PATENTING OF HUMAN GENETIC MATERIAL IN AUSTRALIA

by

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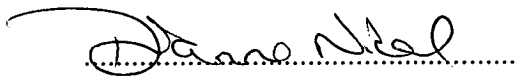
Candidate's Statement

I declare that the work presented in 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 to the best of my knowledge and belief no material previously published or written by another person except where due acknowledgment is made in the text of the Thesis.



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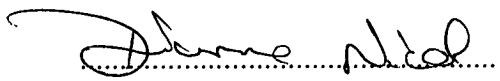

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ABSTRACT

Attempts to patent human genes by large biotechnology companies are viewed with intense suspicion within the wider community. Religious groups, indigenous peoples, scientists and even companies themselves are beginning to recognise that excessively broad patents on genes may be inappropriate. Research on human genes, on the other hand, is recognised as providing many benefits to society, particularly in the diagnosis and treatment of genetic diseases. Effective diagnosis and treatment will require considerable investment in research by biotechnology companies. Companies will not provide that investment without protection of the type usually afforded by the patent system. Tensions between the need for companies to patent their research and the perceived inappropriateness of patenting human genes have not yet been fully explored in Australia. My aim in this thesis is to explore these tensions and suggest means for reconciliation.

The threads of the debate on patenting genes are difficult to unravel. Before a full assessment of the issues can be made, a description of the two highly technical areas of Australian patent law and genetics is required. I first provide those descriptive backgrounds, thereby establishing the framework around which the other issues can be assessed.

1. The ethics of human genetic research. Regimes already exist outside the patent system for ethical scrutiny of all biomedical research, including human genetic research.
Human genetic research also raises questions involving invasion of privacy and genetic discrimination, for which the law may not yet provide adequate safeguards.

2. The role of commercialisation in human genetic research and its applications.
Development of genetic products occurs within a competitive commercial environment. There is a need to moderate the excesses that might occur in a purely market-driven system.

3. Patenting of human genetic material.
Australian patent law principally requires:

- an invention

- full disclosure
- commercial applicability
- novelty and
- an inventive step.

Provided that these requirements are met human genetic material is patentable, apart from gene sequences of unknown function and naturally occurring sequences.

Patent rights should not be confused with real property rights. Nor should human genes be confused with life and humanity. Patents merely provide a temporary right to exploit an invention, they do not imply ownership. Once this distinction is realised many of the ethical concerns are adequately addressed by the current system. I conclude by recommending that the tensions associated with patenting human genetic material can be resolved within the patent system, principally through limitations that already exist but are seldom used.

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INTRODUCTION

The science of genetics has changed radically over the last two decades since the advent of genetic engineering, which enables the identification, isolation and mass production of genes, whether they be from humans or from other species of animals or plants. What was until recently thought of as the province of science fiction is now mainstream genetic research, which has spawned a thriving new biotechnology industry. That industry has made major contributions to new and improved technologies in the areas of agriculture and pharmaceuticals. In the medical field, however, the biotechnological revolution has been slower to provide concrete improvements to existing techniques for the treatment of human genetic disease. Nevertheless, there is a distinct possibility that in the next two decades techniques which have their roots in biotechnology will become more routinely available for diagnosis and treatment of human genetic diseases and other more common diseases that have genetic components. These developments will have a number of consequences socially, economically and legally.

Patents are now a recognised means by which investment in all areas of research and development is encouraged, by providing a limited and temporary right to exploit inventions and to licence others to do the same. However, whether patents are the appropriate mechanism for encouraging investment by the biotechnology industry in human genetic research is a matter of debate. On the one hand, it could be argued that commercialisation of human genetic research by the biotechnology industry is no different from the development and manufacture of drugs by the pharmaceutical industry. The aims of both are to supply products for the treatment of human ailments. Using this rationale, a human gene can be seen as just another chemical, which has very little to identify it as being intrinsically human or life-giving once it has been isolated from the body. In this respect, there is no reason why existing commercial practices including patenting should not play the same role as they would for any new drug or device. On the other hand, human genes, which are the chemical products that are employed in human genetic technology, are not simply man-made drugs but are things that already exist in nature in all humans. It has been argued that the sum total of human genes - the human genome - is so much a part of human identity that it should be shielded from

all commercial practices.[1] On this basis, human genetic research should not be commercially exploited. Some justification for such a conclusion is provided by the general abhorrence of commercial transactions in human body parts in many jurisdictions. The tension between these two extreme viewpoints is obvious, and reconciliation is becoming more urgent as the influence of patenting grows and at the same time the voices of those opposed to patenting of human genetic material gain in strength.

At its most extreme, the anti-patenting lobby would seek to exclude from patenting all inventions derived from living material. In 1995, for example, representatives of over 80 different faiths and denominations in the USA declared their opposition to patenting of genetically engineered animals and human genes, cells and organs on the basis that humans and animals are the creations of God not humans and as such should not be patented as human inventions.[2] Subsequently a group of scientists, clergy and activists met in the Blue Mountains in the USA and proposed the Blue Mountains Declaration:

> "The humans, animals microorganisms and plants comprising life on earth are part of the natural world in which we are born, The conversion of these life forms, their molecules or parts into corporate property through patent monopolies is counter to the interests of the peoples of the world.
>
> No individual, institution, or corporation should be able to claim ownership over species or varieties of living organisms. Nor should they be able to hold patents on organs, cells, genes or proteins, whether naturally occurring, genetically altered or otherwise modified."[3]

More importantly, specific concerns have also been expressed about patenting of human genes and cell lines and methods of medical treatment.

The practical value of such views is dubious for three key reasons. First, from an economic perspective, governments will be loathe to exclude inventions which use human genetic material from patenting if it means that they are likely to lose lucrative biotechnology industries to other countries

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1 Note UNESCO's *Revised Outline of a Declaration on the Human Genome and its Protection in Relation to Human Dignity and Human Rights* (1995), which provides in Article 1 that the human genome should be part of the common heritage of humanity.

2 Stone, R., "Religious leaders Oppose Patenting Genes and Animals" (1995) 268 *Science* 1126.

3 This part of the Blue Mountains Declaration was extracted in a letter to *Science:* Bereano, P.L., "Genetic Patents" (1996) 271 *Science* 14.

which continue to offer adequate forms of protection. Even if international agreement were reached on this matter, biotechnology patenting havens would continue to exist. Secondly, although democratic governments have an obligation to follow the will of the majority, there is no convincing evidence that the position outlined above is a majority viewpoint. For example, the Institute of Theological Studies in Berkeley has been quoted as saying, in response to the Blue Mountains Declaration, that for religious leaders to think that they have made a contribution to social justice by such statements is "a form of blindness in the middle of seeing".[4] Thirdly, I suggest that objections to the use of patents in human genetic research and clinical practice are open to challenge because they are based on five faulty premises:

- that patent rights over a gene or gene sequence equate with ownership of the gene in its tangible form;
- that human genes are equated with life and humanity;
- that the patent system has a primary regulatory role in human genetic research;
- that patenting of human genetic material implies that all aspects of its commercialisation are appropriate;
- that by allowing patenting of some aspects of human genetic material, it follows that there are no limitations on what is patentable.

I aim to show during the course of this thesis that none of these premises can survive close scrutiny. My argument is that there are strong ethical justifications and sound public health reasons for encouraging human genetic research and its clinical applications, provided that appropriate safeguards are in place to ensure both that appropriate ethical consideration is given to each case and that fundamental human rights are protected. The patent system has much to offer in achieving this end by providing the necessary incentive to the business community to invest in that research and practice. But it must be recognised that there is an inevitable tension between needs and goals of the business sector on the one hand and of academic science and the health care system on the other. The dominant measure of success of a company is seen in terms of profit margin, whereas the health care system has to take into account basic ethical principles requiring that the welfare of the individual patient and of the community as a whole are given due recognition.

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4 In Straus, J., "Intellectual Property Issues in Genomic Research" (1996) 3(3) *Genome Digest* 1.

Commercial considerations have also been secondary to the scientific community, given that academic excellence is both the dominant measure of success and the primary criterion for research funding.

It is no longer the case that academia and health care are entirely immune from commercial considerations. Academic funding bodies now look more favourably on research that has economic implications and that can be linked to industry. Health care systems have also been affected by commercialisation in the supply of pharmaceuticals and medical devices. Yet neither the health care system nor the scientific academy should ignore the fundamental premises on which they are based. This tension between health care and pure scientific research on the one hand and commercialisation on the other is nowhere more obvious than in human genetic research. The public purse is simply not capable of fully supporting this expensive and risky research. Commercial interests will only be prepared to contribute, however, if their investment can be recouped, and provision of the appropriate security will inevitably increase the economic pressures placed on science and on the health care system.

The objections that have been voiced against patenting of human genetic material warrant mention and will be discussed more fully in Chapter 1 of this thesis. My argument, however, is that there are other more real and pressing issues that must be resolved in relation to commercialisation of human genetic research and patenting of human genetic material. I explore these issues in the next five chapters by presenting a comprehensive analysis of each of the elements that are needed to construct the proper framework upon which to base an informed conclusion, namely:

- the patent system (Chapter 2);
- the research and clinical practice of human genetics (Chapter 3);
- ethics and regulation of that research and clinical practice (Chapter 4);
- the role of commercialisation in research and practice (Chapter 5); and
- the extent to which human genetic material can be patented (Chapter 6).

In the final chapter I will build upon this framework to support my arguments as to the appropriateness of the existing system for patenting human genetic material. My thesis is that there is no requirement for wholesale modification of the system, but that refinement of the limitations already existing within the patent system will suffice. The thesis ends with a

series of fourteen key conclusions, the aim of which is to provide a more balanced system for achieving the goals of encouraging investment in research and at the same time protecting the public interest.[5]

To the best of my knowledge the law is as stated to 1st January 1997.

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5 Some of the work presented in this thesis has already appeared in print. See Nicol, D., "Should Human Genes Be Patentable Under the Australian Patent System?" (1996) 3 *Journal of Law and Medicine* 231; Chalmers, D.R.C. and D. Nicol, "Current Regulation of Human Genetic Research and Therapy in Australia" (1996) Proceedings from the International Turku Symposium on Genetic Ethics, *Doing the Decent Thing with Genes*, 9-11 August 1995, 82; Chalmers, D.R.C. and D, Nicol "Take Two Genes a Day" (1997)*Today's Life Science.* in press All of the material extracted from these papers is solely the work of the author. Background work for the first paper was initiated in an undergraduate course on intellectual property, undertaken by the author in partial fulfilment of the degree of Bachelor of Laws.

CHAPTER 1: SETTING THE SCENE

Before I begin my analysis of patenting human genetic material in Australia it is necessary to place the topic within the appropriate context. For this reason I include in this chapter a review of the objections to patenting of human genetic material, which can be separated into three broad themes:

- that life in any form should not be patented;
- that human genes and cells should not be patented; and
- that methods of medical treatment should not be patented.

Part 1: Patenting of Life Forms

Legally, inventions derived from living material are generally considered to be patentable, and there are numerous examples of such patents. One of the earliest cited examples was a patent for a biologically pure culture of yeast, granted to Louis Pasteur in 1873.[1] Accordingly, the fact that genes and gene sequences are derived from living material is not an adequate argument to deny them patentability through existing patent law. Although the Blue Mountains Declaration seeks to prevent patenting of all living material, the main debate in this area from both the ethical and legal perspective has been associated with the narrower issue of the extent to which whole living organisms can and should be patentable inventions. Although these objections to patenting of whole living organisms are not directly relevant to my analysis of the patentability of human genetic material, they warrant some consideration because of their intensity and their close linkage to the debate on patenting of human genes. Some commentators have expressed surprise that this issue has been the subject of more public and legal discussion than the patenting of human genes.[2] I suggest that this is perhaps more to do with ignorance of the extent to which human genes have been patented than a genuine greater concern about animal and plant patents.

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1 Cited by Thomson, J.A., *Biopatenting the Splice of Life: A Consideration of the Interface between Biotechnological Inventions and Patent Law* (1994) Ph.D. Thesis, University of Western Australia, at 92.

2 See, for example, Moufang, R., "Patenting of Human Genes, Cells and Parts of the Body? - The Ethical Dimensions of Patent Law" (1994) 25 *IIC* 487.

1.1 The Law

It is well established in patent law that whole living organisms can be patented. The seminal US Supreme Court case of *Diamond v Chakrabarty*[3] was the first instance in which a court recognised that living organisms themselves, just as much as non-living things, were patentable. That decision has been generally accepted both in the USA and other jurisdictions. In Australia living organisms are considered to be patentable by the Patent Office,[4] although the issue has not yet received judicial consideration in the courts. Living organisms are not expressly excluded from patenting in any jurisdiction.[5]

Microorganisms that have been modified by genetic engineering can satisfy the criteria for patenting and many already have been patented. The position is less clear for genetically engineered higher organisms. Although most genetic engineering involves the insertion of genes into bacteria or cell lines, the technology now exists to insert a gene from one species into another, to produce a so-called "transgenic".[6] Transgenics play a major role in agriculture. They can be made to have resistance to particular viral infections, or to grow faster than normal, or to produce better quality products. Transgenics are also valuable tools in biomedical research, in the study of human disease, and in pharmaceuticals, where they are used to produce therapeutic proteins required for the treatment of disease in far larger quantities than can be produced by other means.[7] This technique is commonly referred to as

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3 206 USPQ 193 1980. The law in this area is discussed more fully in Chapter 6, section 1.1.2.

4 In *Rank Hovis McDougall Ltd's Application* (1976) 46 AOJP 3915, for example, a patent was granted by the Assistant Commissioner of Patents for a new strain of micro-organism that could be used in a process for the production of an edible protein.

5 Crespi, S., "The EC Directive on Biotechnology Patents - An Evaluation of the Ethical, Social and Political Objections" (1992) 4 *Intellectual Property in Business* 17.

6 Office of Technology Assessment, *Transgenic Animals* (1988), cited in Dresser, R., "Ethical and Legal Issues in Patenting New Animal Life" (1988) *Jurimetrics Journal* 399 at 405.

7 Erythropoietin, for example, is an important protein in the production of red blood cells. A cell line has been genetically modified to produce large quantities of erythropoietin, which can be harvested and used in the treatment of anaemia. Amgen Inc holds the patent for the erythropoietin gene sequence: US Patent No 4,703,008, referred to in Maebius, S.B., "Novel DNA Sequences and the Utility Requirement: the Human Genome Initiative" (1992) *Journal of the Patent and Trademark Office Society* 651.

"pharming" of human proteins.[8] Patents have been granted for transgenic animals in Australia and the USA,[9] and the US Commissioner of Patents and Trademarks Office expressly considers them to be patentable.[10] In Europe patents may be valid for some transgenic higher organisms, but certain additional criteria must be satisfied in relation to public order and morality, biological processes and animal or plant varieties.[11]

1.2 Objections to Patenting of Living Organisms

Objections to patenting of higher living organisms (particularly animals) fall into two main categories: first objections to animal patenting *per se*; secondly, and more importantly here, objections based on slippery slope arguments that once animals can be patented then so too will humans or human-animal hybrids.[12]

1.2.1 Living Organisms

The objection to patenting of higher living organisms can be subdivided into what have been referred to as the deontological argument that patenting of animals is inherently wrong, and the instrumentalist argument which focuses on the indirect harmful effects of patenting on society.[13] The first argument carries little weight if it is put in the context of past practice. Animals have been

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8 See Dresser at 407-409; Manspeizer, D., "The Cheshire Cat, the March Hare, and the Harvard Mouse: Animal Patents Open Up a New Genetically-Engineered Wonderland" (1991) 43 *Rutgers Law Review* 417, at 423-428.

9 Lane, M.J., "Patenting Life: Responses of Patent Offices in the US and Abroad" (1991) 32 *Jurimetrics Journal* 89.

10 Commissioner's Notice 17 April 1987, 1077 OG 24, cited in Armitage, R.A., "The Emerging US Patent Law for the Protection of Biotechnology Research Results" [1989] *European Intellectual Property Review* 47; also cited in Dresser.

11 Respectively, Articles 53(a) (public order/morality), 53(b) (biological processes and animal and plant varieties) of the *European Patent Convention* 1973. The case law considering these provisions will be discussed in Chapter 6.

12 Hoffmaster, B., "The Ethics of Patenting Higher Life Forms" (1988) 4 *Intellectual Property Journal* 1.

13 Dresser, R., "Ethical and Legal Issues in Patenting New Animal Life" (1988) *Jurimetrics Journal* 399.

subject to human ownership and commerce for centuries and as such it is difficult justify the singling out of patenting as an undesirable form of commercialisation.

With regard to the second instrumentalist argument, the perceived harmful effects on society of patenting higher organisms can be seen as four key issues.

- Costs to small farmers are likely to increase because of royalty or licence payments for use of patented animal or seed stock.
- Biodiversity may decrease through the dominant use of a few favoured transgenic animals and plants.
- There are inherent dangers associated with the release of genetically modified organisms.
- Animal suffering may be increased. It has been shown, for example, that a transgenic pig that has been patented in Australia has the advantage that grows quickly because it possesses the gene for human growth hormone. But it also is prone to arthritis and poor vision and dies prematurely.[14] Another example is the Harvard onco-mouse, which was created specifically to develop cancers.

Counterarguments have been presented in the literature against each of these concerns.

- Increased productivity, made possible through the use of genetically modified organisms, may outweigh the costs associated with licence fees.[15] The increased costs currently faced by small farmers are more probably a direct consequence of economic policy than of patenting.[16] The important issue is to ensure that farmers have access to, and are encouraged to employ new technological developments.
- Patenting may actually increase biodiversity by encouraging the marketing of new strains of plants and animals.
- The patent system is not the appropriate forum to assess safety issues. A ban on patenting will not alleviate concerns associated with the use of

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14 *Ibid.*, at 422.

15 Kulseth, R.A., "Biotechnology and Animal Patents: When Someone Builds a Better Mouse" (1990) 32 *Arizona Law Review* 691.

16 Hoffmaster, B., "The Ethics of Patenting Higher Life Forms" (1988) 4 *Intellectual Property Journal* 1.

genetically modified organisms. Safety should be ensured and controlled by the relevant regulatory agency.[17]

- Stringent regulation is in place in most jurisdictions aimed at ensuring that animal suffering is kept to a minimum. The suffering of animals has been deemed by the European Patent Office to be acceptable provided that the benefit to humans is calculated to outweigh that suffering.[18]

These arguments and counterarguments exemplify many of the confusions in the debate, the focus of which is not on patenting *per se*, but on concerns that are more generally associated with genetic engineering and with its commercialisation. The same confusions exist in the objections to patenting of human genetic material. I will emphasise throughout the body of this thesis, that those objections are based on faulty premises and in this form they are not sufficiently convincing to justify a change in patent policy. The position of the Australian Federal Government in this regard is clearly and emphatically pro-patenting. In 1992, a major report commissioned by the Federal Government was published.[19] All of the arguments opposing patenting were rejected in the report and no justification could be found to deny patent rights to the biotechnology industry. The Committee expressed the view that the *Patents Act* was not the place for hindering or preventing the development of technologies to which society might have an objection.

1.2.2 The Slippery Slope

With respect to the slippery slope argument that patenting of animals will inevitably lead to patenting of humans, the Australian *Patents Act* 1990 explicitly prohibits patenting of humans and biological processes for their

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17 The relevant regulations in the USA are set out in Lauroesch, M.W., "Genetic Engineering: Innovation and Risk Minimisation" (1988) 57 *The George Washington Law Review* 100, at 117-118.

18 These are the criteria used by the European Patent Office in its interpretation of Article 53(a) of the EPC. See, for example, *Re Harvard College (President and Fellows)* (Decision T 19/90) [1990] OJEPO 476.

19 House of Representatives Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory* (1992) AGPS. See particularly Chapter 7: Legal Issues. Part A Property Rights - The Patenting of Living Organisms.

generation.[20] Few other countries state the prohibition so explicitly, but it is generally accepted as being implicit in their laws. In the USA, for example, patenting has been said by the Commissioner of the US Patents and Trademarks Office to be contrary to the Constitution.[21]

The slippery slope argument cannot be dismissed without some consideration of human-animal hybrids. Some commentators see the production of such creatures through genetic engineering as "a very real possibility".[22] The realisation of that possibility depends on what is meant by the term. Certainly it is now quite possible to insert human genes into embryos or cell lines of other species, and to patent the cell line, the animal, and the protein expressed by the gene or the process. Few human genes are used in such techniques, which makes it difficult to argue that the animal or cell line has any intrinsic "humanness". It has been suggested, however, that it may be possible to produce and patent near-humans or sub-humans by embryo fusion. This technique involves the introduction of embryonic human cells into the embryo of a non-human. The creature produced would manifest both human and animal traits, and could therefore be described as having human attributes. Although this technique has met with some success, for example in the fusion of embryonic cells from sheep and goats to produce hybrids known as geeps,[23] there are no plans for it ever to be used to create human-animal hybrids. It will become obvious from my analysis of the regulation of human genetic research in Chapter 4 of this thesis that the existing regulatory framework would never allow experiments of that type to take place, because they are contrary to fundamental ethical principles.[24] To raise them as possibilities obscures more

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20 In section 18(2).

21 Commissioner's Notice 17 April 1987, 1077 OG 24, cited in Armitage, R.A., "The Emerging US Patent Law for the Protection of Biotechnology Research Results" [1989] *European Intellectual Property Review* 47.

22 See, for example, Kulseth, R.A., "Biotechnology and Animal Patents: When Someone Builds a Better Mouse" (1990) 32 *Arizona Law Review* 691, at 708.

23 See Dresser, R., "Ethical and Legal Issues in Patenting New Animal Life" (1988) *Jurimetrics Journal* 399, at 406.

24 The less invasive procedures of insertion of single genes into the human germ line and cloning of human embryos are generally considered to be ethically unacceptable and are prohibited, see Chapter 4. Dresser, however, presents arguments suggesting that such a possibility should not be dismissed totally, at 415. Professor Ricketson has also expressed

pressing ethical debates, including those associated with access to human genetic information and access to human genetic tissue.

Part 2: Patenting of Methods of Medical Treatment

Patents have, for many years, been available for products used in medical treatment. At the same time, there has been some doubt as to the extent to which the methods used in that treatment should themselves be patentable.

2.1 The Law

In all jurisdictions it is well recognised that patent claims can be made both for inventive products and for inventive processes. In the area of medical treatment, although the products used in treatment are considered to be patentable, this has not always been the case for methods of treatment.[25] In Europe the exclusion for methods of medical treatment remains in force through Article 52(4) of the *European Patent Convention*. The GATT TRIPS Agreement also allows members to exclude "diagnostic, therapeutic and surgical methods for the treatment of humans or animals".[26] The exclusion is not recognised in the USA and appears to have been discarded in Australia in the decision of the Full Federal Court in *Anaesthetic Supplies v Rescare.* [27] This means that certain patents would be valid in the USA and Australia but not in Europe. In the area of human genetics, both diagnostic and therapeutic treatment methods could come within the ambit of the exclusion.[28]

2.2 Ethical Considerations

The justification for the exclusion is primarily based on ethics, that doctors should not be faced with patent infringement actions for performing their duties using the best available methods. In Australia the majority view of

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concern over the difficulties in distinguishing between humans and non-humans: Ricketson, S., "The Patentability of Living Organisms" (1984). In : D.J. Galligan (ed.) *Essays in Legal Theory*, Melbourne University Press, Melbourne, chapter 5.

25 See Chapter 6, sections 1.1.3 and 1.3.2.

26 Article 27(3).

27 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383.

the Full Federal Court in *Rescare* was that the Court would not entertain arguments for exclusion for methods of medical treatment based on ethics, and that it would be for Parliament to act, if it is necessary to do so.[29] The matter hinges on the clash between the need for economic incentives to take an invention to the stage of clinical application versus the undesirability of bringing commercial pressures to bear in areas that many believe should be immune from such considerations. Commercialisation of health care raises questions as to the basic rights of members of the community to autonomy and privacy, and potential problems of conflict of interest for health care providers. Further, there may be a number of undesirable effects on the doctor patient relationship. The best interests of the patient, the confidentiality of the doctor patient relationship and the autonomy of the doctor are all put at risk.

The commentators are divided on the question of whether these undesirable features are outweighed by the desirability of encouraging innovation in medical practice. Both Burch[30] and McCoy[31] believe that they are, Loughlan[32] does not. According to Burch, patents will only be available for methods of medical treatment in specialist areas which require great economic investment, and in such cases, the balance is in favour of providing economic incentive. If this is the case then the considerations should be no different than for patenting of the products used in medical treatment. It is a recognised fact that doctors are put under considerable pressure by commercial interests to favour their products over other brands. Trust is placed in doctors to be able to withstand such sorts of pressure. I can see little justification in distinguishing processes and products. In either case the duty of the doctor is to use the best tools that are available to discharge their duty to exercise reasonable skill and care in the treatment of the patient.

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28 The case law concerning the exclusion in both Australia and Europe is discussed in some detail in Chapter 6.

29 See the judgments of Lockhart and Wilcox JJ in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383.

30 Burch, G.F., "Ethical Considerations in the Patenting of Medical Processes" (1987) 65 *Texas Law Review* 1139.

31 McCoy, T.J., "Biomedical Process Patents Should They Be Restricted by Ethical Limitations?" (1992) 13 *Journal of Legal Medicine* 501.

32 Loughlan, P., "Of Patents and Patients: New Monopolies in Medical Methods" (1995) 6 *Australian Intellectual Property Journal* 5.

Part 3: *Patenting of Human Cell Lines and Genes*

Opposition to patenting of human cell lines and genes has, until recently, been less vocal than the opposition to patenting of whole living organisms. That situation is now changing. The specific arguments against patenting of genes and cell lines may well be more convincing here than in the more general area of living material.

