be due to the fact that the biotechnology industry is comprised of small, start-up companies for whom the costs of litigation are prohibitive.[123] Empirical evidence indicating that restrictive licensing is not especially problematic at the current time for the US biotechnology industry may also assist in explaining this absence of litigation.

It is difficult to predict the future direction US courts (and in particular the Supreme Court) are likely to take in relation to the issue of refusals to license intellectual property. If the approach taken by the Federal Court in *Xerox* is followed (and there is some doubt as to whether it will be), then a refusal to license a patented medical biotechnology research tool would be unlikely to ever contravene section 2. If, however, the approach in *Image Technical* is followed, the rebuttable presumption may provide stronger grounds for arguing that a refusal to license a patented biotechnology product or method constitutes a section 2 violation. Nevertheless, it will be difficult in a vast majority of cases to establish the elements of section 2 where access to a patent is refused.

It is submitted that a rebuttable presumption may well be applied to a refusal to license copyrighted information.[124] The question is whether this is also likely to be the test that will apply to a refusal to license a patent. Although the Court in *Image Technical* applied this presumption to patents, it is not clear that a subsequent court would follow this decision.[125] Nevertheless, it would be open to a court to apply the presumption in respect of patents, and consider objective evidence justifying the refusal to license.[126] Objective justifications for a refusal to license a patent may be

---

[123] Above, 1.5.2.

[124] In line with the decision in *Data General Corporation and Data General Service Inc v Grumman Systems Support Corporation* 761 F Supp 185, 191-192 (D Mass 1991), aff'd in part and remanded, 36 F 3d 1147 (1st Cir 1994). See above, 7.2.1.2(b). Note that the Federal Circuit in *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001) applied this presumption (in respect of copyright) but in limiting the circumstances in which the presumption could be rebutted effectively reduced it to a per se rule.

[125] Primarily on the basis that evidence of subjective motivation was taken to rebut the presumption.

[126] In *Data General Corporation and Data General Service Inc v Grumman Systems Support Corporation* 761 F Supp 185, 191-192 (D Mass 1991), aff'd in part and remanded, 36 F 3d 1147 (1st Cir 1994), competitive conditions prior to the conduct were considered by the Court, and it was concluded that the market for repair was not considerably more competitive before the refusal to license.

present in most cases but it is submitted that there is unlikely to be an adequate efficiency justification where a refusal to license prevents the development of a new product in a separate downstream market.[127] Thus, the application of the rebuttable presumption laid down by the First Circuit in *Data General* to patents may pave the way for consideration of refusals to license gene patents and other research tools necessary to conduct follow-on research, as contraventions of section 2.

This would depend on whether principles from general refusal to license cases, or essential facilities analysis, were applied to this factual scenario. Principles from the refusal to license cases discussed would probably be applied to a refusal to license a party with whom the patent holder does *not* compete.[128] It does not follow from this that establishing a contravention of section 2 would be an easy matter, but it is submitted that it would be *possible* to establish a contravention. If a vertically integrated patent holder refused to supply a downstream *competitor*, essential facilities principles would probably be employed.[129] Although some authors have argued the US essential facilities doctrine is capable of applying to intellectual property, this has been far from universally accepted.[130] It is submitted that it is very unlikely that a US court would find that a patent, even a broad patent whose claims encompass a number of uses, would constitute an essential facility.[131] Consequently, while limb [2](ii) of the framework *may* be made out under US law, it is extremely unlikely that a contravention of section 2 would be established in respect of a factual scenario in line with limb [3].

7.3 EUROPEAN JURISPRUDENCE

This section considers EU cases dealing with refusals to license intellectual property, and discusses the most important cases that have dealt with this issue. The European Court of Justice (ECJ) has considered the matter on a number of occasions and established relatively firm grounds on which a refusal to license will be anti-

---

[127] This matter is explored in greater detail in Chapter 8 in the context of the application of s 46 to refusals to license medical biotechnology patents; below, 8.3.4.1.

[128] It is a requirement of the essential facilities doctrine that the party refusing to deal compete in the downstream market with the party seeking supply; above, 7.2.3.1. This would preclude its application where the parties do not compete.

[129] Although where complementary markets are involved, general refusal to license principles would be employed. See the categorisation of cases by Glazer and Lipsky, above n17, discussed at 7.2.1.1. Note that complementary markets cannot be classified as separate downstream markets.

[130] See the discussion above, 7.2.3.2.

[131] US principles relating to refusals to license will be discussed further in the context of medical biotechnology patents in Chapter 8.

competitive. This contrasts with the position in the US where a number of Circuit Courts have been required to consider the same issue, resulting in conflicting rules.

7.3.1 EUROPEAN CASE LAW DEALING WITH REFUSALS TO LICENSE

Chapter 5 provided a basic overview of Article 82 of the *Treaty Establishing the European Community*,[132] the provision that will be invoked in the case of a unilateral refusal to license intellectual property. Article 82 clearly applies to dealings in intellectual property.[133]

7.3.1.1 *THE BASIC POSITION*

European jurisprudence dealing with refusals to license intellectual property offers an interesting point of comparison with the likely Australian position under s 46 (and indeed with the position under US law). The specific provisions in Article 82 most likely to be invoked are Article 82(b), which prohibits a dominant company from limiting the production, markets or technical development of its competitors to the prejudice of consumers, and Article 82(c), which prohibits discrimination with trading partners. This list is not, however, exhaustive[134] nor mutually exclusive.

It will become evident that refusals to license are treated more strictly in the EU than they are likely to be under the *TPA* (and indeed under section 2 of the *Sherman Act*), although there are important limitations to the extent to which an intellectual property

---

[132] *Treaty Establishing the European Community* [2002] OJ C 325/65. Article 82 was discussed in Chapter 5 and provides that:

> Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States.
>
> Such abuse may, in particular, consist in:
>
> (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
>
> (b) limiting production, markets or technical development to the prejudice of consumers;
>
> (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
>
> (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

The elements of Article 82 were briefly discussed above, 5.4.2.1. Note that Article 82 was formerly Article 86, and earlier cases that consider Article 86 instead of Article 82, will refer to Article 86. Thus, these references are intended to refer to the same provision.

[133] See generally Steven D Anderman, *EC Competition Law and Intellectual Property Rights: The Regulation of Innovation* (1998), 148-150.

[134] Joined cases C-395/96P, *Compagnie Maritime Belge*, March 16, 2000.

owner will be compelled to license. Article 82 had been interpreted in favour of protecting competitors rather than consumers generally for a considerable period of time during which intellectual property was viewed with a degree of hostility.[135] The basic position is accurately summarised as follows:

> When a licence of an intellectual property right is asked for, the refusal to license is unlawful only if the effect of a refusal would be exploitative or anti-competitive in some way not merely resulting from the refusal to license itself. There must be some seriously undesirable element in the situation in addition to the natural result of the refusal to license, This usually is, and perhaps must be, some specific loss caused to parties other than the competitors which may be excluded from the market by the intellectual property right.[136]

Prior to considering the case law in relation to refusals to license intellectual property, it is worth noting that the Commission generally defines markets fairly narrowly, whether the subject matter is intellectual property or some other form of property. This trend on the part of the Commission is prompted by a desire to control abuse by de facto monopoly holders.[137]

The starting point in any analysis of European case law dealing with refusals to license intellectual property is *Volvo AB v Erik Veng (UK) Ltd* (*Volvo v Veng*).[138] In *Volvo v Veng*, the European Court of Justice (the ECJ) stated that the right to refuse to license intellectual property constitutes the very subject-matter of intellectual property, and that a refusal to license an exclusive intellectual property privilege will

---

[135] See generally Anderman, *EC Competition Law and Intellectual Property Rights* above n133, 195-196; Valentine Korah, 'The Interface Between Intellectual Property and Antitrust: The European Experience' (2002) 69 *Antitrust Law Journal* 801, 808, 839.

[136] John Temple Lang, *Compulsory Licensing of Intellectual Property in the European Community Antitrust Law*, Paper Prepared for the Department of Justice/Federal Trade Commission Hearings, Washington DC, 19 April 2002.

[137] Steven D Anderman '*Microsoft* in Europe', (*Paper prepared for the Department of Justice/Federal Trade Commission Hearings, Washington DC*, 22 May 2002) 10; John Temple Lang, 'Defining Legitimate Competition: Companies Duties to Supply Competitors and Access to Essential Facilities' [1994] *Fordham Corporate Law Institute* 245.

[138] *Volvo AB v Erik Veng (UK) Ltd* [1989] 4 CMLR 122. See also *CICRA v Renault* [1988] ECR 6039. In *Volvo AB v Erik Veng (UK) Ltd* [1989] 4 CMLR 122, the limitations of the existence/exercise dichotomy were acknowledged by the ECJ, and this case marked the beginning of the end of the utilisation by the European Commission and Courts of the distinction. See further Thomas C Vinje, 'The Final Word on *Magill*: The Judgment of the ECJ' (1995) 17(6) *European Intellectual Property Review* 297, 299-300; above, 5.4.2.2.

not, in itself, constitute an abuse of a dominant position.[139] This general principle, however, is not without qualification.

7.3.1.2 *MAGILL*

The ECJ stated in *Volvo v Veng* that the presence of some additional element by way of abusive conduct could result in a finding that there had been an abuse of a dominant position.[140] This proviso was taken up in *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* (*Magill*).[141]

In *Magill*, an Irish publisher (Magill) prepared the first weekly television guide that included weekly listing information for all six channels operating in the area. Three television broadcasters operated in the area, and each ran two channels. Prior to the release of Magill's guide, there was no single source of this weekly information: viewers obtained listings from three separate guides produced by the respective broadcasters, which each gave listing information for their particular channels.

The broadcasters refused to license further listings information to Magill, and sought an injunction preventing the publication of further weekly guides by Magill on the basis of breach of copyright. Magill had, however, filed a complaint with the European Commission alleging breach of a dominant position by the broadcasters. The ECJ upheld the ruling of the Commission[142] and The Court of First Instance of the European Communities (CFI),[143] in finding that the broadcasters had abused a dominant position by virtue of their refusal to license their copyright in the listings information.

The ECJ applied the ruling of the CFI and held that a refusal by a copyright holder occupying a dominant position[144] to grant a licence to that copyrighted information,

---

[139] *Volvo AB v Erik Veng (UK) Ltd* [1989] 4 CMLR 122, [8] (Judgment). Note that the case concerned Article 86, now Article 82 of the *Treaty Establishing the European Community* [2002] OJ C 325/65.

[140] Examples given in that case were a refusal to supply spare parts to independent repairers, discontinuing the manufacture of parts for models in widespread use, or charging 'unfair' prices for spare parts; *Volvo AB v Erik Veng (UK) Ltd* [1989] 4 CMLR 122, [9] (Judgment).

[141] *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416.

[142] *Magill TV Guide Ltd v Independent Television Publications Ltd, British Broadcasting Corporation and Radio Telefis Eireann* (Case IV/31.851) [1989] 4 CMLR 757.

[143] *Radio Telefis Eirann v EC Commission* [1991] 4 CMLR 586; *British Broadcasting Corporation and BBC Enterprises Limited v EC Commission* [1991] 4 CMLR 669; and *Independent Television Publications Limited v EC Commission* [1991] 4 CMLR 745. Although the court gave separate judgments, they are very similar in content.

[144] The ECJ devoted little explanation to the issue of dominance, which is probably due in part to the fact that this issue was not appealed from the decision of the CFI. Dominance will ordinarily be tested

would not, in itself, amount to an abuse of a dominant position. However, in 'exceptional circumstances' a refusal to grant access to intellectual property will constitute abusive conduct. The ECJ adopted the reasoning of the CFI, in laying down three such circumstances as the basis for their decision that the broadcasters had engaged in abusive conduct:

- the lack of an effective substitute for the weekly guide offered by Magill, and the 'specific, constant and regular ...' potential consumer demand for this new product;[145]
- there was no objective justification for the refusal to license Magill;[146] and
- the broadcasters used their de facto monopoly in one market to preserve a monopoly in a secondary market by denying access to the raw material indispensable to the publication of a weekly guide.[147]

It was also clear from the ruling of the ECJ in *Magill* that exceptional circumstances must be present in order to ground a finding that a refusal to license intellectual property constitutes abusive conduct. The court failed however to elaborate on the application of these special circumstances, and whether they must be treated as cumulative or alternative requirements.

Potential application of the exceptional circumstances test demarcated by the ECJ certainly involved a considerable amount of ambiguity. While some commentators post-*Magill* argued that the conditions listed in *Magill* were required to be imposed

---

by the ability of a firm to act independently of competitors and consumers; Vinje, above n138, 299. The ECJ held that the broadcasters occupied a dominant position because they effectively held a de facto monopoly over information as to the channel, day, time and title of television programmes and were able to prevent effective competition on the market in weekly television magazines, *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416, [47] (Judgment).

[145] *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416, [52-54] (Judgment).

[146] *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416, [55] (Judgment). As Anderman points out, the implication following from this reasoning is that the mere possession of intellectual property will not amount to an objective justification; Anderman, *EC Competition Law and Intellectual Property Rights* above n133, 209.

[147] *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416, [56] (Judgment). That product being a weekly guide containing not only listings material, but also non-listings material such as articles, readers' letters and advertising material; see *Radio Telefis Eirann v EC Commission* [1991] 4 CMLR 586, [8].

cumulatively,[148] others favoured an interpretation that treated the conditions as alternative,[149] or considered that satisfaction of the third requirement could be sufficient.[150] Another possibility was that the conditions listed in *Magill* were merely examples of conduct capable of constituting abusive conduct.[151] The Court had found all three conditions to be present in *Magill*,[152] but it remained unclear whether this was essential in any case where the exceptional circumstances test was likely to be applied. In reality, even a close reading of the ECJ's decision fails to afford significant guidance as to the Court's intention. As Anderman points out, a non-cumulative reading of the conditions listed in *Magill* would have led to the conclusion that the exceptional circumstances test applied in two main situations:[153]

- where the intellectual property holder possessed a de facto monopoly in one market and refused to license an indispensable input into a secondary market in which its competitor intended to introduce a new product; and
- where the intellectual property holder possessed a de facto monopoly in one market but refused to license that intellectual property in order that a secondary market be reserved for its own use. This could possibly constitute an abuse regardless of whether the competitor intended to introduce a new product.

Consequently, the judgment gave rise to immediate alarm as to the scope of the decision.[154] Many commentators voiced concern that a broad reading of the circumstances enunciated by the ECJ could have ramifications for owners of intellectual property, particularly where those rights involved copyright protection

---

[148] See, eg, Korah, The Interface Between Intellectual Property and Antitrust: The European Experience, above n135, 814; Hedvig K S Schmidt, 'Article 82's "Exceptional Circumstances that Restrict Intellectual Property Rights' (2002) 23(5) *European Competition Law Review* 210, 214-5.

[149] See, eg, Rosa Greaves, '*Magill* Est Arrive...*RTE and ITP v Commission of the European Communities*' (1995) 16(4) *European Competition Law Review* 244, 246; Frank Fine, 'NDC/IMS: A Logical Application of Essential Facilities Doctrine' (2002) 23 *European Competition Law Review* 457, 460-462 who asserts that it is clear from subsequent interpretations (in *Ladbroke* and *Bronner*) that the existence of two markets is not necessary for the application of Article 82.

[150] Greaves, above n149, 246.

[151] It may be that the Court intended to preserve flexibility in this respect and not limit itself as it had conceivably done in *Volvo AB v Erik Veng (UK) Ltd* [1989] 4 CMLR 122; Vinje, above n138, 301.

[152] The ECJ stated that 'in the light of all those circumstances the Court of First Instance did not err in law in holding that the appellants' conduct was an abuse of a dominant position ...' [57] (Judgment).

[153] Anderman, *EC Competition Law and Intellectual Property Rights* above n133, 211-214. See also Anderman, *Microsoft* in Europe, above n137, 13-14.

[154] See, eg, Schmidt, above n147; Dolman, above n81.

over information technology or software.[155] Similar issues arise in respect of patents, and instances where upstream patent owners could be compelled to license their inventions could be envisaged.[156] The decision also paved the way for consideration of intellectual property privileges as essential facilities,[157] being an area in which the EC Commission had already become active.[158]

It would appear however, from subsequent decisions, that the potentially very broad scope of *Magill* has been limited.

7.3.1.3 *THE NARROWING OF THE SCOPE OF MAGILL*

The issue of refusals to license was next considered in *Tierce-Ladbroke SA v EC Commission* (*Ladbroke*),[159] when Ladbroke's subsidiary was refused a license to show films of French horse races after bets on those races had been shown in its betting shops in Belgium. The CFI held that *Magill* was distinguishable on the following grounds:[160]

- Ladbroke had the largest share of the market for betting services in Belgium and did not require the use of films to enter the market.[161] The refusal to license did not restrict competition by preventing the appearance of a new product for which there was consumer demand;[162]

---

[155] See, eg, Narciso, above n121; Vinje, above n138. Cf Ulrika Bath, 'Access to Information v Intellectual Property Rights' (2002) 24(3) *European Intellectual Property Review* 138.

[156] See Valentine Korah, 'Patents and Antitrust' (1997) 4 *Intellectual Property Quarterly* 395. See further below, 7.3.4.

[157] Although the ECJ did not use the term 'essential facility', it effectively applied the doctrine in this case by holding that an undertaking with a dominant position in a market may be compelled to license the intellectual property that allows it to maintain a position of dominance. See further below, 7.3.2.

[158] See the examples in the opinion of Advocate General Jacobs in *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs-und Zeitschriftenverlag GmbH & Co KG and Other* [1999] 4 CMLR 112.

[159] *Tierce-Ladbroke SA v EC Commission* [1997] 5 CMLR 309.

[160] See also Valentine Korah, 'The *Ladbroke* Saga' (1998) 19(3) *European Competition Law Review* 169, 173.

[161] The CFI endorsed the view of the Commission that the product market was the market for transmissions, or films of races, but determined that this market was ancillary to the principal market of betting. Because they considered betting to be a national market, they declared that the ancillary market for films should correspondingly be treated as national; see *Tierce-Ladbroke SA v EC Commission* [1997] 5 CMLR 309, [82-89]. The CFI's decision in relation to Article 82 was therefore influenced by this somewhat restrictive definition of the relevant market; ibid, 169-171, 173.

[162] *Tierce-Ladbroke SA v EC Commission* [1997] 5 CMLR 309, [130].

- Although films of French races were an 'additional, and ... suitable ...' service for bettors, they were not essential to Ladbroke in operating betting shops;[163] and
- since films are shown after the placing of bets, they did not affect the choices made by bettors and were not indispensable to bookmakers' activities.[164]

Consequently, the Court provided some clarification of what the term 'exceptional circumstances' in *Magill*, meant.[165] Although not expressly addressing the issue of whether the requirements in *Magill* were cumulative or alternative, the implication from the ECJ's judgment in *Ladbroke* is that they were alternatives.[166] Indeed, the judgment has been read to mean that the appearance of a new product is unnecessary provided the product or service in question constitutes an essential product or service for the activity in question.[167]

The ECJ stated more clearly that the conditions were cumulative in *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs-und Zeitschriftenverlag GmbH & Co KG and Others.*[168] Although this case did not concern intellectual property, the comments of the ECJ in relation to *Magill* can be generalised to provide guidance as to the application of the 'exceptional circumstances' test.[169] In this case, Oscar Bronner sought access to Mediaprint's nationwide newspaper home-delivery network in Austria. The ECJ accepted Mediaprint's arguments that although it occupied a dominant position in the relevant market, it had not abused that position by failing to provide access to Oscar Bronner.

The ECJ stated that previous judgments had regarded a refusal to supply as abusive only where that refusal 'was likely to eliminate all competition on the part of that

---

[163] *Tierce-Ladbroke SA v EC Commission* [1997] 5 CMLR 309, [131-132].

[164] *Tierce-Ladbroke SA v EC Commission* [1997] 5 CMLR 309, [132].

[165] Fine, *NDC/IMS*, above n149, 460-461.

[166] See, eg, Darren Fitzgerald, '*Magill* Revisited' (1998) 20(4) *European Intellectual Property Review* 154, especially 160-161.

[167] See, eg, *National Data Corporation Health Information Services (NDC) v IMS Health Inc (Interim Measures)* [2002] 4 CMLR 3, [68], [180]; Fine, NDC/IMS, above n149, 461; John Temple Lang, 'The Principle of Essential Facilities in European Community Competition Law – The Position Since *Bronner*' (2000) 1 *Journal of Network Industries*, 375, his n2. Fine's view is that this is the correct position and entirely consistent with US case law on essential facilities; see Fine, *NDC/IMS*, above n149, 461. See also generally Frank Fine, '*NDC/IMS*: In Response to Professor Korah' (2002) 70 *Antitrust Law Journal* 247.

[168] *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs-und Zeitschriftenverlag GmbH & Co KG and Other* [1999] 4 CMLR 112 [1999] 4 CMLR 112 (*Oscar Bronner*).

[169] Pat Treacy, 'Essential Facilities – Is the Tide Turning?' (1998) 19 *European Competition Law Review* 501, 504.

undertaking.'[170] In the event that *Magill* applied to a case such as this where access to tangible property was sought,[171] on the surface it would appear that the ECJ indicated that they considered the conditions laid down in *Magill* were to be interpreted cumulatively.[172] Thus, in this case Oscar Bronner would need to establish:

> [N]ot only that the refusal of the service comprised in home delivery be likely to eliminate all competition in the daily newspaper market on the part of the person requesting the service *and* that such refusal be incapable of being objectively justified, *but also* that the service in itself be indispensable to carrying on that person's business, inasmuch as there is no actual or potential substitute in existence for that home-delivery scheme (*emphasis added*).[173]

The ECJ held that these conditions were not satisfied in this case. Specifically, the court found that the delivery service was not indispensable to Oscar Bronner's business, because other distribution methods were available.[174] Further, there was no technical, legal or economic barrier preventing Oscar Bronner, either alone or in

---

[170] *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs-und Zeitschriftenverlag GmbH & Co KG and Other* [1999] 4 CMLR 112, [38] (Judgment). The court referred to two judgments: *Istituto Chemioterapico Italiano SpA and Commercial Solvents Corporation v EC Commission* [1974] 1 CMLR 309 (*Commercial Solvents*) and *Centre Belge d'Etudes de Marche-Tele-Marketing SA v Compagnie Luxembourgeoise de Telediffusion SA and Information Publicite Benelux SA* [1986] 2 CMLR 558 (the *Tele-marketing* Case). See further below 7.3.2.

[171] It is arguable that the ECJ did not intend its Judgment to apply to refusals to license intellectual property: see the wording at [41] of the Judgment; Estelle Derclaye, 'Abuses of Dominant Position and Intellectual Property Rights: A Suggestion to Reconcile the Community Courts Case Law' (2003) 26(4) *World Competition* 685, 694-696.

[172] *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs-und Zeitschriftenverlag GmbH & Co KG and Other* [1999] 4 CMLR 112, 40-41] (Judgment). Note, however, that it is less clear that there is a requirement for two markets as was required in *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416. There is also no reference to a requirement for a new product, which was specifically required in *Magill*. Fine points out that this leaves the judgment in *Oscar Bronner* as entirely consistent with *Magill*; Fine, NDC/IMS, above n149, 461 It did, however, leave some doubt as to the application of the 'exceptional circumstances' test in *Magill*, and whether a new product requirement was an alternative to an essential facility requirement; Fine asserts that a new product requirement was clearly not a constituent element of the Magill test as clarified in *Tierce-Ladbroke SA v EC Commission* [1997] 5 CMLR 309.

[173] *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs-und Zeitschriftenverlag GmbH & Co KG and Other* [1999] 4 CMLR 112, [41] (Judgment).

[174] *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs-und Zeitschriftenverlag GmbH & Co KG and Other* [1999] 4 CMLR 112, [43] (Judgment). Korah suggests that although the ECJ failed to specify the basis for their finding on indispensability, this places a further limitation on the essential facilities doctrine in that the doctrine will not apply once there are two firms with a particular facility; Korah, The Interface Between Intellectual Property and Antitrust: The European Experience, above n135, 819.

conjunction with other publishers, from establishing a nationwide home delivery scheme.[175]

7.3.1.4 *THE IMS DECISION*

(i) NDC v IMS: The Commission Decision

A subsequent decision by the EC Commission (the Commission) reignited debate over the duty of intellectual property holders to license their intellectual property. The facts of *National Data Corporation Health Information Services (NDC) v IMS Health Inc (IMS)*[176] were that IMS developed a system for supplying information to pharmaceutical companies, on sales and prescription of pharmaceutical products. The system divided particular territories into small 'bricks', which each incorporated information about several pharmacies. Although the pharmaceutical companies had been partially responsible for establishing the system, IMS had expended considerable resources and effort in designing and maintaining the structure.

Because IMS held a dominant position in the market and indeed had been the only firm providing sales data (on the basis of the brick structure) for some time, NDC found when it entered the market that customers were unwilling to accept information based on a different structure, and it was therefore unable to compete with IMS. NDC and another new entrant used the brick structure and were sued by IMS for breach of copyright. IMS successfully obtained an injunction, but NDC appealed the decision that found that they were in breach of copyright.

On an interim basis,[177] the EC Commission determined that IMS should license its brick structure to the new entrants pending a final decision on the breach of copyright issue given the inability of new market entrants to compete with IMS in the absence of the availability of the structure.[178] This decision was based on the fact that NDC would be likely to go out of operation without use of the structure, which was

---

[175] *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs-und Zeitschriftenverlag GmbH & Co KG and Other* [1999] 4 CMLR 112, [44-46] (Judgment). The ECJ indicated that in this respect it was not open to Oscar Bronner to argue that the small circulation of their newspapers made it economically unviable to establish an equivalent home-delivery service; at [45] (Judgment).

[176] *National Data Corporation Health Information Services (NDC) v IMS Health Inc (Interim Measures)* [2002] 4 CMLR 3.

[177] The Commission has the power to grant interim relief where there is a likelihood of serious and irreparable harm to an applicant and urgency: see *Camera Care v Commission* [1980] ECR 119.

[178] *National Data Corporation Health Information Services (NDC) v IMS Health Inc (Interim Measures)* [2002] 4 CMLR 3, [184-185].

'incapable of being replicated by means of a non-infringing parallel creation.'[179] In other words, it constituted a '*de facto* industry standard.'[180] In interpreting *Magill*, the Commission stated that:

> The Court ... recognised that in exceptional circumstances the exercise of an exclusive right deriving from an intellectual copyright may be abusive even in the absence of abusive additional conduct when, *inter alia*, it prevents the appearance of a new product.[181]

However, the Commission referred to later cases and held that this condition was not an essential component of the exceptional circumstances test laid down in *Magill*.[182] The fact that competition would be reduced in the market in which IMS operated, and that there was no objective basis for the refusal to license, was considered to be sufficient to establish that exceptional circumstances existed in this case.[183] The Commission's decision gave rise to a flurry of commentary, but the decision was predictably appealed to the CFI.

(ii) The Appeal to the CFI

On appeal to the CFI,[184] the President suspended the Commission's decision on the basis that there was a serious doubt[185] as to the correctness of the legal proposition underlying the Commission's decision.[186] *First*, there were important differences between the facts of this case and the facts of *Magill*, centred around the fact that NDC was offering merely 'new variations of the same services and on the same market as the dominant undertaking ...'[187]

Secondly, the President briefly considered the authorities dealing with refusals to license, and questioned whether there were exceptional circumstances justifying the

---

[179] *National Data Corporation Health Information Services (NDC) v IMS Health Inc (Interim Measures)* [2002] 4 CMLR 3, [184].

[180] *National Data Corporation Health Information Services (NDC) v IMS Health Inc (Interim Measures)* [2002] 4 CMLR 3, [180].

[181] *National Data Corporation Health Information Services (NDC) v IMS Health Inc (Interim Measures)* [2002] 4 CMLR 3, [67].

[182] *National Data Corporation Health Information Services (NDC) v IMS Health Inc (Interim Measures)* [2002] 4 CMLR 3, [67-70], [180-184].

[183] *National Data Corporation Health Information Services (NDC) v IMS Health Inc (Interim Measures)* [2002] 4 CMLR 3, [75-174].

[184] *IMS Health Inc v EC Commission* [2002] 4 CMLR 2 (Order dated 26 October 2001).

[185] This would justify suspension of the Commission's decision.

[186] *IMS Health Inc v EC Commission* [2002] 4 CMLR 2 (Order dated 26 October 2001) [106].

[187] *IMS Health Inc v EC Commission* [2002] 4 CMLR 2 (Order dated 26 October 2001) [101].

imposition of a duty to license where the holder of intellectual property was itself offering the same product as the complainant.[188] As noted by the CFI, in deciding this issue the Commission would appear to have relied upon a non-cumulative interpretation of the conditions listed in *Magill* as regarding exceptional circumstances.[189] This, the CFI observed, is an expansive interpretation of the concept of exceptional circumstances,[190] and the possibility that these conditions must be concurrently established, remains.[191] Accordingly, only a final determination by the CFI on this problematical issue, could justify an order compelling IMS to license its competitors.[192] The ECJ confirmed the suspension without making specific comment on the content of the CFI's decision.[193]

The Commission subsequently announced that its interim measures decision against IMS had been withdrawn on the basis that a German national court had permitted the development by competitors of structures that could be deemed to have been derived from IMS's structure.[194] There was, therefore, no urgency in relation to access.

(iii) The Reference to the ECJ

The national court then requested that the ECJ provide it with a preliminary ruling on the interpretation of Article 82. The ECJ's ruling[195] confirmed that the conditions in *Magill* must be treated as cumulative,[196] and emphasised the importance of establishing an upstream and a downstream market:

---

[188] *IMS Health Inc v EC Commission* [2002] 4 CMLR 2 (Order dated 26 October 2001) [101-105].

[189] *IMS Health Inc v EC Commission* [2002] 4 CMLR 2 (Order dated 26 October 2001) [100].

[190] *IMS Health Inc v EC Commission* [2002] 4 CMLR 2 (Order dated 26 October 2001) [102].

[191] *IMS Health Inc v EC Commission* [2002] 4 CMLR 2 (Order dated 26 October 2001) [103-104].

[192] *IMS Health Inc v EC Commission* [2002] 4 CMLR 2 (Order dated 26 October 2001) [106]. In this respect, the President observed that although the interpretation adopted by the Commission may be correct, the alternative interpretation was equally capable of finding support in the case law.

[193] The ECJ upheld the CFI's suspension of the Commission's order pending review of the main copyright action; *NDC Health Corporation and NDC Health GmbH & Co KG v EC Commission* [2002] 5 CMLR 1.

[194] See 'Commission Intervention no Longer Necessary to Enable NDC Health to Compete with IMS Health', *Press Release*, 13 August 2003, <http:europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/1159&format=HTML&aged=0&language=EN&guiLanguage=en> at 20 September 2004). See also 'Commission Withdraws Interim Measures in *NDC Health/IMS Health* Case' (2003) *EU Focus* 4.

[195] *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* [2004] 4 CMLR 28.

[196] *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* [2004] 4 CMLR 28 [38] (Judgment).

> [I]t is determinative that two different stages of production may be identified and that they are interconnected, the upstream product is indispensable in as much as for supply of the downstream product.[197]

In considering the indispensability of intellectual property, the Court held that:

> [I]t must be determined whether there are products or services which constitute alternative solutions, even if they are less advantageous, and whether there are technical, legal or economic obstacles capable of making it impossible or at least unreasonably difficult for any undertaking seeking to operate in the market to create, possibly in cooperation with other operators, the alternative products or services ... on a scale comparable to that of the undertaking which controls the existing product or service.[198]

The ECJ established that a refusal to license intellectual property will constitute abusive conduct contrary to Article 82 where the following conditions are fulfilled:[199]

- [T]he undertaking which requested the licence intends to offer ... new products or services not offered by the [intellectual property right] owner and for which there is a potential consumer demand;[200]
- the refusal is not justified by objective considerations; [and]
- the refusal is such as to reserve to the [intellectual property right] owner the [downstream] market ... in the Member State concerned by eliminating all competition on that market.

The ECJ thus reiterated the requirements laid down in *Magill*, and confirmed the importance of these requirements in determining whether a product protected by intellectual property constitutes an indispensable or essential requirement for entry into a market. The case reverted to the national court for determination of this issue.

---

[197] *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* [2004] 4 CMLR 28 [45] (Judgment).

[198] *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* [2004] 4 CMLR 28 [28].

[199] *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* [2004] 4 CMLR 28 [48-52] (Judgment).

[200] Note that the Advocate General in his opinion reworked this concept slightly by stating that the undertaking seeking the licence must intend 'to produce goods or services of a different nature which, although in competition with those of the owner of the right, answer specific consumer requirements not satisfied by existing goods or services.'; *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* [2004] 4 CMLR 28 AG62 (Advocate General's Opinion). Thus, while the Advocate General refined the test laid down in *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416, the ECJ declined to adopt this condition and reverted to the wording laid down in *Magill*.

The *IMS* case highlights the difficulty in determining the circumstances in which access to intellectual property should be compelled, and the difficulty in interpreting judicial pronouncements on the matter. Nevertheless, there were some marked similarities between the facts of *IMS* and *Magill*[201] which probably aids in explaining the Commission's decision.[202] There was however, an important difference[203] that assists in explaining the ECJ's reluctance to uphold the Commission's decision: in *IMS*, NDC did not offer a fundamentally new product.[204] Moreover, *IMS* did not involve a downstream market in the sense of a leverage of power into a market secondary to that in which exclusivity had been granted.[205] In laying down the requirement that a licence will only be compelled where a new product on a downstream market is offered, the ECJ effectively restricted the applicability of *Magill* to a very limited set of circumstances.

7.3.2 THE STATUS OF THE ESSENTIAL FACILITIES DOCTRINE

Under EU law, an essential facilities doctrine operates which is derived from US essential facilities principles.[206] In *IMS*, the issue arose as to whether an order that the copyrighted information be declared an essential facility, would mean that European law conflicted with US law. In response to this question, some commentators have submitted that the Commission's ruling was entirely consistent with established US

---

[201] Ian S Forrester, 'Compulsory Licensing in Europe: A Rare Cure to Aberrant National Intellectual Property Rights?' (2002) *Paper Prepared for the Department of Justice/Federal Trade Commission Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy: Comparative Law Topics*, 22 May 2002, 22. Forrester points out that there was one important factor relied upon by the Commission that set *IMS* apart from *Magill*: in *IMS*, the brick structure represented an industry standard in that it had been developed by industry participants as an open standard. Exclusion by IMS based on this standard therefore constituted an abuse; at, 12-15, 22. The law relating specifically to industry standards will not be discussed in detail in this thesis, although reference may be made to the concept at various points.

[202] Not only was the intellectual property 'questionable' or 'unusual' in both cases, but in both cases there was some discrimination in supply where refusals were directed only at competitors. Also, in both cases the Commission found that all competition would be eliminated in the absence of an order compelling licensing; ibid n22; David Aitman and Alison Jones, 'Competition Law and Copyright: Has the Copyright Owner Lost the Ability to Control his Copyright?' (2004) 26(3) *European Intellectual Property Review* 137, 141.

[203] Forrester, above n201, 22.

[204] In another respect, however, NDC had a stronger case in that it was merely seeking a delivery vehicle for information it had obtained. In contrast, Magill simply sought to use information compiled independently of it; ibid 22.

[205] See also Aitman and Jones, above n202, 141.

[206] On the development of the doctrine in the EU see Temple Lang, Defining Legitimate Competition, above n137. This article has been widely cited and influential. See also Derek Ridyard, 'Essential Facilities and the Obligation to Supply Competitors Under the UK and EC Competition Law' (1996) 17(8) *European Competition Law Review* 438;

jurisprudence on the subject of essential facilities.[207] Arguably, the EU doctrine is, however, more likely to be applied to dealings in intellectual property than the US doctrine.