3.1 The Law

Cell lines and genes of known function are susceptible to patenting. A large number of patents have been granted which include in their claims human cell lines or genes, and challenges to their validity have not yet met with success. In Europe, for example, opposition proceedings were brought against the Australian Howard Florey Institute for its European patent on the H2-relaxin gene.[33] The proceedings were brought by Green members of the European Parliament who urged the Opposition Division of the European Patent Office to accept their argument that the patent was contrary to the immorality provision in Article 53(a) of the *European Patent Convention*.[34]The Greens argued that the patent was an affront to human dignity, and could be equated with patenting of life and slavery. The Board refused to accept any of these arguments on the bases that: use of donated ovarian tissue to extract the gene was no more immoral than use of donated blood as a source of life saving substances; DNA is not life; ownership of the patent is not akin to slavery because it does not give the owner any right over the human donor, but merely the right to prevent others from practising the same invention outside the human body. Further, in relation to the more specific argument that patenting of genes was, of itself, contrary to Article 53(a), it was held that there was no public consensus that human genes should not be patented and therefore it was not appropriate to exclude them.

No jurisdiction other than the European Union and its member States has express provision for consideration of morality issues. Patent law in all

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33 *Relaxin* [1995] OJEPO 388.

34 Article 53(a) excludes from patenting inventions, the exploitation of which would be contrary to "ordre publique" or morality.

jurisdictions does place other restrictions on patenting of genes and cell lines. All patent applications must fulfil the essential patenting criteria, which are discussed in Chapter 2. Naturally occurring cells, genes and gene sequences fail because they are discoveries rather than inventions, although isolation from their natural environment may be enough to constitute an invention. Patent law further excludes gene sequences of unknown function, because they lack commercial applicability.[35] Other patent applications which include genes, gene sequences or cells may also fail for want of novelty or inventive step or other essential criteria.

3.2 Acceptability of Research v Acceptability of Patenting

Public concerns associated with patenting genes fall into two parts, objections to the types of human genetic research that are being conducted on the one hand and to their patenting on the other. A number of surveys have indicated general support for human genetic research, and particularly gene therapy because it offers the possibility of alleviating suffering caused by genetic disease.[36] There has been much less public disquiet about these issues than genetic engineering of plants and animals.

The fact that a particular form of experimentation is ethically acceptable does not necessarily mean that it is also patentable. Although the transplantation of human organs is now a commonly-used medical treatment, commercial dealings in human organs are generally regarded with abhorrence, and legislation is in place in many jurisdictions which treats such dealings as crimes.[37] The same considerations apply to dealings in human embryos and gametes.[38] It is unclear, however, whether this prohibition extends to commercial dealings with all of the component parts of humans.[39] Arguably the patenting of any invention derived from the human body conflicts with the notion that humans cannot be the subject of property rights or commercial dealings. The pro-patenting lobby strongly refutes this suggestion on the basis

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35 These critical issues will be discussed more fully in Chapter 6.

36 For example, Macer, D., "Public Acceptance of Human Gene Therapy and Perceptions of Human Genetic Manipulation" (1992) 3 *Human Gene Therapy* 511.

37 For example, *Human Organ Transplants Act* 1989 (UK)

38 *Human Fertilisation and Embryology Act* 1990 (UK)

39 See Nuffield Council on Bioethics *Human Tissue Ethical and Legal Issues* (1995) at 82.

that it is not the human body part that is being patented, but the invention that is derived from that body part, either in the form of a product or process.

3.3 Objections to Patenting of Genes and Cell Lines

The opposition to patenting of human genes is growing and becoming more broadly based. Patenting of inventions associated with human cell lines and genes engenders strong personal feelings within the population, for precisely the reasons stated in the Greens' arguments in the *Relaxin case*.[40] People do equate patents on genes with ownership of life. The extreme response elicited by patent applications for cell lines derived from indigenous peoples in a number of countries is testimony to this concern.

An early attempt by the National Institutes of Health (NIH) in the USA to patent a cell line derived from a member of the Guyami tribe in Panama was discovered in a routine check on patent applications by the Rural Advancement Foundation International (RAFI), which is a private Canadian organisation whose aim is the monitor the extent of patenting in agriculture. RAFI publicised the matter widely and brought it to the attention of the Guyami people. The World Health Organisation and other international bodies were lobbied, and ultimately the NIH patent application was withdrawn. More recently, however, a patent has been granted for a cell line derived from a member of the Hagahai tribe in Papua New Guinea, and other similar patents are pending. The Hagahai patent is for, *inter alia*, "a human T-cell line (PNG-1) persistently infected with a Papua New Guinea (PNG) HTLV-1 variant and the infecting virus (PNG-1 variant)".[41] It offers the potential for vaccine development and therefore has important implications both therapeutically and commercially.[42]

Terms such as biopiracy have been used to describe the actions of the NIH, because, it is claimed, the permission of neither the PNG government nor

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40 *Relaxin* [1995] OJEPO 388.

41 US Patent Number 05397696.

42 Note, however, that to date the patent appears not to have been a commercial success. This may well have led to a reported decision by the NIH to abandon the patent: "US to Surrender Hagahai Patent?" (1996) *GenEthics News* September-October, 1.

the Hagahai people was sought.[43] Others have argued that the Hagahai were in fact consulted by Dr. Carol Jenkins, one of the patentees. She is an anthropologist who has studied with the Hagahai for over ten years and is employed by the PNG Medical Research Institute. She claims that the Hagahai consented to patenting of the cell line, and further that they were offered and accepted a 50% share of the royalties flowing from the patent.[44] Irrespective of the correct factual circumstances, the RAFI disclosures have brought patenting human cell lines to the public's attention.

The issue of patenting cell lines from indigenous peoples is associated with two other more far-reaching problems. The first is associated with the commercialisation of donated tissue.[45] There are no requirements at present in patenting legislation that people who donate material which is subsequently used as a substratum for a patentable invention should either be consulted with reference to the patent application, or should have a right to a share in the profits from the patent. According to *Moore's case*,[46] if the commercial potential of the tissue is known at the time of removal, and not disclosed, this may lead to infringement of informed consent requirements or breach of fiduciary duty. But this will not, of itself, either void the patent or create a right to a share in the profits. Some have argued that irregularities in the acquisition of tissue should be considered by patent authorities when granting a patent,[47] but for the time being there is no express requirement to do so. The same considerations apply whether the tissue is derived from first or third world peoples.

The second problem is that a number of developing countries are rich sources of unique plant and animal varieties which are being exploited by large biotechnology companies from the developed world. The patenting of those peoples' own cell lines is perceived by them as being one further layer of

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43 See, for example, RAFI, "New Questions About Management and Exchange of Human Tissues at NIH Indigenous Person's Cells Patented" [1996] *RAFI Communique* March/April 1,2.

44 Taubes, G., "Scientists Attacked for 'Patenting' Pacific Tribe" (1995) 270 *Science* 1112.

45 Note that this issue is discussed more fully in Chapter 4.

46 *Moore v Regents of the University of California* (1990) 51 Cal. 3d 120.

47 For example Bently, L. and B. Sherman, "The Ethics of Patenting: Towards a Transgenic Patent System" (1995) 3 *Medical Law Review* 275, at 290.

exploitation. There are important reasons why the exploitation of those resources, whether in the form of seed stocks or human cell lines, should continue. For example, indigenous plant varieties may have resistance to microbial attack, or may have medicinal properties, and human cell lines may have immunity to particular diseases. In this particular area, the whole research base could be undermined by objections to patenting irrespective of whether they are based on the right or wrong premises. Thus it may become necessary to remove commercial influences and limit the effect of patents in order to provide the right incentive to encourage indigenous groups to allow the research to proceed. The views expressed by Maori and Pacific Islander groups at a recent Health Research Council of New Zealand conference, *Whose Genes Are They Anyway?* are instructive.

> "Maori at the conference support genetic research and application that enhances the quality of life for Maori as defined by Maori. Any genetic research and application with Maori must occur within the paradigms of a Maori world view.
>
> Maori who attended both the Hui at Takapuwahia and the conference were unanimous that tissue and other body material taken from Maori belongs to Maori. Maori must always be in a position to make informed decisions as to how their genetic material is or can be used."[48]

3.4 Endorsement of Patenting Genes

On the other side of the debate, the international Human Genome Organisation has endorsed patenting of human genetic information, apart from DNA sequences of unknown function.[49] A wide range of other organisations, including the British National Academies Policy Advisory Group,[50] the European Group of Advisers on Ethical Implications of Biotechnology[51] and

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48 Report of the HRC Conference on Human Genetic Information, Wellington, New Zealand. July 1995.

49 Caskey, C.T., R.S. Eisenberg, E.S. Lander and J. Straus, "HUGO Statement on Patenting of DNA Sequences" (1995) *Genome Digest* 6.

50 National Academies Policy Advisory Group, *Intellectual Property and the Academic Community* (1995) Royal Society, London.

51 *Ethical Aspects of Patenting Inventions Involving Elements of Human Origin* (1996) 8th position paper.

the International Bar Association[52] have all given similar guarded endorsements.

Part 4: Summary of the Debate

In summary, those in favour of patenting living material, in particular human genetic and cellular material, argue that there is nothing intrinsically unpatentable about inventions in this area (apart from DNA sequences of unknown function) and that there is no justification to treat them differently from inventions in any other technology. Those against patenting argue that even if inventions derived from human genetic research are patentable there are strong ethical reasons why they should not be, and appropriate provision should be made in patenting legislation to exclude them.

Indigenous groups are not lone voices in opposition to patenting of genes and cell lines. For example, a coalition of women's rights groups plans to oppose the patenting of the breast cancer gene BRCA1.[53] Similar strong views have been expressed by a group of European scientists who object to a patent on human umbilical cord blood cells, primarily on ethical grounds.[54] This has had the indirect effect of turning public sentiment away from the research itself. Calls have been made for express exclusions from patenting to be added to existing patents legislation, and a moratorium on granting of patents by Patents Offices around the world in the interim. It seems certain that continued patenting of human genes and cells will have to be vigorously defended now that the opposition to patenting has the support of indigenous, women's and religious groups.

One of the difficulties with any proposition involving the exclusion of genes and cells from the patent system is finding an appropriate means of exclusion, an appropriate limit on exclusion and an appropriate means for ensuring that research and practice continues. My argument in this thesis is that there is little to be gained by expressly excluding human genetic material

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52 *Draft Convention on the Human Genome.*

53 "Gene Battle" (1996) *New Scientist* 25 May 12; "US Coalition Counters Breast Gene Patents" (1996) 381 *Nature* 265.

54 Butler, D., "US Company Comes under Fire over Patent on Umbilical Cord Cells" (1996) 382 *Nature* 99.

from patenting, and much to be lost if the progress of human genetic research and clinical practice slows. It is more appropriate to find suitable means for limiting the disadvantageous effects of patenting human genetic material from within the patent system. I suggest a number of possible means for achieving this end in Chapter 7.

CHAPTER 2: AUSTRALIAN PATENT LAW

Introduction

The principles of patent law are recognised universally, and were reaffirmed in the Uruguay Round of the General Agreement on Tariffs and Trade. Article 27 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* 1994 states that:

> 1. ...patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step [synonymous with the term "non-obvious"] and are capable of industrial application [synonymous with the term "useful"]. ...

Patents have many of the same features as do classical real and personal property rights. Once granted, patents confer the right on the patentee to:

- use, make or sell the invention;
- exclude others from making, using or selling the invention for a limited period.
- sell, licence or assign to others the right to make use or sell the invention for a limited period.

In other respects, however, patents are quite different from conventional property rights. As a patentee neither possesses nor owns the physical object of the patent (nor any future product of the patent), any direct comparison with real property ownership fades. Unfortunately, many of the arguments voiced against patenting of human genes presuppose that the patentee materially "owns" the object of the patent. This view is entirely misconceived. Patent rights are merely akin to real property rights; they are not the same. This *legally* misconceived view, however, also exemplifies genuine public concerns about developments in genetic research and commercialisation of health care which may justify legislative action.

In this regard, it could be argued that gene patents are fundamentally different from patents in other areas because they deal with the hereditary material of all living things. Accordingly, it is not in the public interest to allow patents for genes and it is necessary to provide either specific exclusions within the patent system or an alternative form of protection. The opposing argument is that gene patents require the same consideration as for all other patents, and that there is no justification for giving genes special treatment. On this basis, existing interpretations of the particular requirements set out above in the

GATT TRIPS Agreement, as well as the requirement for full disclosure of the invention provide sufficient limitations as to the extent of patenting in this area. This thesis assesses the validity of the two divergent arguments.

In this chapter I will explore the fundamental nature of the patent system, first by presenting a brief description of the history of the patent system followed by an examination of the economic rationale for its continued existence in Australia. A more detailed statement of the leitmotif of patent law in Australia follows, with regard to the construction of the patent, the disclosure requirements, each of the requirements set out in Article 27 of the GATT TRIPS Agreement, and the new threshold requirement that there be an invention on the face of the patent application, as propounded by the High Court in *Philips v Mirabella.* [1]

Part 1: The Patent System

1.1 History

The Australian patent system is based on medieval English patent law. Australia shares this origin with many other countries, notably the USA, England and other countries of Europe. The first grants of patents probably arose in the fifteenth century in England.[2] Subsequently, in 1624, the *Statute of Monopolies* gave statutory recognition to patents and specifically excluded

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1 *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 32 IPR 449. The most influential accounts of Australian patent law are provided by Professor James Lahore in a loose leaf service: Lahore J., J. Garnsey, J.W. Dwyer, A. Duffy and W. Covell, *Intellectual Property in Australia: Patents, Designs and Trademarks Law* (1994) Butterworths, Sydney, Volumes 1 and 2; Jill McKeough in her textbook and casebook: McKeough, J. and A. Stewart, *Intellectual Property in Australia* (1991) Butterworths, Sydney (second edition to be released in 1997) and McKeough, J., *Intellectual Property Commentary and Materials* (1992) Law Book Company, Sydney, second edition; and Professor Sam Ricketson in his textbook and casebook: Ricketson, S., *The Law of Intellectual Property* (1984) Law Book Company, Sydney, and Ricketson, S., *Intellectual Property Cases, Materials and Commentary* (1994) Butterworths, Sydney.

2 Boehm, K., *The British Patent System, Vol 1: Administration* (1967). In: Ricketson, S., *Intellectual Property Cases, Materials and Commentary* (1994) Butterworths.

them from a general prohibition against monopolies.[3] The over-arching requirement that there be a "manner of manufacture" in that Jacobean Statute is still retained in the modern Australian *Patents Act* 1990 as the touchstone for patentability.[4]

Calls for reform of the English patent system were made in the nineteenth century primarily in response to the excessive costs and complex procedures involved in obtaining a patent, as well as the general movement in favour of free trade and a lack of evidence of any link between the patent system and economic growth. A number of review committees were set up and Patent Bills proposed.[5] The reform process ended with the *Patents Act* 1883 (UK). Similar concerns have again been expressed in both England and Australia and the review process has been repeated, culminating in new legislation in the shape of the *Patents Act* 1977 (UK) and *Patents Act* 1990 (Cth).

There is now considerable variation in the legislative requirements for patenting between England, the USA and Australia. In England, for example, reference to the *Statute of Monopolies* was removed from the *Patents Act* 1977 in order to achieve harmonisation with the *European Patent Convention.* Any such differences have to be taken into account in comparing the law from these

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3 Section 6 of the *Statute of Monopolies* states that "Provided also and be it declared and enacted that any declaration before mentioned shall not extend to any letters patent and grants of privilege for the term of fourteen years or under, hereafter to be made, on the sole working or making of any manner of new manufactures within this realm, to the true and first inventor and inventors of such manufactures which others at the time of making such letters patent and grants shall not use, so far as they be not contrary to the law, mischievous to the state, by raising prices of commodities at home, or hurt at trade, or generally inconvenient; the said fourteen years to be accounted from the date of the first letters patent or grant of such privilege hereafter to be made, but that the same shall be of such force as they should be if this Act had never been made, and of none other."

4 Section 18(1)(a) refers to the manner of manufacture requirement, and the definition of invention in the dictionary in Schedule 1 defines an invention as "any manner of new manufacture ...".

5 See Boehm, *op cit.*

jurisdictions. Indeed, a number of warnings have been issued by the judiciary as to the use of inappropriate case law.[6]

The Australian Commonwealth government has power to enact patents legislation through s51(xviii) of the Constitution. In 1903 the first *Patents Act* entered into force and was not superseded until 1952. Both Acts were generally based on existing English legislation at the time. The 1952 Act was replaced by the 1990 *Patents Act,* which gave effect to recommendations of a Report by the Industrial Property Advisory Committee.[7] The legislation was extensively redrafted and rearranged using "plain English" although the core concepts remained unchanged.

1.2 International Obligations

A number of international treaties and conventions have been agreed upon in order to create greater harmonisation in patent law between countries.

1.2.1 The Paris Convention for the Protection of Industrial Property 1883, revised in Stockholm, 1967.

The main aims of this convention are to ensure first the equal treatment of foreign and national applications for patents, and secondly that the first applicant in one country has priority over other applicants for the same invention in different countries.

1.2.2 The Patent Cooperation Treaty 1970

In 1970 Australia signed the Patent Cooperation Treaty, which treats a single international application for a patent as having the same effect as if

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6 In *Genentech Inc's Patent* [1989] RPC 147 in the English Court of Appeal both Purchas LJ (at 198) and Mustill LJ (at 259) commented that the 1977 *Patents Act* had displaced residual common law and it would be a mistake to use the old cases to interpret the statute. Similarly, in *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 28 IPR 481 at 558 the Australian Federal Court urged care in using English cases from after the 1977 Act to interpret the Australian statute.

7 *Patents, Innovation and Competition in Australia* (1984) AGPS (hereafter referred to as the IPAC Report).

applications had been filed separately in each of the countries in which patent protection is requested. The application is then processed separately in each country.

1.2.3 The World Intellectual Property Organisation (WIPO) Convention 1970

WIPO is an agency of the United Nations. Its function is to administer conventions and agreements related to intellectual property.

1.2.4 The GATT TRIPS Agreement 1993.

Calls were first made in the United States to bring intellectual property matters within the ambit of the General Agreement on Tariffs and Trade, through a desire to reduce the economic losses suffered through trade in counterfeited goods. The *Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeited Goods* arose out of the Uruguay round of negotiations, completed in 1993. The objectives of the Agreement are stated in Article 7, and focus on the contribution of the protection and enforcement of intellectual property rights to the promotion of technological innovation and transfer and dissemination of technology. The principal aims of members are to:

- reduce distortions and impediments to international trade;
- promote the effective and adequate protection of intellectual property rights; and
- ensure the measures and procedures to enforce intellectual property rights do not themselves become barriers to international trade.

Australian obligations under the GATT TRIPS Agreement were implemented through the *Patents (World Trade Organisation Amendments) Act* 1994 (Cth).

The effect of these international conventions and agreements on patenting is that it is now common practice to lodge patent applications in a number of countries. Indeed, a survey conducted by Mandeville *et al* in 1981 indicated that the majority of applications for patents in Australia come from foreign applicants.[8] This is also the case in the European Union. A recent

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8 Mandeville, T.D., D.M. Lamberton and E.J. Bishop, *Economic Effects of the Australian Patent System* (1982) AGPS, Commissioned Report to the Industrial Property Advisory Committee (hereafter referred to as the Mandeville Survey), at 71.

survey has indicated that 70 percent of all patents issued by the European Patent Office belong to either Japanese or North American companies.[9] This predominance of foreign patents may well put into question the validity of the patent system, since the main rationale for its existence is the economic advantage that patents provide to the country in encouraging indigenous innovation (see below, Part 2). One possibility that has been raised to ameliorate the disadvantages arising out of the grant of patents to foreigners is that Australia should weaken its patent protection, so that it can free-ride on inventions from other countries.[10] This option, however, is clearly not in Australia's best interests from the perspective of international relations. Indeed, it has been recommended that what Australia should be doing is ensuring that there is international cooperation to prevent others from free riding.[11] I would agree that it is not in Australia's interests to be seen to be flouting attempts by other countries to harmonise national laws. In the long term Australia is much more likely to benefit than to lose from an internationally harmonised patent system, one of the aims of which is to remove havens in which patented inventions can be exploited with impunity.

Part 2: Economics and the Patent System

It is generally recognised that the justification of the present patent system is that the grant of patents encourages innovation, which is beneficial to the Australian economy. For example, a Report by the Senate Standing Committee on Science and the Environment[12] stated that:

> "the primary function of patent legislation should be to serve as an instrument of national economic policy aimed at the stimulation of indigenous industrial innovation not as a means for giving effect to the 'natural right' of the inventor."[13]

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9 Thomas, S.M., A.R.W. Davies, N.J. Birtwistle, S.M. Crowther and J.F. Burke, "Ownership of the Human Genome" (1996) 380 *Nature* 387.

10 For example: Bureau of Industry Economics, *The Economics of Patents* (1994) AGPS, Occasional Paper 18.

11 *Ibid.*

12 *Industrial Research and Development in Australia* (1978) AGPS. The Jessop Report.

13 *Ibid.*, 129.

This has not always been accepted as the only rationale for the existence of the patent system. Four distinct theses have been proposed as providing possible justifications for the nineteenth century patent system:[14]

- the natural law thesis: that people have a natural right to property in their own ideas;[15]
- the reward-by-monopoly thesis: that there should be some reward to the inventor for his efforts in producing a useful invention, and the greater the usefulness, the greater should be the reward;
- the monopoly-profit-incentive thesis: that, assuming that innovation and economic growth are desirable, there should be some incentive to encourage inventive activity, which further assumes that inventive activity is causally linked to economic growth; and
- the exchange-for-secrets thesis: that the patent is a bargain between the inventor, who gains a temporary monopoly, and the public, who gain by disclosure of the invention.

The comments made by the Senate Standing Committee, extracted above, indicate that the dominant role of the modern patent system is in providing economic benefit to the country. On this basis, the main benefit of the patent system should not be in providing reward for the hard work of the inventor, nor should that system recognise any natural right of the inventor. Further, although the grant of a patent does involve a trade-off of a temporary monopoly to the inventor in return for disclosure, the primary focus of the system should not be seen as providing for private agreements between the inventor and the public. Patents are public documents granting state sanctioned monopolies and the patent system should therefore provide benefit to the public.

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14 Machlup, F. and E. Penrose, "The Patent Controversy in the 19th Century" (1950) 10 *Journal of Economic History* 11.

15 A detailed analysis of the arguments for and against patents as natural rights is presented by Thomson, J.A., *Biopatenting the Splice of Life: A Consideration of the Interface between Biotechnological Inventions and Patent Law* (1994) Ph.D. Thesis, University of Western Australia. It could be argued that the only right conferred by statute is the right to exclude others from making, using or selling the invention. The inventor can already do these things herself. But of course licensing or selling the rights is only worthwhile if others can be excluded.

This rationale makes two important assumptions: that technological innovation leads to greater economic and social welfare, and that patenting encourages innovation. This is not the place to analyse the first assumption, since it would require a detailed analysis of economic theory. A case can be made for the second assumption on the bases that:

- the award of a monopoly in the exploitation of the invention should encourage the inventor both to create new inventions and to take the patented invention through to commercial application;
- public access through disclosure of the invention should encourage other innovation in areas related to the patented invention; and
- once the patent has expired the invention is freely available and can be further developed.

Empirical evidence of a causal link between the patent system and innovation, however, is decidedly lacking.[16] Indeed the anti-competitive effect of awarding a patent monopoly may be a disincentive to innovation. Machlup suggests as much:

> "If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it."[17]

Machlup's view has to be placed in the Australian context. Clearly, the social benefits and costs of the patent system will vary from country to country. Australia is industrially developed but small, therefore the considerations are different from those that apply in large industrialised countries, like the USA. Smaller countries or those which are poorly developed in industrial terms are much less likely to have a substantial indigenous innovation base than larger more industrially developed countries. In that regard, I suggest that the patent system may provide more of an advantage to foreign innovators seeking to exploit their inventions in the host country than to the economy of the host country. This may be the price that Australia has to pay for a harmonised patent system.

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16 See, for example, the Mandeville Survey.

17 Machlup, F., *An Economic Review of the Patent System* (1958) US Government Printing Service, Washington.

2.1 The Australian Context

In 1984 a report was published by the Industrial Property Advisory Committee (IPAC), the aim of which was to suggest ways in which the patent system might better enhance Australia's long term economic development through innovation.[18] The patent system is most clearly justified when social benefits outweigh social costs. Social benefits have been said to include:

- incentive for innovation
- disclosure of the invention.

Social costs include:

- direct costs of running the patent system
- indirect costs to society of the grant of a monopoly.[19]

In practice, there is no convincing evidence that the patent system does in fact encourage innovation. By hindering competition the patent system could actually inhibit innovation. Furthermore, there is no clear benefit to the public in disclosure. In terms of costs, the Mandeville survey estimated that the direct costs of administering the system were approximately $17 million in 1979-80. Social costs were said to be too difficult to quantify with any accuracy, although probably the greatest cost was identified as restrictive terms and conditions in licensing agreements.[20]

The reports by Mandeville and IPAC indicate that the benefit cost ratio in Australia is negative, or at the very best in balance. Even so, there may still not be sufficient justification for abolishing the patent system. In terms of international commercial relations, the costs of abolishing it may be large. The primary recommendation of IPAC report was that Australia should continue to operate a patent system. But there is no justification for increasing the ambit of that system. With this in mind, patenting of human genetic material should not be allowed to extend beyond the limits that are already set within the patent system.

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18 The IPAC Report.