7.3.2.1 *THE DOCTRINE'S EVOLUTION FROM GENERAL REFUSAL TO SUPPLY CASES*

The essential facilities doctrine in the EU is well entrenched, and had its genesis in a number of refusal to deal cases, most notably *Istituto Chemioterapico Italiano SpA and Commercial Solvents Corporation v EC Commission* (*Commercial Solvents*)[208] and *Centre Belge d'Etudes de Marche-Tele-Marketing SA v Compagnie Luxembourgeoise de Telediffusion SA and Information Publicite Benelux SA* (*Telemarketing*).[209] As such, the Commission[210] has stated that the essential facilities doctrine will operate in the following circumstances:

> An undertaking which occupies a dominant position in the provision of an essential facility and itself uses that facility (ie a facility or infrastructure, without access to which competitors cannot provide services to their customers), and which refuses other companies access to that facility without objective justification or grants access to competitors only on terms less favourable than those which it gives its own services, infringes Article 86 if the other conditions of that Article are met. An undertaking in a dominant position may not discriminate in favour of its own activities in a related market. The owner of an essential facility which uses its power in one market in order to protect or strengthen its position in another related market, in particular, by refusing to grant access to a competitor, or by granting access on less favourable terms than those of its own services and thus imposing a competitive disadvantage on its competitors, infringes Article 86.[211]

---

[207] See Pitofsky, Patterson and Hooks, above n100.

[208] *Istituto Chemioterapico Italiano SpA and Commercial Solvents Corporation v EC Commission* [1974] 1 CMLR 309 (*Commercial Solvents*). See also *United Brands Co v Commission*, Case 27/76 [1978] ECR 207, [1978] 1 CMLR 429.

[209] *Centre Belge d'Etudes de Marche-Tele-Marketing SA v Compagnie Luxembourgeoise de Telediffusion SA and Information Publicite Benelux SA* [1986] 2 CMLR 558.

[210] Although the Commission has used the term 'essential facilities', as Advocate General Jacobs noted in his Opinion in *Oscar Bronner*, the ECJ has not; *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs-und Zeitschriftenverlag GmbH & Co KG and Other* [1999] 4 CMLR 112, 124 [35] (Opinion).

[211] Commission Decision 94/19 Relating to A Proceeding Pursuant to Article 86 EC (*Sea Containers v Stena Sealink* – Interim Measures) [1994] OJ L 15/8, [66].

The doctrine operates under fairly strict conditions, and a number of preconditions to its operation exist. Temple Lang has usefully summarised the operation of the essential facilities doctrine in the EU as follows:[212]

- as was illustrated in *Oscar Bronner*,[213] indispensability will be assessed on an objective basis rather than on the subjective characteristics of a particular company requesting access;
- there is a need for two markets in order for the doctrine to operate, and a legitimate competitive advantage in a single market should not constitute an essential facility;[214]
- there must be a substantial effect on competition in a downstream market, and it is probably the case that competition must be eliminated entirely;[215]
- there must be scope for competition in a downstream market; and
- the dominant company must generally be present on the downstream market.

It is evident from the case law that essential facilities principles are being applied by the judiciary in a narrow set of circumstances and within the bounds of the strict conditions that have evolved in the US in relation to the doctrine,[216] and calls for a strict application of the doctrine in relation to intellectual property have been made.[217]

7.3.2.2 *INTELLECTUAL PROPERTY AND ESSENTIAL FACILITIES*

The doctrine undoubtedly has a number of limitations, but has now been held to apply to intellectual property dealings. Essential facilities analysis was a hallmark of most of the cases discussed above.[218] In *Magill*, for example, the third ground or condition

---

[212] See generally Temple Lang, Compulsory Licensing, above n136, 8-18.

[213] See, in particular, *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs-und Zeitschriftenverlag GmbH & Co KG and Other* [1999] 4 CMLR 112, [41-47].

[214] Cf Fine, *NDC/IMS*, above n149, 459-460. Fine contends that the requirement for two markets has proved to be 'troublesome', and that in most cases the essential facility merely constitutes a tool rather than a market in which discrete trade takes place. He therefore commends the Commission's decision in *IMS* in dispensing with this requirement; at 459-460.

[215] But see the discussion by Christopher Stothers, 'Refusal to Supply as Abuse of Dominant Position: Essential Facilities in the European Union' (2001) 22(7) *European Competition Law Review* 256, 258-259.

[216] See generally Treacy, above n169. See also Alan Overd and Bill Bishop, 'Essential Facilities: The Rising Tide' [1998] 19(4) *European Competition Law Review* 183.

[217] See, eg, Steven D Anderman, 'Copyright, Compulsory Licensing and EC Competition Policy' in Eric Barendt (ed), *Yearbook of Media and Entertainment Law* (1995) vol 1, 215.

[218] Despite the fact that the ECJ has not explicitly used the term 'essential facility', it is clear that the Court has engaged in essential facility analysis.

is the essential facility ground. This confirms that in intellectual property cases, strict preconditions must be present before the essential facilities doctrine will operate.[219] In strictly circumscribed instances, intellectual property holders will be under a duty to deal with competitors with whom they may,[220] or may not, have previously dealt. On the basis of the case law discussed above, the following comments can be made about intellectual property and the essential facilities doctrine:

- in relation to the test of indispensability, a competitor seeking access to a patent will need to demonstrate on an objective basis that it was not possible to invent around the patent.[221] This will often be difficult to establish in relation to a single patent,[222] but may be easier when access to a group of patents is required in order to compete;
- competition in a downstream or secondary market must be precluded by the refusal to grant access. In other words, the intellectual property must constitute an input into a product in a market that is outside the scope of the intellectual property;[223]
- in intellectual property cases, the requirements that there be a substantial effect on competition, and that there be scope for competition in a downstream market, would appear to require that the development of a new product for which there is consumer demand, is curtailed;[224] and
- similarly, it would appear that access to intellectual property required for the development of a new product which the holder of the right is also capable of developing, must have been denied.

---

[219] Anderman, *EC Competition Law and Intellectual Property Rights* above n133, 209.

[220] On the general duty to supply existing customers, see Romano Subiotto and Robert O'Donoghue, 'Defining the Scope of the Duty of Dominant Firms to Deal with Existing Customers Under Article 82 EC' (2003) 24 *European Competition Law Review* 683. In the area of refusals to deal with tangible property, there is a distinction between new and existing customers that has been described as arbitrary: see, at 686-689. So, in relation to new customers, it would appear that a duty to deal will only be imposed where the conditions set out in *Oscar Bronner* are met. In relation to existing customers, there is more likely to be a duty imposed, particularly where supply to another party is taking place; at 686-689.

[221] Temple Lang, Compulsory Licensing, above n136, 10.

[222] Although it may be the case in relation to a number of the foundational research tools discussed in Appendix 2, as well as other biotechnology inventions such as gene sequences, that it is impossible to invent around these patents; see further below, 7.3.4.

[223] Temple Lang, Compulsory Licensing, above n136, 13-14.

[224] Ibid, 15.

Generally, the essential facilities doctrine will be invoked in cases involving intellectual property where leveraging into a downstream market takes place.[225] A compulsory licence will ordinarily constitute the most effective remedy, although the right to utilise the protected product in the upstream market after grant of a compulsory licence will be an important consideration.[226] In practice however, it has been suggested that the main obstacle to a person seeking access will be that, although a finding of dominance may be made, a refusal to license intellectual property will be capable of being objectively justified.[227] The issue will be whether the intellectual property gives rise to a position of dominance, or whether it is merely a component of a position of dominance.

7.3.3 Synthesis and Summary of the European Approach to Refusals to License

Academic commentary post-*Magill* focused on whether strong competition regulation of intellectual property could have a deleterious effect on incentives to produce those rights.[228] It correspondingly questioned the basis on which *Magill* had been decided, and sought to clarify whether a cumulative or concurrent interpretation of the conditions listed in *Magill* would, in future, be employed.

It would now appear to be settled that the conditions listed in *Magill* as constituting the 'exceptional circumstances' test must be cumulatively applied. The ECJ's preliminary ruling in *IMS v Commission* should be taken as clear authority that *Magill* set out a series of cumulative tests that must be satisfied prior to the imposition of a finding of abuse pursuant to Article 82. At the same time, there can be taken to be a duty to continue to deal with existing competitors: this follows from the ruling in *Commercial Solvents* and cannot be said to be precluded from the exceptional circumstances test laid down in *Magill* and *IMS*.[229] Thus, the conditions laid down in these cases may not be exhaustive on the circumstances in which exceptional circumstances pursuant to Article 82 will exist.[230]

It is evident from this that the essential facilities doctrine does not constitute an alternative ground on which an Article 82 claim may be grounded, but is an integral part of a claim that a refusal to license intellectual property violates Article 82.

---

[225] Ibid, 19.

[226] Ibid.

[227] Stothers, Refusal to Supply, above n215, 261-262.

[228] See, eg, Vinje, above n138, 297.

[229] Anderman, *Microsoft* in Europe, above n137, 17-19.

[230] Ibid.

Consequently, any claim that a refusal to license intellectual property breaches Article 82 must be based partly on essential facilities principles. This arguably makes more stringent the requirements for establishing an Article 82 contravention in these circumstances, but nonetheless leaves some scope for competition intervention in cases of market failure.[231]

It is submitted that this is the correct position, and that although preserving incentives to patent holders to innovate is an important consideration, their right to refuse to license should not be unfettered. Competition law should play an equally important role in providing incentives to innovate. The ECJ in *IMS* apparently recognised this in retaining a role for competition law in 'exceptional circumstances'. It has been argued that to require less than satisfaction of all three conditions would have a detrimental effect on innovation in that:[232]

- incentives to undertake initial investment may be undermined if intellectual property holders are not afforded adequate protection under both intellectual property and antitrust laws; and
- incentives to create competing products or to 'invent around' existing privileges protected by patent law would be reduced if access to existing privileges are too readily granted.

In line with this, to require satisfaction of each of the cumulative requirements is the minimum that a competitor should be required to establish before access to intellectual property is granted.[233] Viewed this way, *Magill* and *IMS* have not radically changed existing precedent.[234] The ECJ in *IMS* did, however, curtail the operation of the 'exceptional circumstances' test, although it remains unclear whether other circumstances justifying the intervention of competition law may exist. Nonetheless, a number of issues remain unclarified and unresolved, and recent literature has identified a number of difficulties in application of the 'exceptional circumstances' test:

---

[231] See Christopher Stothers, '*IMS Health* and its Implications for Compulsory Licensing in Europe' (2004) 26(10) *European Intellectual Property Review* 467, 470.

[232] See also Temple Lang, Compulsory Licensing, above n136, 29-30 discussing the implications of some of the 'very surprising and controversial' features of the Commission's ruling in *IMS*.

[233] Cf Fine, *NDC/IMS*, above n149, 457, 460-462.

[234] Ibid, 466-467; Fine, In Response to Professor Korah, above n167, 253. In relation to the implications of *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416, see Greaves, above n149.

- the ECJ in *IMS* made it clear that the existence of a potential or hypothetical market will be sufficient to satisfy the requirement for a downstream or secondary market,[235] arguably giving rise to uncertainty in the minds of intellectual property holders as to what might constitute a new product in a 'separate' market;[236]
- some commentators have questioned the need for a second market in essential facility or leveraging cases on the basis of *Magill*;[237]
- there is an issue as to when an input will constitute an indispensable input, and when it will simply constitute part of a product.[238] The ruling in *IMS* will invariably lead to problems in identifying what constitutes a new product;[239]
- the status of the essential facilities doctrine in European law (and in particular intellectual property law) remains subject to some uncertainty given the requirement in *IMS* for two markets;
- pricing may be difficult to determine if a compulsory licence is ordered and there will be associated difficulties in determining what constitutes a reasonable royalty rate;[240] and
- the European Commission and courts have failed to articulate what might constitute an objective justification for refusing to license intellectual property.[241]

---

[235] *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* [2004] 4 CMLR 28 [44].

[236] David W Hull, 'Compulsory Licensing of IP Rights: The ECJ's Judgment in the *IMS* Case' (2004) *Competition Law Insight* 10, 12-13. This analysis will need to be industry specific; Steven D Anderman, 'The Aftermath of *Magill*' in Eric Barendt (ed), *The Yearbook of Media and Entertainment Law* (1996) vol 2, 235, 245.

[237] Forrester, above n201, 22; Fine, *NDC/IMS*, above n149, 458-460.

[238] Anderman, *EC Competition Law and Intellectual Property Rights* above n133, above n133, 213; Brenda Sufrin, 'The *IMS* Case' [2004] *Competition Law* 18, 24-25, 27-28.

[239] See, eg, Sufrin, above n238, 24-25; Aitman and Jones, above n202, 141. See also Stothers, *IMS Health* above n231, 470-471.

[240] Anderman, *EC Competition Law and Intellectual Property Rights* above n133, 214. Often it will be difficult to determine what constitutes a reasonable royalty rate, as holders of intellectual property would prefer the unfettered freedom to use a right over a royalty; Temple Lang, Compulsory Licensing, above n136, 20, citing *Volvo AB v Erik Veng (UK) Ltd* [1989] 4 CMLR 122. The corollary of this, however, is that in some cases, the possibility of a generous royalty rate will not be sufficient to induce licensing, as it will be worth more to the holder of intellectual property to maintain that privilege as a competitive asset.

[241] See AG Jacobs in *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungs-und Zeitschriftenverlag GmbH & Co KG and Other* [1999] 4 CMLR 112 [47] who lists some objective justifications from US case law (such as legitimate technical or commercial reasons, efficiency grounds). See also Temple Lang, Compulsory Licensing, above n136, 22-23; Sufrin, above n238, 28; Temple Lang, The Principle

In relation to this last requirement, a number of possible justifications have been suggested, and these generally fall into efficiency, quality or safety grounds.[242] In any case, the greatest difficulties from this succession of judgments are likely to stem from the requirements that there be a new product that constitutes an indispensable input, and that there be two markets, one of which feels the impact of the refusal to license.

It is unlikely, given the conditions that must be met, that there will be many factual scenarios that are found to contravene Article 82. There is a general suggestion in the literature that both *Magill* and *IMS* involved intellectual property privileges that were 'questionable', and that this may go some way towards explaining why findings of abusive conduct were made by the ECJ and Commission respectively.[243] These decisions could thus be seen as responses to aberrations in the application of national copyright laws, coupled with discriminatory conduct.[244]

In most cases, it will be difficult for a party who has been refused a licence to make out the stringent preconditions for a finding of abuse. Frequently, the requirement of indispensability will be an onerous hurdle for those seeking access to intellectual property. The principles may potentially be applicable in situations where a patent thicket prevents entry into a downstream market,[245] or where truly unique and essential intellectual property is used by a vertically integrated monopolist to maintain control of a downstream market.

It is submitted that the ECJ in *IMS* significantly limited the circumstances in which an intellectual property holder will be required to license under EU law. Nonetheless, it does not preclude determinations that refusals to license fall within limb [2] of the proposed framework. It is less clear that a refusal to license a party with whom the

---

of Essential Facilities in European Community Competition Law, above n167, 375, 385-388; Dolman, above n81, 469-471.

[242] The review of Article 82 that is in progress will consider the issue of objective justifications for abusive conduct that allegedly contravenes Article 82; see above, 5.4.2. Chapter 8 contains a discussion of efficiency justifications that might be raised in a case involving a refusal to license a medical biotechnology patent; below, 8.3.3. This discussion takes place in the context of s 46 of the *TPA*, but business justifications that are relevant to s 46 would also be relevant in respect of the 'objective justification' limb of the ECJ's test.

[243] See, eg, Korah, The Interface Between Intellectual Property and Antitrust: The European Experience, above n135, 830-831; Forrester, above n201, 12; Cf Anderman, The Aftermath of *Magill*, above n236, 244; Anderman, *EC Competition Law and Intellectual Property Rights* above n133, 211 ('There is little doubt that the decision in *Magill* means that Article 86 reaches more widely into the realm of the exercise of [intellectual property rights]').

[244] Cf Hull, above n236.

[245] Stothers, *IMS Health*, above n231, 471.

patent holder may indirectly compete (and falling into limb [3]), would be examinable under EU law. For example, a patent holder may be involved in using its patented technology to develop a particular cancer vaccine. A party who wishes to use the technology to develop a vaccine for a different type of cancer may be held to operate in the same economic market as the patent holder. Consequently, there could not be said to be a new product for which there was unsatisfied consumer demand. Despite this, it would appear that the specific factual matrix of each individual case will be determinative of whether a finding of abuse is made, and the circumstances in which the exceptional circumstances test will apply are not completely rigid.

As a final point, it is worth noting the Commission's decision in *Microsoft*,[246] in which the Commission found inter alia, that Microsoft was dominant in the market for server operating systems, and ordered Microsoft to disclose information (some of it protected by intellectual property) that would enable interoperability between non-Microsoft servers and Windows PCs and servers.[247] The matter is on appeal, and the principles from the series of cases culminating in *IMS* will be applicable.[248] It must be considered to be doubtful, on the basis of the requirements confirmed in *IMS*, that disclosure by Microsoft will be compelled, because it is difficult to see how Microsoft's competitors are introducing a new product to the market.[249]

In any case, this line of authority has left no doubt that competition regulation operates as a 'second tier of regulation of the exercise of intellectual property in the new economy as in the old.'[250] EU Competition authorities are clearly concerned to preserve competition even where monopolies would appear to be fragile and prone to a temporary existence.[251]

---

[246] Commission Decision of 24 March 2004 relating to a proceeding under Article 82 of the EC Treaty (Case COMP/C-3/37.792 – *Microsoft*) (unreported) 24 March 2004, C (2004) 900 final, <http://europa.eu.int/comm/competition/antitrust/cases/decisions/37792/en.pdf> at 17 November 2004.

[247] For further detail see Sven B Volcker, 'The Implications of *Microsoft* and *IMS Health*: Interesting Times for Dominant Intellectual Property Holders in Europe' (2004) *Competition Law Insight* 14, especially 14-16.

[248] Although as Volcker points out, the Commission in *Microsoft* did not rely on the test in *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416, consequently *IMS* may be of limited precedential value on appeal; Ibid, 18.

[249] See, in particular, Hull, above n236, 13.

[250] Steve Anderman, 'EC Competition Law and Intellectual Property Rights in the New Economy' (2002) Summer-Fall *The Antitrust Bulletin* 285.

[251] Ibid, 308.

7.3.4 Application of Principles From EU Case law to Refusals to License Medical Biotechnology Patents

As a consequence, it would be difficult to establish that the owner of a valuable patent should be compelled by the European Commission or Courts to provide a licence to that patent to a competitor operating in a related or downstream market. The EU can probably be considered to be the most stringent of the three jurisdictions in terms of enforcing competition law against intellectual property holders. Even so, it is probably only in extremely rare cases that a holder of a patent over a medical biotechnology invention will be required to license it to competitors.

An initial question is whether the principles espoused in the cases discussed above can be generalised to apply to patents. All of the cases dealt with protected information,[252] and the factual scenarios were fairly specific. While some commentators consider that the principles may extend to other forms of intellectual property protection such as patents,[253] others are more skeptical that the principles are analogous in cases where other intellectual property is involved.[254] Korah suggests that it might be appropriate to extend the principles from *Magill* to privileges other than copyright in information only in extremely limited circumstances, that is, where there is a genuine bottleneck and the third party is able to produce a very novel and valuable invention.[255] She cites the enormous investment required to produce a patentable invention, and the differences between the nature of the protected information in *Magill*, and patents.[256]

Difficulties inherent in essential facilities cases, in particular, are magnified in cases involving high technologies where it is difficult to predict the outcome of a refusal to license on the development of technology.[257] There has been some analysis of the implications of this case law for copyrighted interface information.[258] In any case

---

[252] Further, that protected information was applied in an industrial context; Vinje, above n138, 302.

[253] See, eg, Korah, Patents and Antitrust, above n156, 403-405; Abraham I van Melle, 'Refusals to License Intellectual Property Rights: The Impact of *RTE v EC Commission* (*Magill*) on Australian and New Zealand Competition Law' (1997) 25 *Australian Business Law Review* 4, 12.

[254] See, eg, Treacy, above n169, 503-505; Derclaye, above n171, 704; Forrester, above n203201, 24. See also the judgment of Laddie J in *Philips Electronics NV v Ingman Limited and Another* [1998] 2 CMLR 839, [63-66].

[255] Korah, Patents and Antitrust, above n156, 403-405.

[256] Ibid, 404-405.

[257] John Temple Lang, 'European Community Antitrust Law: Innovation Markets and High Technology Industries' (1997) 20 *Fordham International Law Journal* 717, 812.

[258] A number of commentators have considered the applicability of the principles espoused in the cases discussed in the preceding sections, to information technology. See, eg, Narciso, above n121; Anderman, The Aftermath of *Magill*, above n236; Vinje, above n138.

where a refusal to license intellectual property is alleged to contravene Article 82, there will be a number of obstacles including:[259]

- the expense involved in alleging a contravention of Article 82 and the fact that the Commission is likely to attack only breaches with grave consequences;
- the difficulty of demonstrating dominance;[260]
- the high threshold required to establish abuse in light of the nature of the relevant markets and the surrounding circumstances of the refusal would have to be examined.

Holders of copyright over computer software are also subject to the interoperability provisions contained in the Council Directive for the Legal Protection of Computer Programs,[261] so that those wishing to use copyrighted software may reproduce it without permission in order to write and produce a new independent program that will nonetheless be interoperable with it.[262] In contrast, there is no such obligation in respect of patents.[263] The conditions listed in *Magill* and confirmed in *IMS* arguably reinforce these obligations[264] by providing an additional ground under competition law by which to access copyrighted software.[265] They provide the sole possible method of attaining access to gene and biotechnology patents required for follow-on innovation.

The obstacles facing those alleging a contravention on the basis of a refusal to license a gene patent or other biotechnology patent are likely to be even greater. Patents confer stronger privileges than other forms of intellectual property such as copyright. This may mean that they should be accorded greater protection under competition law, so that a refusal to license a patent will be dealt with more leniently than a refusal

---

[259] Vinje, above n138, 303.

[260] Note that it is now established that dominant positions may be joint; see *Compagnie Maritime Belge Transports SA v Commission* [2000] 4 CMLR 1076. See also Richard Whish, *Competition Law* (4th ed, 2001), 163; Valentine Korah, *An Introductory Guide to EC Competition Law and Practice* (7th ed, 1997), 92.

[261] Council Directive for the Legal Protection of Computer Programs OJ 1991 L 122/42.

[262] Council Directive for the Legal Protection of Computer Programs OJ 1991 L 122/42, art 6(1). On the operation of this obligation, see Anderman, *Microsoft* in Europe, above n137, 21-22; Anderman, The Aftermath of *Magill*, above n236, 245-246; Vinje, above n138, 302-303.

[263] Note that the European Parliament recently voted by a very significant majority to reject a software patents directive, known as the Directive on the Patentability of Computer Implemented Inventions which sought to harmonise the patentability requirements of individual EU members. See 'EU Software Patent Directive Rejected' Financial Times (July 6 2005) <http://news.ft.com/cms/s/028f5b2e-ee43-11d9-98e5-00000e2511c8.html> at 11 August 2005.

[264] See also Anderman, The Aftermath of *Magill*, above n236, 246.

[265] The provisions operate in respect of copyright rather than as a product of competition law; Anderman, *Microsoft* in Europe, above n137, 22.

to license copyrighted information. It is submitted, however, that the implications of abuse of patents may be far graver. As a result, their use should be subject to the same restrictions under competition law as any other form of intellectual property.

It is possible to envisage situations where research will be precluded because gene sequences and research tools that constitute indispensable inputs into future applications are not licensed. On the face of it, the requirements laid down in *Magill* and subsequent cases could be established under these circumstances. Very broad patent rights have the potential to give rise to liability under Article 82. It has been suggested that broad patents in the biotechnology area are unlikely to be a problem in the EU because they are unlikely to be granted.[266] It is submitted, however, that it will depend on the technology or product in question, and that many research tool patents in medical biotechnology have potentially very broad application. Further, many broad patents have already been granted, and it is unlikely that all of these patents will be subject to challenge.

Finally, broad individual patents are unlikely to be as problematic as narrower rights upstream that are essential for research in a downstream market that is not currently being exploited, or patent rights amassed for the purpose of foreclosing downstream research by others.[267] A group of patents may preclude research, making inventing around potentially impossible. Strategic patenting may prevent a competitor from continuing to engage in useful research that would appear to be leading to the development of a new product for consumers. In circumstances such as these, the requirements reiterated in *IMS* would *appear* to be capable of satisfaction. This will depend primarily on whether a finding that an objective justification excuses the conduct, is made.[268] It will also depend on whether a finding that the patented product or technology constituted an indispensable input into the downstream product was possible.

Patents block independent invention, and the concept of indispensability confirmed in *IMS* may be important in demonstrating that a patent constitutes an indispensable input into downstream research. Given that their claims limit their scope they will block entry in very few cases.[269] There will often be substitutes, and in many cases it

---

[266] Korah, Patents and Antitrust, above n156, 397.

[267] See also Temple Lang, The Principle of Essential Facilities in EC Competition Law, above n167, 388-389.

[268] The matter of efficiency justifications for refusals to license in downstream markets will be discussed further below, 8.3.4.1.

[269] Stothers, *IMS Health*, above n231, 470.

will be possible to invent around the patented technology. Establishing that a patent gives rise to an economic market and does not have substitutes will also be difficult.[270] Concern has been expressed, however, that many biotechnology patents are not substitutable. Gene patents, in particular, are difficult to invent around,[271] as are many of the foundational research tools discussed in Appendix 2. The nature of biotechnology research suggests that it will be difficult to establish a contravention pursuant to Article 82, particularly where the patent is useful for research that is still fairly upstream. A third party wishing to use the patent would need to show that either:

- there is an unsatisfied demand for a new product that the patent holder is not producing; or
- competition on the downstream market is lacking in some other way, for example, the patent holder occupies a dominant position in that market and abuses that position, or there are a significant lack of competitors in that market.[272]

The difficulty where a party wishes to use a licence for upstream or intermediate research, is in demonstrating a lack of competition. Similarly, much biomedical research is carried out without a definite end product in mind. Much of this research is far removed from an end product in the sense of a product that will be available to consumers. In many cases, it will be difficult to show that consumers have suffered detriment, and the most that could be established is that there is a possibility that a new product could be available for on-licence. In this case, it is possible that a stricter analysis would need to be employed than that developed in the case law.[273] It has been pointed out that antitrust issues arising from new technologies will necessitate a return to 'basic principles of antitrust law or antitrust economics.'[274]

A decision of the English Court of Appeal provides some indication of the position that might be taken where licences to broad biotechnology patents are refused. In *Chiron Corporation v Murex Diagnostics (No 2)*[275] the applicability of Article 86 as a

---

[270] Christopher Stothers, 'The End of Exclusivity: Abuse of Intellectual Property Rights in the EU' (2002) 24(2) *European Intellectual Property Review* 86, 92.

[271] See Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper*, Discussion Paper (2002), 54.

[272] Temple Lang, Compulsory Licensing, above n136, 14-17.

[273] Stothers, Refusal to Supply, above n215, 260.

[274] Temple Lang, Innovation Markets and High Technology Industries above n257, 816.

[275] *Chiron Corporation v Murex Diagnostics (No 2)* [1994] 1 CMLR 410.

defence to patent infringement[276] was considered. Essentially, Chiron patented the genome of the Hepatitis C virus and exclusively licensed those patents to just two parties. This enabled those parties to produce diagnostic HCV kits for detecting Hepatitis C in blood samples.[277] When Murex manufactured and parallel imported its own HCV kits, Chiron instituted proceedings for infringement. Murex alleged abuse of dominant position by virtue of Chiron's failure to license the patents to Murex.[278]

The Court of Appeal refused to disturb the holding of Aldous J at first instance who struck out this defence, affirming that:

- the relevant market was the market for HCV kits;
- it was doubtful (but still possible) that Chiron occupied a dominant position in this market;
- there was no abusive conduct because there was doubt as to whether Murex's kit was better than Chiron's or whether using two kits would be better than using one. There was therefore no abusive conduct sufficient to render a refusal to license an abuse;
- there was sufficient nexus between the alleged abuse and the relief sought; but
- the alleged abuse of charging unfair prices was not capable of affecting trade between member states.

The decision is indicative of the fact that a patent holder will rarely be denied its exclusive rights of exploitation where a downstream market in which a licence is sought (in this case the market for HCV kits) is being positively exploited by either the patent holder or a licensee.[279] Despite the breadth of Chiron's patents and the power these patents gave Chiron to control the manufacture and distribution of HCV kits, the fact that Chiron was active in the same market as Murex was probably enough to preclude a finding of abuse. In contrast, it is submitted that had Murex been involved in developing, for example, a pharmaceutical treatment for HCV using the

---

[276] Patent infringement was alleged due to the parallel importation of an allegedly infringing product. Recall that Article 86 is the predecessor to Article 82. For a brief explanation of parallel importation, see above, 4.3.3.1.

[277] For further details of the invention patented by Chiron, see Appendix 2. The decision will be discussed further below, 8.2.1.2(ii) in the context of market definition.

[278] Murex also alleged abuse of dominant position by virtue of Chiron charging excessive prices for their kits.

[279] See also Phillip Tucker, 'Refusal to License Intellectual Property Rights and Misuse of Market Power – Where is the Line in the Sand?' (1999) 10 *Australian Intellectual Property Journal* 78, 86.

HCV antigens, it is possible that this may have constituted an abuse of dominant position.

7.4 CONCLUSION

It is difficult to construct a rigid framework for dealing with refusals to license intellectual property. Economists have long grappled with the issue of how to provide a framework for assessing the legality of refusals to license.[280] The issue is essentially one of facts versus formalism – whether to apply (or attempt to apply) guidance based on rules (as in *Xerox*), or whether fact-based analysis is more appropriate.[281] As Glazer and Lipsky have recognised, there are many different fact situations that can give rise to a refusal to license.[282] The fundamental premise behind the framework set out in Chapter 5 is that it be applied flexibly, but provide a general guide as to when a refusal to license is most likely to be anti-competitive.[283] It attempts to provide guidance but recognises that fact-based analysis is appropriate in any allegation that a refusal to license is anti-competitive.

The foregoing review of US and EU case law indicates that there has been no cohesive position adopted by US courts. By contrast, EU law on the matter would appear at the present time to be relatively settled. These jurisdictions have a significant body of case law dealing generally with refusals to license intellectual property. It can be tentatively said that they are likely to adopt slightly different positions to the position that is likely to be adopted under Section 46. Australian courts would be likely to consider case law from these jurisdictions if they were required to consider the issue of refusals to license intellectual property. It will fall to the next chapter to consider in some detail how Section 46 is likely to be applied if Australian courts are required to consider a refusal to license scenario in relation to medical biotechnology patents.

It is difficult to assess the impact this body of case law is likely to have on Australian competition law regulation of refusals to license. Because of the uncertainty over which approach the US Supreme Court is likely to follow, it is difficult to say whether or not US case law on refusals to license is likely to be applied by Australian courts. The decision of the ECJ in *Magill* understandably led to a flurry of articles discussing

---

[280] See, eg Mackie-Mason, above n10.

[281] See Melamed and Stoeppelwerth, above n65.

[282] Above, 7.2.1.1.

[283] See above, 5.5.5.

the implications of the decision in Europe. Several commentators also considered the likely impact of the decision under the *TPA*.[284] Whatever the potential scope of *Magill*, it would appear that it has been restricted in subsequent cases, particularly by the ECJ in *IMS*. It is submitted that the implications of *Magill* have consequently been narrowed, and the effect of this jurisprudence on refusals to license patents in the Australian context are discussed in the following chapter.

This raises important issues about the role that regulation should take, and the message that regulators should send to intellectual property holders about refusals to license. Conclusions about the role that competition law should play provide important guidance as to how policy in this area should be shaped. Given that Australia has no precedent in this area, an opportunity exists to undertake careful consideration of the how refusals to license intellectual property should be dealt with.

[284] See, in particular, van Melle, above n253; Tucker, above n279. See also Charles Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition' (2002) 30 *Federal Law Review* 97, especially 118-120; Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health* Report 99 (2004), 562-565.

CHAPTER 8

REFUSALS TO LICENSE MEDICAL BIOTECHNOLOGY PATENTS IN THE AUSTRALIAN CONTEXT: AN ANALYSIS OF THE POTENTIAL APPLICATION OF SECTION 46

8.1 INTRODUCTION

The two previous chapters have considered in some detail the application of competition law to refusals to license intellectual property. Chapter 6 provided a detailed analysis of s 46 of the *Trade Practices Act* 1974 (Cth) and its current status. *First*, it considered the current interpretations of the provision and argued that courts are likely to interpret the market power standard as involving close to monopoly power. *Secondly*, it argued that the 'take advantage' test may not require consideration of efficiency considerations. Chapter 7 considered comparative case law with a view to obtaining some guidance as to how this issue is likely to be resolved under provisions that correspond to s 46.

This chapter combines these themes and gives detailed consideration to how refusals to license medical biotechnology patents are likely to be treated under s 46. It draws on principles from the comparative jurisprudence in attempting to determine whether or not s 46 is likely to be applied consistent with the framework outlined in Chapter 5. Although there is some doubt as to whether this framework would be adhered to in other jurisdictions, there is reason to believe that recent interpretations of s 46 render it largely ineffectual. This concern is likely to be heightened when the difficult issue of refusals to license intellectual property is contemplated. It will be argued that a position close to that adopted by United States (US) courts is likely to be adopted in Australia. Specifically, the position in *Xerox* is the position most likely to be adhered to.[1]

As indicated in Chapter 7, there is no Australian case law dealing with the issue of refusals to license intellectual property.[2] There may be a number of reasons for this. *First*, costs of litigation are high, which is likely to discourage litigation, particularly where many industry participants are either publicly funded or small, start-up companies. *Secondly*, litigation rates in Australia are generally low. *Thirdly*, it may be that refusals to license are not being encountered. As the first three chapters of this thesis indicate, there are a number of factors suggesting that an industry such as medical biotechnology may be particularly prone to restrictive licensing practices such as refusals to license patents. Despite this, empirical evidence presented in Chapter 4 suggests that refusals to license medical biotechnology patents are currently impacting on research only rarely. It may be that refusals to license in other industries

[1] In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001).

[2] Above, 7.1.

are not occurring, with the result that there has been no litigation in respect of this issue.

Finally, it may suggest that mechanisms for dealing with refusals to license under Australian law are inadequate, which would tend to militate against action pursuant to those mechanisms. An absence of jurisprudence may point to deficiencies in provisions such as s 46, and raises questions as to whether statutory modification is required. Even where companies are able to change research direction in order to accommodate existing patents in an area to which they are unable to gain access, there may be negative implications for follow-on research. A specific issue that this chapter addresses is whether the lack of case law in this area could be attributed in part to deficiencies in s 46.

To recapitulate, research tools in medical biotechnology were divided into three categories.[3] In considering the applicability of s 46, it is important to bear in mind that there appear to be few cases in which category three technologies are not freely licensed. Thus, if a refusal to license in medical biotechnology is alleged it is likely to be in respect of a technology falling into category one or two. While discussion in this chapter will necessarily be general, it will attempt to draw on some concrete examples of conduct that may attract an allegation of a refusal to license and bear in mind these categories. An evaluation of a refusal to license pursuant to s 46 will be fact-based, and the structure of this chapter recognises this. The framework set out in Chapter 5 guides this fact-based analysis.[4] In this context the specific issues examined are:

---

[3] The categories were:

> 1. technology that is being used by the patent holder and another researcher to conduct similar research, and one researcher subsequently finds the technology is already patented (category one);
>
> 2. patented technology that is useful for a range of follow-on uses, the products of which may ultimately compete (category two); and
>
> 3. patented technology is useful for a range of non-competing, follow-on uses (category three).

See further above, 4.3.2.

[4] The framework is as follows:

> [1] Generally speaking, a refusal to license intellectual property will not contravene competition law.
>
> [2] A refusal to license will, however, become examinable under competition law where the refusal is for the purpose of (i) expanding the scope of the intellectual property or (ii) extending market power into another distinct market not covered by the intellectual property.
>
> [3] Where a refusal becomes examinable under [2](ii), the refusal should be examinable whether or not the holder of the intellectual property is currently exploiting the separate market, and the reservation of another market for its own (actual or potential) use should not necessarily allow it to foreclose competition by others.

- how the question of market definition is likely to be resolved in cases involving medical biotechnology patents;
- the circumstances in which a holder of a patent is likely to be held to have market power;
- whether a refusal to license a medical biotechnology patent will constitute a 'taking advantage' of market power; and
- whether there are any circumstances in which evidence is likely to support a finding that a patent licence is refused for a proscribed purpose.

8.2 INTELLECTUAL PROPERTY AND MARKET POWER

Chapter 6 demonstrated that any plaintiff bringing an action under s 46 has a number of hurdles to overcome. As this section will demonstrate, patent holders face an additional obstacle: in order to demonstrate that a patent owner has market power, a very narrow market definition must be employed. Indeed, it will virtually involve a finding that a patent encompasses a market in itself. Once the market has been defined, it must be shown that the patent (or group of patents) conveys market power, a notoriously difficult impediment in a competition claim involving intellectual property. This section explores possible trends in market definition and debate on market power where access to medical biotechnology research tools is refused in line with the framework. Its focus is on refusals to license that have some consequent impact on downstream competition in a particular market.

8.2.1 MARKET DEFINITION AND MEDICAL BIOTECHNOLOGY PATENTS

It is difficult to state with any degree of precision how market definition issues are likely to be resolved in cases involving medical biotechnology, particularly those involving research tools. Each case will need to be individually assessed. It is possible, however, to make some generalisations to assist in argument relating to patented medical biotechnology patents, particularly research tools.

8.2.1.1 *THE APPLICABILITY OF OVERSEAS PRINCIPLES OF MARKET DEFINITION*

The principles of market definition engaged in by US courts are relatively similar to those utilised by Australian courts, with substitutability being the key consideration. EU case law has also influenced the way markets are defined under Australian

See further above 5.5.5.

competition law, in that the method of assessing market power espoused in EU case law have been enshrined in the *TPA* via s 46(3).[5] Each of these jurisdictions adopts a purposive approach to market definition.[6] As a consequence, there are likely to be similarities in the way that courts in each of these jurisdictions embark on the process of market definition.

8.2.1.2 *MARKET DEFINITION AND MEDICAL BIOTECHNOLOGY IN AUSTRALIA*

There is no doubt that market definition will be critical in any evaluation of a refusal to license under s 46.[7] The more broadly a market is defined, the more difficult it will be to establish market power. Conversely, a narrowly defined market may lead to a finding of market power, but may make it more difficult to establish that conduct was anti-competitive.

(i) The Appropriate Focus in Market Definition

Market definition is an important step in quantifying market power, but recall that the *TPA* requires that markets need to be defined in light of the conduct that allegedly places the corporation in breach.[8] There may be two avenues open to plaintiffs in respect of market definition. First, the concept of sub-markets may be utilised in the case of complex markets where there are a number of inputs into a final product. As discussed above, the concept of sub-markets has gained favour with some commentators who suggest they may be utilised as a tool of analysis in some circumstances.[9] A recent judicial pronouncement on the subject of sub-markets, however, indicates the concept is unlikely to gain universal acceptance as an analytical tool.[10]

The biotechnology area would be one area where the concept could conceivably be relevant. It is unlikely to play a significant role, however, given its limited acceptance. It is also unlikely that it would result in significantly narrower primary market definition, but may operate to allow a finding that a particular intellectual property privilege constitutes a sub-market of a particular market. Although this would allow

---

[5] See above 6.3.3.

[6] Above, 6.3.2.

[7] Phillip Tucker, 'Refusal to License Intellectual Property Rights and Misuse of Market Power – Where is the Line in the Sand?' (1999) 10 *Australian Intellectual Property Journal* 78, 86-88.

[8] See above, 8.2.1.

[9] Above, 6.3.2.3.

[10] *ACCC v Universal Music Australia Pty Ltd* (2001) 115 FCR 442, 521 (Hill J).

more detailed analysis, it would not assist a plaintiff in making an argument that a patent generates market power.

A better argument may be to focus on narrow market definition in respect of the market in which the intellectual property is held. If markets were defined, as they have been in some areas, very broadly, this would generally operate to preclude a finding of market power. Indeed, the Trade Practices Commission (TPC) observed in their 1991 Background Paper[11] that:

> It may be that on occasions a new development will be so advanced as to establish a new market as that concept is applied under the *Trade Practices Act*. However, such examples will be rare. In the majority of cases, intellectual property rights protect a new development in an established market. Competition will exist from existing products....[T]he existence of intellectual property rights is an important element in assessing the barriers to entry to a market.[12]

It should be noted, however, that courts are currently favouring defining markets narrowly, particularly in relation to s 46 matters. For example, in *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission*[13] *(Boral)*, the Full Federal Court rejected the finding of the primary judge that the market comprised all materials used in the construction of walls, and defined the relevant market more narrowly as the market for concrete masonry products in Melbourne. In doing so, the court focused on demand substitutability, close competition and the appropriateness of particular building products for certain tasks.[14] Similarly, in *Rural Press Ltd v Australian Competition and Consumer Commission,*[15] *(Rural Press)* the Full Federal Court was prepared to accept the trial judge's finding that the market in that case was the Murray Bridge regional newspaper market. They declined to adopt a broader definition that also encompassed radio advertising.[16]

---

[11] Trade Practices Commission, *Application of the* Trade Practices Act *to Intellectual Property*, Background Paper (1991) (TPC Background Paper).

[12] TPC Background Paper, above n11, 15. In relation to assessing intellectual property as a barrier to entry, the TPC highlights this factor as being particularly important, and suggested some considerations in assessing whether intellectual property has created barriers to entry; at 16.

[13] *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609.

[14] See *Australian Competition and Consumer Commission v Boral Ltd* (2001) 106 FCR 328, 377 (Beaumont J, Merkel and Finkelstein JJ agreeing).

[15] *Rural Press v ACCC* (2002) 118 FCR 236.

[16] *Rural Press v ACCC* (2002) 118 FCR 236, 268-272. This finding was upheld on appeal to the High Court; *Rural Press Ltd v ACCC* (2003) 78 ALJR 274, 284.

A purposive approach to market definition means that markets could foreseeably be defined narrowly,[17] and even conceivably as single brand markets. Where the single issue for determination is a refusal to license a patent, the court must examine the constraints inherent upon the corporation by ascertaining the market. This would tend to dictate that the subject matter of the patent would become crucial, as the scope of the patent would direct the court as to the level of competition faced by the corporation.

For this reason, it is submitted that narrow market definition would (and should) be the preferred line of argument in respect of a refusal to license. Of course, in some cases, a purposive approach to market definition will preclude narrow definition. But in the case of many research tools, narrow market definition should be more readily employed due to a lack of substitutability on both the demand and supply sides. It should be noted that in the limited number of cases where Australian courts have considered market definition in the context of intellectual property, they have demonstrated a tendency to define markets widely.[18] For example, there have been several cases where courts have refused to recognise markets for individual intellectual property and have defined markets more broadly.[19] In *Regents Pty Ltd v Subaru (Aust) Pty Ltd*[20] (*Regents Case*) RD Nicholson J recognised that it is possible to establish a single brand market at law, but declined to do so on the facts of the case at hand.[21] Instead, his Honour held that the relevant market was the general market for supply of motor vehicles, parts and ancillary services.[22]

---

[17] A good example is *ACCC v Australian Safeway Stores Pty Ltd* (2003) 129 FCR 339. In that case, the majority adopted a purposive approach to market definition, and determined that the real issue to be determined was the ability of Safeway to influence the terms of trade at the wholesale level. This precluded any consideration of Safeway's power at the retail level, and so the market was restricted on a functional level to the market for sale and acquisition of bread by wholesale in Victoria.

[18] See also Charles Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition' (2002) 30 *Federal Law Review* 97, his n204.

[19] See *Ah Toy Ltd v Thiess Toyota Pty Ltd* (1980) 30 ALR 271, where Forster CJ defined the relevant market as the wholesale market for Toyota vehicles and parts in the Northern Territory; *Broderbund Software Inc v Computermate Products (Aust) Pty Ltd* (1992) ATPR 41-155, where Beaumont J defined the relevant market as the national product market for computer software having either an educational or entertainment character.

[20] *Regents Pty Ltd v Subaru (Aust) Pty Ltd* (1998) 84 FCR 218.

[21] *Regents Pty Ltd v Subaru (Aust) Pty Ltd* (1998) 84 FCR 218, 228. His Honour was required to consider whether a separate wholesale market for Subaru spare parts existed.

[22] *Regents Pty Ltd v Subaru (Aust) Pty Ltd* (1998) 84 FCR 218, 228, 236. The market for parts at wholesale level and the market for parts for Subaru vehicles at wholesale level were determined by RD Nicolson J to be sub-markets of the market as defined; *Regents Pty Ltd v Subaru (Aust) Pty Ltd* (1998) 84 FCR 218, 228, 236. For commentary on this finding, see Stephen G Corones, *Competition Law in Australia* (3rd ed, 2004), 60-61.

Commentary on the matter takes a similar line of reasoning. For example, some specific comments have been made in relation to market definition in pharmaceuticals.[23] The National Competition Council suggested that a patented pharmaceutical product such as a headache tablet is likely to compete in the same market as herbal and other alternative therapies.[24] Hanks and Williams assert that it may be more appropriate in some circumstances to consider a patented pharmaceutical product with no close alternatives in the context of the broader range of activities of the patent owner (such as research and drug production), rather than as an individual market.[25] They acknowledge that this would entail taking a long-term view of competition, which, it has been submitted would be appropriate in high-technology industries or industries in which long-term contractual arrangements are evident.[26] The biotechnology and pharmaceutical industries certainly fall into these categories in a large number of instances.

In contrast, Edwards argues that there should be no impediment to finding a market exists in respect of a single pharmaceutical drug produced by one company.[27] It is contended that the issue will really depend on the particular patented product in question. Many pharmaceutical drugs will compete with a number of other products, but often these products will be complementary rather than substitute products. Many consumers will refuse to substitute a pharmaceutical product for an herbal remedy, and in reality the drugs that are appropriate to treat a specific condition or a particular

---

[23] It is recognised that markets for pharmaceuticals have different characteristics to markets for more 'upstream' biotechnology products and technologies. Nevertheless, the following discussion is intended to be illustrative of the issues that may arise in relation to market definition in areas involving human health.

[24] National Competition Council, Parliament of Australia, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999) (NCC Report), 171. The Intellectual Property and Competition Review Committee also pointed out that in the normal course of trade there are almost always alternative or suitably equivalent products or processes in the market place, and instances in which IP dealings likely to result in a substantial lessening of competition likely to be rare; Intellectual Property and Competition Review Committee, Parliament of Australia, *Review of Intellectual Property Legislation Under the Competition Principles Agreement: Final Report* (2002) (IPCRC Report), 214. Clearly, this will also have implications for market definition.

[25] Frances Hanks and Philip L Williams, 'Implications of the Decision of the High Court in *Queensland Wire*' (1990) 17 *Melbourne University Law Review* 437, 452-453. The basis of this assertion is the reasoning of the High Court of *New Zealand in Tru Tone & Ors v Festival Records Retail Marketing Ltd* CCH (1988) 2 NZBLC 103,081, 103,089, affirmed on appeal, [1988] 2 NZLR 352, that record distributors did not run their businesses on the basis of one album, therefore it was unrealistic to examine market power on the basis of one album. See also *Universal Music Australia Pty Ltd and Others v ACCC* (2003) 131 FCR 529.

[26] See above, 6.3.2.2.

[27] Geoff A Edwards, 'Sub-Markets as Competition Law Markets: the Appropriate Approach to the Sub-market Concept in Market Definition' (1998) 6 *Competition and Consumer Law Journal* 156, 161.

patient are extremely limited. Pharmaceutical products undergo rigorous therapeutic testing and quality control procedures.[28] Thus, there is limited supply-side substitutability in respect of many pharmaceutical products.

(ii) Defining Markets in Medical Biotechnology

Similarly, many medical biotechnology companies engage in specific areas of research and are discerning about research tools they are prepared to license-in.[29] Markets for patents with broad claims are likely to be much more broadly defined. This may mean that some patented biotechnology research tools with broad claims would be considered to have useful application in a broad economic market, resulting in wide market definition. Many category three technologies would fall into this category. Indeed, if their potential application as indicated in their claims is far-reaching, they may encompass more than one economic market.[30] On the other hand, narrower patents, or patented research tools for which the full range of applications are not yet known, will compete with a smaller number of other products.

To take a well known example, Chiron's hepatitis C virus (HCV) patents were the subject of a claim in respect of Article 86[31] of the *Treaty Establishing the European Community*[32] for a refusal to license the patents to Murex.[33] This litigation was discussed in Chapter 7.[34] It is interesting to note the finding of the Court of Appeal in relation to the relevant market. The markets pleaded were '(a) the market for licences under the patent; (b) the market for antigenic material used in the manufacture of HCV kits; and (c) the market for HCV kits.'[35]

---

[28] In Australia, this monitoring and assessment is undertaken by the Therapeutic Goods Administration unit of the Commonwealth Department of Health and Ageing pursuant to the *Therapeutic Goods Act* 1989 (Cth).

[29] In many respects, issues in relation to market definition in pharmaceutical goods are merging with market definition issues in medical biotechnology given the diversification of both pharmaceutical and genomics companies into biopharmaceutical research and development.

[30] A good example is the Intron Sequence Analysis or 'junk DNA' patents discussed in Appendix 2. Use of this technology is necessary in a considerable amount of biomedical research. Thus, markets for this patented technology are likely to be widely defined.

[31] Now Article 82.

[32] *Treaty Establishing the European Community* [2002] OJ C 325/65.

[33] *Chiron Corporation v Murex Diagnostics Limited (No 2)* [1994] 1 CMLR 410. Discussed above, 7.3.4.

[34] Above, 7.3.4.

[35] *Chiron Corporation v Murex Diagnostics Limited (No 2)* [1994] 1 CMLR 410, 415.

The Court of Appeal refused to disturb the finding of the trial judge that the relevant market was the market for HCV kits.[36] As to the other markets pleaded, the trial judge found that these markets simply did not exist. The number of licences granted had been limited, and there was no supply of the material used to make the kits other than in kit form.[37] As a result, the relevant market was held to be fairly broad, making it difficult for Murex to establish dominance. Even though the patents in question encompassed the genome of the HCV virus, this did not necessarily impact on the antitrust market pleaded or found. This finding is a good demonstration of how an upstream market is not likely to impact to any great degree on how a downstream antitrust market is defined.

A similar position would probably be reached under s 46. However, in adopting a purposive approach to market definition the conduct in issue was a refusal to licence the patents that would allow Murex to use the antigenic material necessary to manufacture HCV testing kits. It is submitted that it would surely be possible to argue that a market for the antigenic material existed, given that Murex sought access to that material. From the perspective of both demand and supply-side substitutability, this would seem to be an equally appropriate market. Chiron used the antigenic material to manufacture testing kits. Without the patented material, making HCV kits was impossible, and without a licence Murex was guilty of infringement. It is clear that under s 46 a market may exist if there is the potential for transactions and despite the fact that is currently no market for a product or service.[38] The patent over the genome constituted a barrier to entry that prevented Murex entering a potential market. If such a narrow market could be successfully pleaded, this may facilitate a finding of market power.

This example serves to highlight the disparities that may exist in market definition, and the difficulty of predicting how market definition issues are likely to be resolved. Many patented biomedical products and technologies would be equally difficult to categorise. Chiron's Hepatitis C patents fit into the class of a Category 2 technology, which would seem to lend itself to narrower market definition.[39] The approach that

---

[36] See *Chiron Corporation v Murex Diagnostics Limited (No 2)* [1994] 1 CMLR 410, 415-416.

[37] *Chiron Corporation v Murex Diagnostics Limited (No 2)* [1994] 1 CMLR 410, 415-416.

[38] Above, 6.3.2.5.

[39] The technology could also be categorised as a Category 3 technology given that the patented technology is potentially useful for not only diagnostic application, but also therapeutic and pharmaceutical application. This would tend to suggest that wider market definition might be appropriate. On the basis of a purposive approach to market definition, however, the function for which the material was requested (and for which Chiron itself used the material) would be relevant, and it is submitted, would narrow the requisite market.

will be taken to market definition will depend on the patented research tool or technology in question, and the conduct complained of.

A patent owner may refuse to license a gene sequence useful for research into cancer to a downstream corporation because the sequence has been exclusively licensed to a corporation undertaking research into heart disease. As has been demonstrated by the empirical evidence presented in Chapter 4, many patents in the biotechnology area are exclusively licensed.[40] This will often be because this allows the realisation of maximum value for the patented technology,[41] but it may also be because a licensee demands exclusivity. There is nothing to prevent licensees seeking restrictions on the use of a patented technology by others, even where that use does not conflict with the use made of the technology by the licensee.

In the event of an allegation of misuse of market power, the downstream corporation would need to attempt to establish that a fairly narrow market existed. From the point of view of demand substitutability it may be possible to establish a market for research into a specific form of cancer (or more specifically, for the licensed technology necessary to undertake this research),[42] although this would depend on whether other parties were also engaged in similar research, and demand for the particular patented product. Category three technologies are most likely to comprise markets in themselves, as they are not substitutable and many parties use them for different research purposes.[43] In contrast, a gene that was broadly useful for research into a particular kind of cancer would be likely to fall within a broader market, and would compete not only with other genetic technologies, but also other alternative forms of treatment.

---

[40] Above, 4.4.3.

[41] The exception is broadly applicable research tools that are non-exclusively licensed. The complaint from potential users in relation to these technologies is frequently the fee that is charged for a licence.

[42] Under US antitrust law, market power or monopoly power may be assessed using product markets, technology markets or product markets; see above 5.4.1. Technology markets are markets for 'the process and output of the act of innovating'; Herbert Hovenkamp, Mark A Lemley and Mark D Janis, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2002), (Hovenkamp, Lemley and Janis), vol I, [4.3c]. Innovation markets are markets for research and development; see US Department of Justice and the Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property*, (1995) (US Licensing Guidelines) <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm> at 27 October 2003; §3.2.3. In the case of medical biotechnology, it may be necessary to employ similar methods of defining markets under the *TPA*, because it will not always be possible to define a market by an end product. Indeed, much research output will be intermediate in the sense that it will still not be clear exactly what applications the output will be useful for. Consequently, markets should be capable of being defined as 'markets for research', and 'markets for licences' to use particular patented technologies.

[43] Examples might be recombinant DNA technology and PCR Taq Polymerase; see Appendix 2.

As far as supply-side substitutability is concerned, an important consideration would be whether the downstream corporation had other research opportunities open to it. If it could be demonstrated that the downstream corporation could obtain another gene or alternative product that did not rely on gene sequence information that enabled it to undertake similar research activities, this may also preclude such narrow market definition. Note that the market may be more broadly defined as the technology necessary to undertake both forms of research, with the result that the patent holder is far less likely to have market power. It may also be defined more generally as the market for licences to use the patented technology. It is likely that a fairly long-term view of these markets will be taken given the pace at which innovation is proceeding in biotechnology in general, and the relatively short periods of time for which technologies assume primacy.

Empirical data presented in Chapter 4 indicates that at present, research is generally continuing despite the fact that licences to patented materials might be refused or unavailable.[44] This is primarily due to the breadth of research opportunities currently available to downstream users of patented genomic technologies. For example, in Chapter 4 it was reported that some respondents to the Australian study stated that licences were not sought if it was perceived that they would be refused.[45] Although refusals to license may impact on innovation, narrow market definition may be precluded due to the difficulty that might exist in establishing that there are no research opportunities available to a downstream user as a result of a refusal to licence. This situation may well change as research areas become more cluttered and patent activity steadily increases.

Despite this, it may be possible in some instances to argue that biotechnology products exist for which there are no effective substitutes. The WARF patents that have been licensed to Geron are a good example, although technological advances mean that this may not be the case indefinitely.[46] The Nuffield Council on Bioethics have acknowledged that many gene sequence patents are difficult or impossible to invent around.[47] Lawson argues that broad claims on gene sequences and their applications potentially impact on a range of products and processes because often they cannot be substituted or imitated.[48] The inability to imitate certain technologies

[44] Above, 4.4.2, 4.5.

[45] See above, 4.4.1.2.

[46] See Appendix 2. Note that this technology is not patented in Australia in any event.

[47] Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper*, Discussion Paper (2002) (Nuffield Discussion Paper), 54.

[48] Lawson, Patenting at the Expense of Competition, above n18, 128-130.

gives effective ownership over not only the technologies, but also through any application that uses those technologies.[49] Lawson cites the example of Amgen's broad patent protection over a cloned gene that enabled them to produce erythropoietin and subsequently, pharmaceutical products. The patents prevented the development by a competitor of an alternative method of producing erythropoietin.[50]

Where these patents are broad in scope (as are the WARF patents), this would tend to lead to broad market definition in any event. However, where they are more restricted in the scope of their claims, narrow market definition may be indicated. An example may be a gene sequence useful for a very limited therapeutic or diagnostic application, or a drug target specific to a particular disease.[51] Similarly, the accumulation of a group of patents may result in a narrowly defined research area being closed off. A refusal to license a small downstream company in these circumstances could have grave implications for the continuation of their research activities. Again, the issue of market definition would be largely determined by the level of demand for the patented products, and alternative research opportunities available to the downstream company.

(iii) Barriers to Entry in Medical Biotechnology

In many markets in biotechnology, patents may constitute significant barriers to entry. The TPC suggested that there are a number of factors that may be relevant in considering whether intellectual property has created significant barriers to entry:[52]

- the cost of production of substitutable, non-infringing products;
- the lead time and sunk costs of research and development;
- the level of technological advancement inherent in a particular protected product;
- structural rigidities in the market that have resulted from the new technology.

Patents will only constitute a barrier to entry if they completely block entry. It is submitted that patents will not constitute barriers to entry if downstream users have

---

[49] Ibid, 129.

[50] See also Charles Lawson, 'Patents, Substitution, Imitation and Competition: Amgen, TKT and the Erythropoietin Patents' (2001) 37 *ACCC Journal* 22.

[51] Most pharmaceutical companies have significant patent and research portfolios and aim to produce a number of 'blockbuster' drugs. It is unlikely that a refusal to license, for example, a patented drug target to a significant pharmaceutical company would ever result in that drug target constituting a market.

[52] TPC Background Paper, above n10, 16.

the ability to invent around, modify research direction, or obtain alternative technologies. The empirical data suggests that these courses of action are frequently utilised to overcome access issues in medical biotechnology.[53] Consequently, at present it is probably the case that patented biomedical inventions are unlikely to constitute barriers to entry. Of course, the circumstances might be different if a patent holder strategically refuses to license that patent to prevent the continuation of a research program that is already underway.[54] In this instance, it may be possible to demonstrate that the strategic use of the patent constitutes a barrier to entry into a particular market. Again, market definition would be contingent on a number of factors, including the availability of substitute technology, the technology in question, and the nature of the research.

It is also worth commenting on functional market analysis in respect of biotechnology products. Frequently, access will be sought to patented upstream technologies. Until recently, most genomics companies were simply engaged in sequencing data, but many are now competing with downstream users through research being undertaken on sequenced information. This has implications for market analysis, and may in fact have implications for functional market categorisation. Similarly, the fact that market power exists in an upstream market should not preclude a finding that s 46 has been contravened in respect of a downstream market, and this matter is likely to be clarified by way of legislative amendment to s 46.[55]

(iv) Some Guidelines to Defining Markets in Cases Involving Intellectual Property

It is difficult to provide guidelines for defining markets where intellectual property is concerned. Nevertheless, in accordance with the framework identified in Chapter 5, any court considering whether a refusal to license constitutes a contravention of s 46 must consider two fundamental questions.

The *first* is whether or not the intellectual property privilege in question constitutes a separate market (and accordingly, whether the right conveys market power). This issue will be considered in the following section. The *second* is whether there can be

---

[53] Above, 4.5.

[54] Many research programs may be commenced without knowing exactly how 'cluttered' the intellectual property environment is. Thus, it is possible to conceive of a situation where a company learns they are infringing a patent after research on a particular project is underway. Although little empirical evidence of research being abandoned was obtained, some respondents did report commencing research projects prior to seeking licences either intentionally or otherwise; above 4.5.3.

[55] See above, 6.3.2.5.

said to be one market that requires analysis, or whether in reality there are two markets, an upstream market and a downstream market which is *capable of constituting a separate market.*[56] This issue is important, because a downstream market may comprise part of the primary market. Alternatively, it may comprise a separate, downstream market into which the intellectual property is an essential input.[57]

A refusal to license a patent will generally only constitute a misuse of market power in situations where a discrete downstream market is affected, and this is reflected in limbs [2](ii) and [3] of the framework. It follows that in order for competition law to be invoked, the downstream market must be capable of definition as a separate market, in that it must be a discrete market that is not, in reality part of the primary market. The main example of a downstream market that would actually comprise part of the primary market is an after-market for repair of a product protected by intellectual property.[58]

Identifying whether a truly discrete market exists, or whether a downstream market actually forms part of a primary market, may be a difficult task. An important issue to consider will be whether the intellectual property is useful as an input into a product in a downstream market, or whether the product in the downstream market is ancillary to a product in the upstream market (as for example in the case of a repair market).[59] Research investigating the properties of a gene would probably result in single, market definition. Research using the gene for a particular downstream application is more likely to result in a separate downstream market being defined.

---

[56] See also Tucker, above n7, 86-88; Abraham I van Melle, 'Refusals to License Intellectual Property Rights: The Impact of *RTE v EC Commission* (*Magill*) on Australian and New Zealand Competition Law' (1997) 25 *Australian Business Law Review* 4, 33-35. The import of this factor was discussed in Chapter 7 in the context of EU case law. This case law has made it clear that the success of a refusal to license claim under Article 82 will hinge on whether there can be said to be two separate markets; above, especially, 7.3.3.

[57] During the remainder of this chapter, the terms used to describe a separate downstream market will be 'separate or 'discrete'. Van Melle defines a separate downstream market as a 'derivative' market; van Melle, above n56, 33. Consequently this term will be used when discussing arguments advanced by van Melle in relation to downstream markets and efficiency considerations; below, 8.3.4.1.

[58] The major US refusal to license cases have all concerned after-markets; above, 7.2.1.2.

[59] As discussed in Chapter 7, the European Court of Justice in *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* [2004] 4 CMLR 28 confirmed that a plaintiff alleging a refusal to license contravenes Article 82 must show that the intellectual property constitutes an indispensable input into a new product. It was pointed out that it may be difficult to determine in a particular case whether a patent in fact constitutes an indispensable input, or whether it comprises part of the product in the downstream market; above, 7.3.3.

In the case of medical biotechnology, the nature of the upstream product will be crucial. Although all uses of an upstream research tool may not be capable of being ascertained, many upstream products will be useful as inputs into a downstream products, and their value to the patent holder will lie primarily in licensing them. Licensing forms an integral part of the medical biotechnology industry, and therefore many products or technologies may fall into this category. In this case, it may be that two distinct markets can be identified.

Accordingly, consideration of the following broad guidelines suggested by Tucker may usefully provide some insight into the nature of the intellectual property in question and the existence of a discrete market:

1. Is the (primary market) product or service a separate (perhaps "raw") constituent element of a secondary market or service, or is the secondary market product or service better described as ancillary to a product or service created in an upstream market?

2. Is the intellectual property utilised by its holder in the process of generating products or services, or does the holder generate a significant proportion of its business income by granting licences of its intellectual property?

3. Does the respondent generate its products (or services) in separate facilities, one employing intellectual property, and the other(s) not? ....[60]

While these guidelines may assist in market delineation, market definition will invariably be problematic in some instances. Some research tools are clearly useful as inputs into further research, but the boundaries between markets may be blurred. However, the incremental nature of medical biotechnology research will tend to make identification of a separate downstream market difficult. There may be many steps, for example, between researching the properties of a gene and an ultimate consumer product. These intermediate markets would invariably be difficult to define and may be subsumed into larger markets that include the upstream, genomic research.

The WARF patents provide another example.[61] Geron holds exclusive licences over a number of WARF's US patents, to undertake research and development in relation to a number of different tissue types. It would be difficult to discern whether a secondary market exists in this case due to the fact that research in the area is at an early stage. It is not clear whether the patents will lead to the development of products in discrete

[60] Tucker, above n7, 87-88 (references omitted).

[61] See Appendix 2.

markets, so that any party refused a license over the relevant patents would have difficulty demonstrating that they require those patents as inputs into product development in a separate, downstream market. Nevertheless, the guidelines provide a useful starting point for assessing the composition of antitrust markets.

(v) Summary

This section sought to identify how markets may be defined in cases involving medical biotechnology patents. It has been proposed that plaintiffs would be advised to argue for narrow market definition where possible, but a number of factors including demand and supply-side substitutability will frequently militate against narrow market definition. Market definition will inevitably be uncertain in high technology industries. Markets must be defined on a case-by-case basis, and relevant factors will include the conduct in issue and the nature of the patented technology.

8.2.2 INTELLECTUAL PROPERTY AND MARKET POWER

The proposition that intellectual property should not be presumed to give rise to market power has gained widespread acceptance.[62] In particular, the OECD has given unqualified support to the principle in their roundtable dealing with *Competition Policy and Intellectual Property Rights*.[63] As a result, market power should never be inferred from intellectual property ownership alone.[64]

Intellectual property will certainly be relevant, however, to the computation of market power, in that it affects the ability of rivals to respond to price increases in protected products, and may constitute a barrier to entry.[65] Because of the difficulty in ascertaining whether many products protected by intellectual property produce returns above cost, attempting to ascertain market power from price-cost information will

---

[62] See the discussion above, 5.5.3.1, and the references cited therein.

[63] Organisation for Economic Cooperation and Development (OECD), *Competition Policy and Intellectual Property Rights* (1998), 8-9.

[64] Note that there is a long line of US authority which has held that a patent creates a rebuttable presumption of market power where a patent licence is tied to unpatented goods; see Hovenkamp, Lemley and Janis, above n42, vol I, [4.2e]. The canon had only been referred to in dicta over the last few decades until in a recent case, the Federal Circuit effectively revived it; see *Independent Ink Inc v Illinois Tool Works Inc and Trident Inc* 396 F.3d 1342 (Federal Circuit, January 25, 2005). The US Licensing Guidelines specifically state that the US agencies will not presume that a patent, copyright or trade secret necessarily confers market power; US Licensing Guidelines, §2.1.

[65] Hovenkamp, Lemley and Janis, vol I, [4.1b].

have little utility.[66] Accordingly, it becomes necessary to investigate alternative technologies currently or potentially available.[67]

8.2.2.1 *ASSESSMENT OF MARKET POWER IN CASES INVOLVING SINGLE MARKETS*

In assessing market power in technology markets, the US Licensing Guidelines recognise that patent owners may operate only in markets for the patents themselves, that is, there may be a market for licences of the protected technology.[68] In this case, the Guidelines direct that the market will comprise the licensed technology together with its close substitutes.[69] This allows an assessment of market power where the owner of intellectual property is seeking to charge a monopoly price for a licence to use its technology (or engage in other exclusionary conduct). Market power will depend on the value of the protected product to licensees, and the availability of alternatives.[70] It should be remembered that the high threshold for application of s 2 of the *Sherman Act*[71] is monopoly power. A similar position has been reached in the EU. While the standard of market power required is dominance, if a finding is made that intellectual property is sufficiently strong so as to convey market power, it is likely that a finding of dominance will follow.[72]

Under the *TPA*, it is now clear that market power may in some circumstances be generated as a result of patent ownership. The fact that market power can arise as a result of ownership of intellectual property was recognised in the Explanatory Memorandum accompanying the 1986 Trade Practices Revision Bill, where it was stated that '... market power can be derived from statutory limitations on competition (eg through the creation of statutory monopolies) in the same way as any other constraints on competition can affect the operation of the market.'[73] In the High Court, Dawson J in *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd*

---

[66] Ibid, vol I, [4.1c].

[67] Ibid, vol I, [4.1c].

[68] Known as technology markets. See above, n42, and see US Licensing Guidelines, §3.2.2, which notes that it may be necessary to define markets in this manner where 'rights to intellectual property are marketed separately from the products in which they are used...'

[69] Ibid.

[70] Hovenkamp, Lemley and Janis, above n42, vol I, [4.3a].

[71] *Sherman Act* 15 USC (1890).

[72] As indicated in *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416 and implied by other decisions discussed above , 7.3.

[73] Explanatory Memorandum, Trade Practices Revision Bill, 1986, [44]. This signalled an intention to overrule a line of Federal Court authority in which rights arising under statute or contract were held not to give rise to market power. See further below, 8.3.1.

(*Queensland Wire*) confirmed this by stating that it is not '... helpful to categorise conduct, as has been done, by determining whether it is the exercise of some contractual or other right',[74] and the matter was implicit in the reasoning of the other judges.[75]

More recently, the High Court in *NT Power Generation Pty Ltd v Power and Water Authority*[76] rejected the proposition that the ownership of a property right was incapable of giving rise to market power and held that a property owner who refused access to that property was taking advantage of its market power. As a result, it would now appear to be accepted that property rights and statutory rights such as those conveyed by intellectual property are capable of giving rise to market power.

Under current High Court interpretations of the concept of market power, however, it is unlikely that a patent owner will ever be considered to possess a substantial degree of power in a market. Arguably, the result of the High Court's decision in *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (*Boral*)[77] is that near-monopoly power is required to satisfy the market power requirement in s 46.[78] As such, market definition becomes a crucial determinant of whether market power is possessed in a particular case.

Consider the example of Chiron's HCV therapy discussed in the preceding section.[79] In order to establish that Chiron's patents gave it market power, Murex would have needed to establish that a narrow market existed, a finding the UK Court of Appeals declined to make. Instead, the Court of Appeals assessed whether Chiron occupied a dominant position in a broadly defined market, a situation in which dominance will always be difficult to establish. Arguably the market power requirement under s 46 now also provides a prohibitive obstacle for plaintiffs seeking to establish that a refusal to license a patent constitutes a misuse of market power.

While a patent may well constitute a barrier to entry for those who unsuccessfully seek a licence, there are likely to be other factors that militate against a finding of

---

[74] *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, 202 (Dawson J).

[75] Brenda Marshall, 'The Relevance of a Legitimate Business Rationale Under Section 46 of the *Trade Practices Act*' (2003) 8(1) *Deakin Law Review* 49, 56.

[76] *NT Power Generation Pty Ltd v Power and Water Authority* (2004) 210 ALR 312.

[77] *Boral Besser Masonry Ltd (now Boral Masonry Ltd) v Australian Competition and Consumer Commission* (2003) 195 ALR 609.

[78] Above, 6.3.5.

[79] Above, 8.2.1.2(ii).

market power.[80] Most obviously, few patent claims are likely to be broad enough to encompass an antitrust market. Even if markets are defined narrowly, in order to confer market power, the patent claims must be broad enough to include the market in its entirety.[81] Kitch suggests that this is only likely to occur when an invention involves a fundamental or basic invention, rather than an improvement on an existing invention.[82] While this may occur in new, high technology areas, the steps required before commercialisation mean that demand for the invention is limited.[83]

Another major impediment to establishing that a patent (or group of patents) comprises an antitrust market is the fact that many patents can be overcome by research and development.[84] Empirical evidence discussed in Chapter 4 supports this, and suggests that many parties in medical biotechnology who have been refused licences, or have perceived that licences would be refused if requested, were commonly able to invent around existing patents.[85] At the same time, there are biotechnology patents that are difficult or impossible to invent around, and this may assist in demonstrating that the patent holder possesses market power.[86]

8.2.2.2 *THE REQUIREMENT FOR TWO MARKETS*

In the US, there must be two distinct markets in order for the essential facilities doctrine to operate.[87] Similarly, specific requirements have evolved in the EU in relation to when a refusal to license intellectual property will constitute a contravention of Article 82, although the requirements under EU case law are more

---

[80] See also the discussion in Geoff Adams and Dan McLennan, 'Intellectual Property Licensing and Part IV of the Trade Practices Act: Are the TPA's Pro-Competitive Provisions Anti-IP Commercialisation?' (2002) 51 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 10, 14.

[81] See Edmund W Kitch, 'Elementary and Persistent Errors in the Economic Analysis of Intellectual Property' (2000) 53 *Vanderbilt Law Review* 1727, 1730.

[82] Ibid, 1730-31.

[83] Ibid, 1731. Query, however, whether this is likely to be the case where a licence has been requested and refused.

[84] IPCRC Report, above n24, 25; Antra Hood, 'Barriers and Impediments to Entry in Australian Health Care Markets After *Stirling Harbour*, *Boral* and *Melway*' (2002) 20 *Australian Business Law Review* 6, her n 67.