19 *Ibid.*

20 Mandeville survey, at 112.

2.2 Appropriateness of Monopoly Rights

The 1993 Hilmer Report[21] set the benchmark for Australia's national competition policy. By granting a monopoly, the patent system of its very nature may be seen as anti-competitive, and that anti-competitive feature makes the patent system a key consideration in free market debates. It has been pointed out elsewhere that both competition policy and patenting have a common central economic goal of maximising wealth by producing what consumers want at the lowest cost, and therefore they need not necessarily be seen as antagonistic to one another.[22] The Hilmer Report did not oppose patents outright, seeing them as limited exceptions to the national competition policy. The difficulty with the two systems is finding the right balance in their interaction.[23] If one accepts that the award of a temporary monopoly for inventions is justifiable on the basis of being in the public interest, the legislature must seek to ensure that the patent monopoly is not extended beyond those appropriate limits. Thus the debate that is of interest here is not about patenting as such but about the appropriate and justifiable limits on the patent system. My focus is on possible abuses of the monopoly which could include:

- refusal or inability to adequately exploit the invention;
- refusal to licence others to perform that exploitation;
- imposition of restrictive or onerous terms in licensing agreements; and
- extension of the monopoly beyond its time or scope.

Two mechanisms exist which may minimise some of these undesirable effects of granting the patent monopoly: compulsory licensing and provisions in Part IV of the *Trade Practices Act* 1974 (Cth).

2.1.1 Compulsory licensing

Provisions in Chapter 12 of the *Patents Act* enable a person to apply to the court for an order requiring the patentee to grant the applicant a licence to work the invention, provided that the applicant can convince the court that the "reasonable requirements of the public" have not been satisfied and the

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21 *National Competition Policy* (1993) AGPS.

22 Bowman, W.S., *Patent and Antitrust Law: A Legal and Economic Appraisal* (1973) University of Chicago Press, Chicago.

23 The Hilmer Report, at 150.

patentee gives no satisfactory explanation.[24] Section 135 sets out how the reasonable requirements of the public are shown not to have been satisfied. To date few applications have been made for compulsory licences. In *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corp*[25] Menzies J examined the equivalent provision in the 1952 Act and held that even though the reasonable requirements of the public had not been met when the petition was lodged, they were being met at the time of judgment. Moreover, his Honour was not satisfied that the petitioner was a suitable company to be granted a licence to work the invention. In consequence a compulsory licence was denied.

Given the lack of case law considering this provision, it is difficult to say with any certainty the types of cases that will persuade the court to grant a compulsory licence. One of my principal conclusions in Chapter 7 is that there may be some circumstances, for example when patent claims are made for new products to be used in the treatment of serious disease, when delay in bringing the invention to the phase of commercial application is inexcusable in terms of public interest. In such circumstances it is entirely appropriate for the courts to look favourably on applications for compulsory licences.[26]

2.1.2 *Part IV Provisions of the Trade Practices Act 1974*

Enactment of the *Trade Practices Act* 1974 (Cth) (TPA) provided an important package of legislation in two spheres of commercial law. Part V concerns consumer protection and Part IV is aimed at preventing abuse of market power.[27] The provisions of Part IV are most relevant to the present discussion. These include:

- Prohibition on anti-competitive agreements: "s45 sections".[28] The primary focus of inquiry is whether the agreement has the purpose or likely effect of substantially lessening competition.

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24 Section 133.

25 (1970) 44 ALJR 7.

26 Note, however, that applications can only be made three years after grant. For there to be unacceptable delay, therefore, it must be longer than three years.

27 A useful overview of this area of law is provided by Hurley, A. and G. Wiffen, *Outline of Trade Practices and Consumer Protection Law* (1994) Butterworths, Sydney.

28 *Ibid.*, Chapter 4.

- Misuse of market power: s46. The corporation must both have a substantial degree of market power and take advantage of that market power by eliminating or substantially damaging a competitor, preventing market entry, or deterring a person from engaging in competitive conduct.
- Exclusive dealings: s47. Again, the main focus is whether the agreement has the purpose or likely effect of substantially lessening competition.
- Resale price maintenance: s48 and Part VIII.
- Price discrimination: s49. Section 49 has now been repealed,[29] on the recommendation of a number of committees, because of its potential to discourage pro-competitive conduct.
- Mergers and acquisitions: s50.

Mere acquisition of a monopoly right through issue of a patent may not of itself be a breach of any of these provisions of the TPA, although s51(1) of the TPA provides that anti-competitive conduct permitted under intellectual property legislation is not exempt from the TPA. Section 51(3) then goes on to provide an exemption from ss 45, 47, 48 and 50 but not from s 46,

> "to the extent that the condition relates to ... (iii) the invention to which the patent relates or articles made by use of the invention".

The operation of the s51(3) provision was reviewed for the Trade Practice Commission by the Minter Ellison Group in 1991.[30] The group listed conduct that it saw as having an anti-competitive effect, including: enforcement actions and settlement; acquisition of intellectual property rights; refusal to licence; licence terms and conditions. As I suggested earlier, the last option is the one most likely to be used in an anti-competitive fashion.[31] In this respect Part IV of the TPA only gives limited assistance in guarding against anti-competitive conduct, since provided that the clauses used in a particular licensing agreement "relate to the invention to which the patent relates"[32], they will be

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29 Repealed by the *Competition Policy Reform Act* 1995 (Cth).

30 *Application of the Trade Practices Act to Intellectual Property* (1991) AGPS.

31 The TPC report lists thirteen possibilities: exclusive grant; territorial restraints; price restrictions; quota restrictions; quality requirements; minimum royalty/quality; post-termination restrictions; sub-licence restrictions; grant back provisions; no challenge provisions; non-competition clause; full or third line forcing; leveraging.

32 As per s51(3).

protected by s51(3). The only case that has considered s51(3) is *Transfield Pty Ltd v Arlo International Ltd*[33]: in which Mason J (as he then was) stated that:

> "In bridging the different policies of the Patents Act and the Trade Practices Act s51(3) recognizes that a patentee is justly entitled to impose conditions on the granting of a licence or assignment of a patent in order to protect the patentee's legal monopoly... Section 51(3) determines the scope of restrictions the patentee may properly impose to the use of the patent. Conditions which seek to gain advantage collateral to the patent are not covered by s51(3)."[34]

The need for the exemption in s51(3) was questioned by Professor Baxt in his report to IPAC.[35] IPAC subsequently recommended the removal of that provision from the TPA. This was justified on the basis that there is no reason for special treatment of patent related conduct. Pt IV sections operate with regard to substantial lessening of competition and hence if the likely public benefit of the patent monopoly outweighs its anti-competitive effect, there is no breach. The Trade Practices Commission made a similar recommendation in its submission to the Hilmer inquiry.[36] On the other hand, the Australian Industrial Property Organisation, the Australian Information Industry Association and the Institute of Patent Attorneys of Australia all supported its retention.[37] Although the Hilmer committee saw force in arguments for the removal of s51(3) it claimed that it was unable to make expert recommendations and merely recommended further examination.[38] For the time being, therefore, the provision remains. Provided that the focus is on the invention itself, it allows considerable scope for anti-competitive conduct which may further marginalise the public benefit arising out of the patent system, since it allows the imposition of onerous licensing conditions, and even outright refusal to licence at all. I will provide a case study in Chapter 5 which demonstrates possible detrimental consequences that may flow from refusal to licence. I conclude in Chapter 7 that now is the appropriate time for

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33 (1980) 30 ALR 201.

34 *Ibid.*, at 217.

35 Monash University Law School *Report to the Industrial Property Advisory Committee* (1983). Volume 2 Interface Between Anti-trust and Intellectual Property Legislation by Professor R. Baxt.

36 Hilmer Report, at 149.

37 *Ibid.*

38 Hilmer Report, at 151.

expert examination of the relationship between patent law and the provisions of Part IV of the TPA.

Part 3: The Australian System

The *Patents Act* 1990 (Cth) and associated regulations establish the parameters within which the Australian patent system functions. The main changes from the 1952 Act sought to "internationalise" patenting requirements, by testing novelty and inventive step against disclosures anywhere in the world.[39] In the second reading speech of the Patents Bill 1990, Senator Ray referred to the impact of these changes:

> "The most significant changes made by the Bill focus on fostering indigenous innovation and the use of the international patent system in developing export markets to improve Australia's international competitive position."[40]

The fundamental principles of modern Australian patent law are described below in order to provide a framework within which the issues associated with patenting of inventions arising out of human genetic research and its applications can be placed.

3.1 Applying for a Patent

The *Patents Act* 1990 (Cth) enables any person to apply for either a standard or a petty patent for a patentable invention. The term of a standard patent is 20 years,[41] and cannot be extended.[42] A petty patent extends for only 12 months, extendable for another 6 years.[43] The requirements for petty patent applications are less onerous than for a standard patent. The present discussion focuses primarily on the requirements for a standard patent.

Section 4 *Patents Act* 1990 lays out flow charts of the typical steps involved in obtaining a patent. A person may either make a provisional

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39 These changes are discussed in more detail below.

40 Parliamentary Debates 29 May 1990 Senate, 1271.

41 Section 67 *Patents Act* 1990 (Cth).

42 Division 2 - Standard patents in Part 3 - Extension of Term was repealed by the *Patents (World Trade Organization Amendments) Act* 1994 (Cth).

43 Section 68.

application or a complete application.[44] If the application is provisional, the applicant can make one or more complete applications associated with the provisional application at any time within the prescribed period.[45]

3.2 Disclosure Requirements

The application must include a specification, which, for a provisional application, need only describe the invention.[46] The requirements for a complete specification are set out in section 40 (2). It 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 a petty patent - end with a single claim, or a single independent claim and not more than 2 dependent claims, defining the invention.

Section 40 further provides that the claim or claims must be clear and succinct and fairly based on the matter described in the specification, and must relate to one invention only.

3.3 Invention Requirements

Patents will only be granted for patentable inventions. Section 18(1) requires that four elements are satisfied:

18. (1) Subject to subsection (2), a patentable invention is an invention that, so far as is 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 the 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.[47]

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44 Section 29.

45 Section 38.

46 Section 40(1).

47 Also refer to section 9 for acts which are not to be taken to be secret use.

Invention is further defined in the dictionary of terms in Schedule 1:

> "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.

3.4 Examination Requirements

On request by the applicant, the Commissioner of Patents must examine the application to determine whether it is patentable.[48] Section 45 requires that the Commissioner report on whether the specification complies with section 40 and whether, to the best of his or her knowledge, the invention satisfies the criteria in section 18(1)(a) and (b), the manner of manufacture, novelty and inventive step requirements.

3.5 Challenges to Patent Validity

Validity of the patent is not guaranteed by the Patent Office.[49] Validity may be challenged at three stages:

- within the prescribed period after a complete specification has been filed for failure to comply with paragraph 18(1)(b), that is, the novelty or inventive step requirements.[50]
- in opposition proceedings after acceptance but before granting, only on grounds that the nominated person is not entitled to grant and/or the invention is not patentable because it fails to comply with paragraph 18(1)(a) or (b) and/or the specification does not comply with subsection 40 (2) or (3).[51] Opposition hearings are heard by the Commissioner, but may be appealed to the Federal Court.[52]
- or revocation proceedings at any time after grant.[53] The Minister or any other person may apply to a prescribed court of a revocation order.

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48 Sections 44 and 45.

49 Section 20(1).

50 Section 27(1).

51 Section 59.

52 Section 60(4).

53 Section 138.

Subsection 138(3) sets out that there are only six allowable grounds for revocation, the most relevant of which for present purposes are:
(b) that the invention is not a patentable invention; and
(e) that the specification does not comply with subsection 40(2) or (3).

3.6 Grant of Patent

The Commissioner must grant the patent if a standard patent is in approved form and there is no opposition to grant, or in spite of opposition, the decision is that the patent should be granted.[54] The Commissioner should only refuse acceptance when "it is practically certain that the letters patent granted on the specification would be held invalid"[55] because refusal of acceptance is final but acceptance in itself is not.[56] In these circumstances it is the duty of the Commissioner to refuse the application. On the other hand, when validity is uncertain the applicant should be given the benefit of doubt.[57]

The grant of a patent gives the patentee the exclusive rights during the term of the patent to exploit the invention and authorise others to exploit the invention.[58] The patent can also be assigned by the patentee and devolved by law.[59] The patentee or an exclusive licensee may start infringement proceedings.[60] A defendant in infringement proceedings may counter-claim for revocation of the patent.[61]

3.7 Publication Requirements

Publication requirements include prescribed information about the applicant and application in the *Official Journal* when the application is

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54 Section 61.

55 *Commissioner of Patents v Microcell Ltd* (1959) 102 CLR 232, at 244.

56 *Ibid.*

57 *International Business Machines Corporation v Commissioner of Patents* (1991) 22 IPR 417.

58 Section 13(1).

59 Section 13(2).

60 Section 120(1).

61 Section 121.

made,[62] notification in the *Official Journal* that the complete specification is open for public inspection,[63] and public inspection.[64]

Part 4: Testing the Validity of a Patent

4.1 Construing the Patent Document

Before a patent is granted the examiner must assess its validity. Validity is also open to question in both opposition and revocation proceedings. The first task in assessing the validity of a patent, whether it be at the examination stage, or in opposition, infringement or revocation proceedings, is to construe the patent document as a whole. It has been said many times that the patent specification should be construed in the same way as any other written document. But a patent is not a private agreement; it is a public document granting a monopoly to the patentee, and must therefore be capable of being interpreted in such a way that its meaning cannot be misunderstood. One of the most important considerations in construing the document is the different functions of the claims and the specification. Mummery J in *Glaverbel v British Coal* confirmed that the claims mark out the legal limit of the monopoly granted, whereas the specification describes how to carry out the process claimed and the best method known to the patentee for doing this.[65] The role of the specification in construing the claims is to supply background information and the meaning of technical terms and in resolving ambiguities on the face of the claims.[66]

Lord Diplock in *Catnic Components* referred to the need for a purposive construction rather than a purely literal one.[67] Although this has been accepted as the appropriate method of patent construction in both England[68] and Australia,[69] Gummow J has cast doubt on whether the result would be any

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62 Section 53.

63 Section 54.

64 Sections 55, 56.

65 *Glaverbel SA v British Coal Corp* [1994] RPC 443, at 486.

66 *Ibid.*

67 *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, at 243.

68 For example, *Van Der Lely NV v Rushton's Engineering Co Ltd* [1985] RPC 461.

69 For example, *Windsurfing International Inc v Petit* (1984) 3 IPR 449.

different using the previously accepted method in Australia.[70] His Honour further cautioned that this approach does not justify any new category of non-textual infringement.[71]

The judgment of Sheppard J in *Decor Corp v Dart Industries*,[72] gives more comprehensive guidance as to how a patent will be construed. His Honour distilled from the authorities ten relevant rules of construction. I have further summarised these rules, and present the crucial requirements below.

1. The claims define the invention. Construe using ordinary principles.
2. Do not confine the scope of the claims by reference to limitations in the specification which are not expressly or by proper inference reduced to the claims themselves.
3. Even so, read the specification as a whole.
4. In some cases, it is permissible to refer to the specification to qualify or define words used in the claims.
5. If a claim is clear, don't allow it to be obscured by obscurities elsewhere in the document. But where an expression is unclear or ambiguous, consult the body of the specification to define or clarify it.
6. Give a purposive rather than a literal construction.
7. Remember the document is not a written instrument *inter partes* but a public document. The monopoly claimed should not be capable of being misunderstood.
8. The aim is to instruct those skilled in the art in carrying out the invention. The language used is not important provided it is comprehensible and does not mislead the skilled reader.
9. Since the claims define the monopoly, construe as carefully as for any other document defining a legal right.
10. The invention will be invalid if it is impossible to ascertain what it is from a fair reading of the specification as a whole, but remember to construe in the light of the common general knowledge before the priority date.

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70 In *Nicaro Holdings Pty Ltd v Martin Engineering Co* (1990) 16 IPR 545, referring to *Commonwealth Industrial Gases Ltd v MWA Holdings Pty Ltd* (1970) 44 ALJR 385.

71 See also Gummow J's judgment in *Rehm Pty Ltd v Websters Security Systems (International) Pty Ltd* (1988) 11 IPR 289, at 301.

72 *Decor Corp Pty Ltd v Dart Industries Inc* (1989) 13 IPR 385, at 400.

The task of construing the patent is a matter for the examiner or for the court. It has been stated emphatically that this task should not be delegated to expert witnesses.[73] The role of expert witnesses is in informing the judge as to scientific or technical terms, or special meanings given to ordinary words by those skilled in the art. Further, the specification should be construed without reference to prior documents, or to subjective thoughts, intentions, etc of the patentee or his witnesses, or to actions of the patentee either pre- or post-grant.[74]

4.2 Specification Requirements: Compliance with Section 40

The specification is crucial to any inquiry into the validity of a patent. The purpose of the specification requirement is twofold: first it must describe the nature of the invention and secondly it must describe the manner in which it can be performed. Defects in the specification requirements, as set out in section 40 in both the 1990 and 1952 Acts, can be triggers for inquiry at examination, opposition and revocation stages. There are areas of overlap both between the different specification requirements and with the utility requirement.

4.2.1 Full Description of the Invention, Including Best Method of Performance: Insufficiency (s40(2)(a)).

In describing the best method of performing the invention, the description must be sufficient to enable the skilled person to work the invention.[75] Mistakes and omissions will not render the patent invalid for insufficiency provided that they can be rectified by the skilled addressee without the exercise of inventive faculty.[76] The description will be insufficient, however, if the addressee is required to undertake prolonged experimentation to make the invention work.[77] In the case of inventions which are

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73 *Sartas No 1 Pty Ltd v Koukourou & Partners Pty Ltd* (1995) 30 IPR 479, at 485-486, per Gummow J, adopting the propositions of Mummery J in *Glaverbel SA v British Coal Corp* [1994] RPC 443.

74 *Ibid.*

75 See *Peptide Technology Ltd v The Wellcome Foundation Ltd* (1992) 23 IPR 319, at 325.

76 *No-Fume Ltd v Frank Pitchford & Co Ltd* (1935) 52 RPC 231.

77 *Valensi v British Radio Corp Ltd* [1973] RPC 337, at 377.

improvements over the prior art, the true nature of the invention should be readily distinguishable from the prior art.[78]

4.2.2 Definition of the Invention in the Claims and Clarity of the Claims: Ambiguity and Lack of Clarity (s40(3)).

The difference in function between the body of the specification and the claims is well recognised.[79] The claims must define the invention and in doing so must not go beyond it.[80] The legislation requires that they do so clearly and succinctly, so that the precise extent of the monopoly claimed is known. Where the claims are ambiguous or otherwise unclear, resort may be had to the body of the specification to resolve the ambiguity.[81] If this is not possible the patent will be invalid. This is the case irrespective of whether the application was prepared in good faith or the ambiguity was purposely introduced.[82] If the claims have a plain and unambiguous meaning, however, it is not permissible either to add a gloss or to confine the scope of the claims by reference to the specification.[83] Terms will be interpreted in "a practical and commonsense way"[84] from the perspective of those skilled in the art. A claim will be sufficiently clear if a skilled addressee can readily determine whether their act would or would not infringe the patent.[85]

4.2.3 Fair Basis (s40(3)).

Patent claims cannot be made in isolation, but must be backed up by material presented in the specification, that is, they must be fairly based on the disclosure in the specification. The term "fair basing" is a recent concept,

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78 *Nelson v Hillmark Industries Pty Ltd* (1991) 19 IPR 628, at 636.

79 See, for example, Lockhart J in *Elconnex Pty Ltd v Gerard Industries Pty Ltd* (1993) 25 IPR 173, at 187.

80 See *Sami S. Svendsen Inc v Independent Products Canada Ltd* (1968) 119 CLR 156, at 165.

81 *Interlego AG v Toltoys Pty Ltd* (1973) 130 CLR 461; *Rehm Pty Ltd v Websters Security Systems (International) Pty Ltd* (1988) 11 IPR 289.

82 *Martin v Scribal Pty Ltd* (1954) 92 CLR 17, at 59.

83 *Welch Perrin & Co Pty Ltd v Worrell* (1961) 106 CLR 588.

84 *Elconnex v Gerard Industries,*(1993) 25 IPR 173 at 188.

85 See *Glaverbel v British Coal* [1994] RPC 443, at 495; *Lumenyte International Corp v Light Transmission Cables Pty Ltd* (1985) 31 IPR 527, at 540.

appearing for the first time in the *Patents Act* 1949 (UK)[86] and the *Patents Act* 1952 (Cth). The Full Federal Court discussed the origin of the fair basing concept in *CCOM v Jeijing*,[87] stating that it was derived from two propositions, first that the claim should be no wider than warranted by the disclosure in the specification, and secondly that the complete specification should conform with the provisional specification. The traditional justification for such a requirement is that since disclosure is the consideration that the patentee gives in return for protection of the article embodying the inventive idea, they should cover the same things.[88] The Court in *CCOM* expressed some concern about use of the *Mullard* rationale now that fair basing is firmly established in statutory form. It pointed to Barwick CJ's words of caution, that the question of fair basing should be narrow one, focussing on whether the claims travel beyond the matter disclosed in the specification, and not by considering whether grant of a monopoly would be undue reward for the disclosure.[89] The Court in *CCOM* further cautioned against "an over meticulous verbal analysis."[90] A number of cases have considered the requirements for the two aspects of fair basing, first, of the complete specification, with regard to the provisional specification, and secondly, of the claims, with regard to the body of the complete specification.

- Fair basing of the complete specification, with regard to the provisional specification.

  Where an application includes only a provisional specification, the complete specification must be lodged within 12 months.[91] It is often of vital importance to validate the link between the provisional specification and the complete specification, because in the interim between the two the prior art base or common general knowledge may have changed sufficiently to put the novelty and inventive step requirements in doubt. Challenges are usually made on the basis that the patent is not entitled to the priority date

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86 Sections 4, 5 and 6. Note that the term does not appear in the *Patents Act* 1977 (UK), see Chapter 6.

87 (1994) 28 IPR 481, at 496-501.

88 See, for example, Lord Macmillan in *Mullard Radio Valve Co Ltd v Philco Radio and Television Corp Of Great Britain Ltd* [1936] RPC 323.

89 In *Olin Corp v Super Cartridge Co Pty Ltd* (1977) 14 ALR 149.

90 At 500-501.

91 Regulation 3.10.

in the provisional specification, because the complete specification is not fairly based on it. This becomes critical in the assessment of what was prior art or common general knowledge at the priority date.

In answering the question of whether the complete specification in issue is fairly based on the provisional specification, the primary focus of inquiry is whether there is a "real and reasonably clear disclosure" of the invention in the provisional specification.[92] The task of the court is quite clearly not a matter of isolating the essential features of the invention claimed in the provisional specification and determining whether they correspond with those claimed in the complete specification.[93] This test is inappropriate because all that is required of the provisional specification is to "describe generally and fairly the nature of the invention".[94] The comparison that should be made is between the claims in the complete specification with the whole of the provisional specification: the provisional specification should reveal the "essence" of the invention claimed.[95] The Full Federal Court most recently endorsed these principles of interpretation of this aspect of the fair basis requirement in *Leonardis v Sartas.*[96]

- Fair basing of the claims, with regard to the body of the complete specification.
  As Lockhart J pointed out in *Decor Corp v Dart Industries,* the function of the claims is to precisely define the monopoly claimed, the primary object being to limit and not extend the monopoly.[97] In drawing up a claim, the patentee is faced with a trade-off. Narrowly drafted claims lower the likelihood of infringement, but are more likely to be novel than broadly based claims.[98] Fair basing is designed to ensure that the invention claimed is the same as the invention disclosed in the specification. It would appear

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92 *CCOM v Jiejing,* (1994) 28 IPR 481 at 501.

93 These types of comparisons are performed by the court in determining issues of infringement and novelty, see later.

94 Per Lockhart J in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383.

95 *Ibid.*

96 *Leonardis v Sartas No 1 Pty Ltd* (1996) 35 IPR 23.

97 *Decor Corp Pty Ltd v Dart Industries Inc* (1989) 13 IPR 385, at 391.

98 See Gummow J in *Sartas v Koukourou* (1995) 30 IPR 479, at 497.

that three questions need to be asked to determine whether the claims are fairly based on the disclosure:

- whether the invention is broadly (generally) described in the specification;
- whether the description of the invention is inconsistent with the claims;
- whether the claim includes a characteristic of the invention not included in the specification.[99]

Gummow J has pointed out that in the same way that fair basing is ascertained as between the complete and provisional specifications, so too here it is not appropriate to isolate and compare the essential integers of the specification and the claim in question.[100] It is sufficient for there to be a real and reasonably clear disclosure.

Part 5: Elements of a Patentable Invention and Patent Validity

For a invention to be patentable, it must not only fulfil the specification requirements, but must also satisfy each of the criteria set out in subsection 18(1) *Patents Act* 1990. Only then does it become a patentable invention. To recapitulate, section 18(1) requires:

- a manner of manufacture;
- novelty;
- inventive step;
- usefulness; and
- no secret use.

There is no equivalent to subsection 18(1) in the 1952 Act. The only reference to the requirements for a patentable invention in that Act is in the Definitions in section 6. The same language is used for the definition of invention as in the 1990 Act. Although not explicitly recognised in the definition of invention, it is evident that by 1952 the notion of invention incorporated the separate elements of manner of manufacture, novelty, inventive step, utility and secret use, because these were recognised as grounds

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99 See, for example, *Rehm v Websters Security Systems* (1988) 11 IPR 289, at 303; *W.R. Grace & Co v Asahi Kasei Kogyo Kabushiki Kaisha* [1993] AIPC ¶90-974, at 39,277. Adopted from *Re Mond Nickel Co Ltd's Application* [1956] RPC 189 at 194.

100 In *Rehm v Websters Security Systems* (1988) 11 IPR 289, at 304.

for challenging the validity of the patent, either in opposition[101] or revocation[102] proceedings. Note, however, that at the examination stage there was no requirement in the 1952 Act for the Examiner to ascertain whether the invention involved an inventive step.[103] In addition, prior to this in the 1903 *Patents Act* inventive step was not even a ground for opposition, but could be raised in revocation proceedings. The lack of this requirement had considerable impact on judicial interpretations of the novelty requirement.[104] An extensive body of case law has considered each of the elements that is required to satisfy a valid patent claim in the 1952 *Patents Act*,[105] and much of this remains relevant to the 1990 Act.

Differences between the 1952 Act and 1990 Act have been subject to some analysis.[106] Although the 1990 Act revoked the 1952 Act, regard must be had to the transitional provisions in section 233. These provisions are important, because patents that were granted under the 1952 Act are still open to challenge in revocation proceedings. Subsection 233(1) ensures that the 1990 Act applies to any patent granted under the 1952 Act as if it had been granted under the 1990 Act. Through subsection 233(4), however, challenges to the validity of a patent can only be made on a ground that was also available under the 1952 Act.[107] According to Wilcox J in *Philips* the purpose of subsection 233(4) "is to maintain the existing rights of the 1952 Act patent-holders, but no more."[108] This requires that the relevant ground is made out under the provisions of

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101 Section 59, 1952 Act.

102 Section 100, 1952 Act.

103 Section 48(1), 1952 Act.

104 See, for example, *Griffin v Isaacs* (1938) 12 ALJ 169 and the discussion by Gummow J in *R.D. Werner & Co Inc v Bailey Aluminium Products Pty Ltd* (1989) 13 IPR 513.

105 Reviewed in Ricketson, S., *Intellectual Property Cases, Materials and Commentary* (1994) Butterworths, Chapters 13 and 14.

106 Collins, T.J., "Patents Act 1990: Opposition to Grant of a Standard Patent" (1993) 4 *Australian Intellectual Property Journal* 174; Montague, P.E., "Biotechnology Patents and the Problem of Obviousness" (1993) 4 *Australian Intellectual Property Journal* 3; Speagle, D. and M. Dowling, "The 1990 Patents Act: Unfinished Reform" (1993) 4 *Australian Intellectual Property Journal* 166.

107 See the judgment of Wilcox J in *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1992) 24 IPR 1; approved by the Full Court (1993) 26 IPR 513.

108 At 11.

both Acts. By these means, according to Lockhart J in the Full Court decision in the same case, the 1952 Act patentee clearly will be no worse off than if the 1952 provisions had continued to operate, but may also be better off if a part of a ground in the 1952 Act does not appear in the 1990 Act.[109] Subsection 233(4) is particularly relevant when the novelty and inventive step elements are under consideration (see below at 5.2).

5.1 Manner of Manufacture

Manner of manufacture can be thought of as the starting point in determining patentability. The Industrial Property Advisory Committee (IPAC) in its 1984 Report[110] strongly urged that this test should be retained in its existing form in the new Act, rather than replacing it with a more explicit statement of what is patentable. The Committee argued that the manner of manufacture test has exhibited the capacity to respond to technological innovations through an extensive body of case law. The government endorsed this recommendation, stating in the Explanatory Memorandum to section 18 that this test was preferred over a more inflexible codified definition. In Europe, in contrast, a specific set of exclusions was opted for in the *European Patent Convention*, and adopted in the *Patents Act* 1977 (UK).[111]

Numerous attempts were made in the early English cases to define the term "manufacture", the tendency being to interpret it as having a flexible and expansive meaning, including both the products of manufacture and the process of manufacture itself. In *Boulton v Bull*,[112] for example, Eyre CJ included in the concept "any new results of principles carried into practice" and also "new processes in any art producing effects useful to the public".[113] Furthermore, even if the products or processes were known, the novel combination of the two

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109 At 518.

110 Industrial Property Advisory Committee *Report on Patents, Innovation and Competition in Australia* (1984).

111 Sections 1 and 4 of the *Patents Act* (1977) UK. These provisions are set out in full in Chapter 6.

112 (1795) 1 H Bl 463; 126 ER 651. A number of the other early cases are discussed in *National Research and Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (henceforth referred to as *NRDC*).

113 *Ibid.*, at 666.

together may be patentable.[114] Later, however, attempts were made to narrow the scope of manner of manufacture by introducing the requirement of a "vendible product" arising out of the process of manufacture, and in *Re GEC's Application*,[115] Morton J, while denying that he was laying down a hard and fast rule, proposed that

> "a method or process is a manner of manufacture if it (a) results in the production of some vendible product or (b) improves or restores to its former condition a vendible product or (c) has the effect of preserving from deterioration some vendible product to which it is applied."[116]

The Morton "rule", as it became known, was adopted in a number of subsequent cases,[117] and proved to be a major obstacle to patenting of biological processes, because of the difficulty in demonstrating that a vendible product had been produced. Although the rule could not prevent patenting of biological products, it created problems where attempts were made to patent a process where a previously described product was given a new, previously unknown or unthought of application. This difficulty was overcome in 1959 in the Australian High Court case of *National Research and Development Corporation v Commissioner of Patents (NRDC)*.[118] The High Court widened the notion of vendible product, by treating the word "product" as any artificially created state of affairs and "vendible" as having an economic effect. Using these broad criteria, the High Court was able to approve the patent for a known herbicide which was used in a novel way to selectively kill weeds from crop areas. The Court emphasised that it is a mistake to ask whether a process or product is a manner of manufacture.

> "The right question is: 'Is this a proper subject of the letters patent according to the principles which have been developed for the application of s6 of the Statute of Monopolies?'"[119]

The decision in *NRDC* has been described as a watershed,[120] and has had important consequences. It has been adopted as the test for manner of

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114 For example *Crane v Price* (1842) 1 Webb PC 393; 134 ER 239.

115 [1942] RPC 1.

116 *Ibid.*, at 4.

117 Reviewed by Dixon CJ, Kitto and Windeyer JJ in *NRDC* (1959) 102 CLR 252.

118 *Ibid.*

119 *Ibid.*, at 269.

120 By Barwick CJ in *Joos v Commissioner of Patents* (1972) 126 CLR 611.

manufacture in Australia[121] and New Zealand,[122] and was accepted in England prior to enacting of the new *Patents Act* in 1977.[123] For subject matter to be a manner of manufacture as interpreted in *NRDC*, it must belong to the useful rather than the fine arts, it must provide a material advantage and its value to the country must be in the field of economic endeavour.[124] Subject matter which may be considered to be suitable for patenting includes new products, new methods of producing old products, and new uses for old products.

5.2 Novelty

Perhaps novelty is the most obvious requirement for patenting: an invention must be new. Even so, novelty is very much a technical term in this area of the law and has lost much of its natural meaning. Novelty can also be referred to as anticipation, prior publication or disclosure. Novelty is lost when the invention has already been disclosed in recorded form, or orally, or by use.

5.2.1 Novelty in Relation to the Other Patenting Requirements

All three key requirements in the present Act of manner of manufacture, novelty and inventive step have their origin in the "manner of new manufacture" in section 6 of the *Statute of Monopolies*. The three areas gradually became distinct entities through the 18th and 19th century case law, and are now recognised as such in section 18(1) of the 1990 Act. In many respects, however, the areas overlap and it is difficult to avoid the temptation of introducing aspects of one of the tests into another area. The problems associated with this were discussed in detail by Gummow and Lockhart JJ in *R.D. Werner v Bailey Aluminium*[125] with respect to novelty and inventive step, and reiterated in *Nicaro Holdings v Martin Engineering*.[126] The introduction of a requirement for inventiveness into the novelty ground arose

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121 This view has been strongly endorsed in the recent cases of *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383 and *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 28 IPR 481.

122 *Swift & Co's Application* [1960] NZLR 775 and *Wellcome Foundation Ltd v Commissioner of Patents* [1979] 2 NZLR 591.

123 For example, *Swift & Co's Application* [1962] RPC 37.

124 These requirements are listed in *NRDC* (1959) 102 CLR 252 at 275.

125 *R.D. Werner & Co Inc v Bailey Aluminium Products Pty Ltd* (1989) 13 IPR 513.

126 *Nicaro Holdings Pty Ltd v Martin Engineering Co* (1990) 16 IPR 545.

in the early patent cases because of the lack of an inventive step ground for challenging the validity of a patent in opposition proceedings in the 1903 Act. In *R.D. Werner,* Gummow J explained that where want of invention was manifest the courts were reluctant to allow the grant of the patent which could subsequently be revoked for lack of inventive step.

The presence of an inventive step ground in opposition proceedings in both the 1952 and 1990 Acts[127] suggests that assessment of the novelty requirement should not now involve a need for there to be an inventive step. Even so, according to Lockhart J, where there is clearly no inventive merit whatsoever over the prior art there will be no novelty. What Lockhart J requires for a patentable invention is "something more than a mere workshop variation or mechanical equivalent". The requirement of inventiveness and use of the terms such as "workshop adjustment". "workshop improvement" and "workshop alteration" are usually restricted to consideration of the inventive step requirement.[128] Gummow J preferred to avoid all discussion of inventiveness under the novelty test. But even for him, the invention can still be categorised as a mere workshop improvement over the prior art without reliance being placed on the ground of obviousness. The invention will simply lack novelty because it is sufficiently disclosed in the prior art,[129] as required by the long-accepted formulation of Lord Westbury in *Hills v Evans:*

> "the antecedent statement must be such that a person of ordinary knowledge of the subject would at once perceive, understand, and be able practically to apply the discovery without the necessity of making further experiments and gaining further information before the invention can be made useful."[130]

5.2.2 *Novelty Requirements*

The novelty requirements are set out in section 7(1) of the *Patents Act* 1990.

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127 Paragraph 59(1)(h) 1952 Act; subsection 59(b) 1990 Act.

128 See, for example, the comments of Gummow J in *Nicaro Holdings v Martin Engineering* (1990) 16 IPR 545, at 560 and 565.

129 See Gummow J in *R.D. Werner v Bailey Aluminium* (1989) 13 IPR 513, at 541 and in *Nicaro Holdings v Martin Engineering* (1990) 16 IPR 545, at 566.

130 *Hills v Evans* (1862) 31 LJ Ch 457.

7. (1) For the purposes of this Act, an invention is to be taken to be novel when compared with the prior art base unless it is not novel in the light of any one of the following kinds of information, each of which must be considered separately:

(a) prior art information (other than that mentioned in paragraph (c)) made publicly available in a single document or through doing a single act;

(b) prior art information (other than that mentioned in paragraph (c)) made publicly available in 2 or more related documents or through doing 2 or more related acts, if the relationship between the documents or acts is such that a person skilled in the relevant art in the patent area would treat them as a single source of information;

(c) prior art information contained in a single specification of the kind mentioned in subparagraph (b) (ii) of the definition of "prior art base" in Schedule 1.

The definitions of *prior art base* and *prior art information* in Schedule 1 are also pertinent:

"prior art base" means:

(a) in relation to deciding whether an invention does or does not involve an inventive step:

(i) information in a document, being a document publicly available anywhere in the patent area; and

(ii) information made publicly available through doing an act anywhere in the patent area; and

(iii) where the invention is the subject of a standard patent or an application for a standard patent - information in a document publicly available outside the patent area; and

(b) in relation to deciding whether an invention is or is not novel:

(i) information of a kind mentioned in paragraph (a); and

(ii) information contained in a published application filed in respect of a complete application where:

(A) if the information is, or were to be, the subject of a claim of the specification, the claim has, or would have, a priority date earlier than that of the claim under consideration, and

(B) the specification was published after the priority date of the claim under consideration; and

(C) the information was contained in the specification on its filing date and when it was published;

"Prior art information" means:

(a) for the purposes of subsection 7 (1) - information that is part of the prior art base in relation to deciding whether an invention is or is not novel; and

(b) for the purposes of subsection 7 (3) - information that is part of the prior art base in relation to deciding whether an invention does or does not involve an inventive step.

For the definition of *document* section 7 refers to the *Acts Interpretation Act* 1901 (Cth):

25. In any Act, unless the contrary intention appears: "document" includes: (a) any paper or other material on which there is writing; (b) any paper or other material on which there are marks, figures, symbols or perforations having a meaning for persons qualified to interpret them; and (c) any article or material from which sounds, images or writings are capable of being reproduced with or without the aid of any other article or device; "record" includes information stored or recorded by means of a computer; "writing" includes any mode of representing or reproducing words, figures, drawings or symbols in a visible form.

Patent area is defined in Schedule 1 of the 1990 Act:

"patent area" means: (a) Australia; and (b) the Australian Continental shelf; and (c) the waters above the Australian continental shelf; and (d) the airspace above Australia and the Australian continental shelf.

5.2.3 *Comparison Between the 1990 Act and the 1952 Act*

The considerations that the Examiner had to take into account in determining novelty were set out in s48(1) in the 1952 Act. Opposition and revocation grounds were set out in ss59 and 100, respectively. The main change in novelty requirements in the 1990 Act is the geographical area in which the prior art base is determined. Under the 1952 Act, the prior art base was restricted to those things published, orally disclosed or used within Australia, that is, there was a national standard of novelty.[131] At the time of the IPAC Report many countries had already adopted a universal standard. Europe has an absolute universal standard, which includes anything made public by any means anywhere in the world. In the USA, on the other hand, there is a limited universal standard, which includes publications from anywhere in the world, and national use. The Committee recommended adoption of the limited universal standard. This was justified on two bases: first, that the universal standard should apply because transfer of information was so improved that it was no longer sensible to assess publications on a national level; secondly, that an absolute universal standard would increase uncertainty of validity because of the impossibility of verifying the lack of prior oral disclosures or use

131 See IPAC Report at 44.

anywhere in the world by the patentee.[132] These recommendations were adopted in paragraph 7(1)(a) and paragraph (a) of the definition of prior art base in the 1990 Act.

The other major change from the 1952 Act was the abolition of prior claiming, through which a prior claim in an earlier patent specification which was unpublished at the priority date of the patent in issue could be used to show lack of novelty. The opinion of IPAC was that this approach was too narrow and that a "whole contents" approach was preferable, through which any disclosure in an earlier unpublished patent specification, irrespective of whether it was in the claim or the body of the specification, could be used. This recommendation was adopted in paragraph 7(1)(c) and subparagraph (b)(ii) of the definition of prior art base of the 1990 Act.

These changes have considerably broadened the scope of objection to patents on the ground of want of novelty, although the breadth of the prior art still does not match that in Europe. There is no case law to date through which to assess the effect of the changes.

5.2.4 The Test for Novelty

The accepted test for novelty probably remains the "reverse infringement test" as propounded by Aickin J in *Meyers Taylor:*

> "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."[133]

The test is the same as that propounded by the English Court of Appeal in the *General Tire case.* [134] The same test applies whether the prior disclosure is in documentary form or through use.[135] The prior art in question must

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132 *Ibid.*, at 45.

133 *Meyers Taylor Pty Ltd v Vicarr Industries* (1977) 137 CLR 228 at 235. See also *Minnesota Mining and Manufacturing Co v Briersdorf (Australia) Ltd* (1980) 144 CLR 253; *R.D. Werner v Bailey Aluminium* (1989) 13 IPR 513; *Nicaro Holdings v Martin Engineering* (1990) 16 IPR 545.

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

135 *Windsurfing International Inc v Petit* [1984] 3 IPR 449.

disclose all of the features of the invention, in clear, unequivocal and unmistakable terms. According to the Court of Appeal:

> "To anticipate the patentee's claim the prior publication must contain clear and unmistakable directions to do what the patentee claims to have invented ... A signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee."[136]

Although the prior publication must disclose all of the relevant features, or essential integers of the invention, the authorities make it clear that it must be taken as being read by one skilled in the art. Provided that the prior publication gives enough information for a competent workman in the art to produce the invention there will be anticipation, even when the prior publication contains a minor defect,[137] or the invention in issue contains a slight modification of it. The accepted measure is whether the changes are to essential integers of the invention, or to inessential integers, for example by the mere substitution of mechanical equivalents which perform analogous purposes.[138]

In *Advanced Building Systems v Ramset Fasteners,* Hill J set out the task as determining the essential integers of the prior publication and the alleged invention, and if the only difference arises from an inessential integer there will be anticipation.[139] This requires reading and interpreting the prior publication and the patent specification in the light of what was generally known at their respective dates of publication.[140] Although construction of the material is a matter of law for the court, it must be construed from the perspective of the person skilled in the relevant art at the relevant date. The question of whether the patentee's claim is anticipated by the prior publication is a question of fact. If the directions contained in the prior publication would, if

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136 *General Tire v Firestone Tyre* [1972] RPC 457, at 486.

137 *Acme Bedstead Co Ltd v Newlands Bros Ltd* (1937) 58 CLR 689.

138 *Sunbeam Corp v Morphy Richards* (Australia) Pty Ltd (1961) 35 ALJR 212 at 220; *R.D. Werner v Bailey Aluminium* (1989) 13 IPR 513; *Dennison Manufacturing Co v Monarch Marking Systems Inc* (1983) 66 ALR 265; *Nicaro Holdings v Martin Engineering* (1990) 16 IPR 545.

139 *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* (1993) 26 IPR 171 at 182.

140 *General Tire v Firestone Tyre* [1972] RPC 457, at 485.

carried out after the grant of patent, inevitably infringe the patent there is anticipation. If, on the other hand, the directions can be carried out in ways which would not infringe the patent there is no anticipation.[141]

In assessing the prior art base for anticipation, it is only permissible to look at single documents, unless other documents are incorporated by reference.[142] That incorporation must be unequivocal and must demonstrate a clear intention on the part of the draftsman that the cross referencing system was merely used as a shorthand means of creating a single document. To do otherwise would be to make a mosaic by picking out individual items of information from of existing pieces prior art and assembling them together. According to Aickin J, "that is an understandable, though not permissible, process."[143] The degree of connection required to make two documents dependent or independent of one another depends on the case in question and the nature of the art.[144]

Where the claim is for a combination patent, that is, a patent which "combines a number of elements which interact with each other to produce a new result or product,"[145] it is the combination that must be disclosed in the prior publication. This is because, although each of the integers may not be novel, it is the interaction of the combined integers to produce the new result which constitutes the invention.[146] Unless "each item of prior art, taken alone"[147] discloses all of the integers of the combination there will be no anticipation.

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141 *Ibid.*, at 486.

142 *R.D. Werner v Bailey Aluminium* (1989) 13 IPR 513; *Nicaro Holdings v Martin Engineering* (1990) 16 IPR 545.

143 *Minnesota Mining and Manufacturing v Beiersdorf* (1980) 144 CLR 253, at 293.

144 See Gummow J in *Nicaro Holdings v Martin Engineering* (1990) 16 IPR 545, at 570.

145 *Minnesota Mining and Manufacturing v Beiersdorf* (1980) 144 CLR 253, at 266 per Aickin J.

146 *Nicaro Holdings v Martin Engineering* (1990) 16 IPR 545. at 553.

147 Lockhart J in *E Street Enterprises Inc v CPS Housewares Pty Ltd* (1995) 32 IPR 465 at 476.

5.3 Inventive Step

It is not enough for an invention to be novel. There must also be some inventive ingenuity, "some difficulty overcome, some barrier crossed."[148] In the terms of the statute, the invention must "involve an inventive step".[149] This element has also been expressed in terms of the need for the invention to be non-obvious.

5.3.1 Inventive Step Requirements

The test for inventive step appears in subsections 7(2) and (3) of the 1990 Act:

> 7 (2) For the purposes of this Act 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 area before the priority date of the relevant claim whether the knowledge is considered separately or together with either of the kinds of information mentioned in subsection (3), each of which must be considered separately.
>
> (3) For the purposes of subsection (2), the kinds of information are:
>
> (a) prior art information made publicly available in a single document or through doing a single act; and
>
> (b) prior art information made publicly available in 2 or more related documents, or through doing 2 or more related acts, if the relationship between the documents or acts is such that a person skilled in the relevant art in the patent area would treat them as a single source of that information;
>
> being information that the skilled person mentioned in subsection (2) could, before the priority date of the relevant claim, be reasonably expected to have ascertained, understood and regarded as relevant work in the relevant patent area.

The expressions *prior art base, prior art information* and *patent area* are defined in Schedule 1 and *documents* are defined in section 25 of the *Acts Interpretation Act*. All of these are extracted in the novelty section, above. As for novelty, prior art base covers documentary disclosures from anywhere in the world and prior oral disclosures and prior use from within Australia. Note, however, that for inventive step the prior art base does not include prior patents which were unpublished at the priority date of the patent in issue.

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148 *R.D. Werner v Bailey Aluminium* (1989) 13 IPR 513, at 523 per Lockhart J.

149 Section 18(1)(b)(ii).

This test for inventive step is somewhat different from that developed in the cases for the 1952 Act, and therefore the two Acts need to be considered separately. To reiterate section 7, the 1990 Act test includes reference to both the common general knowledge and to single items of prior art information which the skilled address could reasonably have been expected to have ascertained, understood and regarded as relevant. The 1952 Act test is restricted to the common general knowledge in the field, with no reference to documents in existence but not part of the common general knowledge.[150] Consequently, through subsection 233(4) of the 1990 Act, the broadened inventive step test in the 1990 Act cannot be used in relation to patents granted under the 1952 Act.[151]

5.3.2 *Inventive Step under the 1952 Act: the Aickin Test*

Under the 1952 Act, the inventive step ground in both opposition and revocation proceedings required:

> that the invention, so far as claimed in any claim, was obvious and did not involve an inventive step, having regard to what was known or used in Australia on or before the priority date of the claim.[152]

The test for inventive step can be broken up into three considerations:

- who is the hypothetical skilled addressee?
- what is the state of their knowledge?
- in the light of these considerations, what was obvious?[153]

5.3.3 *The Hypothetical Skilled Addressee*

The focus of inquiry is not on the inventor but on the relevant skilled addressee.[154] That person must be both skilled in the art and non-inventive. Early patent cases described such people as being "not just skilled artisans... [but]

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150 See, for example, *E Street Enterprises v CPS Housewares* (1995) IPR 465, at 474.

151 See, for example, *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1993) 24 IPR 1; *Winner v Ammar Holdings Pty Ltd* [1993] AIPC ¶90-971.

152 Paragraph 59(1)(g) (opposition); Paragraph 100(1)(e) (revocation).

153 See, for example, Brysland, G., "A Comment on Infringement and Obviousness in Australian Patent Law" (1981) 12 *Federal Law Review* 344, at 350.

154 *W.R. Grace v Asahi Kasei Kogyo Kabushiki Kaisha* [1993] AIPC ¶90-974, at 39,274.

trained engineers and scientists"[155] or "highly qualified technologist[s] in the research department".[156] As technologies improve so too do the skills of the skilled worker in the field, who may now be a team of Ph.D. level researchers. It becomes difficult to credit such workers with no inventive faculty. According to Professor Ricketson, the notion of a skilled but uninventive addressee has an air of unreality about it.[157] This is particularly the case for genetic research which requires a very high level of skill of its researchers. Nevertheless, the requirement remains that there should be some inventiveness, no matter how small, that goes beyond the skill of the calling.[158]

5.3.4 Knowledge to Be Imputed to the Skilled Addressee

According to Williams J in *HPM Industries v Gerard Industries*[159] the words "known or used" in the 1952 Act included not only the common general knowledge in the field but also prior publications which were not part of the common general knowledge. This test has been said to create a presumption of omniscience on the skilled addressee.[160] It was criticised, but not overruled, in a number of cases because it imposed too high a standard, by requiring that there be an inventive step when compared with all prior disclosures, albeit in only Australia. Moreover, it merged the novelty and inventive step requirements.[161] Ultimately, in the *Minnesota Mining and Manufacturing case,* the High Court was given the opportunity to overrule *HPM Industries.* Aickin J gave the leading judgment. After reviewing the history of the Australian legislation, he was satisfied that the observations of Williams J should *not* be regarded as "correctly stating the law in Australia."[162]

For Aickin J the proper question is: "is the invention itself obvious, not whether a diligent searcher might find pieces from which there might have

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155 *Sunbeam Corp v Morphy-Richards (Australia) Pty Ltd* (1961) 35 ALJR at 212.

156 *Johns-Manville Corporation's Patent* [1967] RPC 479.

157 Ricketson, S., *Cases and Materials on Intellectual Property* (1994) Butterworths, at 684.

158 See *Allsop Inc v Bintag Ltd* (1989) 15 IPR 686.

159 *HPM Industries Pty Ltd v Gerard Industries Ltd* (1957) 98 CLR 427.

160 For example, Brysland at 352.

161 For example, Windeyer J in *Sunbeam Corp. v Morphy-Richards* (1961) 35 ALJR.

162 *Minnesota Mining and Manufacturing v Beiersdorf* (1980) 144 CLR 253, at 292.

been selected the elements which make up the patent."[163] If it were otherwise, new combinations of old integers would always be obvious. For combination patents, therefore, it is the selection of integers that must be shown to be obvious.[164] It is inappropriate to separate out the integers and determine whether each one individually was obvious.[165] The focus of inquiry, according to Aickin J is:

> "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."[166]

Justice Aickin's reworking of the test for inventive step was generally accepted in subsequent cases. For example, Waddell J in *Windsurfing International Inc v Petit* affirmed that the same test applies whether the prior art in issue is publication or use, that is, both must have become part of the common general knowledge of the hypothetical skilled addressee in the field for them to be relevant to the consideration of obviousness.[167]

Common general knowledge must be clearly distinguished from public knowledge. Public knowledge incorporates any prior publication whereas common general knowledge includes only that which would be known to the ordinary skilled addressee. According to the Full Federal Court in *W.R. Grace v Asahi,*

> "[it] represents the matters that the skilled person will have at the back of his or her mind when coming to consider the prior art, so that each document alleged to constitute the prior art is to be regarded as the addressee would regard it in the light of common general knowledge."[168]

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163 *Ibid.*, at 293.

164 *Ibid.*

165 *Ibid.* See also *Elconnex Pty Ltd v Gerard Industries Pty Ltd* (1992) 25 IPR 173.

166 Aickin J in *Wellcome Foundation Ltd. v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262, at 270.

167 [1984] 3 IPR 449.