[85] Above, 4.5.2.

[86] For example, gene patents are difficult to invent around, as are many of the foundational research tools discussed in Appendix 2. See further above, 8.2.1.2(ii).

[87] Above, 7.2.3. As discussed, the doctrine is unlikely to operate in respect of intellectual property in the US. This doctrine may be applied where a vertically integrated intellectual property holder refuses to license to a competitor in a downstream market. If this approach is applied, it follows that a refusal to license to a competitor in a downstream market is unlikely to contravene US antitrust law.

clearly spelt out. In addition to the requirement that there be a new product for which there is an unsatisfied consumer demand (as well as no objective justification for the refusal), the essential facilities component of the conditions laid down by European case law demands that there be a separate downstream market that is not currently being exploited. It will be sufficient if there is the potential for a downstream market to exist.[88]

This requirement that market power be leveraged from one market to another is not readily apparent in the Australian legislation. It appears likely that s 46 will be amended to allow s 46 to be invoked in a leverage situation.[89] What is not clear, however, is whether it is necessary that market power be extended from one market to another before s 46 will operate to render a refusal to license unlawful.

It is submitted that under Australian competition law, there is no requirement that there be two markets before s 46 would operate in the case of a refusal to license. Provided a company possesses substantial market power in a market, one element of s 46 will be satisfied. It is not clear, however, whether the two-market requirement laid down in *Magill* and *IMS* would be become an implied requirement of a refusal to license action under s 46.[90] It was contended in Chapter 5 that it would probably only be in cases where market power from one market is used in another market that a refusal to license would contravene s 46.[91] If a plaintiff can establish the existence of substantial market power in these circumstances, there is a *greater likelihood* that the 'taking advantage' element will be satisfied.[92]

8.2.2.3 *Some Circumstances Specific to Medical Biotechnology*

If patents constitute a sufficiently high barrier to entry, this may lead to the accrual of substantial market power. The following circumstances may arise in medical biotechnology, and may be conducive to a finding of substantial market power in a particular market:

- strategic use of a broad fundamental patent;
- the accumulation of patents;
- oligopolistic market structures.

---

[88] Above, 7.3.1.

[89] See Chapter 6.3.2.5.

[90] See Van Melle, above n56, 26-27.

[91] Above, 5.5.5.

[92] See below, 8.3.4.

(i) Patents Over Fundamental Research Tools

Holding a broad, fundamental patent that precludes competing research or that may be used to prevent the advancement of research in a number of research areas, may result in a finding of market power. Not all problematic patents are capable of being circumvented. In biotechnology, research and development costs are prohibitive. The high cost of inventing around or producing competing technology may be so great as to inhibit potential competitors from attempting to compete.[93] It may also preclude the undertaking or continuation of downstream research. The significant number of fundamental and broad patents in medical biotechnology means that inventing around many of these patents is prohibitively expensive or impossible. While new technologies may emerge in time, this may be a long-run phenomenon, and research (and market entry) opportunities may be lost as pioneer technologies are withheld from competitors or downstream companies.

(ii) Accumulation of Patents

Further, the accumulation of patents through defensive patenting strategies may have the effect of protecting whole research areas. The accumulation of patents through vertical integration could produce a similar result. In this case, the structure of the medical biotechnology industry in itself is problematic, because it lends itself to the accumulation of patents, which may give rise to market power.

All of the patents held by a corporation will be relevant in assessing market power. Section 46(2) of the *TPA* also provides:

> If:
>
> (a) a body corporate that is related to a corporation has, or 2 or more bodies corporate each of which is related to one corporation together have, a substantial degree of power in a market; or
>
> (b) a corporation and a body corporate that is, or a corporation and 2 or more bodies corporate each of which is related to that corporation, together have a substantial degree of power in a market; the corporation shall be taken for the purposes of this section to have a substantial degree of power in that market.

While expressly stipulating that market power may arise through the aggregation of bodies corporate, this provision is limited to related bodies corporate. It does not apply to the accumulation, through any means, of market power between unrelated

[93] Adams and McLennan, above n80, 14-15.

corporations. It is clear from this provision, however, that vertical integration that allows the collection of patents that collectively account for a whole area of research will be relevant in assessing market power.

Due to the requirement that corporations be related, licensing agreements among unrelated corporations that facilitate the accretion of market power would not fall within the ambit of the provision. Arrangements that result in competitors within a market accruing a monopoly position may attract a charge of monopolisation in the US.[94] There is no authority on this point in Australia, and it is unclear whether a similar position would apply. It would certainly be relevant, however, to a consideration of market power, to take into account all of the patents and licence agreements held by a corporation, in assessing the degree of market power held by that corporation.[95]

This was confirmed by Hill J in *ACCC v Universal Music Australia Pty Ltd*,[96] who held that a temporary monopoly could be conferred by an aggregation of intellectual property privileges for which there was no substitutable alternative.[97] Aggregation of biotechnology patents has been revealed by the empirical evidence to be a common practice, and is frequently undertaken for the sole purpose of closing off areas of research.[98] If it has the effect of foreclosing research in a downstream segment, it may attract s 46. This would hinge on the temporal view taken of the relevant market, and whether a 'temporary monopoly' would be sufficient to give a patent holder substantial market power in the relevant market.

(iii) Oligopoly Markets and Market Power

The cumulative nature of the industry also highlights the potential for research blockages if access to an important technology is withheld from a downstream party (as it may be if exclusively licensed to another party). Technologies falling into all three research categories may be capable of conveying market power in certain circumstances, although the withholding of category one technology from competitors

---

[94] See the discussion in John D Heydon, The Law Book Company Limited, *Trade Practices Law*, vol 1, [5.720]. The acquisition of patents leading to an overly strong patent portfolio may give rise to a claim under *Clayton Act* 35 USC §7 (1914); see *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001), and the discussion in Hovenkamp, Lemley and Janis, above n42, vol I, [13.4c], ch 14.

[95] These agreements would need to relate to a specific research area in order to satisfy the market power requirement.

[96] *Universal Music Australia Pty Ltd and Others v ACCC* (2003) 131 FCR 529.

[97] *ACCC v Universal Music Australia Pty Ltd* (2001) 115 FCR 442, 536-537.

[98] Above, 4.4.4.

is a natural by-product of the competitive process and unlikely to contravene s 46. Most category three technologies are widely licensed, and it is technologies that fall into category two that are most likely to be problematic from a competition law perspective.

The medical biotechnology industry is exemplified by a number of large participants with large patent portfolios, and smaller participants with growing patent portfolios. To some degree, the industry exhibits elements of an oligopolistic market structure where corporations hold (in some cases) mutually blocking patent portfolios obtained primarily for defensive purposes.[99] But the breadth of research opportunities available in medical biotechnology would be a factor militating against a finding of market power against a group of corporations, just as it would be a factor suggestive that market power did not exist in the case of an individual corporation. Recent determinations in relation to the market power standard also mean that market power would be unlikely to exist in an oligopoly situation.[100]

8.3 'Taking Advantage' of Medical Biotechnology Patents

The following section considers whether a refusal to license could constitute a 'taking advantage' of market power. Relevant authorities in relation to this element were discussed in Chapter 6.[101] Courts must apply a hypothetical competitive market test in determining whether this element is satisfied, and consider the conduct of the corporation under workably competitive conditions. What is not clear is whether future courts will assess this element by asking whether the corporation 'would' have engaged in the conduct under competitive conditions, or whether the corporation 'could' have engaged in the conduct under competitive conditions.[102]

8.3.1 'Taking Advantage' of Patents and Market Power

As discussed, it has been stated that intellectual property is capable of giving rise to market power.[103] A line of Federal Court authority that preceded the Trade Practices

---

[99] See John H Barton, 'Antitrust Treatment of Oligopolies with Mutually Blocking Patent Portfolios' (2002) 69 *Antitrust Law Journal* 851. Barton points out that these trends are evident in the agricultural biotechnology industry; at 855-856. However there is also evidence of broad, overlapping patents amongst industry leaders in medical biotechnology.

[100] Above, 6.3.5.

[101] Above, 6.4.1.

[102] Above, 6.4.1.

[103] See above, 8.2.

Revision Bill 1986 had held otherwise, relying on the proposition that the exercise of a contractual, property or statutory right involves taking advantage of the right conferred by contract or statute, and not market power.[104] In *Warman International v Envirotech Australia Pty Ltd*[105] for example, Warman was dominant in the market for slurry pumps and replacement parts. However, Wilcox J held that Warman was seeking to take advantage of its intellectual property rather than the market power it possessed.[106]

The High Court's decision in *Queensland Wire*,[107] as clarified by the High Court in *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd (Melway)*,[108] confirms the incorrectness of focusing on the source of market power.[109] Instead, comparing behaviour under competitive conditions becomes the paramount issue.[110] As a result it is unlikely this succession of decisions will be followed.[111] Focusing on the competitive market test means that efficiency justifications will become relevant considerations. The implications of this for intellectual property owners must be considered.

8.3.2 The Relevance of Efficiency Considerations to Dealings in Intellectual Property and the 'Take Advantage' Element

It is not clear whether the 'would' or 'could' approach is likely to be adopted in future s 46 cases. If a strict 'could' approach is adopted, then given that this approach tests physical possibilities, technically there could never be a taking advantage for a refusal to license a patent. Under the hypothetical competitive market test, anything is

---

[104] See, eg, *Top Performance Motors Pty Ltd v Ira Berk (Qld) Pty Ltd* (1975) ATPR 40-004; *Warman International v Envirotech Australia Pty Ltd* (1986) ATPR 40-714; *Williams Papersave Pty Ltd* (1987) ATPR 40-781.

[105] *Warman International v Envirotech Australia Pty Ltd* (1986) 40-714.

[106] Wilcox J relied on the judgment of Joske J in *Top Performance Motors Pty Ltd v Ira Berk (Qld) Pty Ltd* (1975) ATPR 40-004.

[107] *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177, especially 202 (Dawson J).

[108] *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1.

[109] See also *NT Power Generation Pty Ltd v Power and Water Authority* (2004) 210 ALR 312.

[110] Marshall, above n75, 56; David Meltz, '"Market Entry – See Adjoining Map": *Melway* and the Right Not to Supply' (2002) 10 *Trade Practices Law Journal* 96, 109.

[111] See, however, the discussion by Marshall, who points out that there have been decisions subsequent to *Queensland Wire* and even *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1 that have retained the distinction; Marshall, above n75, 57-58, referring to the judgment of Lockhart J in *Dowling v Dalgety Australia Ltd* (1992) ATPR 41-165 and Lee J in *NT Power Generation Pty Ltd v Power and Water Authority* (2002) 122 FCR 399, 404-405. Marshall suggests this indicates 'an ongoing measure of judicial uncertainty'; at 58.

possible where a test of physical possibility is applied. If a would test is employed, the test would ask whether the conduct would be likely to have been engaged in under competitive conditions, with efficiency justifications becoming the paramount issue in respect of this element.

Lawson asserts that by allowing consideration of efficiency arguments, the High Court's decision in *Melway* narrows the operation of s 46.[112] In relation to patent holders, Lawson argues that the very nature of patents is that they promote beneficial innovation, and that this tends to lay the foundation for efficiency justifications in respect of most patenting practices.[113] This, according to Lawson, significantly narrows the scope for aggrieved parties to assert that a use of patents constitutes a misuse of market power, although he acknowledges that this will depend on the attitude of particular judges toward the application of competition law to dealings in intellectual property.[114]

Richardson argues that there are likely to be many competing efficiency considerations where the exploitation of intellectual property is concerned.[115] It is unclear how courts are likely to weigh these efficiency considerations, and Richardson cautions against competition law focusing too specifically on dealings in intellectual property.[116]

Contrary to Lawson's argument, the test established in *Melway* provides a sound basis for assessing the legitimacy of particular practices engaged in by patent holders. There is no policy reason for treating intellectual property dealings differently to other transactions to which the competitive market test applies. Some commentators have argued that efficiency justifications should not be relevant to the take advantage element at all.[117] Assuming, however, that efficiency justifications will be relevant if a

---

[112] Lawson, above n18, 127.

[113] Ibid, 127.

[114] Ibid, 127-128.

[115] Megan Richardson, 'The High Court of Australia Revisits Misuse of Market Power: Implications for Australian Intellectual Property Rightholders' (2002) 24(2) *European Intellectual Property Review* 81, 86.

[116] Ibid.

[117] See the discussion in Stephen Corones, 'The Characterisation of Conduct under Section 46 of the Trade Practices Act' (2002) 30 *Australian Business Law Review* 409, 415. And note that under a 'could' test (applied in conditions of workable competition) efficiency considerations would not be relevant.

'would' test is employed by future courts,[118] there is no reason in principle why restrictions on patent licensing should not be subject to the same test.

Leaving aside the issue of parity, efficiency considerations are central to whether or not a particular restriction in intellectual property licensing should be permitted. It has been argued that intellectual property should be subject to competition law, particularly in an industry such as medical biotechnology where progressive concentration and high levels of patenting are typical.[119] It is entirely in keeping with the aims of intellectual property law to undertake an economic analysis of the efficiency basis of a refusal to license a patent in determining whether competition law should intervene to condemn it.[120] Licensing is an important method of technology diffusion. If efficiency effects outweigh the potential negative effects of the transaction, the dealing should be permitted. Incorporating this principle into the take advantage element is entirely in keeping with the balance the *TPA* seeks to achieve between intellectual property and competition law.

8.3.3 Relevant Efficiency Considerations

Scant guidance exists in the cases discussed, as to specific efficiency justifications that might be advanced to justify the use of market power. No specific guidance has been given in respect of statutory monopolies, either as to the operation of the take advantage test, or as to possible efficiency justifications for potentially anti-competitive conduct.[121] Nevertheless, it is possible to envisage some justifications that might be advanced by a patent owner where they refuse to license that patent. Although it is acknowledged that efficiency justifications will not always be universally agreed upon, this problem is not unique to intellectual property dealings.

---

[118] And arguably even upon application of a 'could' test if the court applies the test in the same manner as a 'would' test.

[119] Above, 5.5.3.2.

[120] To reiterate the third principle espoused by Gallini and Trebilcock with regard to the relationship between intellectual property and competition dealings:

> [Principle 3] A licensing restriction should be permitted if it is not anticompetitive relative to the outcome that would result if the licence were proscribed; otherwise, an evaluation of the potential efficiency effects of the restriction on the pricing and diffusion of the intellectual property should be made; Nancy T Gallini and Michael J Trebilcock, 'Intellectual Property Rights and Competition Policy: A Framework for the Analysis of Economic and Legal Issues' in Robert D Anderson and Nancy T Gallini, *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (1998) 17, 22.

This principle has not gained universal acceptance, but does highlight that efficiency plays an important role in determining the legality of a particular licensing transaction.

[121] Lawson, above n18, 125-127.

Every s 46 case invoking arguments relating to economic efficiency must involve a qualitative assessment.[122]

Hanks and Williams propose four possible reasons that may be advanced for a refusal to supply goods pursuant to s 46:[123]

- the corporation is not maximizing profit, or acting rationally;
- the refusal promotes efficiency;
- the corporation refusing access has market power; or
- pressure to refuse supply is exerted from certain downstream buyers.

Hanks and Williams argue that the third reason is the only basis for a successful s 46 action, and corporations will generally promote efficiency considerations to defend a s 46 action.[124] Indeed, the effect of *Queensland Wire* and subsequent cases is to compel the advancement of efficiency considerations. Nevertheless, there may be circumstances in which the evidence is not conducive to the fact that conduct would have been engaged in under competitive conditions.[125]

There may be a broad range of reasons for intellectual property holders refusing to license their rights. It has been suggested that refusing to licence is often a strategy engaged in by new entrants to existing markets seeking to consolidate their position in that market.[126] In the case of patents, simply wishing to retain exclusive use of technology would certainly be considered to be an efficiency consideration sufficient to justify a refusal to license if exclusive use provides the best method of profit maximisation.[127] This is likely to be a frequently pleaded justification for a refusal to

---

[122] See also US Licensing Guidelines, above n42, § 4.2.

[123] Hanks and Williams, above n25, 445-446. It is submitted that the same analysis can be applied to refusals to license intellectual property.

[124] Ibid, 446.

[125] O'Bryan suggests that where supply to an existing licensee is discontinued, or licence terms made more onerous, an intellectual property holder will have more difficulty in proving their conduct is efficient: Michael O'Bryan, 'Refusal to License Intellectual Property Under the Australian *Trade Practices Act*' (1992) May *Patent World*, 10, 12-13.

[126] Adams and McLennan, above n80, 15.

[127] See also, O'Bryan, Refusal to License, above n125, 10-11. More generally, Korah advocates the acceptance by courts of a reduction in incentive to make the original investment as a justification for a refusal to supply, even where it can be established that supply would have taken place in a competitive market; Valentine Korah, 'Access to Essential Facilities Under the *Commerce Act* in the Light of Experience in Australia, the European Union and The United States' (2000) 31 *Victoria University of Wellington Law Review* 231, 239, 252-253.

license.[128] Similarly, given that many licensees seek exclusive licensing arrangements, such an arrangement might be the optimal method of value realisation for a patent holder. Refusing to license parties except those involved in existing vertical relationships with the patent holder may also in some circumstances constitute valid efficiency considerations, particularly where those arrangements are long-standing or serve to efficiently disseminate the technology.[129] If efficiency justifications provide some off-setting benefit to consumers (or more likely in the case of medical biotechnology, to downstream users), conduct that may, on the face of it, be anti-competitive, may well be tolerated.

Van Melle points out that even holders of intellectual property in competitive markets may refuse to license those rights simply out of a desire to maintain exclusivity.[130] He posits that the 'take advantage' test propounded in *Queensland Wire* is too narrow to allow a finding that a refusal to license contravenes s 46, because the test does not allow consideration of whether conduct is capable of being engaged in by all firms, even those in a competitive market.[131] In this respect, particular conduct will be anti-competitive only when engaged in by a firm with market power, even though it is capable of being engaged in by any firm in the market.[132] In the EU, Article 82 contains no such constraints,[133] and provided the elements of dominance, abuse and an effect on trade between member states can be made out, Article 82 will be satisfied. Thus, Article 82 is more likely to be successfully invoked to condemn a refusal to license.

Thus, van Melle expresses concern that the 'take advantage' test was ameliorated as a result of *Queensland Wire* in respect of issues associated with refusals to license

---

[128] Indeed, the empirical evidence discussed in Chapter 4 demonstrated that in a number of cases where refusals to license were reported, an exclusive licensing arrangement was the reason for the refusal; see generally above 4.4.3.

[129] See also the obiter comments in *Stirling Harbour Services Pty Ltd v Bunbury Port Authority* (2000) ATPR 41-752 (French J), and on appeal *Stirling Harbour Services Pty Ltd v Bunbury Port Authority* (2000) ATPR 41-783 (Burchett, Carr and Healy JJ).

[130] Van Melle, above n56, 28, 30.

[131] Ibid, 28-31.

[132] Ibid, 28-31.

[133] Ibid, 30. Van Melle points to comments made by the Advocate-General in *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416, that 'Many forms of commercial conduct will ... only affect the proper functioning of the common market insofar as they are engaged in by undertakings in a dominant position. In other words a number of circumstances may only be of significance if the right is being exercised by a dominant undertaking.'; at 30 citing *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416, [52] (Advocate-General).

intellectual property.[134] Since the decision in *Melway*, it is submitted that van Melle's concerns in relation to the *Queensland Wire* test have proved to be unfounded. The test as enunciated in *Melway* requires consideration of whether the conduct in question would have been engaged in under workably competitive conditions. Because this hypothetical enquiry allows consideration of efficiency motives for particular conduct, it effectively broadens the *Queensland Wire* test.

A 'would' test requires consideration of whether the conduct would have been likely to be engaged in had the corporation lacked market power by asking whether market power materially facilitated the conduct. In other words, it acknowledges that conduct may be lawful when engaged in by a firm without market power, but will become unlawful upon the acquisition of market power.[135] Of course, adherence to this approach depends on the application of a 'would' test in favour of the 'could' approach, and it is not clear which approach is likely to be adopted. In narrowing the test to be applied under the 'take advantage' element, *Rural Press* has potentially limited the circumstances in which s 46 is likely to apply to refusals to license intellectual property.

A would approach would align s 46 more closely with Article 82, although the application of Article 82 generally proceeds in a more general fashion, with less emphasis on individual elements than is evident in s 46 jurisprudence.[136] Section 46 is not as broadly drafted as Article 82, and it should not be expected that they would yield the same results. It has been suggested that Article 82 will be successfully invoked only rarely where a refusal to license a medical biotechnology patent in a primary market has occurred, but case law in respect of that provision certainly paves the way for the application of Article 82 in circumstances where downstream research is negatively affected, or where patents are obtained for the purpose of preventing research by others.[137]

---

[134] Ibid, 31-32.

[135] Indeed, the basis of the High Court majority's reasoning in *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1 (following Heerey J) was that Melway adopted its distributorship system before it had attained a position of market power; *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 26-27 (Gleeson CJ, Gummow, Hayne and Callinan JJ).

[136] As acknowledged by the majority in *Melway* with reference to Article 82, 'the (European) legislation is different'; *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 29 (Gleeson CJ, Gummow, Hayne and Callinan JJ). The majority did not elaborate on this comment, but generally differentiated Article 82 and s 46; *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 205 CLR 1, 28-29 (Gleeson CJ, Gummow, Hayne and Callinan JJ).

[137] See the discussion above 7.3.4; and see below, 8.3.4.1.

Accordingly, it is submitted that where patents are obtained purely for defensive purposes, or to preclude research by others, there would be no justification available and refusing to license a patent should constitute a taking advantage of market power. In this case, there is a strong argument that the patent holder is seeking to expand the scope of the privilege, because the patent may be used to prevent various research applications from being undertaken. This is arguably the only circumstance in which a refusal to license a patent in a primary market would fall within limb [2](i) of the proposed framework,[138] because it is the only circumstance in which there is unlikely to be a clearly identifiable efficiency justification for the refusal to license.[139]

Although the empirical evidence suggests that patents that are not useful to a patent holder are frequently licensed, there were reported instances where suites of patents were obtained to close off areas of research.[140] In this case, it is difficult to see how efficiency forms the basis of the conduct, given that patents may be held that are not exploited. This conduct should be capable of constituting a taking advantage of market power, particularly where this has the result of closing off a downstream market not currently being exploited.[141] However, competition in the market in which the patent holder operates may also be stifled if a potential competitor attempts to gain access to a patent needed to conduct research in that primary market. While it is conceded that it would be difficult to establish that a patent holder did not *intend* exploiting patents, evidence of non-exploitation over a period of time would be a relevant consideration in this case.

8.3.4 'TAKING ADVANTAGE' OF DOWNSTREAM MARKETS

This section explores the manner in which the 'taking advantage' element contained in s 46 is likely to be interpreted if applied to refusals to license medical biotechnology patents. The focus of the section is on efficiency justifications for this conduct.

---

[138] That a patent holder is seeking to expand the scope of the intellectual property.

[139] Again, this submission is made on the basis that a 'would' approach will prevail, but this may not be the case on the basis of current authority.

[140] Above, 4.4.4.

[141] A related issue arose in *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416. In *Magill*, a potential licensee was precluded from exploiting a downstream market for which there was consumer demand, and this was held to be a contravention of Article 82. See further above, 7.3.1.2.

8.3.4.1 *DOWNSTREAM MARKETS AND EFFICIENCY CONSIDERATIONS*

Van Melle suggests that there can be no efficiency justification for refusing to license a competitor in a discrete, secondary market other than the maintenance of marketing and distribution arrangements, and that efficiency arguments relating to marketing and distribution will justify a refusal to license very rarely.[142] Van Melle places emphasis on whether a market is a 'derivative' market and comprises a discrete secondary market.[143] In contrast, a secondary market may not constitute a market in itself, but may be subsumed into a primary market. An example would be an after-market for spare parts.[144] In biotechnology, an improvement patent may be subsumed into a primary market while a new application may fall within a discrete market. An improvement may consist, for example of a method of delivery patent such as a new manner of administering a drug.

A market may be discrete, but intellectual property will nonetheless be a crucial input into products produced in those markets. The basis of van Melle's assertion is that Chicago-school economics dictates that there can be only one monopoly profit in a given chain of production.[145] In this case, while it may be open to a patent holder to compete in a derivative market, it will not usually increase the patent holder's profits. If a competitor in the downstream market has production efficiency at least equal to that of the patent holder, the patent holder's profits will rarely increase as a result of entering the downstream market.[146]

In medical biotechnology, many small, niche companies do license their patents to downstream users, and are usually engaged in a discrete area of research. However, many licences involving potentially non-rivalrous technologies are exclusive, thus precluding the use of patented technology by others. Moreover, a considerable number of companies have diversified or vertically integrated, and these companies will frequently use their patents as barriers to entry into downstream markets. In these

---

[142] Although van Melle considers this issue in the context of the purpose element; see van Melle, above n56, especially 32-35.

[143] As pointed out above, van Melle defines discrete secondary markets as 'derivative'markets; above, n57.

[144] See above, 8.2.1.2(iv).

[145] Note that a number of US studies have shown that there will always be an incentive for firms to exercise market power and charge supracompetitive prices in their proprietary aftermarkets; see, especially, Severin Borenstein, Jeffrey K MacKie-Mason and Janet S Netz, 'Exercising Market Power in Proprietary Aftermarkets' (2000) 9(2) *Journal of Economics and Management Strategy* 157. Thus, there will be an economic incentive to charge monopoly rents in cases involving after-markets, even under competitive conditions in the primary market.

[146] Van Melle, above n56, 32-33.

circumstances, the ability to foreclose competition in those downstream markets will serve to maximise the profits of patent holders and exclusive licensees.

It follows, therefore, that the conclusion reached by van Melle is correct and very relevant to medical biotechnology. However, evidence for this conclusion can be gleaned from a broader economic base. The problem stems from the cumulative nature of research in industries such as biotechnology. Studies have highlighted the difficulties inherent in the division of profits between initial and follow-on innovators.[147] As discussed in Chapter 3, the spill-over from initial inventions makes it unlikely that either initial innovators or follow-on innovators will be able to recover the entire social surplus from their inventions.[148] A number of commentators have advocated the grant of broad patents to initial inventors on the assumption that the surplus profits from the initial patented invention can be redistributed through ex ante licensing agreements.[149]

It was pointed out during this discussion, however, that it is not always the case that rational bargaining will take place.[150] In medical biotechnology, licensing negotiations are frequently conducted ex post, or after patent protection has been obtained.[151] Impediments to successful bargaining both generally and in relation to medical biotechnology were also identified in Chapter 3.[152] It cannot be presumed that upstream patent holders will behave in a rational manner with regard to licensing in downstream, specifically discrete markets. Where an upstream patent is necessary for research in a downstream market, there must be a mechanism to ensure that the follow-on inventor is equipped to recover an adequate social surplus to render the follow-on invention worthwhile. Competition law provides such a mechanism.

This thesis proposes that s 46 should operate to ensure that inventors in discrete, downstream markets that require the input of upstream patents, have access to those patents. In other words, a refusal to license in a downstream market should be *capable* of constituting a taking advantage of market power. This is necessary to ensure that follow-on inventors are guaranteed an adequate social surplus, and thus have an incentive to innovate. Section 46 should operate where rational licensing

[147] See the discussion above, 3.3.1.

[148] Above, 3.3.1.

[149] Above, 3.3.2.

[150] Above, 3.3.3, 3.3.4.3.

[151] Above, 3.3.4.3.

[152] Above, 3.3.4.4, 3.3.4.5.

arrangements are for some reason not entered into, because in most cases there will be no other efficiency basis for refusing to license a firm in a downstream market.

This is particularly important where the patent holder has no intention of exploiting the downstream market, but is attempting to reserve that market for themselves. An important consideration should be whether the patent holder has the resources to move into a downstream market, or whether to do so would constitute an inefficient use of resources. In this case, there may be little evidence that the patent holder has the ability to exploit downstream markets, and this evidence would point directly to a finding that the conduct would not have been engaged in under competitive conditions. This would mirror the position in the EU, where a refusal to license that inhibits competition in a downstream market will, subject to the cumulative preconditions laid down in EU case law, contravene Article 82.[153]

It is not clear exactly what the position in the US is because the issue has not been addressed by US courts. The cases discussed in Chapter 7 involved allegations of monopolisation of markets for service, that is, after-markets.[154] In other words, a *Magill* type scenario, where a discrete, downstream market is monopolised in addition to a primary market, has never required consideration in the US. The case of *Data General Corporation and Data General Service Inc v Grumman Systems Support Corporation*[155] is instructive. The presumption established in that case arguably leaves room for such a situation to contravene s 2, in that efficiency justifications may constitute a 'presumptively valid business justification for any immediate harm to consumers'.[156] It may also be consistent with the framework advocated in this thesis, although it is difficult to state that this is the case in the absence of specific case law.

---

[153] Above, 7.3.3.

[154] Above, 7.2.1.2.

[155] *Data General Corporation and Data General Service Inc v Grumman Systems Support Corporation* 761 F Supp 185, 191-192 (D Mass 1991), aff'd in part and remanded, 36 F 3d 1147 (1st Cir 1994), 1187. See also above, 7.2.1.2(ii).

[156] Note, van Melle asserts that the computer software that was the subject of the refusal to license in *Data General Corporation and Data General Service Inc v Grumman Systems Support Corporation* 761 F Supp 185, 191-192 (D Mass 1991), aff'd in part and remanded, 36 F 3d 1147 (1st Cir 1994), operated in the primary market for computer repair given that that was the purpose for its development. Thus, although the case did not involve an after-market as such, it also did not involve a true derivative market. The software was not necessary in order to compete in the market for repair; van Melle, above n56, 20. In this case, the holding would allow a finding that s 2 has been breached in a single market situation provided the presumption of validity is not rebutted by evidence. Note also the consideration of subjective intent as a valid business justification in *Image Technical Services Inc and Others v Eastman Kodak Co* 125 F 3d 1195 (9th Cir 1997), cert denied, 523 US 1094 (1998). This is the main basis on which the decision has been criticised.

The case of *Intergraph Corporation v Intel Corporation* (*Intergraph*)[157] should, however, be noted. In this case, it will be recalled that the Federal Circuit specified that a refusal to license will *only* be in breach of s 2 where that refusal is directed against competition. In this respect, this holding may be contrary to the rule laid down in EU jurisprudence, and the stifling of the development of a *new* product in a downstream market would be unlikely to breach s 2. It would not allow success in an action brought under limb [2] of the proposed framework, although success under limb [3] would not be precluded given the requirement for competition between the patent holder and potential licensee.[158]

Again, however, it is difficult to reach a definitive conclusion on the applicability of this decision, because the case involved an after-market rather than a separate downstream market. Similarly, its precedential value is unclear because of the inconsistency in approaches taken by various US courts. The specific terms of s 2 should also be considered. Section 2 is limited in its scope and requires monopolisation. Article 82 and s 46 are arguably more specific in allowing a contravention in a separate market.

To conclude, it is argued that the assertion by van Melle that there is unlikely to be an efficiency justification for a refusal to license into a discrete or derivative market is correct. The exception, as van Melle points out, may be where there is an efficiency justification based on marketing or distribution. Where exclusive licensing arrangements are entered into, this could not be an appropriate efficiency justification. It could also be envisaged as being a successfully pleaded justification where the patented technology is relatively downstream technology in any event. In medical biotechnology, many inventions are upstream, and few inventions have reached the stage of being useful 'consumer' products. In this case, claims by patent holders that they are protecting the marketing of their product by restricting the number of licensees, should not ground a justification for a refusal to license. The nature of the downstream market is also important. Where the patented technology is important for more than one downstream use (as are many genetic technologies) that may ultimately compete (category two technology), this should be a relevant consideration as to whether there has been a taking advantage of market power.

---

[157] *Intergraph Corporation v Intel Corporation* 195 F 3d 1346 (Fed Cir 1999).

[158] Although the status of this decision is open to question following the decision of the US Supreme Court in *Holmes Group Inc v Vornado Air Circulation Systems Inc* 122 S Cr 1889 (2002). See above, 7.2.1.2(v).

8.3.4.2 *CIRCUMSTANCES WHERE THE PATENT HOLDER OPERATES IN THE DOWNSTREAM MARKET*

A patent holder or a licensee may exploit one discrete, downstream market. This should not preclude a finding that there has been a taking advantage of market power where a license is refused to a licensee who wishes to exploit another discrete market. This raises complex issues, and would require consideration of a number of competing efficiency considerations. It really highlights the importance of the terms under which contractual arrangements are entered into when the full potential of technology is not yet known. Economic rationality should not always be assumed; while many patent holders will act in an economically rational manner, in some instances they will not, with the result that a refusal to license may occur for reasons unconnected with profit maximisation or cost minimisation. On the basis of this, however, there would be no breach of s 46 in relation to the example of Chiron and Murex if there was a legitimate efficiency consideration for Chiron's decision to exclusively license their technology and refuse to license Murex.[159]

This is particularly important where an invention constitutes a new application rather than an improvement. It was submitted in Chapter 3 that this is very likely to be the case in an industry such as medical biotechnology.[160] Further, the broad potential of many biotechnology applications is unknown at the time that initial inventions are patented. The nature of medical biotechnology research makes this industry particularly susceptible to breakdowns in bargaining that could lead to new, and socially beneficial research. As such, it provides a useful example of how patents may be used in a manner that hinders the development of new products. Section 46 should be available as a 'backstop' to ensure that these detrimental effects are able to be addressed.

Where the patent holder would compete in a particular downstream market with a potential licensee, the situation becomes more problematic. It may in some instances be difficult to conceive of efficiency justifications on which such a refusal to license could be based. In the context of refusals to supply tangible property, *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd*[161] provides an analogous factual scenario in that BHP's subsidiary was operating in the downstream market alongside their would-be competitor. However, courts might be reluctant to condemn a refusal

---

[159] This is an example of an instance in which it might be argued that successful marketing and distribution are predicated on limiting competition in the downstream market.

[160] Above, 3.3.4.4.

[161] *Queensland Wire Industries Pty Ltd v Broken Hill Pty Co Ltd* (1989) 167 CLR 177.

to license where a downstream or derivative market is being positively exploited, even if that exploitation is by the patent holder or an exclusive licensee.[162]

It was on this basis that the Court of First Instance (CFI) in *IMS Health Inc v EC Commission*[163] questioned whether exceptional circumstances existed that would justify the grant of a compulsory licence. Indeed, a refusal to license would not contravene Article 82 if the patent holder competed with the potential licensee. In contrast, the decision of the US decision of *Intergraph*, leaves room for a contravention of s 2 of the *Sherman Act* in an instance such as this.[164] Under s 46, it may come down to a question of whether patent protection extended to the separate market, and whether the ACCC or a court wished to promote competition in a particular market.[165]

Reference was made in Chapter 1 to conflicting studies that question whether there can be said to be an optimal level of competition within an industry. There is a school of thought that advocates competition within industries as a way of maximising allocative and productive efficiency outcomes, particularly in vertically integrated industries.[166] Following this line of argument, the ability to foreclose and monopolise research avenues in an industry such as medical biotechnology should be curtailed where there are no apparent or logical efficiency outcomes.

8.3.5 Conclusion – The 'Take Advantage' Element

To conclude, there may be many efficiency reasons for a refusal to license that mean the taking advantage element will not be made out. The difficulty lies in predicting specifically what efficiency considerations are likely to excuse a refusal to license. On the basis of the empirical evidence, possibly the main instance in which the taking advantage will be made out is where a potential licensee wishes to exploit a downstream market that is not currently being exploited by the patent holder or by a licensee.[167]

---

[162] See also Tucker, above n7, 86.

[163] *IMS Health Inc v EC Commission* [2002] 4 CMLR 2 (Order dated 26 October 2001) [101-105].

[164] See above n157 and accompanying text.

[165] Van Melle asserts that another reason why it may be desirable to promote competition in derivative markets, is that it would increase the 'transparency of pricing' in those markets, particularly where the intellectual property is of doubtful scope and may not legitimately extend into the derivative market; van Melle, above n56, 33.

[166] See above 1.8.2.2. See also ibid, 33-34.