168 Northrop, Lockhart and Cooper JJ, *W.R. Grace v Asahi* [1993] AIPC ¶90-974.

For material in the prior art to be relevant it must have become part of the stock of common general knowledge in Australia.[169] This depends very much on the art in question. It may be that in a particular art patent specifications would be read routinely and would therefore be part of the common general knowledge. But this is not the case for all areas.[170] A 1991 Practice Notice on Inventive Step[171] indicates the types of evidence that the examiner should consider in determining the common general knowledge. These include standard texts and handbooks, standard and some technical dictionaries, concessions made in the application itself, other publications and, under certain conditions, other patent specifications. It is for the examiner to use his or her judgment to determine whether new concepts in these documents are part of the common general knowledge.

5.3.5 Obviousness

A "scintilla of inventiveness" is enough for an invention to be non-obvious.[172] It is irrelevant that the idea is simple, or that once the idea is conceived it is simple to put it into effect. A number of tests have been suggested in the cases. A 1991 Practice Note of the Patent Office refers to some of the tests for establishing obviousness, including "whether the invention would in effect suggest itself", "... not, could the invention be derived from the prior proposal, but, would it?" and whether it was "so obvious that it would at once occur to anyone acquainted with the subject, and desirous of accomplishing that end."[173]

The test is objective and is a question of fact to be determined on the evidence admitted. The burden of proof is on the person challenging the validity of the patent. Relevant evidence includes: expert evidence; evidence of long felt want; commercial success of the invention; and research and experiments of the patentee.

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169 *Wellcome Foundation v VR Laboratories* (1981) 148 CLR 262, at 284.

170 See the comments of Aickin J in *Minnesota Mining and Manufacturing v Beiersdorf* (1980) 144 CLR 253, at 293.

171 Australian Industrial Property Organisation, *Practice Note 1991 (No. 10) Inventive Step.*

172 Aickin J in *Meyers Taylor v Vicarr Industries* (1977) 137 CLR 228, at 249.

173 *Practice Note 1991 (No. 10) Inventive Step,* at 16,123-16,124.

- Expert evidence

  Expert evidence from people skilled in the field is admissible in determining both the common general knowledge of the non-inventive skilled worker in the field and whether the invention is obvious in the light of that common general knowledge.[174] Indeed, it has been suggested that expert evidence will almost invariably be required and will largely be determinative of the common general knowledge.[175] It is for the court to decide whether the invention was obvious, although it is within the competence of the expert witness to say, for example, that the invention was a routine variation of what was already known in the field.[176]

  The evidence of experts in the field is likely to dominate any trial in which inventive step is raised as a ground for invalidating a patent. My viewing of the affidavit evidence in the *Murex v Chiron* case[177] supports this proposition.[178]

  The level of qualification of the expert will go to the weight of the evidence, and not to admissibility.[179] In *Mölnlycke v Proctor and Gamble,* the English Court of Appeal referred to expert evidence as primary and all other evidence as secondary.[180] There are some problems, however, with reliance on expert evidence because of the so-called trap of hindsight. Once a thing becomes known and used, it becomes easy to say that the initial idea was obvious. Many judges, and particularly Aickin J, have warned of the dangers of hindsight and "ex post facto dissection of the invention". Secondary

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174 *Winner v Ammar Holdings Pty Ltd* [1993] AIPC ¶90-971.

175 See the decision of the delegate of the Commissioner of Patents in *Bodenseewerk Perkin-Elmer Gmbh v Varian Australia Pty Ltd* (1996) IPR 110, at 152, following the English case of *Mölnlycke AB v Proctor and Gamble* [1994] RPC 49.

176 See Lockhart J in *Elconnex v Gerard Industries* (1992) 25 IPR 173, at 187.

177 *Murex Diagnostics Australia Pty Ltd v Chiron Corporation* No. G106 of 1994. Note that the case was ultimately settled out of court. Argued before Burchett J in July and August 1996.

178 I would like to thank Mr. Luigi Palombi, solicitor for Murex, for allowing me access to this affidavit material.

179 *Elconnex v Gerard Industries* (1992) 25 IPR 173.

180 *Mölnlycke AB v Proctor and Gamble* [1994] RPC 49, at 113.

evidence is important in rebutting the hindsight argument.[181] The weight to be attached to this secondary evidence will vary from case to case.

- Long felt want
  According to Lockhart J, evidence of failure of attempts to solve a well known problem may be a powerful indication of non-obviousness, by indicating a "long felt want".[182] Where others have failed to solve the problem for themselves and immediately produce an infringing article, "the inference may be irresistible that the invention was not obvious."[183]

- Commercial success of the invention
  Of itself, commercial success can never be decisive of inventiveness, but is a material consideration.[184]

- Research and experiments of the patentee
  Although the inventive step test is objective and the focus of inquiry is on the notional addressee, evidence of the patentee's experiments has been admitted by the courts. According to Aickin J, admission of such evidence may show either that the experiments were part of the inventive step, or that they were routine work.[185] That evidence will not be determinative, but is merely suggestive of whether the invention could have been reached by trial and error. Use of such material to attack the patent may turn out to be unhelpful, because it will often draw on hindsight and ex post facto analysis of the invention.[186] It should therefore be used with caution.

In all cases in which obviousness is in issue, it is up to the parties to provide the evidence. For example, without evidence of a "long felt want" and commercial success, actual copying of the invention may weigh in neither party's favour.[187] In the end the focus must always be whether the invention was obvious.

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181 See Sheppard J in *Elconnex v Gerard Industries* (1992) 25 IPR 173, at 193-194.

182 Lockhart J in *Elconnex v Gerard Industries* (1992) 25 IPR 173, at 182.

183 *Ibid.*, at 183.

184 Aickin J in *Meyers Taylor v Vicarr Industries* (1977) 137 CLR 228, at 239.

185 In *Wellcome Foundation v VR Laboratories* (1981) 148 CLR 262, at 280-281.

186 *Wellcome Foundation v VR Laboratories* (1981) 148 CLR 262, at 286.

187 See, for example, Lockhart J in *Elconnex v Gerard Industries* (1992) 25 IPR 173, at 183.

5.3.6 *Reform under the 1990 Act*

By the time of the IPAC Report in 1984, the Aickin test was generally accepted as the test for inventive step under the existing legislation. The focus of inquiry of the test, restricted as it was to the common general knowledge, was much narrower than equivalent tests in other countries. A number of options were available to IPAC in its recommendations to the Government:

- The Aickin test could be retained. Only common general knowledge could be considered, and common general knowledge only comprised what was known and used by the hypothetical skilled addressee.
- The presumption of omniscience could be resurrected. All prior publications could be considered.[188]
- The test could include common general knowledge and prior publications which the diligent searcher would have ascertained, understood and regarded as relevant.[189]
- A hybrid test could be formulated.

IPAC recommended a hybrid test falling between the diligent searcher and omniscient artisan tests. First, the focus should not only be on the common general knowledge but also single prior recorded disclosures from anywhere in the world, or single prior uses from within Australia (but not two or more of both or either). Secondly, common general knowledge should include that which is generally known and used and that which is publicly available in recorded form anywhere in the world which a skilled person in the art at the

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188 This would appear to be the accepted English test, both in the 1949 and 1977 *Patents Acts:* for the 1949 Act see the judgment of Lord Diplock in *Technograph Printed Circuits Ltd v Mills & Rockley (Electronics) Ltd* [1972] RPC 346, at 361, approved in *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* [1985] RPC 59, at 72. For the 1977 Act see section 3 and subsection 2(2), which set out expressly that regard is to be had to any matter which forms part of the state of the art, and the state of the art includes anything which has been made available to the public anywhere, by any means. Note, however, that even though these sections would seem to expressly adopt the omniscient artisan test, Thomson, in her Ph.D. thesis at 228, interprets the cases of *Genentech Inc's Patent* [1989] RPC 147 and *Genentech Inc's(Human Growth Hormone) Patent* [1989] RPC 613 as applying the common general knowledge test.

189 Lord Reid preferred this test in *Technograph v Mills & Rockley* [1972] RPC 346, at 355.

time should reasonably have been expected to find, understand and regard as relevant.

This recommendation was rejected and what appeared in the 1990 Act is a hybrid between Justice Aickin's test and the diligent searcher test. The common general knowledge accords with the Aickin formulation, but in addition a single item of public information (or two or more related items) can be included in accordance with the diligent searcher formulation.

This test is no more consistent than was Justice Aickin's test with those in Europe and the USA, which have adopted the presumption of omniscience. I suggest that Australia's anomalous position in this regard is contrary to the desire expressed in the GATT TRIPS Agreement for international harmonisation in patent law. On the other hand, if it encourages foreign investment in Australia in the commercialisation of inventions which are patentable in Australia but not elsewhere, then the lower standard may have some merit.

5.4 Utility

The term usefulness, or, as it is more often referred to, utility, has different breadths of meaning in different jurisdictions. In the USA utility requires that the invention is practically useful.[190] This overlaps with both the manner of manufacture and utility requirements in Australian legislation and industrial applicability requirement in Europe.

The US utility requirement has attracted considerable attention of late. Some of the most highly contested claims to patents in recent years were made by the National Institutes of Health (NIH) in the USA for patents for the sequences of many fragments of DNA known as expressed sequence tags (ESTs).[191] The precise function of ESTs is unknown, but they are thought to be likely to incorporate whole genes or parts of genes. The NIH applications were

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190 *Brenner v Manson* 383 US 519 (1966). See also Maebius, S.B., "Novel DNA Sequences and the Utility Requirement: the Human Genome Initiative" (1992) *Journal of the Patent and Trademark Office Society* 652.

191 ESTs are fragments of cDNA generated in vitro from messenger RNA isolated from a range of human tissues.

rejected by the Patents and Trademarks Office, one of the main reasons being that they were considered to be lacking in practical utility because until function was ascribed to the sequences they were considered to lack commercial value.

In Australia utility requires only that "the invention does what it was intended by the patentee to do, and the end in itself is useful".[192] The intention of the patentee can be gleaned from the title of the patent and the body of the specification. Commercial practicality or viability is not a necessary requirement, except that if a particular result is claimed, that result must be achievable.[193] The issue, then, is not whether the invention is commercially viable, but whether the invention as claimed does or does not attain the result promised by the patentee.[194] As such, if EST patent applications were lodged in Australia, they would be more likely to fail on the manner of manufacture ground than on the basis of lack of utility.

Usefulness is explicitly listed as one of the requirements for a patentable invention in s18(1)(c). Even so, it is not necessary for presence or absence of utility to be determined at the examination stage, nor is utility a ground for opposition. It can be challenged in revocation proceedings through the "patentable invention" head in s138(3)(b).

There is some overlap between the utility requirement (that the result cannot be achieved) and the insufficiency requirement (that the result is insufficiently described to be achievable). Gummow J succinctly pointed out the difference between the two:

> "insufficiency occurs when the apparatus cannot be made, and inutility occurs when the apparatus can be made, but when made, doesn't work."[195]

But His Honour went on to say that the difference is often less clear in practice.[196] Gummow J also pointed out in *Rescare* that even though the result

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192 *Fawcett v Homan* [1896] RPC 398, at 405.

193 *Rehm v Websters Security Systems* (1988) 11 IPR 289, at 305; *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1993) 25 IPR 119, at 143.

194 *Decor Corp Pty Ltd v Dart Industries Inc* (1989) 13 IPR 385, at 394, per Lockhart J; *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1993) 25 IPR 119, at 143.

195 *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1993) 25 IPR 119, at 142.

196 *Ibid.*

promised in the patent is not be achievable in all cases the requisite utility may still be present.[197] Utility will always be determined on the facts of the case in question.

5.5 Secret Use

Public use of an invention prior to the priority date will invalidate the patent for want of novelty. Although mere "closet use" will not ground an attack on the basis of lack of novelty,[198] in some circumstances, secret use of the invention prior to the priority date will also threaten the validity of the patent through s18(1)(d). As for utility, challenges can only be made to patent validity on the secret use ground in revocation proceedings through s138(3)(b). Section 9 sets out the types of secret use that do not threaten validity through the secret use provision in s18(1)(d). These include use by the patentee or with his or her authority: for reasonable trial or experiment; in the course of confidential disclosure; for any purpose other than "the purpose of trade or commerce"; by or on behalf of the Commonwealth, a state or territory where the patentee has disclosed the invention to the Commonwealth, State or Territory.

Invalidity for secret use is justified on the basis that the inventor has made a commercial decision between protection through the patent system or through trade secrecy, and should not have the benefit of both.

5.6 The *Philips* Threshold: an Invention

An additional layer has recently been added to the requirements for a valid patent by the High Court in *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd.*[199] Before the requirements for a patentable invention in s18(1) are assessed, the patentee must first show that there is an invention, as defined in Schedule 1.

In *Philips v Mirabella* the Federal Court and High Court were faced with infringement and revocation proceedings on a patent granted under the 1952 Act for the manufacture of compact fluorescent lamps. At first instance Wilcox

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197 *Ibid.*

198 *Cornish v Keene* (1935) 1 WPC 501.

199 (1995) 32 IPR 449.

J held that there was no infringement of the patent.[200] On appeal, Lockhart J, with whom Northrop J agreed, found that had the patent been valid there would have been infringement.[201] The issue of infringement was not in question in the High Court. The general conclusion of the judges in relation to the call for revocation was that the claim was for nothing more than a new use of an old substance. Difficulties arose for Mirabella because the inventive step ground was conceded at trial and the invention was found to satisfy the novelty requirement. The issue was that even though the claim was found to lack the required inventiveness or newness there may not exist a recognised ground for revoking the patent.

At first instance Wilcox J held that the patent was not an invention or manner of new manufacture. His Honour interpreted s18 as requiring that a "patentable invention" be a manner of manufacture within the meaning of the Statute of Monopolies, which he referred to as a "true invention".[202] The patent was therefore revocable because it lacked the requisite newness. On appeal Philips argued that the omission of the word "new" from "manner of manufacture" in paragraph 18(1)(a) was deliberate so as to separate out the novelty and inventive step requirements. Consequently, the issue of newness could only be raised through s18(1)(b). Lockhart J, with whom Northrop J agreed, rejected this argument. Their preferred interpretation was that paragraph 18(1)(a) together with the definition of invention in Schedule 1 retains the notion of "manner of new manufacture". Accordingly, change in the wording of this provision from "manner of new manufacture", as it appears in the definition of invention in s6 of the 1952 Act and Schedule 1 of the 1990 Act to "manner of manufacture" in paragraph 18(1)(a) was without effect. Lockhart J inferred that this was the intention of Parliament from the explanatory memorandum attached to the Patents Bill 1990, as well as the second reading speech and the IPAC recommendation.

Burchett J dissented. His Honour's rationale was that Parliament had set out the requirements for novelty and inventive step and it would be odd if, having done this, it also allowed for either unfettered or duplicated determination of the same issues through use of the word "new" in the

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200 *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1993) 24 IPR 1.

201 *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1993) 26 IPR 513.

202 At 7.

definition of invention. Burchett J referred to the comment of IPAC that the term manner of manufacture involves little more than that the invention must belong to the useful rather than the fine arts. His Honour added that any attack on the newness of the invention must be through s18(1)(b) and not s18(1)(a), and here it was not possible to do so.

On appeal to the High Court,[203] Philips again put forward the argument that omission of the word "new" from paragraph 18(1)(a) was deliberate, and that all that was required was for there to be a manner or kind of manufacture. Mirabella counter-argued that manner of manufacture in s18(1)(a) should be read as manner of new manufacture in accordance with the *Statute of Monopolies*.

The majority in the High Court (Brennan J, as he then was, Deane and Toohey JJ) came to a conclusion similar to that of the courts below, but through a radically different interpretation of subsection 18(1), For them, the words "a patentable invention is an invention that" required, as a starting point, that there be an invention, before the question of whether there be a patentable invention was determined. On this interpretation, it was necessary to determine whether, on the face of the specification, there was an invention that was the proper subject of the letters patent before the technical requirements of manner of manufacture, novelty, inventive step, were assessed. Where the claim in question was merely the new use of an old product it was not necessary to go any further. But where otherwise, it would still be necessary to determine whether the technical requirements had been met.

The majority backed up this interpretation by referring to three aspects of traditional patent law:

- Claims for new uses of old substances lay outside the scope of invention. These were the words used by Lord Buckmaster in *Re BA's Application*[204] and approved by the High Court in Australia in *Microcell*[205] and *NRDC*.[206]
- The reference to "alleged invention" in the definition of invention focuses on the newness requirement in "manner of new manufacture".

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203 (1995) 32 IPR 449.

204 [1915] RPC 348, at 349.

205 *Commissioner of Patents v Microcell Ltd* (1959) 102 CLR 232.

206 *NRDC v Commissioner of Patents* (1959) 102 CLR 252.

- In relation to the second point, in examining a patent application, the Commissioner is not bound to accept an allegation by the applicant that the claim is new where it is apparent on the face of the specification that thing claimed is not new.

According to their Honours' judgment, therefore, where the specification discloses that the claim is nothing more than new use of an old product, the alleged invention requirement is absent and the application can be rejected by the Commissioner, or if it has been granted, it becomes susceptible to opposition or revocation. If this is the case it is not necessary to go beyond this and assess the novelty and inventive step requirements. It is only where, on its face, the specification indicates that the requisite inventiveness is not lacking, that the specific elements become the focus for analysis.

The majority added that, although they did not have to decide the matter, their interpretation of s18(1)(a) was that it should be understood as referring to proper subject matter of the letters patent. As such, the interpretations of this provision by the trial judge and majority on appeal were correct.

Dawson and McHugh JJ in dissent accepted Philips' argument that a patentable invention must be new in the sense that it is novel and involves an inventive step when compared to the prior art, but that there was no additional newness requirement. Like Burchett J in the Federal Court, their Honours justified this on the ground that the basis for comparison with the prior art was precisely set out in section 7, and since the legislature had not set out a basis for comparison of any newness requirement in s18(1)(a) it was unlikely that such a requirement was intended. Their Honours referred to the explanatory memorandum of the Patents Bill 1990 to support this interpretation, and emphasised the clear distinction that was made in *NRDC* between invention, incorporated in the term "new manufactures" and subject matter, in the word "manufacture". The minority thereby clearly rejected the interpretations of the trial judge at first instance and the Full Court, but did not assess the interpretation of the majority.

I submit that the decision of the majority of the High Court has considerable appeal. Philips should not have been able to enforce its patent when the only thing that was claimed was the new use of an old product. To do

otherwise would be to run counter to well established authority. Decisions such as *Microcell* and *NRDC* establish the ground rules for much modern patent law in Australia. Given that the IPAC Report placed so great an emphasis on existing case law, and the legislature accepted those recommendations, it seems inappropriate to ignore the binding authority of cases such as these. Recent cases such as *W.R. Grace v Asahi* [207] and *Winner v Morey Haigh*[208] affirm that the definition of invention in s6 of the 1952 Act does not incorporate mere new uses of known products. The 1990 Act was aimed at more clearly setting out the requirements for an invention and grounds for challenging its validity. There can be no doubt that in doing so the legislature did not intend to make things which could not be patented under the 1952 Act patentable through the 1990 Act.

The arguments raised by the majority of the High Court in *Philips* are not without precedent in other jurisdictions. In particular, in the English Court of Appeal in *Genentech* Mustill LJ also required that there be an invention before a patent can be granted.[209] For Mustill LJ, as for the majority of the High Court, it is necessary for this requirement to be answered in the affirmative before the technical issues are addressed. In the case of the *Patents Act* 1977 (UK) those technical issues are set out in s1(1)(a)-(d), that the invention is new, involves an inventive step, is capable of industrial application and is not excluded by subsections (2) and (3). Mustill LJ specifically applied his formulation to naturally occurring substances, including human genes and proteins (see Chapter 6). Lord Mustill affirmed his views on this matter in *Biogen Inc v Medeva Plc.*[210] In contrast, Lord Hoffman, who gave the leading judgment in that case, stated that:

> "Judges would therefore be well advised to put on one side their intuitive sense of what constitutes an invention until they have considered the questions of novelty, inventiveness and so forth"[211]

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207 At 39,275.

208 *Winner v Morey Haigh and Associated (A'Asia) Pty Ltd* (1996) IPR 215, at 230.

209 *Genentech Inc's Patent* [1989] RPC 147 at 262.

210 (1996) Unreported judgment of the House of Lords 31 October 1996. An abridged version of the judgment was reported in *The Times* 1 November 1996.

211 House of Lords Unreported Opinions, at 14.

The conflicting viewpoints of the Law Lords in the *Biogen* case suggest that it is not certain whether the requirements of novelty, inventive step, and so on, are the determinants of the patentability of an invention or of the invention itself. The High Court decision in *Philips* indicates that in Australia the former view is preferred. Judges and patent examiners in Australia will now have to do precisely what Lord Hoffman cautioned against: they must intuitively sense whether or not an invention is present before they go on to assess novelty and inventiveness. I submit that it is not entirely inappropriate for them to do so. Logically, a patentable invention must fulfil both the criteria of being an invention and being patentable. A thing may be an invention even though it may be obvious to the skilled addressee, or may be disclosed in the prior art, but it will not be a patentable invention. In theory, the *Philips* test could save a great deal of unnecessary searching through the prior art base where a claim on its face has no inventive merit whatsoever. In the right circumstances, this should considerably speed both the examination process and opposition and revocation proceedings.

There are two continuing difficulties with the High Court's decision, which may make it difficult to apply in practice:

- The High Court omitted to prescribe parameters for how the newness requirement is to be measured. In both of the dissenting judgments it was recognised that the legislature had been explicit in setting out how objections based on lack of novelty or inventive step must be proved. The new test cannot be stated with anywhere near such precision. In *Philips* it was clear that even though the novelty and inventive step grounds could not be made out, what was claimed was merely the new use of an old product. It may be that this is a rare and exceptional case, and that generally if a patent is bad according to the *Philips* formulation it will also be bad for want of novelty or inventive step. In such circumstances it may be preferable to restrict the analysis to the precise formulation recommended by the legislature rather than taking the *Philips* short cut and leaving open the likelihood of prolonged appeals on the basis of improper application of the test. If this is the case then *Philips* may largely be ignored by counsel in opposition or revocation proceedings. Patent Office examiners may not so easily avoid *Philips* if Patent Office practice is modified to take it into account.
- Although the High Court made it clear that the novelty and inventive step grounds survive untouched by *Philips*, the position is less clear for the

manner of manufacture ground. According to the IPAC Report, all that is required for s18(1)(a) to be satisfied is that the invention belong to the useful rather than the fine arts. The majority briefly discussed how this provision should be interpreted, concluding that the invention should be proper subject matter for the letters patent. This is the same requirement as that in the definition of invention in Schedule 1. The *Philips* test requires that the invention criterion is met before the rest of s18 is considered. As such, the requirement in s18(1)(a) will only need to be assessed once that same requirement has already been met. It is unclear where else the analysis of the s18(1)(a) requirement could go. IPAC acknowledged that the term manner of manufacture was underpinned by a substantial body of case law and this should continue to apply. The case law is discussed in some detail in Chapter 6. It provides that certain claims are not to be considered as inventions. Do these case law exclusions from patentability now apply through the definition of invention or through s18(1)(a)?

Conclusion

This chapter provides the first of a series of arguments leading to the conclusion that inventions created out of human genetic material should remain within the patent system. The patent system is set up to provide an incentive for innovation in new technologies. I will argue in later chapters that biotechnology, particularly human genetic research and its applications, is one of the most important new technologies in terms of its benefit to the nation. Therefore a continuing and guaranteed source of incentive for innovation is both necessary and justifiable. This is not to say that the system is working perfectly at present. But I aim to demonstrate that the system has the potential to cope with the challenges of modern biotechnology without the need for a major statutory overhaul. I will present a number of conclusions in Chapter 7 suggesting means by which the limitations on patent rights already existing within the patent system can be better made use of to moderate the adverse effects of patenting in this area. These limitations are in addition to the normal patenting criteria which have been assessed in this chapter.

Inventions are only patentable in Australian law if they satisfy the specification requirements in s40 and the patenting requirements in s18, as well as the invention requirement in *Philips*. Each of these requirements, apart from *Philips*, has been subjected to extensive consideration by the judiciary.

There are some differences between the 1952 and 1990 Act requirements, chiefly associated with the geographical extent of the prior art base. These differences are unlikely to impugn existing case law to any great extent. That case law has decided that the dominant test for each of the requirements for a valid patent is as follows.

- Invention.
  Before the question of whether there is a patentable invention is determined, it must be shown on the face of the specification that there is an invention that is the proper subject of the letters patent. Mere new uses of old products will not satisfy this requirement.[212]
- Manner of manufacture.
  A patentable invention must belong to the useful rather than the fine arts and must provide a material advantage, its value to the country being in the field of economic endeavour, that is, it must have commercial applicability.[213]
- Novelty.
  Novelty will be destroyed when a prior disclosure contains clear and unmistakable directions to do what the patentee claims to have invented. The prior disclosure must disclose all of the essential integers of the invention. For documentary prior disclosure it is only permissible to look at single documents unless others are incorporated by reference.[214]
- Inventive step.
  Under the 1952 Act there will be no inventive step if the invention would have been obvious to a non-inventive skilled worker equipped with the common general knowledge of the field. The 1990 Act allows reference to single documents or two or more related documents that are not part of the common general knowledge, provided they would reasonably be expected to

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212 As per the majority decision of the High Court in *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 32 IPR 449.

213 The leading case on the interpretation of this provision is the decision of the High Court in *National Research and Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.