[167] See also Adams and McLennan, above n80, 16-17; Stephen G Corones, 'Intellectual and Industrial Property – Reconciling Intellectual Property Rights and Competition Law: The *Magill* TV Guide Case' (1992) 20(3) *Australian Business Law Review* 265, 269.

An existing licensing arrangement or a desire to preserve market opportunities may form the basis for a refusal in this case, and it submitted that this should support a finding that market power has been taken advantage of where there are no substitutes for the requisite intellectual property. Similarly, reductions in transaction costs may justify the maintenance of an existing vertical arrangement. It is difficult, however, to predict whether such a finding is likely to be made, as there may be conflicting considerations a court will need to weigh up. It is likely that most courts would be reluctant to make a finding that a refusal to license constitutes a taking advantage of market power contrary to s 46 except in the most extreme cases.

However, courts should be willing to find that a refusal to license into a discrete, downstream market should be capable of constituting a taking advantage of market power, because there are likely to be few plausible efficiency considerations in such a case. This is the case whether or not the patent holder is exploiting the downstream market, although clearly a refusal to license in the absence of exploitation by either the patent holder or an exclusive licensee would make it easier to prove an absence of an appropriate efficiency justification. Nevertheless, the operation by a patent holder in a derivative market should not preclude examination under s 46, given that the operation of the take advantage test hinges on the existence of efficiency justifications. Because it will be difficult to find efficiency justifications in this instance, s 46 should be capable of application.

The preceding discussion is contingent upon the application of a 'would' test in relation to the 'take advantage' element.[168] If a 'could' test were employed, the opportunity to examine efficiency considerations would be removed. The application of a 'could' test in relation to the 'take advantage' element would never yield a finding that the monopolisation of a discrete, downstream, market by refusing to license patents necessary for innovation in that downstream market, satisfied this element. It is not clear, however, whether the High Court in *Rural Press* intended to apply a strict 'could' approach. Certainly *Melway* was never authority for this approach.[169] Consequently, scope may remain for application of a 'would' approach.

8.4 Establishing the Purpose Element

If all the other elements of s 46 can be established, there remains the difficulty of establishing that a refusal to license was for a proscribed purpose. As discussed

[168] Above, 6.4.1.

[169] Above, 6.4.1.

above, all of these purposes focus on damage to competitors, potential competitors or persons attempting to engage in competitive conduct. It will often be difficult to ascertain whether a party is attempting to do damage to a rival, or simply engaging in competitive conduct. On the basis of the preceding discussion, it is only in rare circumstances that a contravention of s 46 will be found where a licence to a party in a straightforward competitive relationship is refused.[170] It is more likely that a contravention will be established where access to the patented technology is necessary for the development of a new technology. That is, s 46(1)(b) is the sub-section most likely to be invoked.

It will be recalled that Marshall, quite reasonably, has suggested that justifications that will be relevant in respect of the purpose element, fall into the category of quality control/consumer welfare' and/or 'reputation/bottom line considerations.[171] Certain justifications have been contemplated in the case of intellectual property, such as previous unsatisfactory dealings,[172] the prevention of free-riding,[173] and a desire to maintain the integrity of a licensing system.[174] Similarly, the maintenance of good credit arrangements may justify a refusal to license where licence fees remain unpaid.[175]

Of these justifications, the most likely to be pleaded is probably the prevention of free-riding. It is submitted that this could certainly be considered to be a justification under the take advantage element, given that it is based on a desire to recoup investment costs. It could also be contemplated as a justification pursuant to the purpose element given that it has as another its bases, consumer welfare and quality control. Note that Tucker considers that the free-rider exemption can only constitute a valid basis for a refusal to license in a single market situation.[176] That is, where competitors are denied access, there is little doubt that this is the motive for the refusal to license.[177] There is, however, likely to be an anti-competitive motive for a

---

[170] As Tucker points out, where parties are competitors in a primary market, it will be difficult to establish a s 46 purpose; Tucker, above n7, 85.

[171] See above, 6.5.1.

[172] Brenda Marshall, 'The Resolution of Access Disputes Under Section 46 of the *Trade Practices Act*' (2003) 22(1) *University of Tasmania Law Review* 9, 41.

[173] Ibid, 40, citing *ACCC v Universal Music Australia Pty Ltd* (2001) 115 FCR 442 (Hill J). At first instance, Hill J was prepared, had there been sufficient evidence, to consider the prevention of free-riding as a justification in respect of the 'take advantage' and 'purpose' elements.

[174] *Australian Performing Rights Association Ltd v Ceridale Pty Ltd* (1991) ATPR 41-074.

[175] *Australian Performing Rights Association Ltd v Ceridale Pty Ltd* (1991) ATPR 41-074.

[176] Tucker, above n7, 85-86.

[177] Ibid.

refusal to license in a situation where a downstream user of the technology is denied access, and the refusal could not be justified on the basis of protection of investment costs or consumer welfare considerations.

In the case of patents, a useful example to consider is that of Myriad Genetics' patents over the BRCA1 gene, which prevented parties other than Myriad from undertaking diagnostic testing.[178] Consider the situation in relation to purpose if an action were to be brought under s 46. Evidence suggesting that Myriad's actions have been prompted by a desire to maintain the quality of testing procedures would negate any finding of purpose under s 46. On the other hand, evidence suggesting that superior testing procedures may be developed by other parties may result in the purpose element being made out. Similarly, if proceedings had been brought by Chiron against Murex in Australia, concern about the quality of test kits produced by a party other than Chiron's exclusive licensees would probably justify a refusal to license and mean that no anti-competitive purpose under s 46 could be made out.

The purpose element provides a distinct requirement to be proved by a complainant. It effectively provides another line of defence for a patent holder, and in this respect, makes s 46 even more inaccessible to plaintiffs. Nevertheless, the problems brought about by certain US cases may be avoided. The creation of presumptions, rebuttable or otherwise, to a certain extent precludes fact-based analysis and flexibility in judicial decision-making.[179] For example, the framework established in Chapter 5 would be incapable of application under the approach laid down in *Xerox*.[180] In contrast, Article 82 gives courts very broad scope to examine the implications of certain conduct alleged to be anti-competitive. In particular, courts are not limited to the examples of abuse listed in Article 82.

The current absence of definitive rules in Australia should be seen as a positive factor, because it enables the consideration of individual cases on their merits. As such, courts in Australia may be willing to find the purpose element made out in the case of refusals to license intellectual property where it is open to infer that an anti-competitive purpose was a substantial purpose for the conduct.

---

[178] See Appendix 2.

[179] Although a rebuttable presumption would allow business or efficiency justifications to be taken into account; see eg, *Data General Corporation and Data General Service Inc v Grumman Systems Support Corporation* 761 F Supp 185, 191-192 (D Mass 1991), aff'd in part and remanded, 36 F 3d 1147 (1st Cir 1994).

[180] In contrast, Article 82 gives courts very broad scope to examine the implications of certain conduct alleged to be anti-competitive. In particular, courts are not limited to the examples of abuse listed in Article 82.

8.5 CONCLUSION

There are two main reasons why refusing to license a patent will not often constitute a taking advantage of market power. First, there will be few cases in which a patent will confer market power. Second, whether or not the refusal would have occurred in a competitive market will be determinative of whether the taking advantage element will be made out. This is in accord with the analysis of Hanks and Williams, who stress that these factors will mean that refusals to license patents will seldom contravene s 46.[181] They suggest a low level of competitiveness will be a sufficient measure against which to evaluate the defendant's conduct.[182]

As to the market power element, it is correct that findings of market power in cases involving refusals to license patents will be relatively rare. Following recent judicial determinations in which narrow markets have been found, however, it is possible to conceive of circumstances in which narrow market definition will be employed in relation to medical biotechnology patents, making it more likely that market power will be found to exist. Nevertheless, recent judicial determinations have meant the threshold for establishing market power has been raised, making it very difficult to establish that a patent holder possesses market power.

The taking advantage element has been the subject of extensive discussion since Hanks and Williams' analysis. It is no longer clear exactly what interpretation future courts will place on the phrase, or whether a 'would' or 'could' test is likely to be employed. If a 'would' test is applied, efficiency considerations based on the likely behaviour of the patent holder in a competitive market will be the benchmark against which to measure the behaviour of the patent holder. On the other hand, a test of commercial possibility may be applied in the event that a 'could' test is used. Strict application of this test would mean that a refusal to license will never contravene s 46. Much rests on this distinction, and it is imperative that the test be clarified as soon as possible.

Regardless of the test employed, Hanks and Williams are correct in their conclusion that '[r]efusals to license are common in competitive industries; and so do not

---

[181] Hanks and Williams, above n25, 457. Cf Henry Ergas, 'Treatment of Unilateral Refusals to License and Compulsory Licensing in Australia' (*Paper Presented to the Federal Trade Commission/Department of Justice Hearings on Antitrust and Intellectual Property Law and Policy in the Knowledge-Based Economy*, Washington, 22 May 2002), 7-10.

[182] Hanks and Williams, above n25, 457 citing *Tru Tone Ltd v Ors v Festival Records Retail Marketing Ltd* [1988] 2 NZLR 352 where the High Court of New Zealand found the market to be competitive even though exclusive licensing arrangements had been entered into.

necessarily constitute a 'taking advantage'.[183] Arguably, however, a higher level of competitiveness may be appropriate in the case of certain medical biotechnology patents, because of the lack of substitutability of many research tools and other patented biotechnology inventions. The availability of many research opportunities is not likely to be a situation that will continue indefinitely. Many downstream market participants are affected in some way by refusals to license. It may be only a matter of time before the implications of refusals to license are far graver, as research fields are narrowed and opportunities available to downstream companies decrease. Further, a distinction should be drawn between access to patents for use in the primary market, and access for use in downstream markets where a patent is necessary in order to further innovation in those downstream markets.

There are probably few circumstances in which a patent holder should be penalised for a refusal to license a patent by compelling access, even in a cumulative industry such as medical biotechnology where follow-on research hinges on the availability of upstream patents. Nevertheless, there are likely to be some circumstances where it would be appropriate to require access, particularly where research is precluded in a downstream market that is not currently being exploited. This is likely to be the scenario that would invoke a decision in favour of the party seeking access in the EU, although it is difficult to state what US courts would decide in this instance as the issue has not required consideration.

As currently interpreted, it is unlikely that s 46 would allow access even in these circumstances. If the market power issue can be overcome, it is submitted that the application of a 'would' approach may bring Australian law in line with EU law. The framework advocated in this thesis is somewhat broader than the EU position. This is because the third limb of the proposed framework would permit a finding that there has been a contravention of s 46 where the upstream patent holder operates in the downstream market, whether in competition with the would-be licensee or not. The decision in *IMS v Commission* specifically precludes such a finding under Article 82.

At present, it is submitted that an Australian court would be unlikely to make a finding that s 46 has been contravened even in a *Magill* type situation. Under current interpretations of s 46, refusals to license are unlikely to be rendered invalid in any circumstance, even under the second and third limbs of the proposed framework. In this sense, the outcome of *Xerox* is the outcome most likely to be reached by Australian courts. Although there may be sound reasons for condemning a refusal to

[183] Ibid, 457.

license in some situations, the individual elements of s 46 now present formidable hurdles to overcome. In some respects, essential facilities type analysis would probably be applied to allegations of refusals to license.

The concluding chapter considers the policy implications of this analysis, and considers the empirical evidence obtained in relation to the medical biotechnology industry. The questions it seeks to address are whether this evidence suggests that legal recourse is likely to be necessary for participants in the industry, and whether such recourse will be available under s 46. Accordingly, it considers whether any policy response is necessary to remedy breakdown in the form of refusals to license within the industry.

CHAPTER 9

CONCLUSION

9.1 OVERVIEW

This thesis has considered the interaction of intellectual property and competition law in the context of refusals to license medical biotechnology patents. Innovation is a key theme that runs throughout this analysis. This theme is intricately linked to the justifications for the patents system. High levels of innovation are desirable, particularly in an industry such as medical biotechnology because the development of new and improved products will benefit consumers. Intellectual property protection necessarily results in concentrated market structures, but there are important questions as to the role of competition in encouraging innovation. The presence of dual systems of intellectual property and competition law for promoting innovation leads to difficult questions as to whether innovation is best served by concentrated or competitive market structures. This sets the scene for debate over the correct parameters for intellectual property and competition law, and their respective roles in enhancing the innovative process.

This is a difficult issue in an industry such as medical biotechnology, which can be characterised as high-technology and dynamic. The Australian government, like governments in other western countries, has endeavoured to retain and advance this dynamic element. An aspect of this push has been a motivation to commercialise upstream and downstream biomedical inventions through intellectual property protection. Both the public and private sectors are heavily focused on protecting innovative output through patent protection. Intellectual property protection is arguably necessary to stimulate research productivity and attract investment funding.

At the same time, an industry with characteristics such as those possessed by medical biotechnology appears to have specific preconditions for restricted access to patented inventions necessary to engage in future generations of research and development. The first three chapters provided a foundation for the analysis undertaken in the remainder of the thesis. Chapters 1, 2 and 3 examined the presence of these factors in biomedical research, and analysed whether these conditions exist in Australian biomedical research. This investigation was undertaken by applying overseas literature in the context of the Australian medical biotechnology industry, and considering the specific characteristics of the Australian industry.

A number of foundational empirical studies have been conducted in overseas jurisdictions that have assessed whether these concerns are borne out in practice. An important component of this thesis is an empirical study that sought to adduce evidence as to whether contractual breakdowns are being experienced in medical

biotechnology in Australia. Chapter 4 presented and evaluated the results of this study. Specifically, this chapter assessed whether access to patents is being refused, and whether associated licensing practices are resulting in difficulties in conducting follow-on research within the Australian biomedical research environment. This evidence was metered against the results of overseas studies in order to gauge the effects of restrictive licensing practices within the Australian industry, and provide a comparative basis on which to evaluate the preponderance of refusals to license in Australian medical biotechnology.

This thesis then considered the role of competition law in compelling licensing where licences to necessary upstream patents are refused, and how effective *Trade Practices Act* 1974 (Cth) (the *TPA*) mechanisms will be in regulating refusals to license patents. Chapter 5 considered the role of competition law in promoting innovation and the scope for the application of competition law to dealings in intellectual property. It concluded by considering this issue in relation to the specific situation of refusals to license patents, and laying down a flexible framework to be applied in considering this issue from a regulatory perspective.

Chapters 6, 7 and 8 analysed the existing law and its limitations. This analysis drew on recent jurisprudence in relation to s 46, and some comparative case-law that would be relied on by Australian courts in the event that this issue required consideration. Chapter 6 gave detailed consideration to s 46 of the *TPA*, and current judicial interpretations of the section. Chapter 7 provided a critical examination of United States (US) and European Union (EU) case law, and the relevance of this body of jurisprudence to refusals to license patents in medical biotechnology. Chapter 8 consolidated these analyses, and considered how s 46 is likely to be interpreted in the event of an allegation that a refusal to license a patent is anti-competitive. It considered whether s 46, as currently interpreted, is likely to be applied in accordance with the framework established in Chapter 5, and the significance of the judicial principles discussed in Chapter 7.

The conclusions reached in this thesis are limited to unilateral refusals to license, as various restrictive licensing practices relating to patents raise unique issues that require individual consideration. Therefore this thesis has addressed the most fundamental issue at the intellectual property/competition law interface, which asks whether there should be limitations on the basic right of a patent holder to exclude others. At the same time, there are many other forms of potentially anti-competitive conduct involving intellectual property that are not analysed in this thesis.

9.2 CONCLUSIONS AND RECOMMENDATIONS

9.2.1 THE BIOMEDICAL RESEARCH ENVIRONMENT IN AUSTRALIA

The first three chapters of this thesis discussed the presence of a number of factors that mean that refusals to license in medical biotechnology are likely to have an impact on innovation. *First*, the nature of biomedical research has resulted in an industry structure typified by small, start-up companies that are heavily reliant on intellectual property protection of their research results. Vertical integration and high levels of concentration are increasingly evident, due primarily to the extended pre-commercial phase of most biomedical research and intra-industry specialisation.

Secondly, the quest to commercialise research output has resulted in massive increases in patent activity, diversification in industry sectors seeking to patent research results, and broad patent protection over many inventions with indeterminate application. These developments have been facilitated by uncertainty over the application of patent law standards to new areas of biomedical research, and the fact that patent holders are given the benefit of doubt during examination of patent applications. *Finally*, the need to vertically integrate and license patented inventions raises the very real possibility of bargaining breakdown. The presence of these preconditions has important implications for follow-on research.

In this respect, this thesis has critically examined legal standards and commentary in relation to other jurisdictions, and applied these in the Australian context. It has determined that these preconditions exist to a similar extent in Australia as they do in overseas jurisdictions. Although a considerable amount of upstream research is currently conducted in Australia, there is a very real possibility that Australian researchers conducting intermediate and downstream research will increasingly need to access patented upstream products and technologies. Not only are many Australian patents in medical biotechnology held by non-Australians, exclusive licensing practices also have the potential to restrict access. As the industry progresses, more Australian companies are likely to find themselves engaging in downstream research. These issues are likely to have ongoing implications for the development of the industry in Australia.

9.2.2 THE ROLE OF COMPETITION LAW IN EVALUATING THE LEGALITY OF REFUSALS TO LICENSE PATENTS

The general conclusion drawn in this thesis relates to the role of intellectual property and competition law in enhancing the innovative process. The interaction between these two bodies of law is far from resolved, and this thesis has confirmed that the

potential for conflict becomes pronounced in the case of high technology industries such as medical biotechnology. It is concluded that competition law does have a role to play in promoting innovation. Adequate mechanisms should exist to ensure that the interests of innovation and consumer welfare are well served. In some circumstances, excessive concentration may harm welfare by reducing the number of potential innovators working in a particular area, and dampening innovative activity. Therefore, relying on patent law alone to advance innovation will not necessarily enhance welfare by maximising dynamic efficiencies. Competition law may, in some instances, recast the balance in favour of a follow-on innovator. In the case of refusals to license, it has been argued that exemption from the competition provisions is unwarranted. Competition law should treat intellectual property as it would any other form of property, bearing in mind the special characteristics of intellectual property such as its ease of appropriability and generally non-rivalrous nature.

The circumstances in which competition law should intervene to restrict privileges of patent holders are limited. Each case should be assessed according to its facts. The framework for analysis presented in Chapter 5 takes this into account in laying down the circumstances whereas it is *more likely* that anti-competitive conduct forms the basis for a refusal to license.[1] The basis on which this conclusion is founded is efficiency considerations. Efficiency explanations will usually justify a refusal to license a patent in a primary market, but are less likely to do so in a discrete downstream market. The only instance in which an unconditional refusal to license in a primary market *may* be anti-competitive is the situation where patents are obtained for defensive purposes, and are not exploited by a patent holder. Again, the basis for this conclusion is that the conduct may not be justified by an efficiency rationale. Although establishing an anti-competitive purpose would be difficult in such a case, an action should be available.

[1] Above, 5.5.5.

Recommendation No 1

Accordingly, it is recommended that the following framework be flexibly applied to guide Australian policy-makers, regulators and courts in assessing the legality of refusals to license intellectual property:

[1] Generally speaking, a refusal to license intellectual property will not contravene competition law.

[2] A refusal to license will, however, become examinable under competition law where the refusal is for the purpose of (i) expanding the scope of the intellectual property or (ii) extending market power into another distinct market not covered by the intellectual property.

[3] Where a refusal becomes examinable under [2](ii), the refusal should be examinable whether or not the holder of the intellectual property is currently exploiting the separate market, and the reservation of another market for its own (actual or potential) use should not necessarily allow it to foreclose competition by others.

This would partly accord with the position under EU law.[2] Despite the potentially wide application of *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission*,[3] subsequent case law has narrowed the circumstances in which a refusal to license is likely to be found to be anti-competitive. A refusal to license to a competitor in a downstream market would not be anti-competitive under current EU law. Nonetheless, a refusal to license to a participant in a discrete downstream market that has the effect of preventing the development of a new product will be potentially anti-competitive.

While EU case law would permit a finding that a refusal to license intellectual property is anti-competitive under limb [2](ii), it is less clear that such a conclusion would be reached under US law because a number of diverging approaches have been favoured by various courts. Further, the US case law has been limited to consideration

[2] The framework would not be adhered to under US law if the approach in *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001) is applied.

[3] *Radio Telefis Eireann and Independent Television Publications Ltd v EC Commission* [1995] 4 CMLR 718; [1995] All ER (EC) 416. See above, 7.3.1.

of after-markets and not truly discrete downstream markets. It is unclear which approach would be followed in the event that a US court were required to determine a matter falling within the second and/or third limbs. An antitrust immunity approach in line with the position in *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation*[4] would be likely to preclude liability under the framework. The application of a rebuttable presumption, on the other hand, may leave scope for a finding of liability in the circumstances specified in limbs [2] and/or [3]. Depending on which approach future courts follow, there is *potential* for US law to be applied in a manner consistent with EU law. It is acknowledged, however, that US courts would probably take a more conservative approach to the issue of refusals to license than EU courts have traditionally taken.

There is no authority in either jurisdiction as to whether a contravention of competition law would be likely in relation to a refusal to license a *patent* into a discrete downstream market however the possibility of such a finding has not been precluded. A finding that a refusal to license a patent falling within limb [3] is anti-competitive would be extremely unlikely in either of these jurisdictions, even in the absence of a valid efficiency justification.

9.2.3 Section 46 of the *Trade Practices Act* 1974 (Cth) and Refusals to License Patents

There will be a number of hurdles for any plaintiff alleging that a refusal to license a biomedical patent is anti-competitive pursuant to s 46. The *first* is that it will be difficult to argue that a patent or group of patents constitutes a market. In particular, the ability of most potential licensees to source alternative research opportunities will often make establishing a lack of supply-side substitutability challenging. *Secondly*, even if narrow market definition is successfully argued, a patent(s) must give a patent holder market power. *Thirdly*, efficiency considerations may justify the conduct, with the result that the 'take advantage' element will not be made out. *Finally*, a plaintiff must establish an anti-competitive purpose for the refusal to license.

The conclusions presented in 9.2.2 suggest that there are few circumstances in which a refusal to license a patent should contravene s 46. Nevertheless, a patent holder may engage in anti-competitive conduct where a refusal to license a patent expands the scope of the patent, or impacts on a downstream market. Therefore, there should be scope under s 46 for a contravention to be made out in these circumstances. The

[4] *In re Independent Service Organizations Antitrust Litigation; CSU, LLC and Others v Xerox Corporation* 203 F3d 1322 (Fed Cir 2000), cert denied, 531 US 1143 (2001).

primary conclusion reached in this thesis is that competition law treatment of refusals to license patents under the *TPA* is likely, at present, to be ineffectual. There are general problems with the manner in which s 46 has been interpreted, but these issues become more pronounced when considering issues associated with the exploitation of intellectual property. Specifically, plaintiffs attempting to make out the elements of s 46 will encounter great difficulty, and recent s 46 jurisprudence means that the elements of s 46 are likely to be made out very rarely.

The central problem lies in recent judicial interpretations of this section. The elements of s 46 will invariably be more difficult to establish where an alleged contravention involves intellectual property. However, there are some circumstances where refusals to license may be anti-competitive. Analysis presented in this thesis demonstrates that it would be difficult for a party to allege a breach of s 46 in respect of a refusal to license a patent. However, the high threshold imposed in respect of a number of the elements of s 46 would render it virtually impossible to establish that a refusal to license contravenes that provision, even where that refusal prevents the appearance of a new product in a discrete downstream market. In this respect, s 46 would probably be interpreted more narrowly than EU, and possibly US law. Refusals to license would not be dealt with in accordance with the proposed framework.

As a general matter, deficiencies in s 46 must be addressed. As foreshadowed, these deficiencies relate to the market power standard and the 'take advantage' test contained within s 46. As a result of recent case law, the market power standard has arguably been set at the high level equivalent to near-monopoly by virtue of the requirement of an absence of competitive conditions. This is at odds with the intention behind amendments to the section that were intended to *reduce* the market power threshold from substantial market control, to substantial market power.[5]

Uncertainty also surrounds the operation of the 'take advantage' element with the result that it is unclear whether satisfaction of this element rests on efficiency considerations or commercial possibility. Efficiency justifications form an important component of analysis in this thesis. That is, they will justify a refusal to license in a primary market in many instances. They are less likely to be present, however, where a refusal to license impacts on a separate, downstream market. High Court jurisprudence has established that the conduct of a defendant to an action under s 46 must be examined under conditions of workable competition. It has been argued in

[5] *Trade Practices Revision Act* 1986 (Cth). See above, 6.3.1.

this thesis that the application of a 'could' test under conditions of workable competition would render s 46 redundant.

There is a general need to ensure that s 46 fulfills its policy objective of promoting competition and enhancing economic efficiency. It is concluded that s 46, as currently interpreted, is unlikely to fulfil this objective. Issues associated with intellectual property are likely to exacerbate these shortcomings. A number of recommendations are made to address this issue.

Recommendation No 2

It is recommended that the operation of the market power standard contained in s 46 be clarified to ensure that it applies to a level of substantial market power less than near-monopoly, or substantial market control. Specifically, it is recommended that the legislative intention behind the 1986 amendments to the market power standard in s 46 be affirmed.

Recommendation No 3

It is recommended that the operation of the 'take advantage' element be clarified, and that consideration be given to legislative amendment to the section. This amendment should confirm that the appropriate test to apply in respect of the 'take advantage' element is whether the defendant 'would' have engaged in the conduct at issue under competitive conditions. Correspondingly, this amendment should stipulate that an evaluation of the defendant's behaviour must be made under workably competitive conditions, taking relevant efficiency considerations into account.

Adoption of these recommendations will certainly not guarantee the establishment of the elements of s 46 in the event that a refusal to license a patent is alleged to be anti-competitive. It will, however, clarify the operation of the section and make it *possible* to establish a contravention where a refusal to license is clearly anti-competitive.

9.2.4 THE EMPIRICAL CONTEXT

The foregoing conclusions have implications for an industry such as medical biotechnology, which possesses characteristics that lend it to bargaining breakdowns. In this context, empirical considerations are relevant. This has been acknowledged in

a number of jurisdictions with established medical biotechnology industries. Studies based on empirical data have been carried out in the United States, and in a number of European countries. This work has provided a preliminary glimpse of the state of patent and licensing activity within the medical biotechnology industry. The importance of the work of international scholars in this area has been recognised in this thesis.

This body of scholarship has demonstrated, with some qualifications that industry participants in overseas medical biotechnology markets are finding working solutions to issues associated with restricted access. An aim of this thesis was to apply a similar empirical approach in respect of the Australian industry in order to provide some basis for evaluating the operation of the national industry against the results of these pioneering studies. This work has, to date, been the only empirical study investigating the issue of patent licensing within medical biotechnology in Australia. A corollary aim was to consider the results in terms of their import for competition law policy. The results presented in this thesis formed a sub-set of the results obtained in the study, which considered restrictive licensing practices generally.

The empirical results obtained offer some assistance in policy development. It can be concluded from the empirical evidence that refusals to license patents are occurring infrequently in practice. Where they do occur, industry participants are generally managing to overcome their effects by changing the direction of their research or avoiding particular research areas. Other licensing practices such as exclusive licensing and non-exploitation of patents are occurring, and are also having an impact on the research programs of some participants. On a tentative basis, however, it is possible to conclude that the Australian industry is overcoming most major difficulties associated with refusals to license patents.

There are a number of caveats to be borne in mind. *First*, there is some limited evidence of refusals to license within the industry. *Secondly*, a considerable portion of the Australian industry is involved in what would be termed upstream research. As downstream opportunities present themselves, companies are likely to diversify into more downstream research. Vertical integration is also becoming more common within the Australian industry. These factors tend to suggest that there is potential for refusals to license to become a more pronounced issue for participants in the industry. *Finally*, given the factors outlined in the first three chapters of this thesis, the potential for bargaining breakdown in the form of refusals to license remains. Although refusals to license have not had a significant effect on research to date, this does not preclude this issue eventuating in future, and it is possible that it may become more prominent as the industry evolves and research opportunities diminish. Given that the

potential for refusals to license patents remains, there must be a means of addressing these issues.

The empirical data presented in this thesis provides some useful insights into licensing behaviour within the Australian medical biotechnology industry. It is, however, by no means exhaustive, but is more likely to provide a portal for further study in this area. There are a number of reasons for this conclusion.

The Changing Nature of the Industry

This thesis outlined a number of factors that typify the environment in which the medical biotechnology industry operates. In particular, the structure of the industry has evolved from the cumulative research environment in which industry participants operate. The industry has been characterised largely by small companies heavily reliant on intellectual property protection, and a small number of large companies have been active in broad research areas. Research institutions are becoming more reliant on patenting research results.

The medical biotechnology industry is an industry that is not static. It possesses characteristics typical of many dynamic, technology-driven industries in that it is moving rapidly and heavily focused on expanding innovative output. Given the rapid pace at which innovation within the industry is proceeding, there is no guarantee the industry will maintain its existing structure. In particular, there is increasing evidence of consolidation and alliance activity. Large companies are seeking to vertically integrate and boost their patent portfolios. Given the potential for change within the environment in which biomedical research is conducted, ongoing empirical work is required to assess the ongoing effects of biomedical patent licensing practices. If research areas become more cluttered and the industry continues to consolidate, restrictive licensing practices, such as refusals to license, have the potential to become more prominent. This highlights an ongoing role for empirical study in this area.

Limitations of Current Empirical Data

The empirical evidence presented is informative, but vigilance must be maintained in order to ensure that research is not impeded, and that implementation of the legislative regime keeps pace with developments in high-technology industries. This thesis is a small and modest step in that direction. The empirical data presented in this thesis formed a component of the data obtained in an empirical study assessing the effects of licensing within Australian medical biotechnology. It builds on overseas studies in the area, but has a number of limitations inherent in small studies. In particular, the

qualitative component of the study involved a relatively small sample size, and there was no systematic attempt to randomly select respondents. In addition, the survey results necessarily yielded a limited amount of data. As such, the study cannot stand as a definitive study, and ongoing research in the area is required to validate the results obtained.

Secondly, ongoing empirical work is necessary in order to provide more detailed data. There are two aspects of further research that would be especially constructive. Data evaluating the longer-term effects of restrictive licensing practices such as refusals to license intellectual property, on innovation and research practice would be particularly useful. Longitudinal studies of licensing practices would therefore provide a useful basis for analysing the impact of refusals to license in a specific research area over time. Another matter that could be usefully explored in more depth is the areas in which industry participants are choosing to change research direction or avoid particular areas of research due to refusals to license or exclusive licensing. This data would be valuable given that these practices inevitably have some welfare effect, and would be relevant to the issues raised in this thesis.

Inter-Industry Differences

The studies discussed in Chapter 4 revealed a pattern consistent across the jurisdictions in which empirical work has been undertaken. At present, research holdups are relatively rare and few industry participants are finding that research is completely impeded. There are, however, subtle differences in the results of the various studies, and these could be usefully investigated. For example, although data obtained in the Nicol and Nielsen study demonstrated that Australian medical biotechnology companies are heavily engaged in licensing, it would appear that licensing practices within the Australian industry are not as prolific as licensing practices within overseas jurisdictions. There are many interpretations that may be placed on this data. It may simply suggest that Australian companies and researchers do not require as many in-licences as overseas counterparts, and are primarily engaged in out-licensing. Equally, it could indicate that Australian industry participants are more reticent to request licences to research inputs where there is a perception that licences are not available. It may also reflect the superior bargaining power possessed by overseas companies. Accordingly, further investigation of issues such as these would assist in providing further grounds for evaluating the effects of restrictive licensing within Australian medical biotechnology.

It is important as ongoing research in this area is conducted in overseas jurisdictions, that comparative research be undertaken in Australia. This research will assist in

informing policy debate and regulatory imperatives. Empirical work building on the work presented in this thesis and the overseas studies relied on would assist in maintaining a watching brief in respect of the impact of refusals to license and other restrictive licensing practices on biomedical research in Australia.

9.3 CONCLUDING COMMENT

The interaction of intellectual property and competition law is far from settled, particularly in dynamic, innovative industries. The scholarship, policy statements and jurisprudence examined in this thesis have grappled with the issue of how to balance these areas of law, and have taken steps to endeavour to resolve the interface. This thesis attempts to pay due recognition to those scholars who have contributed to the debate, and to build on their work from the Australian perspective. It has viewed these issues through the lens of empirical evidence, and identified that real issues exist for plaintiffs in Australia asserting that a refusal to license is anti-competitive. It has not finally resolved these issues and further research remains to be done. However, it has demonstrated the complexity of these issues for plaintiffs in high-technology industries such as medical biotechnology, and highlighted that flexibility is imperative in resolving these concerns.

APPENDIX 1

STUDY METHODOLOGY

This study was conducted in two parts:

- a quantitative component using survey data; and
- a qualitative component using a semi-structured interview format.

The aim of the study was to gather data through the surveys which would identify issues for further analysis within the interviews. Response rates to surveys in this industry are usually relatively low. For example, Hopper and Thorburn reported a 13 percent response rate to their 2002 survey, and attributed this to 'survey fatigue'.[1] Despite the likelihood that this survey would also have a modest response rate, it was considered that the surveys were an important component of the study and represented the most appropriate method of generating preliminary data for further investigation.

SURVEYS

The initial component of the study consisted of written surveys mailed to respondents falling within three sectors of the biomedical industry: private sector biotechnology and pharmaceutical companies, research institutions and diagnostic testing facilities. The surveys were conducted with a view to identifying issues on which to focus in the interview portion of the study.

PRIVATE AND PUBLIC COMPANIES

Respondents for survey mail-out were identified by information from a database of Australian biotechnology and pharmaceutical companies (including international companies with an Australian office). This database was compiled using data obtained from the Australian Securities and Investments Commission, and publicly available information including material from company websites and industry reports. Companies were identified as being relevant to the survey if their activities comprised core biotechnology activities, or if their activities were in some way biotechnology related.[2]

---

[1] See Kelvin Hopper and Lyndal Thorburn, 2002 *Bioindustry Review: Australia and New Zealand* (2002).

[2] Core biotechnology companies are companies whose business is entirely or substantially biotechnology related: See Ernst & Young, *Australian Biotechnology Report* (1999).

Although this research project was concerned with the medical biotechnology industry, this component of the project was not limited to the biomedical sector of the industry. Respondents were asked to describe their area of activity or research, and it was possible to identify companies involved in biomedical research and those involved in other activities. However, the overwhelming majority of responses were from the biomedical sector of the industry. Only four of the responses received were from companies that could not be classified as primarily biomedical. Of the four, three reported no patent activity and two of these reported no collaborative or licensing activity. Data from all of these respondents was included in the overall results, but specific reference to the two non-biomedical companies that reported patent, licensing or collaborative activity is made where appropriate.[3]

Approximately 180 surveys were mailed to companies in June 2002.[4] The same survey was sent to both biotechnology and pharmaceutical companies. Follow-up letters were sent to respondents four weeks after the surveys were mailed out, and follow-up telephone calls were subsequently made. The survey asked 52 questions about the structure and activities of the company, the company's involvement in patenting, collaborations and licensing, and the views of the respondent on patenting within the industry.

Of the surveys sent out, 49 completed surveys were returned, yielding a response rate of 27 percent. In addition, six respondents replied that they did not wish to participate in the survey either because they did not consider it to be relevant to their company's activities, or they considered the information sought to be commercially sensitive. A number of respondents who subsequently participated in face-to-face interviews stated that they had not completed the survey because they believed that they could participate more effectively in providing qualitative rather than quantitative data to us. Consequently, they were willing to take part in interviews. Although the response rate is low in relative terms, it compares favourably with other voluntary mailout surveys conducted within the industry.[5] Further, the response rate would be more favourable if specifically biomedical companies had been targeted in distributing the company survey.[6] It would be fair to assume that the 45 biomedical and pharmaceutical

---

[3] One of these respondents appeared to some degree to be involved in biomedical applications.

[4] A number of the companies targeted in the survey had only peripheral biotechnology-related activities.

[5] See, eg, Hopper and Thorburn, above n1.

[6] Ernst & Young estimated that approximately 47 percent of Australian biotechnology companies are operating in the area of human health, including diagnostics and therapeutics. They further estimated that approximately 13 percent of companies are operating in the areas of genomics, proteomics and bio-

companies from which responses were received represents a significant proportion (perhaps in excess of 40 percent) of Australian companies engaged in biomedical and related applications.