214 The leading recent cases on interpretation of the novelty requirement are the decisions of the Full Federal Court in *R.D. Werner & Co Inc v Bailey Aluminium Products Pty Ltd* (1989) 13 IPR 513 and *Nicaro Holdings Pty Ltd v Martin Engineering Co* (1990) 16 IPR 545.

have been ascertained, understood and regarded as relevant by the skilled person.[215]

- Usefulness.
  The usefulness requirement is not to be equated with commercial practicability. It requires only that the invention as claimed attains the result promised by the patentee.[216]
- Secret use.
  Secret use of the invention prior to application for a patent could threaten the validity of the patent unless it falls into one of the exceptions listed in section 9, *Patents Act* 1990 (Cth).
- Specification.
  - for a specification to be sufficient it must fully describe the invention and the best method for performing it, which requires that a skilled person in the field can work the invention.[217]
  - in determining the extent of the claimed monopoly, resort can only be had to the body of the specification where there is ambiguity and lack of clarity. Terms are to be interpreted in a common sense way from the perspective of those skilled in the field.[218]
  - the claims must be fairly based on the specification in that there must be a real and reasonably clear disclosure of the claimed invention in the specification.[219]
  - the complete specification must be fairly based on the provisional specification, where relevant. Again, this only requires a real and reasonably clear disclosure of the claimed invention in the provisional specification.[220]

The changes made in the 1990 Act have not been wholly successful in achieving the goal of harmonisation with other jurisdictions. In particular the

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215 See particularly Aickin J's judgment in *Minnesota Mining and Manufacturing Co v Briersdorf (Australia) Ltd* (1980) 144 CLR 253 and *W.R. Grace & Co v Asahi Kasei Kogyo Kabushiki Kaisha* [1993] AIPC ¶90-974.

216 See particularly *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1993) 25 IPR 119.

217 A useful recent case in this area is *Peptide Technology Ltd v The Wellcome Foundation Ltd* (1992) 23 IPR 319.

218 See *Elconnex Pty Ltd v Gerard Industries Pty Ltd* (1993) 25 IPR 173.

219 See Gummow J's judgment in *Rehm v Websters Security Systems* (1988) 11 IPR 289.

220 The history of the fair basing requirement was reviewed in *CCOM v Jiejing* (1994) 28 IPR 481.

geographical extent within which prior use can be determined for novelty and inventive step, and the range of prior documents that can be consulted to determine inventive step both are narrower than in Europe and the range of prior documents that can be consulted is narrower than in the USA. As such, the validity of a particular patent cannot necessarily be inferred from the inquiries made in other jurisdictions, but must be determined *de novo* by exploring the requirements under Australian law. This is particularly difficult in the area of patents for genes and gene sequences because there has been no judicial consideration of their ambit. As such, it is necessary to resort to first principles. In this chapter I have presented the fundamental principles of patent law in Australia. My focus in the next chapter is on the scope of research and practice in the field of human genetics.

CHAPTER 3: RESEARCH AND PRACTICE OF HUMAN GENETICS

Introduction

Two premises are central to many of the ethical objections to patenting human genes: first, that genes are to be equated with life; and secondly, that human genes are equated with humanity. First, it is true to say that the sum total of an individual's genes in the form of the genome is the hereditary material of the cell, the individual, the species, and, indeed, all living things. But genes do not, of themselves, create life. It is simply not possible to create a living organism by knowing all of its genes. As an organism develops from a single egg and sperm cell, each of its cells contain the same combination of genes derived from those two cells. Yet as the organism grows and develops its cells gradually differentiate. This can only be achieved with the cocktail of chemicals that comes from the mother in the cytoplasm of the egg cell, and by the subtle environmental cues that different cells are exposed to as they develop. Moreover, very few of the physical traits that become manifested in individuals as they grow and mature are solely genetic. Almost all will be influenced by environmental factors to a greater or lesser extent. In this regard, then, genes are only in part responsible for making individuals what they are. Many commentators have expressed concern about the *geneticisation* of society, in that we are being conditioned to believe that all we are is our genes and our fate is sealed by our inheritance.[1] This is not the case. All aspects of our physical and behavioural development are influenced by environmental as well as genetic factors.

The second premise can also be challenged. The human genome is uniquely human, but there is only slightly less variability within the human genome than there is between the human genome and that of other closely related species. On the level of the individual gene, there is even less to mark it out as being uniquely human than there is at the level of the genome. Many genes are much the same whether they come from humans, chimpanzees or

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1 A number of speakers voiced this concern at a major conference on legal and policy aspects of human genetic research in Montreal, Canada in 1996. See Chalmers, D.R.C. and L. Skene, "First International Conference on DNA Sampling: Human Genetic Research: Legal and Policy Aspects" (1996) *Journal of Law and Medicine* (in press).

mice. Some genes even cross the major boundaries between animal groups. Genes that are active during the development of the nervous system, for example have many similarities in mammals and insects.[2] Genes produce proteins which are vital components of living things. Proteins are enzymes, hormones, antibodies, blood clotting factors, and so on. In part, humanness arises out of the unique combinations of proteins that are present in all humans and the way in which those proteins interact, but there is nothing much that is uniquely human about the individual proteins.

In order to understand fully the issues associated with patenting of human genes it is first necessary to have an understanding of the nature of human genes and human genetics, and precisely what it is that can be achieved through human genetic research and its clinical applications. Genetics is the study of the structure and function of the genome. It is a science that is shrouded in obtuse terminology, but because that terminology is so much a part of any discussion on genetics it is difficult to avoid. Some general comments are made in this chapter to give an overview of the most salient points for future reference throughout the body of this work. It is important to remember that although the basic building blocks of the genome are the same in all organisms, the details of how these are put together do vary. The descriptions that follow refer mainly to human genetics, although much of it applies equally to many other species. For simplicity, some generalisations have been made which may not apply universally.

The main justification for funding and carrying out genetic research is based on the long term goal of finding cures for genetic diseases. Genetic disease has proved to be one of the most intractable forms of human malaise, no member of society being able to claim immunity from its broad sweep. The costs to society are great, both in terms of human suffering and from an economic perspective, and there is a pressing need to find ways to reduce both forms of cost.

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2 A number of experiments have recently been performed in which a genes controlling the development of the nervous system have been transplanted between phyla. One example is of a gene that was discovered in flies, identified by homology in mice, and then inserted back into the fly: Martin, P., and J. Lewis, "From Flies To Mice and Back Again" (1991) 1 *Current Biology* 33.

Genetic research has a long and respected history. The work of the Austrian monk Gregor Mendel in the late nineteenth century laid the foundation for the science of genetics and subsequently, early in this century, the way in which the inherited factors, or genes, behaved was elucidated. It was not until the 1950s, however, that the chemical nature of genes was described, with the Nobel Prize winning discovery of the double helix structure of *deoxyribonucleic acid* (DNA) by Francis Crick and James Watson.[3] In the first part of this chapter I look at these traditional notions of genetics, which I refer to as "the old genetics".

The next major landmark in the study of genetics was the advent of "the new genetics" which was brought about by the discovery that genes could be *spliced* and *cloned*. The first gene splicing was performed by Herbert Boyer and Stanley Cohen in 1973. Gene splicing led to the development of *recombinant DNA technology*, through which short strands of DNA from one species could be spliced with the DNA from other species and by these means could be mass produced. This breakthrough had a number of important implications, one in particular standing out. Genetic diseases are manifested when there are defects in one or more of the proteins that are required for individuals to function normally. Recombinant DNA technology enables the production of useable quantities of these proteins and the genes that produce them, through which it is possible to discover their chemical structures and hence the way in which they function and become defective. Now, as we approach the end of this century, geneticists have developed the technical capabilities to identify, isolate and manipulate individual genes and to understand the ways in which some of those genes malfunction to cause genetic disease. Much of the impetus for these developments has been provided by a huge commitment of funds to a number of international collaborative research ventures known collectively as the Human Genome Project.

Even though our knowledge of genes and genetic disease has increased greatly, many thousands of people continue to suffer from its effects. Genetic diseases do not discriminate; the famous American folk singer Woody Guthrie died of Huntington's Disease in 1967, after suffering the typical genetically programmed deterioration of his nervous system. In the USA alone this

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3 Watson gives a personal account of this discovery in *The Double Helix* (1970) Penguin, London.

disease still affects one in every 10,000 people.[4] One in every 2,500 people is afflicted by the equally pernicious disease of cystic fibrosis.[5] There are around 5,000 other genetic diseases that are caused by defects in single genes, and many of the more common diseases, including the major killers like heart disease and a number of cancers also have a hereditary genetic component. As yet, there is very little real hope or realistic expectation of cure for the sufferers of these genetic diseases, at least for the next decade or two.

Although therapies for curing genetic diseases may not be available for some time, there are nevertheless immediate and important health care implications arising out of the ability to identify and isolate the genes that cause disease. Possible applications include the diagnosis of some genetic diseases and the provision of replacements for some of the defective proteins that cause those diseases. These are discussed in the final part of this chapter.

The two most successful uses of genetic engineering at present in the clinical practice arena are the use of genetically engineered proteins to alleviate the symptoms of genetic disease (in the form of enzyme or hormone replacement therapy) and the production of vaccines to prevent viral infection. Neither of these is strictly human genetic research. Nevertheless, they are important models, because these are the first examples of the routine application of genetic engineering in clinical practice. Furthermore, these are the subject matter of the first patent battles over the patentability of genes and gene sequences. These models will set the benchmark, both in terms of what is achievable through genetic engineering on humans and in the assessment of the extent to which those achievements are patentable.

Part 1: "The Old Genetics"

Any discussion on genetics necessarily includes a description of the unique structure of the DNA molecule. DNA is made up of a sequence of nucleotides, each of which contains one of the four bases *adenine, cytosine, guanine* and *thymine*. Each nucleotide can be identified by the base it contains, A, C, G, or T. In humans there are around 3 billion of these nucleotides

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4 Miller. S.K., "To Catch a Killer Gene" (1993) *New Scientist* 24 April, 37.

5 Delaney, S. and B. Wainwright, "Molecular Biology of Cystic Fibrosis" (1993) *Today's Life Science* September, 22.

arranged in precise order along the chromosomes. Each cell in a particular individual carries an identical sequence of bases, but no two individuals will have precisely the same sequence.

In all but the most simple organisms each molecule of DNA exists as a "double helix". A combination of sugar and phosphate forms the backbone of the helix, with the bases facing inwards. The two strands of the double helix are held together by weak hydrogen bonds between the bases. The chemical structure of the bases is such that cytosine and guanine have affinity only for one another, as do adenine and thymine. In this way the two strands are complementary to each other. When DNA replicates during cell division the two strands separate and new complementary strands are built onto them.

DNA functions by producing all of the proteins required by an organism, each protein being produced by a single gene. The protein is produced by a two step process: first, the two strands of DNA separate in the region of the gene and a precise copy of the gene is made by messenger RNA (*transcription*); secondly groups of three bases on the mRNA, known as *codons* each match up with (or *code* for) particular amino acid and the amino acids are joined together to form the protein (*translation*). It is important to note that there is some redundancy in the code, because there are 64 codons and only 20 amino acids. Most amino acids are therefore complementary to more than one mRNA codon. This is known as *degeneracy* of the code.

Each gene is consists of a unique sequence of bases and is always located in an exact position on one of the chromosomes. In humans the genome comprises the 46 chromosomes in the nucleus of each non-reproductive cell.[6] Of those 46 chromosomes, there are 22 pairs of autosomes and two sex chromosomes. Females have a matching pair of X chromosomes whereas males have one X and one Y chromosome. Because each chromosome is paired in humans, there are two copies of every gene, which may or may not produce the same protein. When the copies are identical, the individual is *homozygous* for that particular gene, and *heterozygous* when they are different. Generally, when the two copies of the same gene are different, one

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6 Note that there are some exceptions. The red blood cells, for example, lose their complement of chromosomes before they reach maturity. Furthermore, DNA is found in regions of the cell other than the chromosomes, for example in the mitochondria.

will be *dominant* (for example the gene for brown eye colour) and the other will be *recessive* (for example blue eye colour). The *genotype* describes the combination of dominant and recessive genes, and the *phenotype* describes their physical manifestation. A person possessing a genotype of two dominant genes (a homozygote) will have the same phenotype as a person carrying one dominant and one recessive gene (a heterozygote), but a different phenotype from someone carrying two recessive genes (a homozygote).

Not all of the genes are active at any one time. Different cells will have different genes switched on or off at different stages of their life cycle. It is only when a gene is switched on that transcription can occur. The story has been complicated recently because it has been found that there is not a straight copy of DNA to mRNA to protein, but considerable modification is required. For example, the DNA in the region of the gene is made up of groups of bases called *exons* and *introns*, and only the exons code for amino acids, so the introns have to be removed. It has also been realised that the genes make up very little of the total DNA, only about 5%. The remaining DNA has been termed "junk" DNA, although this is very unlikely to be an accurate title as further research unfolds.[7] One of the functions of the remaining DNA is in switching the genes on and off.

When sexual reproduction occurs, the offspring inherits only one of each pair of chromosomes from its mother and one from its father. In this way, the offspring inherits a combination of some of the characteristics of its mother and others of its father. The cell division that produces the egg and sperm cells is known as *meiosis*. Separation of the pairs of chromosomes occurs during meiosis. This segregation is random; it is impossible to predict which of each pair of chromosomes will end up in each daughter egg or sperm cell. In addition the pairs of chromosomes often exchange chromosomal material during meiosis by the process of *crossing over*. This means that a dominant gene on one chromosome might change places with the equivalent recessive gene on its pair. In consequence, the offspring that is produced by the fusion of an egg and a sperm cell will inherit a unique set of chromosomes, and hence a unique set of dominant and recessive genes, making the offspring itself unique.

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7 For example, Nowak, R., "Mining Treasures from 'Junk DNA'" (1994) 263 *Science* 608.

Genetic disease most commonly occurs either through chromosomal abnormalities (e.g. Down's syndrome), or through abnormalities in the base sequence of a particular gene, which are the so-called monogenetic diseases (e.g. Huntington's disease, which is a dominant disorder, and cystic fibrosis, which is recessive). It has been known for some time that many of these diseases are genetically based. Precise details as to the location of the genes and the nature of the defects have also been elucidated for some of these diseases. It is only the advent of the "new genetics", however, that has brought about the possibility of routinely locating the genes responsible for disease, determining their gene sequences, identifying the defect causing the disease and developing methods for curing the disease. This is not to say that all monogenetic diseases are now known or that cures are at hand. But a number of these diseases are now well characterised, and there is every possibility that some of these options will eventuate for many others in the near future.

It is becoming apparent that other diseases which traditionally have been thought of as non-genetic also have genetic components, some forms of cancer and heart disease being the prime examples. These are the *polygenic* and *stochastic* diseases which are caused by a combination of changes in a number of genes (polygenic) or interaction with different environmental factors (stochastic). The "new genetics" is becoming increasingly important in the research into the identification and treatment of these diseases.

Part 2: "The New Genetics"

The new genetics lies at the heart of the modern biotechnology industry. The Organisation for Economic Cooperation and Development considers biotechnology to be the third technological revolution of this century, after nuclear energy and information technology.[8] Biotechnology has been recognised as encompassing any "exploitation of biological processes for industrial purposes".[9] Using this broad definition, it is clear that biotechnology has existed in one form or another for centuries. The brewing of beer in

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8 Organisation for Economic Cooperation and Development, *Biotechnology - Economic and Wider Impacts* (1989) 22.

9 Montague, P.E., "Biotechnology Patents and the Problem of Obviousness" (1993) 4 *Australian Intellectual Property Journal* 3.

Mesopotamia over 8,000 years ago has been cited as one good example.[10] Modern biotechnology, however, is more narrowly construed. Its main focus is *recombinant DNA technology*,[11] whereby isolated pieces of DNA are introduced into other living organisms. As the DNA of the host organism replicates, so too does the inserted foreign DNA fragment. This technology is also known as *genetic engineering*. The terms "recombination" and "engineering" exemplify the value of this technique, through which fragments of DNA are artificially induced to replicate by human intervention. At the early stages of its development, recombinant DNA technology was restricted to the insertion of DNA fragments into simple single-celled organisms, like bacteria, but now the capabilities exist to introduce genes into the cells of plants and animals, including humans.

Biotechnology has a wide range of applications:

- in health care and pharmaceuticals, in the production of such materials as insulin, antibiotics, vaccines and drugs, as well as developments specifically related to human genetic research;
- in agriculture, in the improvement of particular plant and animal characteristics, including disease resistance and growth enhancement; and
- in environmental applications, including pollution control, toxic waste treatment, hydrocarbon break down.

Some of the more important applications in the areas of health care and pharmaceuticals are assessed below.

2.1 Scenario for Making a Protein

There are numerous examples of therapeutic proteins that are necessary for the treatment of disease that, until recently, have had to be extracted from human tissue. Examples include insulin, a number of blood clotting factors, human growth hormone, and many others. Generally extracts of therapeutic proteins can only be recovered in small amounts and the risk of

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10 By Richards, J., "International Aspects of Patent Protection for Biotechnology" (1993) 4 *Fordham Intellectual Property, Media and Entertainment Law Journal* 433.

11 The Commission of the European Communities, *Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions* (1988) also includes gene transfer, embryo manipulation and transfer, plant regeneration, cell culture, monoclonal antibodies and bioprocess engineering.

contamination cannot always be avoided. The transfusion of AIDS infected blood to people suffering from haemophilia is one of the more tragic examples. Recombinant DNA technology can be used to produce larger amounts of uncontaminated proteins. An example of the sequence of events that might be required to produce a protein in this way is outlined below. The scenario that is presented is similar to that used by the pharmaceutical company Genentech to produce tissue plasminogen activator (t-PA), which is one of the essential enzymes in the blood clotting process. Purchas LJ described the procedure in some detail during the course of his judgment as to the validity of Genentech's patent for producing t-PA using recombinant DNA technology.[12]

- The first step is to select cells or tissues which are known to produce the protein in substantial amounts. Genentech found that Bowes melanoma cells were rich in t-PA, and were therefore also rich in the mRNA coding for t-PA.
- The mRNA strands which are required to translate the protein are extracted from the cells. At this stage the mRNA of interest cannot be separated out from other types of mRNA. As such, there will be many different types.
- One of the critical factors is the ability to produce complementary copies of DNA, known as *cDNA*, from strands of mRNA. This is the reverse of the transcription process described in Part 1. It is achieved using enzymes found only in viruses, and known as *reverse transcriptases*.
- The cDNA so produced is made into a double strand using another enzyme known as *DNA polymerase*.
- The cDNA is then incorporated into a *vector*, usually a *virus* or a *plasmid*, by a process called *ligation*, using other enzymes. First, a *restriction endonuclease* makes a cut in the vector's DNA at a particular site, and the cDNA is incorporated at this site using *DNA ligase*.
- The vector is capable of introducing the DNA it contains, including the cDNA, into a host cell, which may be a bacterial cell, or a cell isolated from a multicellular organism.
- The host cell then undergoes cell division, during which both the host and the foreign DNA replicate and are passed on to both daughter cells, which also divide, and so on. In this way, a *clone* of the cDNA is produced.

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12 *Genentech Inc's Patent* [1989] RPC 147.

- Clones can be produced of cDNA copies of all the mRNA in a particular cell. These are known as *clone libraries.*
- Clone libraries can then be screened and clones containing strands of cDNA that code for the protein of interest can be isolated. This is one of the most time consuming stages. One of the ways that screening is achieved is by using *oligonucleotide probes.* This requires that parts of the protein sequence have already been characterised. It is possible to synthetically produce a strand of nucleotides complementary to a short sequence of amino acids from the protein. Because most amino acids are coded for by more than one mRNA codon, however, the strand has to be carefully selected to include only those amino acids that are coded for by one or two codons. The oligonucleotide probe produced by this technique then has a radioactive label attached. Because it is also complementary to the cDNA, it will recognise it and *hybridise* to it. By these means the appropriate cDNA clone can be identified.
- The cDNA is then incorporated into an *expression vector* which then has the capacity to produce the same protein that would have been translated from the original strand of mRNA.
- In order to achieve this end, not only must the cDNA for the protein be incorporated but also the special *promoter* sequence that gives a signal to the enzyme *RNA polymerase* to start transcription. The promoter and other essential signals are often built in to the expression vector.

Each step in this process is complex to perform. Many years of work by highly skilled technicians are involved in getting to the stage of commercial production of a known therapeutic protein. On the other hand, each of the steps is now known. Only minor variations to the general theme may be required, depending on the particular protein that is being produced.

2.2 Scenario for Making a Vaccine

A typical scenario of the steps required to make a vaccine to prevent viral infection is described below. The example described is similar to that used by Biogen in its successful attempt to produce a vaccine against the Hepatitis B virus (HBV). Hobhouse J discussed the steps taken by Biogen in the Court of Appeal judgment as to the validity of Biogen's patent for the virus and

vaccine.[13] Chiron undertook a similar challenge in its successful attempts to isolate the Hepatitis C virus (HCV). A vaccine to HCV is not yet available. Morritt LJ described the steps taken by Chiron in the Court's judgment as to the validity of Chiron's HCV patent.[14]

Some knowledge of the nature of the human body's response to viral infection is required to understand how a virus is isolated and a vaccine produced. Part of the immune response to viral infection is the production of *antibodies* which bind to proteins in the virus known as *antigens*. The antibodies bind to discrete binding sites within the antigen, known as *epitopes*. A particular antigen may contain more than one epitope and may therefore elicit the production of more than one antibody by the infected host. Vaccines contain these viral antigens, the aim of vaccination being to stimulate antibody production to give the person the pre-existing ability to fight off viral attack. The aims of Biogen and Chiron, therefore, were to determine the structure of the HBV antigens and the HCV antigens. This required some knowledge of the nature of the virus.

HBV was known to have an outer protein coat, which was a surface antigen of HBV (HBsAg) and an inner protein core (HBcAg) as well as a polymerase enzyme. Biogen had to sequence the genome of HBV so that it could produce a synthetic vaccine. The task of Chiron was more complicated because HCV had not been described. At the outset it was not even known if the infective agent was a virus. Once characterised, it was further discovered that the HCV genome was RNA instead of DNA (a number of viruses have this feature). Since cloning is carried out in a host cell, usually a bacterium, it can only be done using DNA.

- The first step requires cloning of the viral DNA. The same scenario is followed as for producing a protein. Critical choices are required to be made as to the host, the vector and the restriction enzymes. In addition, for HCV, the viral RNA had to be converted into DNA.
- The success of the cloning experiment is determined by hybridisation of the recombinant DNA, and by testing whether the antigens produced by the recombinant DNA bind to antibodies isolated from carriers.

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13 *Biogen Inc v Medeva Plc* [1995] FSR 4.

14 *Chiron Corp v Murex Diagnostics Ltd (No. 12)* [1996] FSR 153.

- The *antigenicity* of the antigens produced from the recombinant DNA, that is, their effectiveness in stimulating production of antibodies, also has to be tested.

As with the production of proteins using recombinant DNA technology, the task of cloning viral DNA or RNA and producing vaccines is formidable and requires a high level of expertise. But again, although time consuming and apt to fail, the steps themselves are relatively predictable. The same sort of steps are also required in order to improve traits or introduce new traits into living organisms using recombinant DNA technology.

2.3 Scenario for Locating a Gene: The Human Genome Project

The "new genetics" fundamentally changed our approach to research into and treatment of human genetic disease, through the use of such techniques as recombinant DNA technology, automated DNA sequencing and the polymerase chain reaction.[15] That technology has made it possible to locate genes more precisely within the genome and sequence their bases. By the mid-1980s there was a realisation within the scientific community that it was possible to locate the position of every gene in the human genome (the low resolution map) and read out the sequence of bases that form the entire human genetic code (the high resolution map). The creation of such maps is vital as a reference system with which to compare aberrant gene sequences that give rise to genetic disease. The Human Genome Project is a collaborative international venture, the aim of which is to map the human genome both at low resolution (mapping) and high resolution (sequencing). A possible scenario for doing this is outlined below.

- The first step in determining the precise location of a gene on a chromosome is to split the chromosomes up into smaller pieces, or fragments by means of *restriction enzymes* which break the strand of DNA when they meet a precise sequence of 4, 6 or 8 bases.
- These fragments can then be replicated in one of two ways, either by *cloning* or by the *polymerase chain reaction.*
- The procedure for cloning is described above, at 2.1. The limitation of the technique is the size of DNA fragment that can be cloned. Recently yeast

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15 This technique allows for amplification of minute pieces of DNA.

has been used instead of bacteria and much bigger fragments have been cloned in the form of *yeast artificial chromosomes*. These can be up to 1 million bases long.

- The polymerase chain reaction is another way of replicating fragments of DNA, but this time the process takes place in a test tube. First the two strands are separated by breaking the hydrogen bonds between them. Then *nucleotide primers* initiate copying of each strand, and as the process is repeated the amount of DNA doubles at each cycle.
- Recombinant DNA fragments can then be selected from the library using probes, as described at 2.1. Particular fragments can be identified on the basis of the proteins they produce. For example, a fragment may produce a protein which is known to contribute to a particular genetic disease.
- These fragments are valuable tools that can be used to locate genes. For example, using *in situ hybridisation*, a fragment can be radioactively labelled and introduced into a cell. It finds its complementary sequence of bases and hybridises to them. This identifies the chromosome that the fragment arose from, and its position on that chromosome.
- The base sequences of the fragments can then be determined using *automated sequencing methods*. The clones that are produced in yeast artificial chromosomes have insufficient resolution to be used as templates for sequencing because they contain internal deletions and therefore new clones have to be made using different techniques.[16]

The Human Genome Project itself is in fact not a single project but a number of different related projects which are aimed at:

- mapping the 100, 000 genes of the human genome; and
- determining the complete base sequence of the 3 billion base pairs of the human genome.[17]

The Human Genome Project was formally initiated in October 1990. Funding was guaranteed for the Human Genome Project by the Department of

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16 Some of the problems with yeast artificial chromosomes were discussed by David Cox in his talk "Status and Future of the Human Genome Project" at the *2nd International Genome Summit* (1996) 16-18 October, Canberra. His preferred options were to use radiation based hybrids or bacterial artificial chromosomes.

17 The HGP is also doing the same thing for other organisms, including bacteria, yeast, nematode, fruit fly, mouse and the plant *Arabidopsis*.