RESEARCH INSTITUTIONS

Printed surveys were mailed out to 39 research institutions on 17 March 2003 and reminder letters were sent in June 2003. These institutions were identified by prior knowledge of the research sector and using standard search engines. The survey asked 42 questions about research activities, the institution's involvement in patenting, collaborations and licensing, awareness of patents held by others and views on patenting. Twenty-three surveys were returned, yielding a response rate of 59 percent.

GENETIC TESTING LABORATORIES

Printed surveys were mailed out to the laboratories offering diagnosis of genetic disorders listed on the Human Genetic Society of Australia's website in November 2002 and reminder letters were sent in December 2002. The surveys asked 61 questions about the laboratory, its clinical activity, research and patent activity and collaborations. A total of 52 surveys were dispatched. Eighteen were returned (35 percent response rate). These detailed surveys were supplemented by short telephone surveys conducted in March and April 2003 asking six questions about the laboratory, the tests it performs, payment of licence fees and/or royalties, receipt of notifications from patent or licence holders, responses to notifications, and views on patents. The six questions were only asked if respondents indicated that they had not returned the written survey. Hence the telephone survey respondents did not overlap with the written survey respondents. There were thirteen responses to the telephone survey, yielding a total response rate of 60 percent.

INTERVIEWS

Forty interviews were conducted with various respondents falling within the categories of private companies, research institutions and diagnostic testing facilities between August 2002 and July 2003. Participants were selected based on prior contacts, media reports, internet based search engines and databases, and snowball sampling.

Within the category of private sector companies, chief operating executives, intellectual property personnel and bench scientists were interviewed. Within the

informatics; Commonwealth of Australia, Ernst & Young and Freehills, *Australian Biotechnology Report* (2001) 13.

category of research institutions directors of research groups, bench scientists and technology transfer personnel were interviewed. Within the category of diagnostic testing facilities, interviews were conducted in respect of directors of research groups. A number of other respondents with expertise in the area were also interviewed, including patent attorneys, licensing consultants and government and trade representatives. Interviews were conducted on an anonymous basis due to the confidential nature of the data being gathered. Anonymity in studies in the industry is standard practice. It also became evident from speaking with industry contacts prior to the commencement of the study that a majority of respondents were unlikely to respond to surveys or participate in interviews unless anonymity could be guaranteed. During a considerable number of interviews, respondents sought assurances to this effect.

Details of respondents by organisation type and occupation are contained in Table 2. Respondents were selected to provide a representative sample of various sectors within the biomedical industry, from research institutions and companies operating at the upstream end of the industry, through to companies involved in downstream drug development and therapeutic applications.

Table 1: Interview respondents

Respondent type	**Business/ IP/ legal manager**	**Lab director/ scientist**	**Managing director/ CEO**	**Total interviews**
University Tech Transfer Office	3			3
Diagnostic Testing Facilities		3		3
Research Institutions	1	4	3	8
Tech Transfer Companies	2		1	3
Upstream Companies*	4	1	1	4
Intermediate	3		1	4

Companies*				
Downstream Companies*			3	3
Pharmaceutical Companies	4	1		4
Device Companies	2			2
Licensing Consultants				2
Patent Attorneys				2
Trade Association Representatives				1
Government representatives				1

The categories marked with an * in Table 2 are fairly fluid in that some respondents conducted activities that could fit into more than one category. These respondents have been placed in the category that best fits their primary activities. Although it was sometimes difficult to classify the interviewees within respondent organisations, they have been described as accurately as possible. In several cases, interviews were conducted with more than one person from within an organisation. Descriptions of all personnel interviewed have been provided, but these interviews were included as one interview within the total tally of interviews.

Within respondent organisations, business, intellectual property and legal managers were the group most interviewed. Nineteen interviews of personnel who fell into this category were conducted compared with nine laboratory directors and scientists and nine managing directors. It is recognised that responses may vary depending on the particular person within an organisation who is interviewed. There are a number of reasons why managers rather than scientists were frequently chosen as respondents. A major factor was their knowledge of intellectual property issues. In some cases another member of an organisation recommended that an interview be conducted with a business manger. Many institutions being considered were relatively small and there

was evidence of close contact and discussion of relevant issues between managers and scientists within respondent organisations. In many cases, business, intellectual property and legal managers came from a science background, often from within the organisation itself. They therefore had a good understanding of the issues associated with the conduct of research and intellectual property in the relevant field, as well as complex technology transfer issues. These personnel were often involved in technology transfer negotiations. Difficulty in persuading scientists to participate in interviews is also a common theme in some other studies.[7]

Similarly, many managing directors and CEOs come from a science background and are well versed in the intellectual property activities of their respective companies. The level of knowledge of technology transfer issues of respondents falling into the categories of business, intellectual property and legal managers, and managing directors and CEOs, made them particularly valuable classes of interview respondents, although the relatively low numbers of scientists interviewed may mean that responses differed to a degree.

The resulting sample gave some reliable insights into views and issues within the industry. This was not a truly random sample. Respondents were selected to enable broad coverage of a range of participants within the industry, but at times were selected fairly opportunistically. However, given the number of respondents interviewed and the areas of the industry covered, the sample paints a broadly representative picture of issues facing the industry and trends within the industry.

Most of the respondents interviewed were involved in human genetic or biomedical research and/or commercialisation. However, several respondents falling outside these categories, or falling into more general or peripheral categories were interviewed in order to obtain some comparative data. One respondent was involved in a biotechnology CRC unrelated to human health applications. Two company respondents were involved in medical device research and development, and one respondent from the bioinformatics sector took part in the study. One of the research institution respondents was involved in plant studies. Some respondents were involved in applications related to human health, in addition to other broader applications. Where data from interviews with these respondents is cited, their specific area of research is identified.

---

[7] See, eg, National Institutes of Health, Report of the National Institutes of Health Working Group on Research Tools (1998) <http://www.nih.gov/news/researchtools/index.htm> at 3 October 2002, 6.

The respondents were asked a series of questions that conformed to a flexible format. Respondents were asked generally about the patent and licensing activity of their company or institution, and were then asked a series of questions designed to examine issues particularly relevant to them in more detail. A number of questions were designed to elicit responses pertaining to whether or not bargaining breakdown is occurring within the Australian industry. The interviews were structured to allow consideration of whether patents and restrictive licensing practices are having an effect on research and/or the commercialisation of patents, and ways in which respondents are overcoming any such effects.

APPENDIX 2

SOME FOUNDATIONAL BIOMEDICAL RESEARCH TOOLS AND THEIR PROPRIETARY STATUS IN AUSTRALIA

The following account of foundational patents is divided into two categories: those that comprise broad patents but have been widely disseminated, and those that comprise broad patents but have been restrictively licensed. It does not provide a comprehensive list of foundational research tools, but it identifies those that have, for various reasons, become more notorious. It also identified the proprietary status of these research tools in Australia.

BROADLY DISSEMINATED FOUNDATIONAL RESEARCH TOOLS

Generally, these patent holders are making their patents widely available albeit at some cost. The issue for licensees is their ability to meet licence fee obligations and continue to finance their research programs. Implications for the innovative process certainly exist. But solace can at least be taken from the fact that these technologies are being disseminated.

PCR and Taq Polymerase

Polymerase chain reaction (PCR) and Taq polymerase allow the rapid amplification of DNA sequences. Enforcement of the patents covering the technology[1] has given rise to considerable outcry given the importance of this technology to laboratories undertaking DNA replication for a variety of purposes. The technology has been widely licensed and made available for a fee to researchers and commercial users.[2] The issue that has generated controversy is the quantum of royalty fees charged which arguably makes the technology inaccessible to many small companies and university

---

[1] There are three main US patents; US4,683,202 (filed 1985), US4,683,195 (filed 1986) and US4,889,818) Australian Patent No AU632 857 (granted in 1996). The patents were granted to Cetus Corporation but were subsequently assigned to F Hoffman La-Roche AG for $300 million. See Paul Oldham, Global Status and Trends in Intellectual Property Claims: Microorganisms, *Submission to the Executive Secretary of the Convention on Biological Diversity* (2004), 13.

[2] See further National Research Council (NRC), *Intellectual Property Rights and Research Tools in Molecular Biology* (1997) (the NRC Report), 43-46.

researchers.[3] The breadth of the patent claims has also been the subject of protracted litigation in the US, Europe and Australia.[4] Opposition proceedings successfully reduced the scope of the claims of the patent and are ongoing in Australia.[5]

Intron Sequence Analysis

A recent development is the debate surrounding the so-called 'junk DNA' patents held by Australian company Genetic Technologies Ltd.[6] Indeed, all of the studies discussed in this chapter predate the controversy surrounding these patents. The patents comprise a series of patents that claim a method of using non-coding DNA (or intron sequences) to predict mutations in coding regions of DNA. The patents potentially have wide reach given that the technology is widely used in research into many therapeutic and diagnostic applications. In fact, use of it in most genetic research is unavoidable. The patents are being actively enforced against companies and public research groups, for the primary purpose of generating licence fees, and a number of licence agreements have been entered into with companies and research institutions.[7]

CCR5 Receptor

In 2000 a US patent was granted to Human Genome Sciences Inc[8] for a chemokine receptor known as the CCR5 receptor. Human Genome Sciences isolated the gene

---

[3] Ibid, 44-46. The technology reportedly generates $100 million in licensing revenue for Hoffman La-Roche per year; Oldham, above n1, 13.

[4] For details see <http://www.roche-diagnostics.com/ba_rmd/pcr_litigation_chronology.html> at 23 June 2005. See also Oldham, above n1, 13-14.

[5] See Oldham, above n1.

[6] The Intron Sequence Analysis patents comprise Australian patents AU67519 (entitled Intron Sequence Analysis Method for Detection of Adjacent and Remote Locus Alleles as Haplotypes), AU647806 (entitled Genomic Mapping by Direct Haplotyping Using Intron Sequence Analysis) and AU654111 (Intron Sequence Analysis Method for Detection of Adjacent and Remote Locus Alleles as Haplotypes). The corresponding United States patents are US5 612 179, US5 851 762 and US5 192 659. Genetic Technologies Ltd has also been granted one patent entitled Fetal Cell Recovery Method (US Patent No US5 447 842, Australian Patent AU649027) with another patent pending (Australian Patent Office Application No 200177352).

[7] Details of licensing deals are given on the website of Genetic Technologies Ltd at <http://www.gtg.com.au/index_news.asp?menuid=210> at 23 June 2005. Licence fees have been determined based on the status of the particular licensee, and offers 'research' licences and 'commercial' licences: see < http://www.gtg.com.au/index_general.asp?menuid=080> at 23 June 2005.

See also Australian Broadcasting Corporation (ABC) Four Corners, 'Patently a Problem' broadcast on 11 August 2003, transcript available at <http://www.abc.net.au/4corners/content/2003/transcripts/s922059.htm> at 5 May 2004 (ABC Four Corners).

[8] US Patent No US6 025 154. The patent is entitled Polynucleotides Encoding Human G-Protein Chemokine Receptor HDGNR10. A number of patents entitled Human G-Protein Chemokine Receptor

that codes for the receptor and filed a patent claiming rights over the gene and the CCR5 protein product. Although their claims over the protein product covered a viral receptor, they were unaware at the time the patent was filed that the HIV virus enters cells through the CCR5 receptor. Subsequent research by the NIH revealed this to be the case.[9]

Concern about the potential breadth of research covered by the relatively narrow CCR5 upstream patent gave rise to a chorus of disapproval in the research community.[10] Use of the patent for university research purposes would not, however, appear to have been inhibited to any large extent,[11] and several licence agreements for research into new drugs using the CCR5 receptor have been agreed to.[12]

Although an application to patent this receptor was made in Australia, a patent has not been granted and it is possible the application lapsed.[13] At the same time, two United States patents have been granted to Euroscreen SA claiming a mutation of the CCR5 receptor relevant to HIV immunity.[14] The effect of these patents on the scope of research controlled by Human Genome Sciences' patents is as yet unknown.

Method of Screening Patents

ICT Pharmaceuticals (now Housey Pharmaceuticals (Housey)) holds a series of patents for methods of screening substances for compounds that may potentially be effective as drugs.[15] The patents are very broad and cover a number of different methods. They do not, however, cover end products or drugs. Legal proceeding arose between Housey and Bayer AG (Bayer) when Bayer allegedly used a method protected by the patents to manufacture a drug in a foreign country. The results of this

---

were also granted by the European Patent Office in 2001 and 2002: EP1149582, EP1148127, EP1148126, EP1146055, EP1366058, EP1146122, EP1145721, EP1253721, EP1263791.

[9] See further Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper*, Discussion Paper (2002) (Nuffield Discussion Paper) 41.

[10] Elliot Marshall 'Patent on HIV Receptor Provokes an Outcry' *Science* 287 (2000): 1375.

[11] Ibid.

[12] Nuffield Discussion Paper, above n9, 41.

[13] Application No 199526632.

[14] Euroscreen SA, 'CCR5 Mutant Gene Sequence Patented for AIDS Diagnosis' Press Release (27 February 2004) available at <http://www.prweb.com/releases/2004/2/prweb107422.htm> at 5 May 2004.

[15] US Patent Nos US4 980 281 entitled Method of Screening for Protein Inhibitors and Activators (granted in 1990), US5 266 464 entitled Method of Screening for Protein Inhibitors and Activators (granted in 1993) and US5 887 007 entitled Method of Screening for Protein Inhibitors and Activators (granted in 1999) (the Housey patents).

litigation are briefly discussed in Chapter 4.[16] Housey had widely licensed the patents to a number of other parties.

It would appear that an application for a patent over this technology was filed in Australia, but subsequently lapsed.[17]

RESTRICTIVELY LICENSED FOUNDATIONAL PATENTS

Debate has arisen with respect to other patented biotechnology inventions to which access has in some way been restricted, or has the potential to be. There is a significant amount of literature containing extensive discussion on the following research tools and exclusionary practices surrounding them. Some of this literature is discussed below.

CD34[18]

A number of patents relating to CD34 are owned by Johns Hopkins University (Hopkins).[19] CD34 is an antigen found on undifferentiated blood cells found in bone marrow. The United States patents were filed following the discovery of a particular antibody (My-10) that selectively binds to (and detects) CD34. In one of the patents, all antibodies that bind to CD34 were claimed.[20] The technology employing the binding of antibodies to CD34 was, at the time, useful in the development of cancer therapies, due to its potential application as an alternative mode of carrying out bone-marrow transplants.[21] The patents were exclusively sub-licensed to Baxter Healthcare Corporation.

---

[16] Above, 4.3.3.1.

[17] Application No 199064271.

[18] The factual details relating to this technology are taken largely from the following case reports: *Johns Hopkins University, Baxter Healthcare Corporation and Becton Dickinson and Company v Cell-Pro Inc* 931 F Supp 303 (D Del 1996); *Johns Hopkins University, Baxter Healthcare Corporation and Becton Dickinson and Company v Cell-Pro Inc* 978 F Supp 184 (D Del 1997). A very thorough analysis of the matter is also contained in Avital Bar-Shalom and Robert Cook-Deegan, 'Patents and Innovation in Cancer Therapeutics: Lessons From Cell-Pro' (2002) 80(4) *The Millbank Quarterly* 637.

[19] US Patent No US4 714 480 entitled Human Stem Cells (granted 1987); US Patent No US4 965 204 entitled Human Stem Cells and Monoclonal Antibodies (granted 1990); US Patent No US5 035 994 entitled Human Stem Cells and Monoclonal Antibodies (granted 1991); and US Patent No US5 130 144 entitled Human Stem Cells and Monoclonal Antibodies (granted 1992).

[20] US4 965 204.

[21] Peter Mikhail, '*Hopkins v CellPro*: An Illustration that Patenting and Exclusive Licensing of Fundamental Science is Not Always in the Public Interest' (2000) 13 *Harvard Journal of Law and Technology* 375, 385.

In the meantime, researchers at the Fred Hutchinson Cancer Research Center produced an alternative antibody, which displayed different properties to the My-10 antibody. Cell-Pro was formed to manufacture two devices to purify stem cells and produce purified stem cell suspensions.[22] Federal Drug Administration (FDA) approval was granted to Cell-Pro to use its process of isolating and separating stem cells before approval had been gained by Hopkins or Baxter.[23]

Litigation initiated by Hopkins eventually resulted in a finding that Cell-Pro had infringed two of Hopkins' patents.[24] Litigation proceeded after Baxter offered Cell-Pro a non-exclusive licence on financial terms that Cell-Pro rejected. Cell-Pro ultimately lost the case on appeal.[25] Despite being allowed to continue to manufacture its devices until Hopkins' devices received FDA approval, Cell-Pro entered bankruptcy.[26] Hopkins' technology was later superseded by rival technologies.

The problems identified in relation to these patents relate to the breadth of the upstream patent in claiming all antibodies that bind to CD-34,[27] and the fact that the patent owner and the exclusive licensee were unable to develop technology under those patents as quickly and effectively as their rival Cell-Pro.[28] Nevertheless, they were able to prevent Cell-Pro from remaining in the market by exercising their patent rights.[29] In doing so, it is asserted that Hopkins' patents and Baxter's exclusive licence enabled them to retard competing research and development.[30]

There is no record of patent applications relating to CD34 being filed in Australia.

---

[22] Eliot Marshall, 'Varmus to Rule in Fight Over Cell-Sorting Technology, 276 *Science* (1997): 1488.

[23] Mikhail, above n21, 386.

[24] *Johns Hopkins University, Baxter Healthcare Corporation and Becton Dickinson and Company v Cell-Pro Inc* 931 F Supp 303 (D Del 1996).

[25] *Johns Hopkins University, Baxter Healthcare Corporation and Becton Dickinson and Company v Cell-Pro Inc* 152 F 3d 1342 (Fed Cir 1998).

[26] John P Walsh, Ashish Arora and Wesley M Cohen 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in Wesley M Cohen and Stephen A Merrill (eds.), *Patents in the Knowledge-Based Economy* (2003) 287 (Walsh Cohen and Arora), 307.

[27] Ibid, 307.

[28] Bar-Shalom and Cook-Degan, above n18, 657-658; Ibid, 307; Mikhail, above n21, 391.

[29] Mikhail, above n21, 392.

[30] Ibid, 391-2. Hopkins and Baxter did, of course, decline to exercise their full rights until they received Federal Drug Administration approval in relation to their own product.

Cox-2

A US patent granted to the University of Rochester in 2000 claims broad rights over the cox-2 enzyme, and any compounds developed to inhibit the enzyme.[31] It now appears that compounds developed to inhibit the enzyme may have broad applicability. In addition to one of these compounds being useful as a pain medicine, it may also have some anti-cancer properties,[32] and the patent may give the patent holder the right to royalties on all drugs falling into the category of cox-2 inhibiters.[33] In consequence, if researchers involved in researching various cox-2 inhibitors doubt their ability to obtain a licence, this may discourage research on a range of drug applications.

Although a number of patents and patent applications relating to cox-2 technology do exist in Australia (including patents held by Searle & Co Inc), there is no record of the specific patent that has been the subject of dispute. A great number of patents relating to cox-2 technology exist in the US, which may be indicative of the fact that researchers have been able to proceed in this area relatively unhindered by the patents owned by the University of Rochester.

NF-κB Messenger Protein

A broad patent covering the treatment of diseases using the NF-κB messenger protein was granted to Harvard College, the Massachusetts Institute of Technology, and the Whitehead Instititute.[34] This particular protein triggers cell suicide, and many researchers have been actively engaged in studying factors that block the activity of the protein. The patent was exclusively licensed to Ariad Pharmaceuticals (Ariad), and is reportedly being actively enforced by Ariad.[35] Ariad have signalled an intention to derive licensing revenue from the NF-κB patent portfolio, although they will not seek licences from academic institutions for non-commercial research.[36] They have

---

[31] US Patent No US6 048 850 entitled Method of Inhibiting Prostaglandin Synthesis in a Human Host.

[32] See Walsh, Arora and Cohen, above n26, 297. See also their n16 outlining unsuccessful infringement proceedings brought by the University of Rochester against Searle & Co Inc.

[33] See the announcement on the University of Rochester's website <http://www.urmc.rochester.edu/cox-2/pr.html> at 7 May 2004.

[34] United States Patent US6 410 516 entitled Nuclear Factors Associated with Transcriptional Regulation (granted in 2002).

[35] Arti K Rai and Rebecca S Eisenberg, 'The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine (2003) 66 *Law and Contemporary Problems* 289, 302; Peg Brickley, 'New Patent Worries Professors' 16 *The Scientist* (2002) <http://www.the-scientist.com/yr2002/jul/brickley_p19_020722.html> at 17 May 2004.

[36] See NF-κB Highlights, available on Ariad's website <http://www.ariad.com/about/about_nfkb.html> at 17 May 2004.

issued research and development licences to Bristol-Myers Squibb Company and DiscoveRx Corporation.[37]

The concern is that some existing drugs already on the market might infringe the patent, as might a considerable amount of ongoing academic research with commercial implications.[38] The scope of the patent means that it may block any therapeutic application relating to the protein, threatening many established research projects.[39] It has also been pointed out that a broad patent and exclusive licence were not necessary to motivate downstream development given the many research projects founded on the generally available knowledge that the NF-κB pathway was implicated in multiple diseases.[40]

There is no record of a similar patent being granted in Australia.[41]

Cre-lox

In 1990, E I DuPont de Nemours and Co (DuPont) was granted a US patent over a method of using site specific recombination of DNA as a genetic engineering tool by inactivating known genes.[42] The technology allows researchers to create 'knock out' mice, or mice with a deleted gene.[43] In 1998, DuPont entered into an agreement with the NIH allowing NIH affiliated researchers access to Cre-lox technology for non-commercial research.[44] Although DuPont had previously offered to licence the technology, for some time universities had baulked at the licence terms demanded by DuPont. Researchers are now required to enter into a Material Transfer Agreement if Cre-lox mice are transferred within the academic environment, and these agreements do impose some conditions on use.[45] One of the primary conditions is that researchers

---

[37] Ibid.

[38] Brickley, above n35.

[39] Ibid.

[40] Rai and Eisenberg above n35, 302.

[41] Ariad reports that it has exclusive licences to a portfolio of four patents relating to NF-κB, three US patents (including the patent referred to in n? above), and one European patent; see above n36.

[42] US Patent No US4 959 317 entitled Site-Specific Recombination of DNA in Eukaryotic Cells (granted in 1990).

[43] Irene Abrams and Martine Kaiser, 'Licensing Transgenic Mice: A Short Tutorial' (2000) 12 *The Journal of the Association of University Technology Managers* <www.autm.net/pubs/journal/00/transgenicmice.html> at 24 June 2005, 1-3.

[44] The agreement can be viewed at <http://ott.od.nih.gov/> at 24 June 2005.

[45] For details see Abrams and Kaiser above n43, 3.

are forbidden from transferring Cre-lox mice to commercial entities unless the commercial entity first obtains a commercial research licence.[46]

It would appear that the Australian Patent Office has also granted a patent over this technology to DuPont.[47]

Oncomouse

During the late 1980s, researchers at Harvard University (Harvard) developed a genetically altered mouse with an increased propensity for developing cancer. A transgenic mouse or Oncomouse is a mouse that has an extra gene added to its cells.[48] Harvard obtained a US patent for this technology in 1988,[49] and the technology quickly became an important cancer research tool. The patent granted to Harvard was very broad, and later patents increased its scope.[50] An exclusive licensing agreement was entered into with DuPont.

As with Cre-lox technology, researchers voiced concern over the terms on which DuPont offered licences. Again, DuPont reached agreement with the NIH for the use of the technology in academic, non-commercial research.[51] Researchers are not required to share royalties resulting from commercial products with DuPont and commercial entities are also required to enter into licence agreements with DuPont. The agreement does, however, require individual non-profit NIH grantees to negotiate separate agreements with DuPont, and DuPont is currently enforcing its rights under the patents against a number of universities on considerably more restrictive terms than those contained in the Memorandum of Understanding.[52]

---

[46] See above n44, cl(3).

[47] Australian Patent AU639059 entitled Site-Specific Recombination of DNA in Plant Cells.

[48] Abrams and Kaiser, above n43, 1.

[49] US Patent No US4 736 866 entitled Transgenic Non-Human Mammals (granted in 1988). Patents were also granted in Europe and Canada. The European and Canadian patents have been the subject of litigation, which has since been resolved. In Europe, the patent was allowed by the EPO Examining Division after consideration of whether the subject matter was patentable, and whether the public order/morality provision should be invoked; see Case V 0006/92 Harvard (April 3, 1992). In Canada, the Canadian Supreme Court decide by a majority of 5-4, that the oncomouse did not constitute patentable subject matter under Canadian patent law; *Harvard College v Canada* (Commissioner of Patents) [2002] 4 SCR 45.

[50] US Patents Nos US5 087 571 entitled Method for Providing a Cell Culture from a Transgenic Non-Human Mammal (granted 1992) and US5 925 803 entitled Testing Method Using Transgenic Mice Expressing and Oncogene (granted in 1999).

[51] Above n44.

[52] Reported in Walsh, Arora and Cohen, above n26, 308.

It would not appear that an equivalent Australian patent has been granted, although an application by Harvard was made in respect of transgenic non-human mammals.[53] It is likely that this application has lapsed. A number of other patents have been granted by the Australian Patent Office in respect of transgenic non-human animals.

Human Embryonic Stem Cell Technology[54]

Wisconsin Alumni Research Foundation (WARF) was issued a number of US patents for the isolation of human embryonic stem cells, which are useful as a tool in the development of various tissue types and organs.[55] Research on stem cells is a major area of research to which significant funding has been allocated.[56] The records of the Australian Patent Office do not appear to contain any record of the central patents held by WARF, although other applications relating to primate stem cells have been filed.[57] The WARF patents have been viewed as being problematic due to their breadth,[58] and because exclusive rights to develop particular tissue types (and options to develop the remaining tissue types) were granted to Geron Corporation (Geron).[59]

---

[53] Application No AU199187358.

[54] Walsh, Arora and Cohen provide a useful summary of the issues surrounding the patents over embryonic stem cell technology, and they rely largely on two articles from *The New York Times*; see Walsh, Cohen and Arora, above n26, their n36. The following discussion uses portions of the material discussed by Walsh, Arora and Cohen at 308-309 and taken from those articles. See also the useful discussion of the issues surrounding stem cell technologies in Australian Law Reform Commission, Parliament of Australia, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99 (2004) (ALRC Report), Chapter 15.

[55] US Patents US6 200 806 entitled Primate Embryonic Stem Cells (granted in 2001) and US6 280 718 entitled Hemotopoietic Differentiation of Human Pluripotent Embryonic Stem Cells (granted in 2001) (the WARF patents). Only one patent has been granted by the EPO in respect of stem cell technology, to Edinburgh University (EP0695351). The patent was opposed and the scope of the claims ordered by the Opposition Division of the EPO to be amended to exclude human and animal embryonic cells. The basis of this decision was that the patenting of human embryonic stem cells is contrary to public order (s53(a) EPC), and no further patents relating to human embryonic stem cells have been granted by the EPO; see ALRC Report, above n54, 384-385. The matter is currently on appeal, and a number of other patents relating to stem cells have been rejected; see Gretchen Vogel, 'Stem Cell Claims Face Legal Hurdles' 305 *Science* (2004): 1887.

[56] For example, significant government funding has been allocated to the Australian Stem Cell Centre. See above, 1.2.

[57] Applications No 199647584 entitled Primate Embryonic Stem Cells, 199938814 entitled Primate Embryonic Stem Cells with Compatible Histocompatibility Genes and 200138491 entitled Method of Making Embryoid Bodies from Primate Embryonic Stem Cells. These applications are generally equivalent to the following US patents: US5,843,780 entitled Primate embryonic stem cells (granted in 1998) and US6,602,711 entitled Method of Making Embryoid Bodies from Primate Embryonic Stem Cells (granted in 2003).

[58] Essentially, the patents claim the cell lines and the methods for isolating them from embryos. The method claims are particularly broad and have far-reaching consequences for follow-on research.

[59] See, eg, Maria Freire, Statement on Stem Cell Research (1999) *Hearing Before the Committee of Appropriations, Senate Subcommittee on Labor, Health and Human Services, Education and Related Agencies*, 106th Congress; Christopher Carroll, 'Selling the Stem Cell: The Licensing of the Stem Cell

These rights effectively excluded other researchers developing for commercial application the tissue types encompassed by the licence. Geron's rights were further solidified by a number of exclusive licences granted by Johns Hopkins University.[60] The technology itself is key to understanding the basic processes of human development, and is important to future generations of biomedical discovery,[61] and the coverage of the WARF patents is sweeping.

WARF and Geron embarked on legal proceedings due to a dispute over the extent of Geron's rights. The matter subsequently settled and Geron's exclusive rights were limited to three cell types. They were granted non-exclusive rights to three other tissue types and their remaining options were removed.[62] Geron thus retains strict control over research in relation to certain tissue types, and has indicated that although academic and government scientists may use the patents for research (but not commercial) purposes, company researchers are not entitled to use them in the absence of a licence. It has been pointed out that Geron's control may be ameliorated to some extent by scientific advances in adult stem cell technology and the ability of researchers to extract stem cells from unfertilised eggs.[63] Certainly the fact that the central US patents have not been patented in Australia is significant for Australian companies and researchers working in the area.

Hepatitis C Virus (HCV)

Across a number of countries, the practices of patent holder Chiron Corporation (Chiron) have prompted considerable criticism. Scientists at Chiron successfully cloned the hepatitis C virus (HCV) in 1987, and since that time Chiron has been granted over 100 patents relating to HCV in over 20 countries.[64] The initial patents granted to Chiron were very broad, and encompassed the viral components of the

---

Patent and Possible Antitrust Consequences' (2002) *University of Illinois Journal of Law, Technology and Policy* 435, 441.

[60] Particularly US Patent US6,090,622 entitled Human Embryonic Pluripotent Germ Cells (granted in 2000).

[61] See Freire, above n59.

[62] The NIH and the WiCell Research Institute Inc (WiCell in a non-profit institution established by WARF and licensed to distribute a number of WARF's stem cells) signed a Memorandum of Understanding that permits NIH researchers to conduct research on WiCell's five existing cell lines. The MOU provides that any intellectual property generated as a result will be owned by the NIH. For details see <http://www.nih.gov/news/pr/sep2001/od-05.htm> at 24 June 2005.

[63] Walsh, Arora and Cohen, above n26, 309.

[64] See Nuffield Discussion Paper, above n9, 41-42.

HCV virus as well as their use in diagnostic and pharmaceutical applications.[65] The patents were exclusively licensed to Ortho Inc (Ortho), and Chiron and Ortho subsequently entered into an agreement with Abbott Laboratories Ltd (Abbott) on terms that restricted Abbott's ability to obtain antigen from any party other than Chiron. Murex Diagnostics Ltd (Murex) was subsequently sued for infringement.

Their validity was the subject of litigation in several jurisdictions, including Australia.[66] In Australia, Murex commenced revocation proceedings against Chiron. Despite going to trial before Burchett J, the matter settled on confidential terms prior to its conclusion. Murex were eventually granted a licence to Chiron's patents. In the UK, proceedings were also instigated by Murex on the basis of an allegation that in refusing to license Murex, Chiron were in breach of competition law provisions of the Treaty of Rome. This litigation will be discussed in more detail in later chapters.

BRCA1 Patent[67]

Two known genes are implicated in breast cancer, BRCA1 and BRCA2. As a result of patents granted to Myriad Genetics Inc (Myriad),[68] Myriad has obtained broad protection over the BRCA1 gene and mutations of the gene, diagnostic testing for mutations, methods for screening samples, and therapeutic and pharmaceutical applications.[69] As a result, a number of European organisations opposed Myriad's European patents on a number of grounds, including lack of inventiveness, insufficient description and lack of industrial applicability.[70] The Opposition Division

---

[65] Ibid, 42. Chiron produced a diagnostic test and the patent precludes development of alternative diagnostic tests in the absence of a licence. It is also arguable that access to Chiron's patents would probably be required in order to produce an HCV vaccine; at 41-42.

[66] The original patent (European Patent 0318216) was opposed in Europe and its claims were amended during the course of appeal; Nuffield at 41. UK Patent 2212511 was also the subject of infringement proceedings which resulted in a challenge to its validity. The scope of this patent's claims were also reduced. In Australia, the matter settled and did not proceed to a final determination.

[67] A concise discussion of the issues surrounding the BRCA1 patents is contained in Matthew Rimmer, (2003) 'Myriad Genetics: Patent Law and Genetic Testing' 25(1) *European Intellectual Property Review* 20.

[68] Myriad owns a number of patents in relation to the BRCA1 gene including (in the United States) Patents No US5 747 282, US5 710 001 (these patent applications were jointly filed by Myriad, the University of Utah Research Foundation and the US Secretary of Health), US5 693 473 and US5 753 441. In Europe, Myriad was granted two patents (EU699754 and EU705903) 2001. The first covers diagnostic use of the BRCA1 gene, while the second covers a method of diagnostic testing for breast and ovarian cancer linked to BRCA1; Nuffield Discussion Paper, above n9, 39-41.

[69] See also ibid, 39. Note that a number of the patents also give Myriad rights over other cancers in which BRCA1 plays a role.

[70] Discussed ibid, 40.

of the European Patent Office (EPO) revoked EP 699754 in 2004.[71] After conducting further opposition proceedings, the Opposition Division recently amended EP 705903 so that the patent now relates to a gene probe of a defined composition and does not include claims for diagnostic or therapeutic methods.[72] Although these proceedings are open to challenge, the decision significantly reduces the scope of Myriad's European patent portfolio.

Myriad's patents give it broad power to control diagnostic testing and the development of new tests and methods of predicting susceptibility to breast and ovarian cancers. Myriad has actively enforced its patents against public and private diagnostic test providers, insisting that all diagnostic testing procedures be undertaken by Myriad's laboratories.[73]

Concern has arisen that the implications of this practice for patients include greater cost for tests and the exclusion of access to tests that may be of superior quality.[74] Patients are likely to suffer because there is less likelihood that testing will be associated with quality counselling services.[75] At worst, researchers will be precluded from developing alternative and perhaps improved tests.[76] Some testing authorities have continued to ignore Myriad's patents and conduct testing using test kits developed without licence from Myriad.[77] Nevertheless, the case of BRCA1 serves to highlight that issues surrounding restricted access to patents are often intensified where diagnostic testing is concerned.[78]

---

[71] '"Myriad/breast cancer" patent revoked after public hearing', European Patent Office Press Release (18 May 2004) <http://www.european-patent-office.org/news/pressrel/2004_05_18_e.htm> at 24 May 2004.

[72] See 'Patent on Breast and Ovarian Cancer Susceptibility Gene Amended After Public Hearing' *EPO Press Release*, 21 January 2005, <http://www.european-patent-office.org/news/pressrel/2005_01_21_e.htm> at 24 June 2005.

[73] See Nuffield Discussion Paper, above n9, 39-40.

[74] Jon F Merz, Antigone G Kriss, Debra DG Leonard and Mildred K Cho, 'Diagnostic Testing Fails the Test' 415 *Nature* (2002): 577. Mildred K Cho and Jon F Merz, 'Letter to Nature' 390 *Nature* (1997): 221. Evidence indicates that this concern has not been borne out in the UK; see Intellectual Property Institute, *Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice* (2004) (The UK Study), 70.

[75] Merz and Others, above n74.

[76] See Debra G B Leonard, Medical Practice and Gene Patents: A Personal Perspective 77 *Academic Medicine* (2002): 1388, 1389; Rimmer, above n67, 27-29.

[77] For example, publicly based national laboratories continue to undertake testing in the United Kingdom, and some provinces of Canada; see Nuffield Discussion Paper, above n9, 39-40.

[78] On this point see generally John H Barton, 'Patents, Genomics, Research and Diagnostics' 77 *Academic Medicine* (2002): 1339, 1339-1340; Australian Law Reform Commission, *Gene Patenting and Human Health*, (2004) Discussion Paper 68, 576-578.

Myriad has been granted a number of patents over the BRCA1 gene in Australia.[79] A licensing agreement has been entered into between Myriad and Genetic Technologies Ltd,[80] although the extent to which Genetic Technologies will enforce Myriad's patents in Australia is not clear at present. Given Myriad's enforcement practices across the globe to date, however, there is certainly concern that Myriad will stipulate strict enforcement of its Australian patents.[81]

[79] For example, AU691968.