Energy (DoE) and National Institutes of Health (NIH) in the USA and similar guarantees of funding were made elsewhere. The rationale for the project was that if we know where all the genes are on the human chromosomes, and we know their sequences of bases then we will be able to understand issues such as the way in which the genome functions, how organisms develop and evolve and the genetic basis of inherited diseases. From the outset it was decided that the project should be a collaborative venture, both between institutes in the same country and between countries, and the international Human Genome Organisation (HUGO) was founded. This organisation has been termed the United Nations for the human genome. HUGO has the object of coordinating developments and advances in molecular biology and genetics. Professor Grant Sutherland from the Adelaide Women's and Children's Hospital is president of HUGO. He is one of the few Australians directly involved in the Human Genome Project, receiving funding from the USA to map chromosome 16.

2.4 Goals of the Human Genome Project

In 1990 goals were set for the following five years of operation of the Human Genome Project. These were to: produce genetic maps that cover all human chromosomes; produce a set of overlapping cloned fragments for large parts of the human genome; improve the current sequencing techniques; and develop software and a data base system to support this research.

2.4.1 Produce Genetic Maps That Cover All Human Chromosomes

Two types of maps are being produced by the Human Genome Project: genetic linkage maps and physical maps.

- Genetic linkage maps show the distance between genes, like towns on a road map. The distance between the genes is estimated by the frequency with which they are inherited together. Genes which are far apart on the same chromosome are likely to be separated by cross-over at meiosis more frequently than genes that are closer together on the chromosome. Consequently, genes that are far apart on the chromosome are inherited together less frequently than those close together. The detail of the road map depends on the number of known genes and their distance apart. The

maps are produced through pedigree studies. Information is derived from families with known propensities to develop particular genetic diseases.

- Physical maps, on the other hand, indicate the actual physical distance between genes, usually by the number of nucleotides. The goal of the HGP was to generate recognisable *markers* for the physical map which will be thousands of bases apart. The markers are in the form of a short identifiable sequence of bases. Low resolution physical maps have already been produced for the entire human genome by a group in France.[18] The aim is now to increase the resolution of those maps. Original expectations were that a high resolution map would require markers to be around 100,000 bases apart, but as technical capabilities have improved so too have expectations as to the level of resolution that can be achieved.[19]

2.4.2 Produce a Set of Overlapping Cloned Fragments for Large Parts of the Human Genome

What is desired in the Human Genome Project is for there to be a library of cloned fragments of DNA that overlap and cover the entire length of each chromosome. Such clones can be used in many of the techniques used to physically map genes and to determine the sequence of their bases.

2.4.3 Improve the Current Sequencing Techniques

When the Human Genome Project was initiated sequencing cost around $1 to $2 per base and it was estimated that to sequence all the bases would take 30,000 work years. It was clearly necessary to find ways both to increase the speed of sequencing and reduce costs. For the sequencing to be a viable prospect, it must cost no more than 50 cents per base. A number of automated sequencing machines now exist and it is predicted that their further

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18 Cohen, D., I. Chumakov and J. Weissenbach, "A First-Generation Physical Map of the Human Genome" (1993) 366 *Nature* 698.

19 See, for example, Nowak, R., "Genome Mappers Have a Hot Time at Cold Spring Harbor" (1995) 268 *Science* 1134.

development will allow sequencing to proceed on schedule and within budget.[20]

2.4.4 Develop Software and a Data Base System to Support this Research

It has been estimated that the base sequence of the human genome would fill 200 telephone books of 1000 pages each. One of the major tasks of the Human Genome Project is to develop an electronic data base storage and management system. This need has spawned a new field of science known as bioinformatics.

For the last five years the research effort has concentrated on the first two goals and has been remarkably successful. There are indications that both the genetic researchers and the funding agencies believe that it is now appropriate to focus research efforts on large scale sequencing. Some have raised the possibility that the project may even be completed before the expected date of 2005.[21] It has been estimated that the cost of the sequencing will be around $3 billion (US). The cost and the time consuming nature of the task suggest that collaboration is essential, which has been recognised by both the scientists and the funding agencies. Agreements have been reached not only between laboratories in the same countries but also between a wide range of countries as to who should sequence which parts of which chromosomes.[22]

Despite the obvious feasibility of the Human Genome Project, it has received extensive criticism. A particular problem is that little effort is being expended in determining *gene function*: the protein that the gene makes, the function of that protein, how the gene is switched on and off and what

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20 See for example, the recent articles by two of the pioneers in sequencing: Olson, M.V., "A Time to Sequence" (1995) 270 *Science* 394; Venter, J.C., H.O. Smith and L. Hood, "A New Strategy for Genome Sequencing" (1996) 381 *Nature* 364.

21 As testimony to the success of the HGP, see "The Genome Directory" (1995) 377 *Nature* Supplement 28 September 1995.

22 At the *Second International Genome Summit* of the Human Genome Organisation in Canberra, 16-18 October 1996, progress reports were received from the People's Republic of China, the European Commission, France, Germany, Japan, Russia, the United Kingdom, the USA, Australia, Brazil, Egypt, India, Israel, Korea, Mexico, South Africa, Thailand and the Netherlands.

regulates the timing of such events. This point was forcefully made by Dr. Victor McKusick, founder president of the Human Genome Organisation, at a conference on legal and policy aspects of human genetic research in Montreal, Canada in 1996, when he said that:

> "Finishing the HGP is merely the end of the beginning. We will not know the function of all those 70,000 genes in isolation let alone in concert; we will not know the variation in the structure and therefore the function of those genes among the 6 billion inhabitants of this globe."[23]

Nevertheless the Human Genome Project does have much to offer. In biology, for example, it will provide valuable information for evolutionary studies. By comparing genomes, it will be possible to identify such things as which genes are essential for multicellular organisms, for the development of the nervous system, and so on.[24] In medicine there will be many offshoots of the Human Genome Project and other genetic research, particularly in the areas of diagnosis and treatment of monogenetic diseases as well as other diseases with a genetic component. Although the creation of the reference maps offers little in the way of improving health care *per se,* the knowledge gained from the maps is being used to dramatically increase the range of diagnostic tests for genetic diseases and, to a more limited extent, to improve the options for therapeutic intervention. The Human Genome Project has been likened to the moon shot, the Manhattan Project and even the Holy Grail, but perhaps a more appropriate analogy is with the discovery of the periodic table of atoms. Eric Lander has explained that:

> "The Human Genome Project aims to produce biology's periodic table - not 100 elements, but 100,000 genes, not a rectangle of electron valences, but a tree structure depicting ancestral and functional affinities among the human genes."[25]

The end product of the Human Genome Project will be a record of the sequence of bases in the human genome. The material used to create this record will have been taken from a number of individuals from around the world, but

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23 McKusick, V.A., "DNA Sampling: What Would Osler Say?" (1996) Keynote Address, *First International Conference on DNA Sampling: Human Genetic Research: Legal and Policy Aspects*, Montreal, Canada, 6-8 September.

24 The genomes of a number of other species are also being sequenced. These include the mouse, the fruit fly *Drosophila melanogaster,* the nematode *Caenorhabditis elegans,* yeast and a number of bacteria.

25 Lander, E.S., "The New Genomics: Global Views of Biology" (1996) 274 *Science* 536, at 536.

chiefly from western cultures. Although there is little variability in the sequence of bases over large tracts of the human genome between individuals (and indeed between humans and other species), variation does exist. It has been estimated that the variability between humans is approximately one base per thousand.[26] Since the human genome has around 3,000 million base pairs, then, if the estimate as to the extent of variability is correct, there must be around 3 million differences between individual genomes. The more closely related particular individuals are, the more similar their sequences will be.

2.5 The Human Genome Diversity Project

The variation in base sequences between individuals and groups of humans is interesting for several reasons. One of the main proponents of this type of research, Professor Luigi Luca Cavalli-Sforza, has identified a number of uses.[27] First, it can be used to explore the relationship between genetic profiles and linguistic and cultural characteristics of various groups throughout the world. Secondly, it could provide a more balanced perspective of the world's human genetic resources. Thirdly it could provide information about the genetic basis for disease susceptibility and immunity. Some populations have a much higher or lower propensity to contract particular diseases than the human population as a whole. In China, for example, there is a much higher incidence of stomach and bowel cancer than elsewhere in the world. Women from the Ashkenazi Jewish population also suffer a higher rate of breast cancer than the general population. In that particular case, the increased occurrence of the disease has been matched with an increased occurrence of mutations in two genes which are believed to be associated with hereditary breast cancer, the BRCA genes.[28]

The Human Genome Diversity Project (HGDP) was established by Cavalli-Sforza to elucidate these scientific questions. The aim of the HGDP is to collect samples of blood and hair from groups of peoples around the world and

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26 These figures were presented by Dr. Jaume Bertrandpetite in his talk "Genome Diversity, the Science" at the Human Genome Organisation's *2nd International Genome Summit* (1996) 16-18 October, Canberra.

27 Reported in Lehrman, S., "Diversity Project: Cavalli-Sforza Answers His Critics" (1996) 381 *Nature* 14.

28 Kahn, P., "Coming to Grips with Genes and Risk" (1996) 274 *Science* 496.

create cell lines in order to determine variation in the base sequences between groups. Although some information has already been collected for the HGDP, its future viability must be seen as doubtful given the deep ethical concerns expressed about the project from a range of quarters (see Chapter 4).

Indigenous groups would appear to be more willing to contribute to work of this nature when it is coordinated and conducted by their national governments rather than foreign interests. A number of spokespeople for participant countries at the 1996 HUGO *Genome Summit* indicated that samples were already being collected for diversity studies. Importantly, two of those countries are Israel and China, both of which have much to contribute because of the increased incidence of particular diseases in their indigenous populations.

Part 3: Clinical Applications of Genetic Research

3.1 Enzyme and Hormone Replacement Therapies, Diagnostics and Vaccines

The main clinical benefit of recombinant DNA is in producing useable quantities of therapeutic proteins, as outlined above at 2.1. There are many examples of such therapeutic proteins that are now routinely applied in clinical practice to aid those suffering deficiencies or abnormalities in the production of their own proteins. Further, recombinant DNA technology has been employed to produce diagnostic tests and vaccines. Every blood sample is now tested for HAV, HBV and HCV, and vaccines for HBV have recently become available.

3.2 Genetic Testing and Screening

Genetic screening refers to the systematic study of a specific gene or chromosome composition in a population or section of a population.[29] Testing refers to the examination of an individual for diseases or traits. There are three main goals to genetic screening and testing:

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29 See Dawson, K. and P. Singer "The Human Genome Project: For Better or For Worse?" (1990) 152 *Medical Journal of Australia* 484.

- to identify asymptomatic individuals who may have a predisposition to a particular genetic disease;
- to identify asymptomatic individuals who carry disease-related genes which may result in their offspring developing a particular genetic disease; and
- to study the frequency of occurrence of a particular genetic disease in a particular population.

The methods which are used to achieve these goals require a comparison between the so-called normal condition and the diseased condition. Three main methods exist: chromosomal analysis, protein analysis, and gene sequencing, the first two of which have been available for a considerable period of time.

3.2.1 Chromosome Analysis.

Chromosome analysis detects gross malformations in the chromosomal complement. For example, chromosomes can be analysed prenatally for Down Syndrome through chorionic villus biopsy (9-11 weeks) or amniocentesis (14-16 week of gestation). Further tests are also available for detecting other rarer chromosomal disorders.

3.2.2 Protein Analysis

Gene malfunction can be inferred using tests which have been developed to detect the end products of gene function. For example, the heel prick test is performed routinely in neonates to detect phenylketonuria (PKU). The disease results from low activity of the enzyme phenylalanine hydroxylase, and can be detected by build up in the blood of the amino acid phenylalanine.

3.2.3 Gene Sequencing

Once the fundamental structure of a gene is known at the level of its base sequence, the presence of monogenetic diseases can be determined by a comparison between normal and aberrant base sequences. Recombinant DNA technology has been used to develop test kits for Huntington's disease, the major manifestations of the cystic fibrosis disease (which is now identified in around 300 mutations), as well as a range of other monogenetic diseases. In

addition, tests are now being developed for aberrant gene sequences which indicate an increased likelihood that the individual will develop certain forms of cancer, including breast cancer (BRCA 1 and 2) and colorectal cancer. Clearly, as the HGP and associated genetic research increases our knowledge of gene sequences, the range of screening tests will also increase.

Genetic testing and screening only serve a purpose if some action can be taken in response to a positive test. At present testing for late onset diseases may allow those who test positive to make plans for their future. Pre-conception testing allows for informed reproductive decision-making. Pre-natal testing offers the opportunity for an informed choice to be made between termination and continuation of the pregnancy. Testing for stochastic diseases allows the individual to make certain lifestyle decisions. The preferred option, however, is for there to be some opportunity for rectifying the diseased state, i.e. a cure. Recombinant DNA technology may offer this possibility, in the form of human gene therapy.

3.3 Human Gene Therapy

The types of genetic engineering that have been described above require human genes to be inserted into cells from other species, usually bacteria or mammalian cell lines. The therapeutic proteins so produced are then extracted from the foreign cells and used to treat disease. There is no reason why the foreign species intermediary cannot be avoided. Gene therapy seeks to insert human genes directly into human cells in living people, so that the proteins can be produced *in situ*.

At its widest, human gene therapy can be thought of as the insertion of any human genes into human cells, and it has a range of possible applications. It can be segregated into three broad categories of somatic cell, germ line and enhancement gene therapy. Each of these creates different ethical issues, and it is important that these should be considered separately. It is also crucial to bear in mind the technical feasibility of each of the three categories. To paraphrase Professor David Danks, somatic cell gene therapy is important but difficult,

germ line gene therapy is simple but useless, and enhancement gene therapy is straight out of fantasy land.[30]

3.3.1 *Enhancement Gene Therapy*

The main public fear about gene therapy is that it will offer the opportunity to insert genes for non-disease related traits, such as intelligence, height, musical ability, looks etc. This is termed *enhancement gene therapy*. It is regarded by both geneticists and ethicists as being totally unacceptable, because it interferes with our notions of humanness and human identity and could be thought of as "playing God". It also harks back to eugenics programmes performed earlier this century, not only by the Nazis but also in other countries. The USA for example had an established eugenics programme in the 1920s.[31] Since those times any suggestion of eugenic practice has been treated with disdain and abhorrence.

Irrespective of any linkage with eugenic philosophy, it is very unlikely that enhancement gene therapy will ever be feasible, because such traits are far too complex to be modified by the intervention of a single gene, but are stochastic, arising from the combined effect of multiple genes and the individual's interaction with his or her environment. Insertion of single genes will, at best, produce only subtle modifications of these traits.[32] The other forms of gene therapy offer more promise.

3.3.2 *Germ Line Gene Therapy*

This technique involves inserting genes into the germ line cells, the eggs, sperm or early embryos. As the cells divide and the embryo develops, each cell will carry a copy of the inserted gene, as well as the complete set of the genes from both the egg and sperm cells. So, as the person develops all the cells

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30 Danks, D.M., "Human Gene Therapy The Present and the Foreseeable Future" (1989) *Collaborating in Health Care. Liberty Rights and Policy-Making, Proceedings of 1989 Annual Conference on Bioethics*, St Vincent's Bioethics Centre, Melbourne, 157.

31 The history of eugenics in the USA is reviewed in Smith, G.P., "Eugenics and Family Planning: Exploring the Yin and the Yang" (1984) 8 *University of Tasmania Law Review* 4.

32 Selective breeding, practised for centuries, is much more effective.

in his or her body will have a copy of the inserted gene. Consequently, the inserted gene will also be present in the germ line cells and will be passed on to future generations. Although the insertion of genes into germ line cells is possible, the technical capability for safely conducting germ line gene therapy on humans has not yet been achieved, nor is it likely to be in the near future.

3.3.3 Somatic Cell Gene Therapy

Unlike the other forms of gene therapy, somatic cell gene therapy has actually been performed on humans. The first approvals for its use were given in 1990 in the USA, for the treatment of adenosine deaminase deficiency (ADA). This disease is sometimes referred to as "bubble baby syndrome" because it causes children to have no immunity to fight disease and consequently they have a very short life span unless kept in a totally disease free environment. Approvals were also given for gene therapy on brain tumours.[33] Since then just over 100 other somatic cell gene therapy trials have been approved in the USA, mostly for various forms of cancer and also for cystic fibrosis.[34] Europe has been much slower to take advantage of the technique, and in Britain only two trials were approved in 1993.[35] In Australia, the first trial was approved in 1995.[36]

The principal reason for the delay in implementing somatic cell gene therapy technology appears to be associated with technical problems.[37] Many of these problems would seem to be as far from being resolved now as they were at the outset six years ago. In 1995 Harold Varmus, the Director of the USA National Institutes of Health (NIH) commissioned two committees to review gene therapy research. The first of these was to review funding of basic research and clinical trials and the second was to review the current mode of

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33 Anderson, W.F., "Human Gene Therapy" (1992) 256 *Science* 808.

34 Thompson, L. "Cystic Fibrosis Trials Approved" (1992) 258 *Science* 1728.

35 Brown, P., "Britain Dithers Over Gene Therapy" (1992) *New Scientist* 12 December 4; Dickson, D., "Britain Plans Broad Strategy on Genome, Approves Therapy" (1993) 361 *Nature* 387; Brown, P., "'Bubble Baby' to Get Gene Therapy" (1993) *New Scientist* 6 February 8.

36 Two trials are currently underway in Australia: a pilot study for gene therapy on the mesothelioma cancer; and a study for gene therapy on the melanoma cancer.

37 Mulligan, R.C., "The Basic Science of Gene Therapy" (1993) 260 *Science* 926-932.

regulation. The report of the first committee was handed down in December 1995. Its principal recommendation was that greater emphasis should be placed on funding of basic research and less on clinical trials.[38]

The success of somatic cell gene therapy depends on the targeting of a specific set of cells for insertion. These are the cells in which the disease manifests itself. Examples include the cells lining the lungs for cystic fibrosis, muscle cells for muscular dystrophy, white blood cells or the bone marrow cells they arise from for ADA or tumorous cancer cells. The technique can be carried out both *ex vivo* and *in vivo,* and the genes introduced may be designed to have a therapeutic effect, or may solely serve as cell markers. The principal limitation is the ability to have access to the right cells. Either the tissue must be accessible for *in vivo* insertion, for example the lungs for cystic fibrosis, or the cells must be easily removable for *ex vivo* insertion and reintroduction into the body, for example white blood cells for ADA. Consequently, diseases like muscular dystrophy or neurological diseases are much more difficult to treat using this technique. Gene therapy is further restricted to recessive diseases at the present time, because the technology exists only to add genes, and not to remove defective genes. Therefore it is not possible to treat Huntington's Disease using currently available gene therapy technology.

Somatic cell gene therapy can be seen as an alternative to conventional drug treatment, enzyme replacement therapy, chemotherapy, and radiotherapy and for some diseases it offers the only available form of treatment. Generally the aims of gene therapy trials have been modest to date: to assess whether treatments have measurable effects, rather than attempting to cure, or even improve conditions. The research effort has been concentrated in two main areas: cancer and monogenetic diseases. At the moment gene therapy trials for cancer treatment predominate. Indeed, it is becoming apparent that the main role that gene therapy may play in the future is in the treatment of cancer and

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38 National Institutes of Health, *Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy* (1995) S.H. Orkin and A.G. Motulsky co-chairs.

other multi-factorial environmental ailments and not in the treatment of monogenetic diseases.[39]

The main technical problems associated with somatic cell gene therapy are getting the genes into the appropriate cells and monitoring what they do once there. Genes can be directly injected, but the preferred option is to use a vector. If the vector is a virus, the virus then inserts the gene into the cells in the same way as it does for normal viral infections. For example, the cold virus is used for cystic fibrosis, because it normally attacks the very cells in the lungs that need to be treated.

The problem with using a virus is that, even though all of its own DNA is removed, it may still be dangerous, for example, it may be able to combine with naturally occurring viruses to create an infection. The gene may be inserted into the wrong cell type, or be expressed at the wrong time or in the wrong amount. It may somehow find its way into the germ line cells. Two main types of viruses are used in gene therapy: retroviruses insert the gene into the DNA of the host cell; adenoviruses, like the cold virus, on the other hand, insert the gene into cells but it does not become incorporated into the host DNA. Consequently, genes inserted using adenoviruses remain active in the system for a much shorter period than those using retroviruses. But because retroviruses insert into the host genome in an uncontrolled way, they may cause a new mutation by upsetting another gene's function or may activate cancer causing genes.[40]

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39 Professor Bob Williamson, head of the Murdoch Institute has said that "[it is a] major misconception that gene therapy is aimed at genetic defects" (lecture, Royal Melbourne Hospital on 23 October 1996, entitled "Gene Therapy").

40 Because of all these problems, it has been recommended that gene therapy should primarily be regarded as research rather than medical treatment, and as such should be subject to high levels of scrutiny scientifically, medically and ethically. See, for example, Medical Research Council of Canada, *Guidelines for Research on Somatic Cell Gene Therapy in Humans* (1990); UK *Report of the Committee on the Ethics of Gene Therapy* (1992) HMSO (the Clothier Committee Report). This is reflected in national research guidelines in Australia: NHMRC *Statement on Human Experimentation and Supplementary Notes* (1992) AGPS, note 7.

Even though the function of the gene therapy trials conducted to date was only exploratory the fact that over 100 trials have been conducted and over 600 people have now received gene therapy creates the obvious expectation that it will produce measurable effects in the near future. Yet this appears not to be the case. According to the NIH Report on funding of gene therapy, its efficacy has not been definitively demonstrated in any gene therapy protocol, and significant problems remain in all basic aspects of gene therapy. The principal recommendation of the Report was that more funding should be channelled into basic research and less into the clinical trial phase. In particular, more basic research needs to be done in the areas of gene transfer and gene expression. Even so, it was recognised that gene therapy has "extraordinary potential in the long term for the management and correction of human disease, inherited and acquired disorders, cancer and AIDS", and that clinical trials were necessary to evaluate various aspects of gene therapy approaches.

Conclusion

Knowledge of the genetic basis of human disease is increasing rapidly. Recombinant DNA technology is largely responsible for this increase. Much has been made of this technology and of its ability to produce genetically enhanced plants and animals and to cure human genetic disease. Though not without promise, its present capabilities must be viewed with some caution. The task of producing a therapeutic protein using this technology, or of producing a diagnostic test kit for a particular genetic disease, though feasible, is both laborious and complex. The prospect of developing routine cures for genetic disease is still remote. A great deal more basic research is required before many aspects of the technology are implemented into practice. Nonetheless, the prospect does exist that our knowledge of genetics will ultimately be used to alleviate much of the human suffering caused by genetic disease and other diseases with genetic components. In the meantime, the exploitation of our current knowledge of genetics in the form of recombinant DNA technology already has a wide range of clinical applications.

There is no doubt that basic research into genetics and the clinical application of that research must continue to be supported. The time consuming, expensive and highly skilled nature of that research, however, suggests that the public purse by itself will be inadequate. Private sources may

be willing to contribute to the research effort only if there is some guarantee that they will recoup their expenditure. The patent system would appear to be the obvious means for providing this guarantee. Whether it can do so without adversely affecting the benefits to the community of genetic research remains to be seen. What must be recognised is that patenting genes does not equate with patenting life or patenting humanity, and therefore objections to patenting based on these premises do not justify the exclusion of genes from the patent system. I suggest that rather than using these emotive and erroneous premises to base decisions on the exclusion of particular inventions from patenting, it is more appropriate to take into account more general public interest considerations. I will discuss means for introducing such considerations in Chapter 7.

CHAPTER 4: REGULATION OF GENETIC RESEARCH AND PRACTICE

Introduction

In the previous chapter I considered the benefits of human genetic research in terms of its actual and potential clinical application. It is well recognised that research of this nature should be allowed to proceed only after the necessary checks and balances have been put in place to ensure that it is carried out in a way that is ethically appropriate. The patent system has been used a forum for addressing concerns associated with the adequacy of these checks and balances in the area of genetic engineering. Many of the arguments raised against patenting of genes are actually objections to the science itself, both in terms of its ethical appropriateness and its safety. This is unfortunate, both because it detracts from genuine concerns that are more directly related to the patenting of genes, and also because the patent system may not be the appropriate forum to address such issues. The patent system has never been seen as a regulator of science, nor is it equipped to do so.

The aim of this chapter is to unravel the threads of the debates about regulation and patenting, and to demonstrate that it is both inappropriate and unnecessary for patent law to play a regulatory role as well as an incentive role in human genetic research or in other, non-human genetic research that has clinical applications. A range of regulatory processes are already in place, and it is not for the patent system to fill any shortfalls in those processes. It is the task of the government to ensure that the regulatory processes are adequate, both in the form of legislation and research guidelines.

In general, mechanisms have been put in place to ensure the safety of all work involving genetic manipulation. Further, animal ethics committees review all experiments involving vertebrate animals to ensure that there is no undue suffering. But it is only in the area of biomedical research involving humans that an extra layer of regulation exists to ensure that fundamental ethical principles are followed. The five main principles are autonomy (the right of the subject to accept or refuse treatment on an informed basis), beneficence (the duty to help others), non-maleficence (the duty to do no harm), confidentiality, and distributive justice (the principle that benefits and burdens should be distributed equitably). Human genetic research and its

applications, just as much as any other forms of biomedical research and practice, must be carried out in such a way as to ensure that these underlying ethical principles are respected.

There is a growing international debate about the types of regulatory regimes that should be established for new areas of biomedical research. Some argue that national regulation should reflect international bioethical principles,[1] whereas others propose that international guidelines must be derived from national practice.[2] While the World Health Organisation and the Council of International Organisations of Medical Sciences have been instrumental in achieving consensus in a number of areas of bioethics,[3] there are also pitfalls in a fully international prospective approach to regulation of biomedical research, chiefly because of the impossibility of agreement between nations on these issues.[4] As an alternative, Professor Bartha Knoppers has suggested an "interactive normative approach"[5] as a means by which cultural and political differences can be reflected in national responses to international "principled" guidance. According to Knoppers, biopolicy will be shaped by both international principles and national practice. I would argue that this sort of approach is already established practice in biomedical research. Much has been learnt from the disparate approaches taken to the regulation of IVF technology.[6] The lesson has been sufficiently instructive that such mistakes

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1 See, for example, Knoppers, B.M. and S. Le Bris, "Recent Advances in Medically Assisted Conception: Legal, Ethical and Social Issues" (1991) 27 *American Journal of Law and Medicine* 329; Macer, D., "Universal Bioethics and the Human Germ-Line" (1994) 13 *Politics and the Life Sciences* 243.