[80] See 'Gene Screeners Test Their Patents', Business Review Weekly, 16 January 2003, <http://www.gtg.com.au/Media.Coverage.html> at 31 August 2005.

[81] See, eg, Dianne Nicol, 'Human Gene Patents: Under Whose Control?' (2003) 179 *Medical Journal of Australia* 181-182; Ian R Walpole, Hugh J S Dawkins, Peter D Sinden and Peter C O'Leary, 'Human Gene Patents: The Possible Impacts on Genetic Service Providers' (2003) 179 *Medical Journal of Australia* 203.

BIBLIOGRAPHY

A

Abadee, Alister, 'The Essential Facilities Doctrine and the National Access Regime: A Residual Role for Section 46 of the *Trade Practices Act*?' (1997) 5 *Trade Practices Law Journal* 27

Abrams Irene and Kaiser Martine, 'Licensing Transgenic Mice: A Short Tutorial' (2000) 12 *The Journal of the Association of University Technology Managers* <www.autm.net/pubs/journal/00/transgenicmice.html> at 24 June 2005

Adams Geoff and McLennan Dan, 'Intellectual Property Licensing and Part IV of the *Trade Practices Act*: Are the *TPA's* Pro-Competitive Provisions Anti-IP Commercialisation?' (2002) 51 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 10

Advisory Council on Industrial Property, *Review of Enforcement of Intellectual Property Rights* (1999)

Advisory Council on Intellectual Property (ACIP), *Review of Crown Use Provisions in Patents and Design Legislation*, Discussion Paper, (2003)

Advisory Council on Intellectual Property (ACIP), *Patents and Experimental Use*: Options Paper, Australian Government Printing Service (2004)

Aitman David and Jones Alison, 'Competition Law and Copyright: Has the Copyright Owner Lost the Ability to Control his Copyright?' (2004) 26(3) *European Intellectual Property Review* 137

Allison John R and Lemley Mark A, 'Empirical Evidence on the Validity of Litigated Patents' (1998) 26 *AIPLA Quarterly Journal* 185

Anderman, Steve, 'The Aftermath of Magill' in Barendt, Eric, *The Yearbook of Media and Entertainment Law* (1996)

Anderman, Steven D, 'Copyright, Compulsory Licensing and EC Competition Policy' in Barendt, Eric, (ed), *Yearbook of Media and Entertainment Law* (1995)

Anderman, Steven D, *EC Competition Law and Intellectual Property Rights: The Regulation of Innovation* (1998), 147

Steven D Anderman '*Microsoft* in Europe', (*Paper prepared for the Department of Justice/Federal Trade Commission Hearings, Washington DC*, 22 May 2002)

Areeda Phillip and Turner Donald F, *Antitrust Law: An Analysis of Antitrust Principles and their Applications* (1978)

Areeda, Philip, 'Essential Facilities: An Epithet in Need of Limiting Principles' (1989) 58 *Antitrust Law Journal* 841

Areeda Phillip E & Hovenkamp Herbert, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* (2nd ed, 2002)

Arrow, Kenneth J, 'Economic Welfare and the Allocation of Resources for Invention' in Nelson, Richard R, (ed), *The Rate and Direction of Inventive Activity* (1962)

Atkinson Richard C, Beachy Roger N, Conway Gordon, Cordova France A, Fox Marye Anne, Holbrook Karen A, Klessig Daniel F, McCormick Richard L, McPherson Peter M, Rawlings Hunter R, Rapson Rips, Vanderhoef Larry N, Wiley John D, and Young Charles E, 'Public Sector Collaboration for Agricultural IP Management' 301 *Science* (2003): 174

AusIndustry, Fact Sheet: *Biotechnology Innovation Fund*, <http://www.ausindustry.gov.au/content/content.cfm?ObjectID=01A28EB4-A066-4D7E-99AAA16094536488&L2Parent=0786C9BE-08B7-4973-93429A645AEEC8E4&L3Parent=FD34329B-F6F6-4C98-B963D0A59C20A603> at 18 May 2004

Australian Broadcasting Corporation (ABC) Four Corners, 'Patently a Problem' broadcast on 11 August 2003, transcript available at <http://www.abc.net.au/4corners/content/2003/transcripts/s922059.htm> at 5 May 2004 (ABC Four Corners).

Australian Competition and Consumer Commission, *Inquiry into the Effectiveness of the Trade Practices Act 1974 in Protecting Small Business: Second Supplementary Submission to the Senate Economics References Committee*, 14 January 2004

Australian Competition and Consumer Commission, *Merger Guidelines* (Canberra 1999)

Australian Competition and Consumer Commission, *Submission to the Intellectual Property and Competition Review Committee*, (1999)

Australian Competition and Consumer Commission, *Submission to Australian Law Reform Commission, Intellectual Property Rights over Genetic Materials and Genetic and Related Technologies – Gene Patenting and Human Health Issues Paper* (2003)

Australian Competition and Consumer Commission, *Submission to the Senate Economics References Committee Inquiry into the Effectiveness of the Trade Practices Act 1974 in Protecting Small Business*, (2003)

Australian Competition and Consumer Commission, *Submission to Australian Law Reform Commission, Intellectual Property Rights over Genetic Materials and Genetic and Related Technologies – Gene Patenting and Human Health: Discussion Paper DP 68*, April 2004

Australian Industrial Property Organisation, *Practice Note 1991 (No 10) Inventive Step*

Australian Law Reform Commission, *Gene Patenting and Human Health*, (2004) Discussion Paper 68

Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, (2004) Report No 99

Australian Patent Office, *Manual of Practice and Procedure – Volume 2: National*, (2002)

Australian Research Council, The Australian Tertiary Institutions Commercial Companies Association, The Australian Vice Chancellors' Committee, The Department of Education, Training and Youth Affairs, The Department of Industry, Science and Resources, IP Australia and The National Health and Medical Research Council, *National Principles of Intellectual Property Management for Publicly Funded Research*, 2001, (*National Principles of Intellectual Property Management*) available at < http://www.arc.gov.au/pdf/01_01.pdf> at 18 May 2004

Azcuenaga, Mary L, 'The Intersection of Antitrust and Intellectual Property: Adaptations, Aphorisms and Advancing the Debate' (1996) <http://www.ftc.gov/speeches/azcuenaga/alis.htm> at 16 December 2004

B

Bain, Joseph, *Barriers to New Competition: Their Character and Consequences in Manufacturing Industries* (1965)

Baldwin William L and Scott John T, Market Structure and Technological Change (1987)

Bar-Shalom Avital and Cook-Deegan Robert, 'Patents and Innovation in Cancer Therapeutics: Lessons From Cell-Pro' (2002) 80(4) *The Millbank Quarterly* 637

Barton, John H, 'Patent Scope in Biotechnology' (1995) 26 *International Review of Industrial Property and Competition Law* 605

Barton, John H, 'Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation', (1997) 65 *Antitrust Law Journal* 449

Barton, John H, 'Paradigms of Intellectual Property/Competition Balances in the Information Sector' Organisation for Economic Cooperation and Development (OECD), *Competition Policy and Intellectual Property Rights* (1998), 295

Barton, John H, 'Reforming the Patent System' 287 *Science* (2000)

Barton, John H, 'Antitrust Treatment of Oligopolies with Mutually Blocking Patent Portfolios' (2002) 69 *Antitrust Law Journal* 851

Barton, John H, 'Patents, Genomics, Research and Diagnostics' 77 *Academic Medicine* (2002): 1339

Barton, John H, Antitrust Treatment of Oligopolies with Mutually Blocking Patent Portfolios (2002) 69 *Antitrust Law Journal* 851

Barton, John, in Transcript of Proceedings, *Federal Trade Commission Hearings into Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, (February 26 2002)

Bath, Ulrika, 'Access to Information v Intellectual Property Rights' (2002) 24(3) *European Intellectual Property Review* 138

Baxt, Robert, 'The Australian Concept of Market – How it Came to Be' in Richardson Megan and Williams Philip, (eds), *The Law and the Market*, (1995)

Baxter, William, 'Legal Restrictions on Exploitation of the Patent Monopoly: An Economic Analysis' (1966) 76 *Yale Law Journal* 267

Beaton-Wells, Caron, *Proof of Antitrust Markets in Australia* (2003)

Bell, John, 'Predicting Disease Using Genomics' *Nature* 429, (2004): 453

Benkler, Yochai, 'Commons-Based Strategies and the Problems of Patents' 305 *Science* (2004): 1110

Bentley, David R, 'Genomes for Medicine' *Nature* 429, 440-445 (2004)

Biotechnology Australia, Commonwealth of Australia, Developing Australia's Biotechnology Future: Discussion Paper (1999)

Biotechnology Australia, Commonwealth of Australia, *Australian Biotechnology: A National Strategy*, (2000)

Biotechnology Australia and Spruson and Ferguson, *Biotechnology Intellectual Property Manual*, (2001)

Biotechnology Industry Organisation, 'Patent Fee Bill Will Help Ensure Continued Biotech Innovation' *Press Release*, 3 April 2004 at <http://www.bio.org/news/> at 15 June 2005

Blumenthal David, Causino Nancyanne, Campbell Eric and Seashore Louis Karen, 'Relationships Between Academic Institutions and Industry in the Life Sciences – An Industry Survey', (1996) *New England Journal of Medicine* 368

Boettinger Sara and Burk Dan L, 'Open Source Patenting (2004) 1 *Journal of International Biotechnology Law* 221

Borenstein Severin, MacKie-Mason Jeffrey K and Netz Janet S, 'Exercising Market Power in Proprietary Aftermarkets' (2000) 9(2) *Journal of Economics and Management Strategy* 157

Bork, Robert H, *The Antitrust Paradox: A Policy at War With Itself* (1978)

Bowman Jr, Ward, *Patent and Antitrust Law: A Legal and Economic Appraisal* (1973)

Boyle Peter M, Lister Penelope M and Clayton Jr Everett J, 'Antitrust Law at the Federal Circuit: Red Light or Green Light at the IP-Antitrust Intersection?' (2002) 69 *Antitrust Law Journal* 739

Brickley, Peg, 'New Patent Worries Professors' 16 *The Scientist* (2002) <http://www.the-scientist.com/yr2002/jul/brickley_p19_020722.html> at 17 May 2004

Brown, T A, *Genomes* (2001)

Brunt, Maureen, 'The Use of Economic Evidence in Antitrust Litigation: Australia' (1986) *Australian Business Law Review* 261

Brunt, Maureen, 'Market Definition Issues in Australian and New Zealand Trade Practices Litigation' (1990) 18 *Australian Business Law Review* 86

Burk Dan L and Lemley Mark A, 'Policy Levers in Patent Law' (2003) 89 *Virginia Law Review* 1575

Burk Dan L and Lemley Mark A, 'Biotechnology's Uncertainty Principle' (2004) 54 *Case Western Reserve Law Review* 691

Burton Mark L, Kaserman David L and Mayo John L, 'Modeling Entry and Barriers to Entry: A Test of Alternative Specifications', (1999) *The Antitrust Law Bulletin* 387

C

Calleja, Nicole, 'Access to Essential Services – Have the Hilmer Reforms Been Successfully Implemented?' (2000) 8 *Trade Practices Law Journal* 206

Carlton Dennis W, and Gertner Robert H, *Intellectual Property, Antitrust and Strategic Behaviour* (Working Paper No 8976, National Bureau of Economic Research, 2003)

Carrier, Michael A, 'Unraveling the Patent-Antitrust Paradox' (2002) 150 *University of Pennsylvania Law Review* 761

Carroll, Christopher, 'Selling the Stem Cell: The Licensing of the Stem Cell Patent and Possible Antitrust Consequences' (2002) *University of Illinois Journal of Law, Technology and Policy* 435

Chang, Howard F, 'Patent Scope, Antitrust Policy, and Cumulative Innovation' (1995) 26 *The RAND Journal of Economics* 34

CHI Research Inc, *Inventing Our Future: The Link Between Australian Patenting and Basic Science* (2000)

Cho Mildred K and Merz Jon F, 'Letter to Nature' 390 *Nature* (1997): 221

Cho, Mildred K, 'Impact of Patents on Provision of Clinical Genetic Testing Services' (2002) (Paper Presented at *OECD Workshop on Genetic Inventions, Intellectual Property Rights and Licensing Practices* Berlin, January 24, 2002)

Christie Andrew F, D'Aloisio Stuart, Gaita Katerina L, Howlett Melanie J, and Webster Elizabeth M, Commonwealth of Australia, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Institutions* (2003) (Christie and Others, *Patent Ownership in Publicly Funded Institutions*)

Clarke, Robert A, 'US Continuity Law and its Impact on the Comparative Patenting Rates of the US, Japan and the European Patent Office (2003) 85 *Journal of the Patent and Trademark Office Society* 335

Clough, Daniel, 'Economic Duplication and Access to Essential Facilities in Australia' (2000) 28 *Australian Business Law Review* 325

Clough, Daniel, 'Law and Economics of Vertical Restraints in Australia' (2001) 25 *Melbourne University Law Review* 20

Clough, Daniel, 'Misuse of Market Power – "Would" or "Could" in a Competitive Market?' (2001) 29 *Australian Business Law Review* 311

Coase Ronald H, 'The Problem of Social Cost' (1960) 3 *Journal of Law and Economics* 1

Cohen, Wesley M, 'Empirical Studies of Innovative Activity' in Stoneman, P, (ed), *Handbook of the Economics of Innovations and Technological Change* (1995)

Cohen Wesley M, and Klepper Steven, 'A Reprise of Size and R & D' (1996) 106 *The Economic Journal* 925

Cohen Wesley M, and Klepper Steven, 'Firm Size and the Nature of Innovation Within Industries: The Case of Process and Product R&D' (1996) 78 *Review of Economics and Statistics* 232

Cohen Wesley, Nelson Richard and Walsh John, 'Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)', (Working Paper No 7552, National Bureau of Economic Research, 2000)

Collins Francis S, Guyer Mark S, and Chakravarti Aravinda, 'Variations on a Theme: Cataloguing Human DNA Sequence Variation' 278 *Science* (1997): 1580

Commission Withdraws Interim Measures in *NDC Health/IMS Health* Case (2003) *EU Focus* 4

Commission Evaluation Report on the Transfer of Technology Block Exemption Regulation No 240/96: Technology Transfer Agreements Under Article 81, COM (2001) 786

Commission Notice on the Definition of the Relevant Market for the Purposes of Community Competition Law, OJ C 372 on 9/12/1997

Commission Proposes New Safe Harbour for the Licensing of Patents and Know-How', *EU Press Release*, (2003)

<http://www.juridicum.su.se/jurweb/utbildning/master/master_of_european_intellectual_property_law/Commissionpressroom.pdf> at 31 May 2004

Commission Regulation (EC) 772/2004 of 27 April 2004 on the Application of Article 81(3) of the Treaty to Categories of Technology Transfer Agreements [2004] OJ L 123/11

Commonwealth of Australia, *Trade Practices Act: Proposals for Change* (1984)

Commonwealth of Australia, *Australian Government Response to the Senate Inquiry into the Effectiveness of the* Trade Practices Act *1974 in Protecting Small Business*

Commonwealth of Australia, *Review of Business Taxation: A Tax System Redesigned: Final Report* (1999)

Commonwealth of Australia, The Virtous Cycle-Working Together for Health and Medical Research, Health and Medical Strategic Review, (1999)

Commonwealth of Australia, The Virtous Cycle-Working Together for Health and Medical Research, Health and Medical Strategic Review, (1999)

Commonwealth of Australia, Backing Australia's Ability: An Innovation Action Plan for the Future (2001)

Commonwealth of Australia, *Government Response to Intellectual Property and Competition Review Recommendations*, Information Package <http://www.ipaustralia.gov.au/pdfs/general/response1.PDF> at 31 May 2004

Commonwealth of Australia, Ernst & Young and Freehills, *Australian Biotechnology Report* (2001)

Cooter, Robert 'Decentralised Law for a Complex Economy: The Structural Approach to Adjudicating the New Law Merchant' (1996) 144 *University of Pennsylvania Law Review* 1643

Cooter Robert and Marks Steven, 'Bargaining in the Shadow of the Law: A Testable Model of Strategic Behaviour' (1982) 11 *Journal of Legal Studies* 225

Corones, Stephen G, 'Intellectual and Industrial Property – Reconciling Intellectual Property Rights and Competition Law: The *Magill* TV Guide Case' (1992) 20(3) *Australian Business Law Review* 265

Corones, Stephen G, 'Reconciling Intellectual Property Rights and Competition Law: The *Magill* TV Guide Case' (1992) *Australian Business Law Review* 265

Corones, Stephen G, 'Remedies under the Trade Practices Act for refusal to supply' (1993) 10(3) *Australian Bar Review* 259

Corones, Stephen G, *'Temporary monopolies and s46 of the Trade Practices Act'* (2002) 30 ABLR 246

Corones, Stephen, 'The Characterisation of Conduct under Section 46 of the *Trade Practices Act'* (2002) 30 *Australian Business Law Review* 409

Corones, Stephen, 'Section 46 of the *Trade Practices Act*: *Boral*, the Dawson Committee and the Protection of Small Business' (2003) 31 *Australian Business Law Review* 210

Corones, Stephen G, 'Has the High Court crippled the effectiveness of s46 of the Trade Practices Act?' (2004) 32 *Australian Business Law Review* 142

Corones, Stephen G, *Competition Law in Australia* (3rd ed, 2004)

Correa, Carlos, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, Working Paper 5, (1999) <http://www.southcentre.org/publications/complicense/toc.html> at 19 April 2001

Cortright Joseph and Mayer Heike, *Signs of Life: The Growth of Biotechnology Centers in the US* (2002)

Council Directive for the Legal Protection of Computer Programs OJ 1991 L 122/42

D

Dam, Kenneth W, 'The Economic Underpinnings of Patent Law', (1994) 23 *Journal of Legal Studies* 247

Dammery, Richard, 'Section 46 of the Trade Practices Act: The Need for Prospective Certainty' (1999) 6 *Competition and Consumer Law Journal* 246

Demsetz, Harold, *Economic, Legal and Political Dimensions of Competition* (1982)

Department of Industry Tourism and Resources, Commonwealth of Australia, *Pharmaceuticals Industry Profile* <http://www.industry.gov.au/content/itrinternet/cmscontent.cfm?objectID=8B4157C0-C0F3-47EE-B3C3994EECB2A4CB> at 18 May 2004

Department of Treasury and Finance, Parliament of Australia, *Commonwealth Regulatory Plan* (2005)

<http://www.treasury.gov.au/documents/936/RTF/_Toc107982889> at 16 August 2005

Derclaye, Estelle, 'Abuses of Dominant Position and Intellectual Property Rights: A Suggestion to Reconcile the Community Courts Case Law' (2003) 26(4) *World Competition* 685

Dierker Dan and Phillips Peter, 'The Search For the Holy Grail? Maximising Social Welfare Under Canadian Biotechnology Patent Policy' (2003) 6 *IP Strategy Today* 45

Dolman, Maurits, 'Restrictions on Innovation: An EU Antitrust Approach' (1998) 66 *Antitrust Law Journal* 455

Douglas Melamed A and Stoeppelwerth Ali M, 'The CSU Case: Facts, Formalism and the Intersection of Antitrust and Intellectual Property' (2002) 10 *George Mason Law Review* 407

Drahos, Peter, 'Biotechnology Patents, Markets and Morality' (1999) 21 *European Intellectual Property Review* 441

Drahos, Peter, 'BITs and BIPs – Bilateralism in Intellectual Property' (2001) 4 *Journal of World Intellectual Property* 791

Drahos Peter and Braithwaite John, *Information Feudalism* (2002)

E

Eagles Ian and Longden Louise, 'Competition in Information and Computer Technology Markets: Intellectual Property Licensing and Section 51(3) of the *Trade Practices Act* 1974' (2003) 3 *Queensland University Journal of Technology Law and Justice Journal* 28

Easterbrook, Justice Frank H, 'Ignorance and Antitrust' in Jorde Thomas M and Teece David J, (eds), *Antitrust, Innovation, and Competitiveness* (1992) 119

EC Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, art 5

Edwards, '*Melway* – a TCE Perspective' (2002) 10 *Trade Practices Law Journal* 77

Edwards, Geoff, 'From Super-League to the Super-Market? The Appropriate Emphasis in Market Definition' (1996) 4 *Competition and Consumer Law Journal* 220

Edwards, Geoff A, 'Sub-Markets as Competition Law Markets: the Appropriate Approach to the Sub-market Concept in Market Definition' (1998) 6 *Competition and Consumer Law Journal* 156

Edwards, Geoff, 'The Hole in the Section 46 Net: The *Boral* Case, Recoupment Analysis, the Problem of Predation and What to do About it' (2003) 31 *Australian Business Law Review* 151

Eisenberg Rebecca S, 'Proprietary Rights and the Norms of Science in Biotechnology Research', (1987) 97 *Yale Law Journal* 177

Eisenberg, Rebecca S, Patents and the Progress of Science: Exclusive Rights and Experimental Use 56 *University of Chicago Law Review* 1017 (1989)

Eisenberg, Rebecca S, 'Intellectual Property at the Public-Private Divide: The Case of Large-Scale cDNA Sequencing' (1996) 3 *University of Chicago Law School Roundtable* 557

Eisenberg, Rebecca S, 'Patenting Research Tools and the Law' in National Research Council (NRC), *Intellectual property and Research Tools in Molecular Biology* (1997)

Eisenberg, Rebecca S, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' *Science* 280 (1998): 698

Eisenberg, Rebecca S, 'Re-examining the Role of Patents in Appropriating the Value of DNA Sequences' (2000) 49 *Emory Law Journal* 783

Eisenberg, Rebecca S, 'Bargaining Over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?' in Rochelle C Dreyfuss, Diane L Zimmerman and Harry First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001)

Eisenberg Rebecca S, and Merges Robert P, 'Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences' (1995) 23 *AIPLA Quarterly Journal* 1

Eisenberg Rebecca S and Nelson Richard D, 'Public vs. Proprietary Science: A Fruitful Tension?' 77 *Academic Medicine* (2002): 1392

EPO, 'Patent on Breast and Ovarian Cancer Susceptibility Gene Amended After Public Hearing' Press Release, (21 January 2005) <http://www.european-patent-office.org/news/pressrel/2005_01_21_e.htm> at 24 June 2005

Ergas, Henry, 'Treatment of Unilateral Refusals to License and Compulsory Licensing in Australia' (*Paper Presented to the Federal Trade Commission/Department of Justice Hearings on Antitrust and Intellectual Property Law and Policy in the Knowledge-Based Economy*, Washington, 22 May 2002)

Ergas Henry and Landrigan Mitchell, 'Not *Another* Article About Section 46 of the *Trade Practices Act*!' (2004) 32 *Australian Business Law Review* 415

Ernst & Young, *Australian Biotechnology Report* (1999)

Ernst & Young, Convergence: Ernst & Young's Biotechnology Industry Report: Millenium Edition (2000)

Ernst & Young, Hay Group & Strategic Industry Research Foundation, *Benchmarking Study of R&D Costs in Selected Segments of the Australian Biotechnology Industry: Final Report* (Canberra: AGPS, 2001)

Ernst & Young, Integration: Ernst & Young's Eighth Annual European Life Sciences Report (2001) (Ernst & Young, Integration), 32

Ernst & Young, *Beyond Borders: Global Biotechnology Report 2005* (2005)

Ernst & Young and Freehills, *Australian Biotechnology Report* (2001)

European Patent Office, "Myriad/breast cancer" patent revoked after public hearing' Press Release (18 May 2004), <http://www.european-patent-office.org/news/pressrel/2004_05_18_e.htm> at 24 May 2004

Euroscreen SA, 'CCR5 Mutant Gene Sequence Patented for AIDS Diagnosis' Press Release (27 February 2004) available at <http://www.prweb.com/releases/2004/2/prweb107422.htm> at 5 May 2004

Evans William E & Relling Mary V, 'Moving Towards Individualized Medicine with Pharmacogenomics' *Nature* 429, (2004): 464

F

Featherston Roger and Edwards Geoff, 'Recent Developments in Misuse of Market Power' (2000) 8 *Trade Practices Law Journal* 79

Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003)

Fikentscher, Wolfgang, 'Historical Origins and Opportunities for Development of an International Competition Law in the TRIPs Agreement of the World Trade

Organization (WTO) and Beyond' in Beier Friedrick-Karl and Schricker Gerhard, (eds), *From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights* (1996)

Fine, Frank, '*NDC/IMS*: A Logical Application of Essential Facilities Doctrine' (2002) 23 *European Competition Law Review* 457

Fine, Frank, '*NDC/IMS*: In Response to Professor Korah' (2002) 70 *Antitrust Law Journal* 247

Fitzgerald Darren, '*Magill* Revisited' (1998) 20(4) *European Intellectual Property Review* 154

Fodor, Stephen P A, 'Packaging the Genome to Accelerate Biotechnology' in Bay Area Science and Innovation Consortium, *Biotechnology: Essays from its Heartland* (2004) 42

Forrester, Ian S, 'Compulsory Licensing in Europe: A Rare Cure to Aberrant National Intellectual Property Rights?' (2002) *Paper Prepared for the Department of Justice/Federal Trade Commission Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy: Comparative Law Topics*, 22 May 2002

Forsyth, Miranda, 'Biotechnology, Patents and Public Policy: A Proposal for Reform in Australia' (2000) 11(4) *Australian Intellectual Property Journal* 202

Fox, Eleanor M, 'Trade, Competition and Intellectual Property – TRIPS and its International Counterparts' (1996) 29 *Vanderbilt Journal of Transnational Law* 481

Fox, Eleanor M, 'Toward World Antitrust and Market Access' (1997) 91 *American University Journal of International Law and Policy* 1

Frederic M Scherer, *Innovation and Growth: Schumpetarian Perspectives* (1984)

Freire, Maria, Statement on Stem Cell Research (1999) *Hearing Before the Committee of Appropriations, Senate Subcommittee on Labor, Health and Human Services, Education and Related Agencies*, 106th Congress

FTC Issues Report on How to Promote Innovation Through Balancing Competition Law with Patent Law and Policy *Press Release* (28 October 2003) <http://www.ftc.gov/opa/2003/10/cpreport.htm> at 5 May 2004

Fung, Jason, 'The Case of an Awkward Interface – Patents v Competition' (1998) 21(3) *University of New Sounth Wales Law Journal* 757

G

Gallini Nancy and Scotchmer Suzanne, 'Intellectual Property: When Is It the Best Incentive System?' in Jaffe Adam, Lerner Joshua and Stern Scott, (eds), *Innovation Policy and the Economy, Vol 2*, (2000) 51

Gallini Nancy T and Trebilcock Michael J, 'Intellectual Property Rights and Competition Policy: A Framework for the Analysis of Economic and Legal Issues' in Anderson Robert D and Gallini Nancy T, *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (1998) 17

Gambrell, James B, 'The Evolving Interplay of Patent Rights and Antitrust Restraints in the Federal Circuit' (2001) 9 *Texas Intellectual Property Law Journal*, 137

Gans Johua, Hsu David H and Stern Scott, *When Does Start-up Innovation Spur the Gale of Creative Destruction?* (Working Paper, Intellectual Property Research Institute of Australia 2002)

Geroski, Paul A, 'Innovation, Technological Opportunity and Market Structure' (1990) 42 *Oxford Economic Papers* 586

Geroski Paul A, *Market Dynamics and Entry* (1991)

Geroski, Paul A, 'Entry and the Rate of Innovation' (1991) 1 *Economic Innovation and New Technology* 203

Gilbert Richard and Shapiro Carl, 'Optimal Patent Length and Breadth', (1990) 21 *The RAND Journal of Economics* 106

Gilbert Richard J and Tom Willard K, 'Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later' (2001) 69 *Antitrust Law Journal* 43

Glazer Kenneth L and Lipsky Jr Abbott B, 'Unilateral Refusals to Deal Under Section 2 Of the *Sherman Act*' (1995) 63 *Antitrust Law Journal* 749

Gleklen, Jonathon I, 'Per Se Legality For Unilateral Refusals to License IP is Correct as a Matter of Law and Policy' (2002) July, *The Antitrust Source* 1, <http://www.abanet.org/antitrust/source/> at 8 November 2004

Gleklen, Jonathon, 'Antitrust Liability for Unilateral Refusals to License Intellectual Property: *Xerox* and its Critics' (*Paper presented to the Department of Justice/Federal Trade Commission Hearings*, Washington DC, 1 May 2002) 5-15

Government Senators, *Government Senators' Report* in Senate Economics References Committee, Parliament of Australia, *The Effectiveness of the Trade Practices Act 1974 in Protecting Small Business*, (2004)

Greaves, Rosa, '*Magill* Est Arrive...RTE and ITP v Commission of the European Communities' (1995) 16(4) *European Competition Law Review* 244

Green Jerry R and Scotchmer Suzanne, 'On the Division of Profit in Sequential Innovation' (1995) 26 *The RAND Journal of Economics* 20

Griggs, Lynden, 'A Teleological Approach to Market Definition – Has it Led to Single Product Market Definition?' (2002) 4 *University of Notre Dame Australia Law Review* 77

Griggs, Lynden, 'Small Business and the Operation of the *Trade Practices Act* – Another Review, Another Election, and the Battle Lines Between Big and Small Business are Once Again Redrawn!' (2004) 11 *Competition and Consumer Law Journal* 348

Griggs Lynden and Hardy Samantha, '*ACCC v Boral* – the High Court Awaits Another Section 46 Case!' (2001) 9 *Trade Practices Law Journal* 201

Guidelines for Examination of Patent Applications (2001) 66 *Federal Regulations* (US) 1092

Guidelines on the Application of Article 81 of the EC Treaty to Technology Transfer Agreements [2004] OJ C 101/02

Gutterman, Alan, *Innovation and Competition Policy* (1997)

H

Hagstrom Warren, *The Scientific Community* (1965)

Hanks Frances and Williams Philip L, 'Implications of the Decision of the High Court in *Queensland Wire*' (1990) 17 *Melbourne University Law Review* 437

Hart, David M, 'Antitrust and Technological Innovation in the US: Ideas, Institutions, Decisions, and Impacts, 1890-2000' (2001) 30 *Research Policy* 923

Hay, Deidre L, 'A Lesson from the US Hypothetical Monopolist about Market Definition Timeframes and Thresholds and the *QCMA* Test' (1998) 6 *Competition and Consumer Law Journal* 73

Hay, George A, 'Market Power in Australasian Antitrust: an American Perspective' (1994) 1 Competition and Consumer Law Journal 215

Hay George A, *Boral* – Free at Last (2003) 10 *Competition and Consumer Law Journal* 323, 330

Heinemenn, Andreas, 'Antitust Law of Intellectual Property in the TRIPs Agreement of the World Trade Organization' in Beier Friedrick-Karl and Schricker Gerhard (eds) *From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights* (1996)

Heller, Michael A, 'The Tragedy of the Anticommons: Property in the Transition from Marx to Markets' (1998) 111 *Harvard Law Review* 621

Heller Michael and Eisenberg Rebecca S, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' 280 *Science* (1998): 698

Henderson Rebecca, Jaffe Adam B, and Trajtenberg Manuel, 'Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting 1965-1988, (1998) 80 *Review of Economics & Statistics* 119.

Henry Michelle R, Cho Mildred K, Weaver Meredith A and Merz Jon F, 'DNA Patenting and Licensing' (2002) 297 *Science* 1279

Henry Michelle R, Cho Mildred K, Weaver Meredith A and Merz Jon F, 'DNA Patenting and Licensing' 297 *Science* 1279 (2002)

Heydon, John D, *Trade Practices Law*, Thomson Lawbook Company

Hoad, Richard, 'Compulsory Licensing of Patents: Balancing Innovation and Competition' (2003) 54 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 28

Hoerner, Robert J, 'The Antitrust Significance of a Patent's Exclusionary Power' (1992) 60 *Antitrust Law Journal* 867

Hood, Antra, 'Barriers and Impediments to Entry in Australian Health Care Markets After *Stirling Harbour*, *Boral* and *Melway*' (2002) 20 *Australian Business Law Review* 6

Hopper Kelvin and Thorburn Lyndal, 2002 *Bioindustry Review: Australia and New Zealand* (2002)

Hovenkamp Herbert, Lemley Mark A and Janis Mark D, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2002)

Howlett Melanie J and Christie Andrew F, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTS)* (2003) IPRIA Working Paper 09/03

Hsu David H and Bernstein Tim, 'Managing the University Technology Licensing Process: Findings from Case Studies', (1997) 9 *Journal of the Association of University Technology Managers* 1

Hull, David W, 'Compulsory Licensing of IP Rights: The ECJ's Judgment in the *IMS* Case' (2004) *Competition Law Insight* 10

Hull David and Toro Amy, 'Reform of the Technology Licensing Rules' (2004) *The European Antitrust Review*, 34

Hylton, Keith N, *Antitrust Law: Economic Theory and Common Law Evolution* (2003)

I

Independent Committee of Enquiry into Competition Policy in Australia, *National Competition Policy* (1993)

Industry Research and Development Board, AusIndustry, *Annual Report 2001-2002* (2002)

Intellectual Property Advisory Committee, Parliament of Australia, *Patents, Innovation and Competition in Australia* (1984) 45

Intellectual Property and Competition Review Committee, Review *of Intellectual Property Legislation under the Competition Principles Agreement: Final Report* (2000)

Intellectual Property and Competition Review Committee, Parliament of Australia, *Review of Intellectual Property Legislation Under the Competition Principles Agreement: Final Report* (2002)

Intellectual Property Institute, *Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice* (2004)

Intellectual Property Institute, UK Department of Trade and Industry, *Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice* (2004)

International Human Genome Sequencing Consortium, 'Finishing the Euchromatic Sequence of the Human Genome' 431*Nature* (2004)

Invest Australia/Biotechnology Australia, Australian Biotechnology: Number One in the Asia Pacific for Biotechnology Investment (2005) <http://investaustralia.hyperlink.net.au/media/IS_BIOTECH_English.pdf> at 3 October 2005

IP Australia, Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms, 1 <http://www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 6 June 2005

IP Australia, *Top 10 Technologies of Granted Standard Patents 92-03* <http://www.ipaustralia.gov.au/pdfs/statistics/Standard%20Grants%20by%20Tech%2092-03.xls> at 30 June 2005

J

Jorde Thomas M and Teece David J, Rule of Reason Analysis of Horizontal Arrangements: Agreements Designed to Advance Innovation and Commercialise Technology, (1993) 60 *Antitrust Law Journal* 579

K

Kanavos, Panos, 'Determinants of Market Structure in the International Biopharmaceutical Industry' in Organisation for Economic Cooperation and Development, Economic Aspects of Biotechnologies Related to Human Health: Part II: Biotechnology, Medical Innovation and the Economy: The Key Relationships (1998)

Kaplow, Louis The Patent-Antitrust Intersection: A Reappraisal (1984) 97 *Harvard Law Review* 1813

Kaplow, Louis, 'Extension of Monopoly Power Through Leveraging' (1985) 85 *Columbia Law Review* 515

Katz Ronald S and Safer Adam J, 'Should One Patent Court be Making Antitrust Law for the Whole Country?' (2002) 69 *Antitrust Law Journal* 687

Kauffman, Michael H, '*Image Technical Services Inc v Eastman Kodak Co*, Taking One Step Forward and Two Steps Back in Reconciling Intellectual Property Rights and Antitrust Liability' (1999) 34 *Wake Forest Law Review* 471

Kaysen Carl and Turner Donald F, *Antitrust Policy* (1959)

Kitch Edmund 'The Nature and Functions of the Patent System, (1977) 20 *Journal of Law and Economics* 265

Kitch, Edmund W, 'Elementary and Persistent Errors in the Economic Analysis of Intellectual Property' (2000) 53 *Vanderbilt Law Review* 1727

Klemperer Paul, 'How Broad Should the Scope of Patent Protection Be?' (1990) 21 *RAND Journal of Economics* 113

Kobak Jr, James B, 'Running the Gauntlet: Antitrust and Intellectual Property Pitfalls on the Two Sides of the Atlantic' (1996) 64 *Antitrust Law Journal* 341

Kobak Jr, James, 'Intellectual Property, Competition Law and Hidden Choices Between Original and Sequential Innovation' (1998) 3 *Virginia Journal of Law and Technology*, 6

Kobak Jr, James, 'The Federal Circuit as a Competition Law Court (2001) 83 *Journal of the Patent and Trademark Office Society* 527

Korah, Valentine,'Patents and Antitrust' (1997) 4 *Intellectual Property Quarterly* 395

Korah, Valentine, *An Introductory Guide to EC Competition Law and Practice* (7th ed, 1997)

Korah, Valentine, 'Access to Essential Facilities Under the *Commerce Act* in the Light of Experience in Australia, the European Union and The United States' (2000) 31 *Victoria University of Wellington Law Review* 231

Korah, Valentine, 'The Interface Between Intellectual Property and Antitrust: The European Experience' (2002) 69 *Antitrust Law Journal* 801

Korah, Valentine, 'Draft Block Exemption for Technology Transfer' (2004) 25(5) *European Competition Law Review* 247

L

Landes William M and Posner Richard A, *The Economic Structure of Intellectual Property Law* (2003)

Landrigan, Mitchell G, 'The Delineation of Sub-Markets Under *TPA* Part IV' (1997) 5 *Competition and Consumer Law Journal* 58

Landrigan, Mitchell, 'The Temporal Dimension of a Market: Illustrations from Case Law and the US Merger Guidelines' (1997) 5 *Trade Practices Law Journal* 242

Landrigan Mitchell, Peters A and Soon J, 'An Effects Test Under s 46 of the Trade Practices Act: Identifying the Real Effects' (2002) 9 *Competition and Consumer Law Journal* 258

Langenfeld, James, 'Intellectual Property and Antitrust: Steps Toward Striking a Balance' (2001) *Case Western Reserve Law Review* 91

Lao, Marina, 'Unilateral Refusals to Sell or License Intellectual Property and the Antitrust Duty to Deal' (1999) 9 *Cornell Journal of Law and Public Policy* 193

Law Council of Australia, *Supplementary Submission by the Trade Practices Committee of the Business Law Section of the Law Council of Australia to the Senate Economics References Committee*, 26 May 2004

Lawson Charles, 'Some Economic Questions for Biotechnology Patenting in Australia' (2000) 41 *IP Forum* 10

Lawson, Charles, 'Patents, Substitution, Imitation and Competition: Amgen, TKT and the Erythropoietin Patents' (2001) 37 *ACCC Journal* 22

Lawson, Charles, 'Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition' (2002) 30 *Federal Law Review* 97

Lawson, Charles, 'Patent Privileges and the National Competition Policy – Patent Scope and Allocation?' (2005) 33 *Australian Business Law Review* 7

Lawson Charles and Pickering Catherine, 'Patenting Genetic Materials – Failing to Reflect the Value of Variation in DNA, RNA and Amino Acids' (2000) 11 *Australian Intellectual Property Journal* 69

Lemley, Mark A, 'An Empirical Study of the Twenty-Year Patent Term' (1994) 22 AIPLA Quarterly Journal 369

Lemley, Mark A, 'Antitrust and the Internet Standardization Problem' (1996) 28 *Connecticut Law Review* 1041

Lemley, Mark A, 'The Economics of Improvement in Intellectual Property Law' (1997) 75 *Texas Law Review* 989

Lemley, Mark A, 'Rational Ignorance at the Patent Office' (2001) 95 *Northwestern University Law Review* 1495

Lemley, Mark A, 'Ex Ante versus Ex Post Justifications for Intellectual Property' (2004) 71 *University of Chicago Law Review* 129

Leonard, Debra DG, Medical Practice and Gene Patents: A Personal Perspective 77 *Academic Medicine* (2002): 1388

Lerner Josh and Tsai Alexander, *Do Equity Financing Cycles Matter? Evidence from Biotechnology Alliances* National Bureau of Economic Research, Working Paper No 7464, (2000)

Levin Richard C, Cohen Wesley M, and Mowery David C, 'R&D Appropriability, Opportunity and Market Structure: New Evidence on Some Schumpeterian Hypotheses (1985) 75 *American Economic Review* 20

Levin Richard C, Klevorick Alvin K, Nelson Richard R, and Winter Sidney G, 'Appropriating the Returns from Industrial Research and Development', (1987) 3 *Brookings Papers on Economics Activity* 783

Lindgren, Justice Kevin, 'The Interface Between Intellectual Property and Antitrust: Some Current Issues in Australia' (2005) 16 *Australian Intellectual Property Journal* 76

Lipsky Jr Abbott B, and Gregory Sidak J, 'Essential Facilities' (1999) 51 *Stanford Law Review* 1187

Long, Clarisa, 'Patents and Cumulative Innovation' (2000) 2 *Washington University Journal of Law and Policy* 229

Long, Clarisa, 'Proprietary Rights and Why Initial Allocations Matter' (2000) 49 *Emory Law Journal* 823

Lowe, Phillip, *Speech Delivered by Phillip Lowe at the Fordham Corporate Law Institute Thritieth Annual Conference on International Antitrust Law and Policy Conference*, Washington, 23 October 2003 <http://europa.eu.int/comm/competition/speeches/text/sp2003_040_en.pdf> at 17 November 2004

Ludlow, Karinne, 'Genetically Modified Organisms and Their Products as Patentable Subject Matter in Australia' [1999] *European Intellectual Property Review* 298

M

Machlup Fritz, *An Economic Review of the Patent System* (1958)

Machlup Fritz and Penrose Edith, 'The Patent Controversy in the Nineteenth Century' (1950) 10(1) *Journal of Economic History* 1

Mackie-Mason, 'What to do About Unilateral Refusals to License?' (2002)

Mackie-Mason, Jeffrey K, 'Antitrust Immunity for Refusals to Deal in (Intellectual) Property is a Slippery Slope' (2002), July, *The Antitrust Source* 1, <http://www.antitrustsource.com> at 1 November 2004

Mansfield, Edwin, 'Patents and Innovation: An Empirical Study' (1986) 32(2) *Management Science* 173

Mansfield, Edwin, 'Academic Research Underlying Innovations: Sources, Characteristics, and Financing', (1995) 77 *Review of Economics and Statistics*, 55

Manual of Patent Examining Procedure, (8th ed, Feb 2003 revision 2003) <http://www.uspto.gov/web/offices/pac/mpep/index.html> at 25 August 2005

Marquardt Paul D and Leddy Mark, 'The Essential Facilities Doctrine and Intellectual Property: A Response to Pitofsky, Patterson and Hooks (2003) 70 *Antitrust Law Journal* 847

Marshall, Brenda, 'Refusals to Supply Under Section 46 of the *Trade Practices Act*: Misuse of Market Power or Legitimate Business Conduct?' (1996) 8 *Bond Law Review* 182

Marshall, Brenda, 'The Relevance of a Legitimate Business Rationale Under Section 46 of the *Trade Practices Act*' (2003) 8(1) *Deakin Law Review* 49

Marshall, Brenda, 'The Resolution of Access Disputes Under Section 46 of the *Trade Practices Act*' (2003) 22(1) *University of Tasmania Law Review* 9

Marshall Brenda and Mulheron Rachel, 'Declarations of Essential Services Under Part IIIA of the *Trade Practices Act*: A 'Discipline' on Access Reform' (2003) 31 *University of Western Australia Law Review* 226

Marshall, Eliot, 'A Showdown Over Gene Fragments' 266 *Science* (1994): 208

Marshall, Eliot, 'Varmus to Rule in Fight Over Cell-Sorting Technology', 276 (1997) *Science* 1488

Marshall, Elliot, 'Patent on HIV Receptor Provokes an Outcry' 287 *Science* (2000): 1375

Mazzoleni Roberto and Nelson Richard R, 'Economic Theories about the Benefits and Costs of Patents' (1998) 32(4) *Journal of Economic Issues* 1031

McCurdy, Gregory, 'Intellectual Property and Competition: Does the Essential Facilities Doctrine Shed Any New Light?' (2003) 25(10) *European Intellectual Property Review* 472

McKeough, Jill, 'Is Intellectual Property different or are all unhappy monopolists similar?' (2003) 26 *University of New South Wales Law Journal* 289

McKeough Jill, Bowrey Kathy and Griffith Philip, *Intellectual Property: Commentary and Materials*, (3rd ed 2002) 3

McMahon, Kathryn, 'Refusals to Supply by Corporations With Substantial Market Power' (1994) 22 *Australian Business Law Review* 7

Mehta Kirtikumar and Peeperkorn Luc, 'Licensing of Intellectual Property Under EU Competition Rules: The Review of the Technology Transfer Block Exemption Regulation' *Statement to the FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, Washington, (2002) <http://www.ftc.gov/opp/intellect/020522mehtadoc.pdf> at 12 March 2004

Meltz, David, '"Market Entry – See Adjoining Map": *Melway* and the Right Not to Supply' (2002) 10 *Trade Practices Law Journal* 96

Merges Robert M and Duffy John F, *Patent Law and Policy: Cases and Materials* (3rd ed, 2002)

Merges Robert P, 'Of Property Rules, Coase, and Intellectual Property' (1994) 94 *Columbia Law Review* 2655

Merges, Robert P, 'Intellectual property and Bargaining Breakdown: The Case of Blocking Patents; (1994) 62 *Tennessee Law Review* 75

Merges, Robert P, 'Contracting into Liability Rules: Intellectual property and Collective Rights Organizations', (1996) 84 *California Law Review* 1293

Merges, Robert P, 'Antitrust Review of Patent Acquisitions: Property Rights, Firm Boundaries, and Organisation' in Anderson Robert D and Gallini Nancy T, (eds), *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (1998) 111

Merges Robert P, Menell Peter S and Lemley Mark A, *Intellectual Property in the New Technological Age* (2nd ed, 2000)

Merges Robert P, Menell Peter S and Lemley Mark A, *Intellectual Property in the New Technological Age* (3rd ed, 2003)

Merges Robert P and Nelson Richard R, 'On the Complex Economics of Patent Scope' (1990) 90 *Columbia Law Review* 839

Merges Robert P and Nelson Richard R, 'Market Structure and Technical Advance: The Role of Patent Scope Decisions' in Jorde Thomas M and Teece David J, *Antitrust, Innovation and Competitiveness* (New York: Oxford University Press, 1992)

Merrett, Alexandra, 'The Court Speaks for Itself: What Australian Decisions Say About Assessing Market Power for the Purposes of s 46 of the TPA' (2004) 11 *Competition and Consumer Law Journal* 330

Merrill Stephen A, Levin Richard C and Myers Mark B, (eds) *A Patent System for the 21st Century* (2004)

Merton, Robert K, The Normative Structure of Science, in Robert K Merton (ed), *The Sociology of Science: Theoretical & Empirical Investigation* (1973) 267

Merz Jon F, Kriss Antigone G, Leonard Debra DG and Cho Mildred K, 'Diagnostic Testing Fails the Test' 415 *Nature* (2002): 577

Mikhail, Peter, '*Hopkins v CellPro*: An Illustration that Patenting and Exclusive Licensing of Fundamental Science is Not Always in the Public Interest' (2000) 13 *Harvard Journal of Law and Technology* 375

Monti, Mario, 'EU Competition Policy After May 2004', *Paper presented at the Fordham Annual Conference on International Antitrust Law and Policy, New York,* (2003) <http://europa.eu.int/comm/competition/speeches/index_speeches_by_the_commissioner.html> at 31 May 2004

Mowery David C, Nelson Richard R, Sampat Bhaven N and Ziedonis Arvids A, 'The Growth of Patenting and Licensing by US Universities: an Assessment of the Effects of the *Bayh-Dole Act* of 1980', (2001) 1(30) *Research Policy* 99

Mueller, Janice, 'No "Dilletante" Affair: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools' (2001) 76 *Washington Law Review* 1

Myrick Ronald and Gleklen Jonathon, 'Antitrust Liability for the Exercise of Intellectual Property Rights Under US Law' (*Paper presented at a meeting of the International Association for the Protection of Intellectual Property*, Lisbon, 20 June 2002) <www.aippi.org/reports/Vortrag_Myrick.pdf> at 28 August 2005

N

Narciso, Alessandra, '*IMS Health* or the Question Whether Intellectual Property Still Deserves a Specific Approach in a Free Market Economy' (2003) 4 *Intellectual Property Quarterly* 445

National Competition Council, Parliament of Australia, *Compendium of National Competition Policy Agreements* (1997)

National Competition Council, Parliament of Australia, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974*, Draft Report, (1998)

National Competition Council, Parliament of Australia, *Review of Sections 51(2) and 51(3) of the* Trade Practices Act *1974: Final Report* (1999)

National Competition Council, *National Competition Council Legislation Review Compendium* (4th ed, 2002)

National Health and Medical Research Council, *Interim Guidelines: Intellectual Property Management for Publicly Funded Research* (2001)

National Institutes of Health, Basic Guidelines for the Transfer of Research Tools To and From Recipients of NIH Funds in National Institutes of Health, Report of the National Institutes of Health Working Group on Research Tools (1998)

National Institutes of Health, *Report of the National Institutes of Health Working Group on Research Tools* (1998)
<http://www.nih.gov./news/researchtools/index.htm> at 3 October 2002

National Research Council (NRC), *Intellectual Property Rights and Research Tools in Molecular Biology* (1997)

Nicol, Dianne, 'Human Gene Patents: Under Whose Control?' (2003) 179(4) *Medical Journal of Australia* 181

Nicol, Dianne, *Patenting of Human Genetic Material in Australia* (Masters Thesis, University of Tasmania, 1997)

Nicol, Dianne, 'On the Legality of Gene Patents' submitted to *Melbourne University Law Review*

Nicol Dianne and Nielsen Jane 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347

Nicol Dianne and Nielsen Jane, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6

Nicol Dianne and Nielsen Jane, 'Australian Medical Biotechnology: Navigating a Complex Patent Landscape' (2005) *European Intellectual Property Review* (forthcoming)

Nielsen, Jane, 'Biotechnology Patent Licensing Agreements and Anti-Competitive Conduct' in Centre for Law and Genetics (ed) *Regulating the New Frontiers: Legal Issues in Biotechnology*, Centre for Law and Genetics Occasional Paper No 4 (2001)

Nielsen, Jane, 'Reach-Through Rights in Biomedical Patent Licensing: A Comparative Analysis of their Anti-Competitive Reach' (2004) 32 *Federal Law Review* 169

Nielsen Jane and Nicol Dianne, 'Pharmaceuticals and Patents: The Conundrum of Access and Incentive' (2002) 13 *Australian Intellectual Property Review* 21

Nielsen Jane and Nicol Dianne, 'Gene Patenting and Human Health: The ALRC's Report on Genes and Ingenuity' (2005) 20(10) *Australian and New Zealand Trade Practices Law Bulletin* 153

NIH News Release 'International Human Genome Sequencing Consortium Describes Finished Human Genome Sequence', (20 October 2004) <http://www.genome.gov/12513430> at 26 May 2005

Nordhaus William D, *Invention, Growth and Welfare: A Theoretical Treatment of Technological Change* (1969)

Norman Neville R and Williams Philip L, 'The Analysis of Market and Competition Under the *Trade Practices Act*: Towards the Resolution of Some Hitherto Unresolved Issues' (1983) 11 *Australian Business Law Review* 396

Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper*, (2002)

Nyskohus David, Then Ee-Ling, Nicoll Paul, Commonwealth of Australia, *Intellectual Property Policies and Practices in Commonwealth Agencies*, (2004)

O

O'Bryan, Michael, 'Refusal to License Intellectual Property Under the Australian *Trade Practices Act*' (1992) May *Patent World*, 10

O'Bryan, Michael, 'Section 46: Law or Economics' (1993) 1 *Competition and Consumer Law Journal* 64

O'Bryan, Michael, 'Access Pricing: Law Before Economics?' (1996) 4 *Competition and Consumer Law Journal* 20

O'Rourke, Maureen, 'Striking a Delicate Balance: Intellectual Property, Antitrust, Contract and Standardisation in the Computer Industry' (1998) 12 *Harvard Journal of Law and Technology* 1

Oddie Carolyn and Eyers Patrick, 'Erosion of Rights – or Redressing the Balance: Competition Challenges to Intellectual Property Rights' (2004) 12 *Trade Practices Law Journal* 6

Organisation for Economic Co-operation and Development, *Glossary of Industrial Organisation Economics and Competition Law* (undated)

Organisation for Economic Cooperation and Development, *Competition Policy and Intellectual Property Rights* (1998)

Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies*, (Berlin: OECD, 2002), <http://www.oecd.org/dataoecd/42/21/2491084.pdf> at 18 November 2003

Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies*, (2002)

Organisation for Economic Co-operation and Development, *Patents and Innovation: Trends and Policy Challenges* (2004) 29

Organisation for Economic Cooperation and Development, *Patents and Innovation: Trends and Policy Challenges* (2004)

Organisation for Economic Cooperation and Development, *Compendium of Patent Statistics*, Internal Working Document (2004)

Organisation for Economic Co-operation and Development, *Draft Guidelines for the Licensing of Genetic Inventions*, (1 February 2005) <http://www.oecd.org/document> at 22 June 2005

Oettinger, Nicolas, '*Sherman Act* Violations: Refusal to License Intellectual Property: *In re Independent Service Organisation Antitrust Litigation* (2001) 16 *Berkley Technology Law Journal* 323

Oldham, Paul, Global Status and Trends in Intellectual Property Claims: Microorganisms, *Submission to the Executive Secretary of the Convention on Biological Diversity* (2004)

Opi, Sergio Baches, 'The Application of the Essential Facilities Doctrine to Intellectual Property Licensing in the European Union and the United States: Are Intellectual Property Rights Still Sacrosanct?' (2001) 11 *Fordham Intellectual Property, Media and Entertainment Law Journal* 409

Overd Alan and Bishop Bill, 'Essential Facilities: The Rising Tide' [1998] 19(4) *European Competition Law Review* 183

P

Palombi, Luigi, 'The Impact of TRIPS on the Validity of the European Biotechnology Directive' (2005) 2(2) *Journal of International Biotechnology Law* 62

Pate, R Hewitt, 'Refusals to Deal and Intellectual Property Rights' (2002) 10 *George Mason Law Review* 429

Patterson, Mark R, 'When is Property Intellectual? The Leveraging Problem?' (2000) 73 *South California Law Review* 1133

Patterson, Ross H, 'Making Hilmer Clear: The Essential Facility Recommendation and the New Zealand Experience' (1994) 2 *Trade Practices Law Journal* 131

Pengilley, Warren, 'Patents and Trade Practices – Competition Policies in Conflict?' (1977) *Australian Business Law Review* 172

Pengilley, Warren, Antitrust Law versus Intellectual Property Law: Where is the Interface? (1989) 4 *Canterbury Law Review* 103

Pengilley, Warren, '*Queensland Wire* and its Progeny Decisions: How Competent are the Courts to Determine Supply Prices and Trading Conditions?' (1991) 21 *Western Australia Law Review* 225

Pengilley, Warren, 'Hilmer and "Essential Facilities"' (1994) *University of New South Wales Law Journal* 1

Pengilley, Warren, 'The National Competition Policy Draft Legislative Package: The Proposed Access Regime' (1995) 2 *Competition and Consumer Law Journal* 244

Pengilley, Warren, 'The Privy Council Speaks on Essential Facilities Access in New Zealand: What are the Australasian Lessons?' (1995) 3 *Competition and Consumer Law Journal 26*

Pengilley, Warren, 'Misuse of Market Power: The Unbearable Uncertainties Facing Australian Management' (2000) 8 *Trade Practices Law Journal* 56

Pengilley, Warren, 'Misuse of Market Power in Australia: Are the Tests Now Those of Fairness, Efficiency or Business Justification?' (2001) 8 *Canterbury Law Review* 70

Pengilley, Warren, '*Rural Press*: A Controversial High Court Decision on Misuse of Market Power and Other Issues' (2004) 19(10) *Australian and New Zealand Trade Practices Law Bulletin* 137

Pengilley, Warren, 'Thirty Years of the Trade Practices Act: Some Thematic Conclusions' (2004) 12 *Competition and Consumer Law Journal* 1

Pitofsky, Robert, 'Challenges of the New Economy: Issues at the Intersection of Antitrust and Intellectual Property' (2001) 68 *Antitrust Law Journal* 913

Pitofsky Robert, Patterson Donna and Hooks Jonathon, 'The Essential Facilities Doctrine Under US Antitrust Law' (2002) 70 *Antitrust Law Journal* 443

Pollack, Andrew, 'Justices Expand Rights to Experiment with Patented Drugs' *The New York Times* (14 June 2005)

Posner, Richard A, *Antitrust Law: An Economic Perspective* (1976)

Powell Walter W, and Owen-Smith Jason, 'Universities and the Market for Intellectual Property in the Life Sciences' (1998) 17(2) *Journal of Policy Analysis and Management* 253

Powell Walter W, Koput Kenneth W, and Smith-Doerr Laurel, 'Interorganizational Collaboration and the Locus of Innovation: Networks of Learning in Biotechnology' (1996) 41 *Administrative Science Quarterly* 116

Prime Minister's Science, Engineering and Innovation Council, Commonwealth of Australia, *Third Meeting Background Paper, Innovation in Medical Biotechnology*

(1999)
<http://www.dest.gov.au/sectors/science_innovation/publications_resources/profiles/medical_biotech.htm> at 30 May 2005

Prince, Peter, '*Queensland Wire* and Efficiency – What Can Australia Learn From US and New Zealand Refusal to Deal Cases?' (1998) 5 *Competition and Consumer Law Journal* 237

Productivity Commission, Parliament of Australia, *Review of National Policy Reforms*, Inquiry Report No 33 (2005)

Q

Queensland Government, *Queensland Biotechnology Strategic Plan 2005-2015: Biotechnology – Setting New Horizons* (2005)

R

Rai Arti K and Eisenberg Rebecca S, 'The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine (2003) 66 *Law and Contemporary Problems* 289

Rai, Arti K 'Regulating Scientific Research: Intellectual Property Rights and the Norms of Science' (1999) 94 *Northwestern University Law Review* 77

Rai, Arti, 'Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust' (2001) 16 *Berkeley Technology Law Journal* 813

Rai, Arti K, 'Genome Patents: A Case Study in Patenting Research Tools' (2002) 77 *Academic Medicine* 1369

Rai, Arti K, 'Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform' (2003) 103 *Columbia Law Review* 1035

Ratliff John, Gutermuth Axel and Bhojnani Rajeshree, 'European Commission Proposes New Competition Rules for Technology Licensing', (2003) <http://www.wilmer.com/files/tbl_s29Publications/FileUpload5665/2904/News_2152432791802190115151013 00.pdf> at 31 May 2004

Reichman, Jerome H, 'Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement' (1995) 29 *International Lawyer* 345

Richardson, Megan, 'The High Court of Australia Revisits Misuse of Market Power: Implications for Australian Intellectual Property Rightholders' (2002) 24(2) *European Intellectual Property Review* 81

Ricketson Sam and Richardson Megan, *Intellectual Property: Cases, Materials and Commentary*, (1998) 664

Ridyard, Derek, 'Essential Facilities and the Obligation to Supply Competitors Under the UK and EC Competition Law' (1996) 17(8) *European Competition Law Review* 438

Rimmer, Matthew, 'The Attack of the Clones: Patent Law and Stem Cell Research' (2003) 10 *Journal of Law and Medicine* 488

Rimmer, Matthew, (2003) 'Myriad Genetics: Patent Law and Genetic Testing' 25(1) *European Intellectual Property Review* 20.

Robertson, Donald, 'Time and Risk: The Temporal Dimension of Competition Analysis and the Role of Long-term Contracts' (1998) 26 *Australian Business Law Review* 273

Robertson, Donald, 'The Primacy of "Purpose" in Competition Law – Part 1' (2001) 9 *Competition and Consumer Law Journal* 101

Rodriguez Hurley, Suzzette, 'Failing to Balance Patent Rights and Antitrust Concerns: The Federal Circuit's holding in *In re Independent Service Organisations Antitrust Litigation*' (2004) 13 *Federal Circuit Bar Journal* 475

Roffe, Pedro, 'Control of Anti-Competitive Practices in Contractual Licences Under the TRIPs Agreement' in Correa Carlos M and Yusuf Abdulqawi A, (eds), *Intellectual Property and International Trade: The TRIPs Agreement* (1998)

Rogers, Elizabeth I, 'The Phoenix Precedents: The Unexpected Rebirth of Regional Circuit Jurisdiction Over Patent Appeals and the Need for a Considered Congressional Response' (2003) 16 *Harvard Journal of Law and Technology* 411

Round, David K, 'Market Definition in Australian Antitrust: Time for a Changed Approach?' (1996) 9 *Corporate and Business Law Journal* 193

S

Saunders, Tom, 'Renting Space on the Shoulders of Giants: *Madey* and the Future of the Experimental Use Doctrine' (2003) 113 *Yale Law Journal* 261

Scherer, F Michael, 'Market Structure and the Employment of Scientists and Engineers' (1967) 57 *American Economic Review* 524

Scherer F Michael, 'Nordhaus's Theory of Optimal Patent Life: A Geometric Reinterpretation' (1972) 62 *American Economic Review* 422

Scherer F Michael and Ross David, *Industrial Market Structure and Economic Performance*, (3rd ed, 1990)

Scherer, F Michael, 'Comments', in Robert Anderson and Nancy Gallini, (eds), *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (1998)

Scherer F Michael, 'The Economics of Human Gene Patents' 77 *Academic Medicine* (2002): 1348

Schmidt, Hedvig K S, 'Article 82's "Exceptional Circumstances that Restrict Intellectual Property Rights' (2002) 23(5) *European Competition Law Review* 210

Schumpeter, Joseph M, *Capitalism, Socialism and Democracy* (1942)

Scotchmer, Suzanne, 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law' (1991) 5 *The Journal of Economic Perspectives* 29

Scotchmer, Suzanne, 'Protecting Early Innovators: Should Second-Generation Products be Patentable?' (1996) 27 *The RAND Journal of Economics* 322

Scotchmer, Suzanne, 'R&D Joint Ventures and Other Cooperative Arrangements' in Anderson Robert D and Gallini Nancy T (eds) *Competition Policy and Intellectual property in the Knowledge Based Economy*, (1998) 203

Scotchmer, Suzanne, *Cumulative Innovation in Theory and Practice*, Goldman School of Public Policy Working Paper 240 (1999) 1

Seah, Weeliem, 'Fair Competition or Unfair Predation: Identifying the Misuse of Market Power Under Section 46' (2001) 9 *Trade Practices Law Journal* 236

Section of Antitrust Law, American Bar Association, *The Economics of Innovation: A Survey*, July 2002 <http://www.ftc.gov/opp/intellect/0207salabasrvy.pdf> at 29 April 2004

Sell, Susan K, *Power and Ideas: North-South Politics of Intellectual Property and Antitrust* (1998)

Sell, Susan K, *Private Power, Public Law: The Globalisation of Intellectual Property Rights* (2003)

Senate Economics References Committee, Parliament of Australia, *The Effectiveness of the Trade Practices Act 1974 in Protecting Small Business*, (2004)

Shapiro, Carl, *Competition Policy in the Information Economy* (1999), paper obtained from author's website < http://faculty.haas.berkeley.edu/shapiro/comppolicy.pdf> at 15 November 2004, 4-6

She Xinwei, Jiang Zhaoshi, Clark Royden A, Liu Ge, Cheng Ze, Tuzun Eray, Church Deanna M, Sutton Granger, Halpern Aaron L & Eichler Evan E, 'Shotgun Sequence Assembly and Recent Segmental Duplications Within the Human Genome' *Nature* 431 (2004)

Shenton French, Justice Robert, 'Competition Law – Covering a Multitude of Sins' (2004) 12 *Competition and Consumer Law Journal* 125

Sher, Brian, 'The Last of the Steam-Powered Trains: Modernising Article 82' (2004) 25(5) *European Competition Law Review* 243

Smith Rhonda and Round David K, 'The Puberty Blues of Competition Analysis: Section 46' (2001) 9 *Competition and Consumer Law Journal* 189

Smith Rhonda and Round David K, 'Section 46: A Strategic Analysis of *Boral*' (2002) 30 *Australian Business Law Review* 202

Smith Rhonda L and Trindade Rachel, 'It's Time: The Temporal Dimension of Competition Analysis' (2004) 12 *Competition and Consumer Law Journal* 142

Smith R and Walker J, 'Australian Trade Practices and the Emerging Role of 'Commercial Reality' versus Substitution in Market Definition' (1997) 5 *Competition and Consumer Law Journal* 1

Smith Rhonda and Walker Jill, 'Part IIIA Efficiency and Functional Markets' (1998) 5 *Australian Journal of Corporate Law* 183

Steinwall, Ray, '*Melway* and Monopolisation – Some Observations on the High Court's Decision' (2001) 9 *Competition and Consumer Law Journal* 93

Stempel Scott A and Terzaken John F, 'Casting a Long IP Shadow Over Antitrust Jurisprudence: The Federal Circuit's Expanding Jurisdictional Reach' (2002) 69 *Antitrust Law Journal* 711

Stigler, George, *The Organisation of Industry* (1968)

Stothers, Christopher, 'Refusal to Supply as Abuse of Dominant Position: Essential Facilities in the European Union' (2001) 22(7) *European Competition Law Review* 256

Stothers, Christopher, 'The End of Exclusivity: Abuse of Intellectual Property Rights in the EU' (2002) 24(2) *European Intellectual Property Review* 86

Stothers, Christopher, '*IMS Health* and its Implications for Compulsory Licensing in Europe' (2004) 26(10) *European Intellectual Property Review* 467

Straus, Joseph, 'An Updating Concerning the Protection of Biotechnological Inventions Including the Scope of Patents for Genes – An Academic Point of View' (2003) *Paper presented at the Conference of Patent Judges*, Special Edition

Straus Joseph, Holzapfel Henrik and Lindenmeir Matthias, *Empirical Survey on Genetic Invention and Patent Law*, unpublished report (2002)

Strausberg Robert L, Simpson Andrew J G, Old Lloyd J & Riggins Gregory J, 'Oncogenomics and the Development of New Cancer Therapies' *Nature* 429, (2004)

Subcommittee on Courts, the Internet, and Intellectual Property, Committee on the Judiciary, US House of Representatives, One Hundredth Ninth Congress, *Holmes Group, The Federal Circuit and the State of Patent Appeals* (March 17 2005) Serial No 109-7 <http://judiciary.house.gov/Oversight.aspx?ID=117> at 9 August 2005

Subiotto Romano and O'Donoghue Robert, 'Defining the Scope of the Duty of Dominant Firms to Deal with Existing Customers Under Article 82 EC' (2003) 24 *European Competition Law Review* 683

Sufrin, Brenda, 'The *IMS* Case' [2004] *Competition Law* 18

Sulston John and Ferry Georgina, *The Common Thread: Science, Politics, Ethics and the Human Genome* (2002)

T

Temple Lang, John, 'Defining Legitimate Competition: Companies Duties to Supply Competitors and Access to Essential Facilities' [1994] *Fordham Corporate Law Institute* 245

Temple Lang, John, 'European Community Antitrust Law: Innovation Markets and High Technology Industries' (1997) 20 *Fordham International Law Journal* 717

Temple Lang, John, *Compulsory Licensing of Intellectual Property in the European Community Antitrust Law*, Paper Prepared for the Department of Justice/Federal Trade Commission Hearings, Washington DC, 19 April 2002

Thompson, Larry D, 'Adrift on a Sea of Uncertainty: Preserving Uniformity in Patent Law Post-*Vornado* Through Deference to the Federal Circuit' (2004) 92 *Georgetown Law Journal* 523

Tom Willard K and Newberg Joshua K, 'US Enforcement Approaches to the Antitrust-Intellectual Property Interface' in Anderson Robert T and Gallini Nancy T, (eds), *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (1998)

Trade Practices Act Review Committee, Parliament of Australia, *Trade Practices Act Review* (2003)

Trade Practices Commission, *Misuse of Market Power Background Paper* (1990)

Trade Practices Commission, *Background Paper: Application of the Trade Practices Act to Intellectual Property* (1991)

Trade Practices Review Committee, *Report to the Minister for Business and Consumer Affairs*, 1976

Trade Practices Consultative Committee, *Small Business and the Trade Practices Act*, 1979

Trade Practices Review Committee, *Review of the Competition Provisions of the Trade Practices Act* (January 2003) <http://www.tpareview.treasury.gov.au/content/report.asp> (at 15 July 2004).

Treacy, Pat, 'Essential Facilities – Is the Tide Turning?' (1998) 19 *European Competition Law Review* 501

TRIPS Council (2003) *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm> at 25 August 2005

Tucker, Philip, 'Refusal to License Intellectual Property Rights and Misuse of Market Power – Where is the Line in the Sand?' (1999) 10 *Australian Intellectual Property Journal* 78

Turnbull, Sarah A, 'Barriers to Entry, Article 86 EC and the Abuse of a Dominant Position: An Economic Critique of European Community Competition Law' (1996) 17(2) *European Competition Law Review* 96

U

United States Department of Commerce, *A Survey of the Use of Biotechnology in US Industry* (2003)

United States Patent and Trademark Office, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000)

US Department of Justice and the Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property*, (1995) <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm> at 27 October 2003

V

Van Caenagem, William, *Intellectual Property*, (2001) 137

Van Melle, Abraham I, 'Refusals to License Intellectual Property Rights: The Impact of *RTE v EC Commission* (*Magill*) on Australian and New Zealand Competition Law' (1997) 25 *Australian Business Law Review* 4

Veljanovski, Cento, 'The Economics of the Relevant Market in EC Competition Law' (1998) *International Review of Competition Law* 4

Venit J and Kallaugher J, 'Essential Facilities: A Comparative Law Approach' [1994] *Fordham Law Institute* 315

Vinje, Thomas C, 'The Final Word on *Magill*: The Judgment of the ECJ' (1995) 17(6) *European Intellectual Property Review* 297

Vogel, Gretchen, 'Stem Cell Claims Face Legal Hurdles' 305 *Science* (2004): 1887

Volcker, Sven B, 'The Implications of Microsoft and IMS Health: Interesting Times for Dominant Intellectual Property Holders in Europe' (2004) *Competition Law Insight* 14

W

Walpole Ian R, Dawkins Hugh J S, Sinden Peter D and O'Leary Peter C, 'Human Gene Patents: The Possible Impacts on Genetic Service Providers' (2003) 179 *Medical Journal of Australia* 203

Walsh John P, Arora Ashish and Cohen Wesley M, 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in Cohen Wesley M and Merrill Stephen A, (eds.), *Patents in the Knowledge-Based Economy* (2003)

Walsh John P, Arora Ashish and Cohen Wesley M, 'Working Through the Patent Problem', 299 *Science* (2003): 1021

Walsh John P, Arora, Ashish and Cohen Wesley M, 'Working Through the Patent Problem', 299 *Science* (2003): 1021

Watson, James D, *The Double Helix: A Personal Account of the Discovery of the Structure of DNA* (2001)

Watson J and Crick F, 'A Structure for Deoxyribose Nucleic Acid' (1953) 171 *Nature* 737

Webster, Elizabeth, *Forces Shaping Firms' Decisions to Innovate: Evidence from Large Australian Organisations* (Working Paper No 03/03, Intellectual Property Research Institute of Australia, 2003)

Welsman, Sandra, 'In *Queensland Wire*, The High Court has Provided an Elegant Backstop to "Use" of Market Power' (1995) *Competition and Consumer Law Journal* 189

Whish, Richard, *Competition Law* (4th ed, 2001)

Willard K Tom and Joshua A Newberg, 'Antitrust and Intellectual Property: From Separate Spheres to Unified Field' (1997) 66 *Antitrust Law Journal* 167

X, Y, Z

Yeung, Karen, 'The Courtroom Economist in Australian Anti-trust Litigation: An Underutilised Resource?' (1992) *Australian Business Law Review* 461

Yip, George, *Barriers to Entry: A Corporate-Strategy Perspective* (1982)

Zumbo, Frank, 'The *Boral* Case: Has the High Court Done Justice to s 46?' (2003) 11 *Trade Practices Law Journal* 1999

Zumbo, Frank, 'The High Court's *Rural Press* Decision: The End of Section 46 as a Deterrent Against Abuses of Market Power?' (2004) 12 *Trade Practices Law Journal* 126