2 Particularly Bonnicksen, A.L., "National and International Approaches to Human Germ-Line Gene Therapy" (1994) 13 *Politics and the Life Sciences* 39.

3 See, for example, CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (1993); and *International Guidelines for Ethical Review of Epidemiological Studies* (1991).

4 See Knoppers, B.M. "Professional Norms: Towards a Canadian Consensus?" (1995) 3 *Health Law Journal* 1.

5 *Ibid.*, at 5.

6 A variety of disparate approaches have been taken by the States of Australia, see Chalmers, D.R.C., "Governments' Role in Human Sexuality & Reproduction" (1994) conference proceedings, *Reproductive Medicine: Beyond 2000*, Monash University, Melbourne, 24-26 November 1994.

will hopefully not be repeated. A new regulatory regime will only be successfully implemented if it has regard to existing professional practices and national structures that have been developed to meet the unique social and cultural features of individual nations. At the same time, however, proper account must be accorded to international norms and established best practices.

Another thread of the regulation debate is the overlap between research and practice. In human genetics, as in other areas of innovative medical endeavour, it is difficult and often artificial to draw the line between research and practice. Medical practice is regulated by professional codes of conduct, common law actions in contract and tort and specific legislative regimes including product liability and consumer protection. Although the same forms of regulation apply to biomedical research, these are further overlaid by more stringent oversight of the research task, the methodology and the consent procedures by institutional ethics committees which are specifically constituted to undertake these tasks. This distinction between research and innovative practice is clearly enunciated in a recent report to the Minister of Health and Community Services, which proposed that:

> "a) Where a particular experimental treatment/intervention is expected to benefit an individual patient it may be considered to be innovative practice rather than research. Where this is the case, the treatment should be governed by doctor-patient ethical considerations.
>
> b) Where any innovative therapy/intervention is trialed on more than one patient, or undergoes some other form of systematic investigation it should be presented for similar ethical assessment to any other research protocol."[7]

In the first part of this chapter I focus on the regulation of research, and include a detailed analysis of gene therapy regulation, since there is international consensus that this should still be classified as research rather than innovative therapy. Drug trials are also included, since these fall within the jurisdiction of the bodies whose responsibility it is to monitor biomedical research. In the second part, the regulation of medical practice in areas that impinge on human genetics will be reviewed. I start with a brief review of the general area of legal liability and self regulation, and follow with a more detailed consideration of the areas of product development, genetic screening and testing, and use of human tissue.

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7 *Report of the Review of the Role and Function of Institutional Ethics Committees* (1996) AGPS (Professor D.R.C. Chalmers, Chair), at 17.

Part 1: *Research*

1.1 Regulation of Biomedical Research

The Nuremburg Code and the later Declaration of Helsinki set out the core principles that must be followed in all research involving human subjects to ensure protection of the human dignity of those subjects. Principle 2 of the Declaration of Helsinki states that:

> "..the design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed".

This and other key principles have been implemented worldwide in the various national codes and statements on research involving humans[8] and by the establishment of institutional or local review bodies. In the USA, for example Institutional Review Boards review proposals for biomedical research prior to funding, and monitor progress of the research. The Boards follow guidelines set out in the Department of Health and Human Services *Regulations for the Protection of Human Subjects.* In Britain this function is served by Local Research Ethics Committees, which are guided to the Royal College of Physicians *Guidelines on the Practice of Ethics Committees in Research Involving Human Subjects.* In Australia Institutional Ethics Committees are guided by the NHMRC *Statement on Human Experimentation* and Supplementary Notes. I will refer to these bodies as institutional ethics committees, because of my familiarity with the Australian system.

According to the NHMRC, the role of institutional ethics committees is:

- to ensure that all proposed research projects are acceptable on ethical grounds;
- to maintain surveillance of approved research;

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8 As an example, see the Council of Europe *Draft Convention for the Protection of Human Rights and Dignity of Human Beings with Regard to the Application of Biology and Medicine: Bioethics Convention* (1996).

- to maintain a register of all proposed research projects; and
- to establish and maintain communication with the relevant national committee charged with oversight of bioethical issues.[9]

Membership must at least include:

- a laywoman not associated with the institution;
- a layman not associated with the institution;
- a minister of religion;
- a lawyer; and
- a medical graduate with research experience.[10]

In carrying out its functions, an institutional ethics committee is directed to follow the requisite guidelines and also to give consideration to local, cultural and social attitudes. The committee will generally be required to conduct a risk-benefit analysis for each research proposal, and to be satisfied that informed consent procedures are adequate. It must ensure that the rights of the individual subject takes precedence over the expected benefits to science or to the community. In some countries the performance of institutional ethics committees is monitored by national bioethics committees. In Australia this function is served by the Australian Health Ethics Committee, which receives compliance reports annually from the institutional ethics committees.

There are some concerns that the institutional ethics committee system needs to be more rigorous.[11] In my experience on an ethics committee of the Red Cross Blood Transfusion Service, however, I have found the committee members to be dedicated and well informed. They are able to critically evaluate research proposals and may make a number of requests for additional information or for modifications until all concerns are adequately addressed.

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9 NHMRC *Statement on Human Experimentation and Supplementary Notes* (1992) note 1, point 5.

10 Supplementary Note 1, point 4 (i).

11 McNeill, P.M, *The Ethics and Politics of Human Experimentation.* (1993) Cambridge University Press; McNeill, P.M., C.A. Berglund and I.W. Webster, Reviewing the Reviewers: A Survey of Institutional Ethics Committees in Australia(1990) 152 *Medical Journal of Australia* 289. See also the review of McNeill's book: McCaughey D., "Review of *The Ethics and Politics of Human Experimentation.* by Paul McNeill, Cambridge, Cambridge University Press, 1993" (1995) 9 *Bioethics* 437.

Realistically, much will depend on the composition of each individual committee.

The sanctions for non-compliance with NHMRC guidelines include withdrawal of funding from the researchers involved, naming the researchers and their institution, and potentially, withdrawal of funding for all projects at that institution. The withdrawal of funding is a powerful weapon to be used against miscreant researchers, although its adequacy has never been put to the test in Australia.

The efficiency and adequacy of the institutional ethics committee system has recently been the subject of a major review.[12] Submissions to the review generally supported the need for separate ethical review, and the current institutional ethics committee system. Problems appear to arise out of inadequate resourcing and lack of consistency in the role and functioning of the 180 or so committees. The most relevant recommendation of the review committee to the present discussion is the need to amend the *Statement on Human Experimentation* so that the systematic use of innovative treatment or therapy is treated as research and subject to overview by IECs. Accordingly, treatment or therapy of this nature would only be recognised as practice rather than research when there is benefit to the individual patient.[13] The report further recommended that the role of institutional ethics committees in monitoring research should be refocused so that ethical scrutiny is tailored to the risks faced by the individual participant.[14]

1.2 Regulation of Drug Trials

Before any new therapeutic goods are allowed to be manufactured and marketed they are required to undergo rigorous testing to ensure their quality, safety and efficacy. Once adequate experiments have been conducted on animal subjects or *in vitro,* testing is conducted on human subjects, usually in the form of clinical trials. National bodies have been established throughout the world with responsibility for oversight of the safety and efficacy of drugs used

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12 *Report of the Review of the Role and Functioning of Institutional Ethics Committees* (1996) AGPS (Professor D.R.C. Chalmers, Chair).

13 *Ibid.*, Recommendation 1, section 4.2.

14 *Ibid.*, Recommendation 4, section 4.9.

in clinical trials. In the USA the relevant body is the Food and Drugs Administration (FDA), and in Australia, the Therapeutic Goods Administration (TGA). The TGA describes a clinical trial as "an experiment conducted in humans in order to assess the effects, efficacy and/or safety of a substance, product or procedure."[15] In the first instance these bodies must be satisfied of the lack of toxicology of the drug, and subsequently that the drug is effective.

In many instances institutional bodies are given primary responsibility for review of the protocols for proposed clinical trials and for monitoring the progress of the trial procedure in order to improve the efficiency of the approval process. In Australia, two types of schemes exist for drug trials: the clinical trials exemption scheme (CTX) and the clinical trials notification scheme (CTN). Drugs that are trialed through the CTN and CTX schemes are exempt form the registration requirements of the *Therapeutic Goods Act* 1989 (Cth): section 18 for the CTN scheme; section 19 for the CTX scheme.[16]

Under the CTX scheme proposals are initially submitted to the TGA for approval. The TGA must be assured of the safety of the proposal. Where the proposal includes supporting material relating only to pharmaceutical data, there is a 30 working day period for evaluation. If no objections are found during this time notification will be given by the TGA that the trial may proceed subject to institutional ethics committee approval. If the proposal includes pre-clinical and clinical data the period is 60 days. The task of the institutional ethics committee is to assess and approve the proposed protocol of the clinical trial.

The input of the TGA into the CTN scheme is minimal, its responsibility in relation to safety being handed down to the relevant institutional ethics committee. The institutional ethics committee is also required to assess all other aspects of the trial. The sponsor of the trial has only

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15 Therapeutic Goods Administration, *Clinical Trials of Drugs in Australia* (1991), at 2.

16 Unless exempt, all therapeutic goods for human use must be included on the Australian Register of Therapeutic Goods, and all manufacturers must be licensed and comply with principles of good manufacturing practice: Therapeutic Goods Administration, *What You Need To Know About the Regulatory Requirements for Manufacture and Supply of Medical Products in, or from, Australia* (1992) AGPS, Canberra, at 2.

to notify the TGA that the trial is to be conducted after approval by the relevant institutional ethics committee. The CTX scheme will generally be used for early phase trials, whereas the CTN scheme is more appropriate for later trials, and for products that have already been in clinical use.

Any clinical investigation using drug products not listed on the Australian Register of Therapeutic Goods or using listed products for new purposes must satisfy notification requirements under the CTN scheme or application requirements under the CTX scheme.[17] Drugs are given a broad definition, covering any "substance or preparation intended for administration to humans in order to prevent, diagnose, alleviate, or cure disease or cure disease or symptoms of disease."[18]

Since introduction in 1991, the CTN system and structure has been subject to review.[19] Generally, participating institutional ethics committees would appear to have appropriate procedures in place. This structure, however, has been criticised because, it is claimed, the capacity of institutional ethics committees to undertake these additional responsibilities has not been assessed.[20]

1.3 Regulation of Human Genetic Research

Human genetics sparks serious and emotionally charged debate in many sections of the community. The laudable goal of alleviating the suffering of those subjected to genetic disease has at times been misconstrued and seen as a desire to rid the population of the genetically infirm. The attempt by the Nazis to implement their eugenic philosophy is often cited as a portentous image of the consequences of such desires. It is not surprising that concerns have been

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17 *Ibid.*, at 5. Note that minor changes not affecting safety or efficacy will not require clinical trials, *ibid*, at 6.

18 *Ibid.*, appendix 1/2.

19 On the CTN scheme see A Question of Balance, a Report on the Future of Drug Evaluation in Australia (1991) (Professor P. Baume, Chair); on the review of the scheme see Review of the Clinical Trials Notification Scheme: Report to the National Manager of the Therapeutic Goods Administration (1993) (Professor R. Day, Chair).

20 Darvall, L., "Deregulating Clinical Trials: In Whose Best Interests?" (1994) 1 *Journal of Law and Medicine* 229.

expressed about the consequences stemming from the Human Genome Project, especially in the areas of law, ethics and sociology. From the outset it was decided in the USA that a portion of the funding for the Human Genome Project (around 5% from the NIH and 3% from the DoE) should go to a separate program called Ethical, Legal and Social Implications (ELSI).[21] Subsequently, in December, 1989, the European Community (EC) Council of Ministers adopted a resolution endorsing European participation in the Human Genome Project, and, at the same time the Council also determined that the EC should participate in research on ethical, social and legal aspects of the project.[22] No such formal framework exists in Australia at the present time. To date, the ELSI program has focused almost exclusively on education and issues of confidentiality and privacy raised by the potential increase in genetic data about individuals.[23]

A number of respected international bodies have addressed the ethical issues associated with human genetic research. These include the International Bioethics Committee of UNESCO,[24] and the International Bar Association.[25] Regionally, the Council of Europe and the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) have assessed a range of issues, as have the President's Commission in the United States[26] and the Nuffield Council on Bioethics in the United Kingdom.[27] In 1995 the Shaw Committee Report on *Human Genetics: The Science and its Consequences* was published in the

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21 Annas, G.J. and S. Elias (eds.), *Gene Mapping: Using Law and Ethics as Guides* (1992) Oxford University Press.

22 MacKenzie, D., "European Commission Tables New Proposals on Genome Research" (1989) *New Scientist* 25 Nov. 1989, 6.

23 United States Department of Energy, *Human Genome. 1991-92 Program Report* (1992) US Government Printing Service.

24 See, for example, "UNESCO Revised Outline of a Declaration on the Human Genome and its Protection in Relation to Human Dignity and Human Rights" (1995). Reprinted in 5 *Eubios Journal of Asian and International Bioethics* 150.

25 *Draft International Convention on the Human Genome.* Reported in Coghlan, A., "Gene Treaty Promises Rewards for Unique Peoples" (1996) *New Scientist* 2 November, 8.

26 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research, *Splicing Life. A Report on the Social and Ethical Issues of Genetic Engineering with Human Beings* (1992), herein after referred to as *Splicing Life.*

27 Nuffield Council on Bioethics, Report on *Genetic Screening: Ethical Issues* (1993)

United Kingdom.[28] The legal aspects of the Human Genome Project were also discussed at a major conference convened in Bilbao in 1993.[29] Prior to the Bilbao conference, the BBV Foundation published the Valencia Declaration on the Human Genome Project in 1990.[30]

The dominant theme in much of the literature is that the Human Genome Project, of itself, creates few new ethical concerns that are any different from those raised by other forms of biomedical research. It is the application of the knowledge gained from the Human Genome Project into clinical practice that raises a range of ethical considerations.

All aspects of human genetic research clearly must be subjected to the same level of scrutiny as for any other form of biomedical research. This necessity will usually be met by the requirements that research protocols are submitted to the relevant ethics committee prior to funding approval, and that the progress of the research is monitored by the same committee. It is questionable, however, whether this level of scrutiny is sufficient for all forms of human genetic research, particularly when the research involves manipulation of the human genome.

The unique safety issues created by genetic manipulation work were recognised by the scientists involved from the outset. In 1975, at the Asimolar Conference, scientists recommended a moratorium on some aspects of this type of research. Expert bodies were established in a number of countries to vet all genetic manipulation work. In Australia, this function is carried out by the Genetic Manipulation Advisory Committee (GMAC). Its primary concern is to prevent the escape of genetically modified organisms into the environment. GMAC was formed in 1987 to replace the Recombinant DNA Monitoring

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28 United Kingdom House of Commons Science and Technology Committee, *Human Genetics: The Science and its Consequences* (1995) HMSO, London.

29 *Legal Problems: Human Genome Project.* The conference was organised by the BBV Foundation which is a research institute established by a leading Spanish bank. This conference followed two earlier meetings organised by the Foundation in 1988 and 1990 both in Valencia, Spain which dealt with the scientific and ethical implications of the Human Genome Project.

30 See Hon Justice Michael Kirby, "Legal Problems: Human Genome Project" (1993) 67 *Australian Law Journal* 894 at 903.

Committee. The terms of reference were enlarged to cover techniques other than recombinant DNA technology. The function of GMAC is to oversee the development and use of novel genetic manipulation techniques. It assesses hazards posed by such techniques to the community and the environment and recommends safety procedures. GMAC assesses all proposals for research involving genetic manipulation and requires any institution involved in such work to abide by GMAC guidelines and to establish its own institutional biosafety committee (IBC).

The regulatory regime for safety aspects of genetic manipulation in Australia is undergoing change at the present time. GMAC is in the process of becoming a statutory body, on the recommendation of the 1992 House of Representatives Report: *Genetic Manipulation: The Threat or the Glory.*

1.4 Regulation of Gene Therapy Research

1.4.1 Germ Line Gene Therapy

The general view about germ line gene therapy until very recently was that it should be banned in some way or other because of its effect on future generations. The GAEIB, for example, attempted an ethical evaluation of germ line gene therapy but concluded that scientific uncertainties prevented them from evaluating risks and benefits. It recommended that the technique should be forbidden on humans until the situation is scientifically clarified, at which point it should be ethically reevaluated.[31]

The early 1990s heralded a willingness to debate these hard questions in some quarters. John Fletcher and W. French Anderson pointed out that the morally relevant differences between somatic cell gene therapy and germ line gene therapy are less significant than the differences between these techniques and enhancement gene therapy.[32] They believe that the time is ripe for detailed public discussion. The Declaration of Inuyama,[33] which arose out of a

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31 GAEIB Press Dossier, 28.

32 Fletcher, J. C. and W.F. Anderson, "Germ-line Gene Therapy: A New Stage of Debate" (1992) 20 *Law, Medicine and Health Care* 26.

33 "The Declaration of Inuyama and Reports of Working Groups" (1991) 2 *Human Gene Therapy* 123.

conference in Japan of the Council for International Organisations of Medical Sciences, endorsed this view. It was stated in the Declaration that germ line gene therapy is technically difficult and presently not possible. However, it may be the only means of treating some diseases and so discussion should continue.

Others, including the Council for Responsible Genetics[34] are unconditionally opposed to germ line gene therapy. They have argued that the target population is future people, not those already suffering, and therefore consent is impossible and accountability is unlikely. In addition they also raised the issue that germ line gene therapy could be seen as treating people as "biologically perfectible artefacts" and those who are not perfect will be seen as damaged goods, thereby reinforcing prejudice and discrimination. Indeed, it has been argued that the consequences of gene therapy could extend to changing human identity, although this suggestion has been refuted.[35] Others also urge caution and restraint, arguing that somatic cell gene therapy is barely off the ground and it needs to be meticulously tested before any such techniques should be applied where there is any chance that they can be passed on to future generations.

But Fletcher and Anderson have actually raised similar issues themselves. Their argument is that, because research money is being invested in developing appropriate techniques for germ line gene therapy, there should be public debate at this stage to assess if research into its potential use in humans should continue. If the outcome of the debate is that it will never be ethically acceptable to perform germ line gene therapy, then such research should cease.[36] A recent symposium on regulating germ line gene therapy[37] is testimony to the increasing willingness of the international community to

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34 Council for Responsible Genetics, Human Genetics Committee, "Position Paper on Human Germ Line Manipulation" (1993) 4 *Human Gene Therapy* 35.

35 See Persson, I., "Genetic Therapy, Identity and the Person-Regarding Reasons" (1995) 9 *Bioethics* 16.

36 See also Walters, L. "Human Gene Therapy: Ethics and Public Policy" (1991) 2 *Human Gene Therapy* 115; Wivel, N. and L. Walters, "Germ-Line Gene Modification and Disease Prevention: Some Medical and Ethical Perspectives" (1993) 262 *Science* 533.

37 "Symposium, Regulating Germ-Line Gene Therapy" (1994) 13(2) *Politics and the Life Sciences* 217-248.

debate the issue, although that debate is not yet at the stage of providing definitive answers.

For the time being Australia has rejected germ line gene therapy through NHMRC guidelines.[38] This mirrors the position in other countries, which either ban the technique through research guidelines or prohibit it through legislation.

1.4.2 Somatic Cell Gene Therapy

Recent reviews have suggested that there is an ethical imperative to pursue research into somatic cell gene therapy in order to alleviate suffering[39] and it can be justified readily in terms of welfare of the individual and fairness to society. On the other hand, it is also clear that somatic cell gene therapy should not be unregulated, and a number of restrictions have been suggested.

It is generally accepted that somatic cell gene therapy requires the creation of no new ethical principles but heightens familiar ethical concerns, particularly autonomy, beneficence and non-maleficence. In particular, the UK Clothier Report stated that somatic cell gene therapy is no different ethically from organ transplantation and blood transfusion. While there may be an ethical obligation to pursue such research in order to alleviate suffering, it should be clearly limited to the treatment of serious or life-threatening disease in individual patients and where there is no other effective treatment. A Report by the Canadian Medical Research Council stated that ethical concerns could be met by a detailed risk benefit analysis of each individual case and by ensuring informed consent of the patient. The GAEIB opinion added that special care would be required for children and incapacitated persons. This troublesome aspect of informed consent is particularly relevant given that most somatic cell gene therapy trials to date have been performed on children.[40]

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38 See Supplementary Note 7.

39 One of the best examples is the UK Clothier Committee Report: *Report of the Committee on the Ethics of Gene Therapy* (1992) HMSO.

40 Children are often favoured subjects for gene therapy trials because there is less likelihood that their tissues have been permanently damaged as a result of their particular ailment, and therefore greater probability of alleviating suffering.

The GAEIB opinion outlined some of the more pertinent points: continued research into and clinical application of the technique should be encouraged; ethical evaluation is required and must have the three features of quality, transparency and efficiency, without introducing unnecessary delays; evaluation processes should be harmonised and standardised across Europe; appropriate measures should be taken to ensure equal access across Europe; and the technique should be restricted to serious diseases because of its present risk assessment.[41]

Although a number of clinical trials have been conducted using somatic cell gene therapy, the lack of positive outcomes and the technical problems that still need to be solved suggest that, despite the name, the technique must be described as research rather than innovative therapy. Consequently, it must at least be subjected to the same form of regulation as for all other biomedical research, as well as legal and professional requirements. The international consensus is that further layers of regulation should be imposed on gene therapy research because of the unique safety and ethical issues it creates.[42] These layers are can be categorised as three levels of review. In summary these are:

- level 1: product safety, quality and efficiency: two tier review by institutional ethics committee and national drug evaluation committee;[43]
- level 2: release of genetically modified organisms: two tier review by institutional biosafety committee and national committee with expertise in recombinant DNA technology; and
- level 3: science, ethics and safety of clinical trials: review by institutional ethics committee and national gene therapy committee.

- Level 1: Safety and Efficacy of the Products Used in Clinical Trials

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41 See generally Gustafson, J., "Genetic Therapy: Ethical and Religious Reflections" (1992) 8 *Journal of Contemporary Health Law and Policy* 183.

42 In this respect, most countries with an interest in gene therapy have adopted the US position, as stated in the President's Commission Report, *Splicing Life*.

43 This level of review is discussed in some detail by Cohen-Haguenauer, O., "Overview of Gene Therapy in Europe: A Current Statement Including Reference to US Regulation" (1995) 6 *Human Gene Therapy* 773.

Since the products used in gene therapy trials come within the definition of drugs, their oversight falls naturally within the ambit of the national body with that responsibility. In Australia somatic cell gene therapy falls within the ambit of the TGA system and therefore all trials must go through either the CTN or CTX scheme. At the present time the CTN scheme is preferred.

- Level 2: Safety of Recombinant DNA Technology

Since gene therapy involves the use of recombinant DNA technology, approval should be required in Australia by the relevant IBC and from GMAC. A recent change to GMAC guidelines, however, provides that most proposals for human gene therapy work are exempted from GMAC review,[44] because this aspect of the trial is seen to be adequately reviewed elsewhere.

- Level 3: Ethics, Science and Safety of Gene Therapy

Somatic cell gene therapy must be subject to the same scrutiny at this level as other forms of biomedical research, which is achieved by the institutional ethics committee review system. For most forms of biomedical research, review by institutional ethics committees is considered to be sufficient. In a number of countries, a more stringent regulatory framework has been imposed for somatic cell gene therapy by creating a second tier of review for scientific ethical and safety aspects of clinical trials. This is justified on the basis that the technique is complex and difficult to perform safely and also because of the ethical concerns expressed by the population about gene therapy. The USA has been the lead country in the implementation of gene therapy trials. Other countries, including Australia, have also followed the lead taken by the USA in the implementation of a regime for scrutinising proposals for gene therapy trials.

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44 Genetic Manipulation Advisory Committee, *Guidelines for Small Scale Genetic Manipulation Work* (1995) sections 1.12 to 1.2.11.

1.5 Review of Regulation of Somatic Cell Gene Therapy

1.5.1 The Recombinant DNA Advisory Committee, USA.

The first application of gene therapy on humans in the USA was for ß-thalassaemia in 1980. Not only was the trial unsuccessful, but it provoked general outrage because no approval had been granted. The inadequacy of government oversight of human gene therapy was also glaringly obvious. As a direct consequence, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research was given the mandate to study the social and ethical issues of genetic engineering with human beings. It handed down its Report in 1982.[45] That Report recommended that Institutional Review Boards, charged with reviewing proposals for gene therapy research in humans, should have access to expert advice during their review process from the Recombinant DNA Advisory Committee (RAC). The RAC was created at the NIH in the mid-1970s to assess the risks of unintended exposure to hazards through experimental genetic engineering techniques.[46] The President's Commission Report also stressed the need for an unusual degree of care in vetting novel applications. Furthermore, it recommended that the RAC should broaden its area of scrutiny to include risks arising from intended uses of genetic engineering techniques and not just unintended exposure. The Report recommended that the RAC should be independent and involve a range of participants, stressing that such an oversight committee is required because of "the profound nature of the implications of gene splicing as applied to human beings".[47]

The chief outcome of the Report was that a Human Gene Therapy Subcommittee of the RAC was established in 1984. In 1985 that subcommittee published guidelines for submission of research proposals, which were revised in 1990.[48] Proposals were required to be reviewed by the Human Gene Therapy

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45 *Splicing Life.*

46 That is, tier 2, level 2 review.

47 *Splicing Life,* 5.

48 National Institutes of Health, *Points to Consider in the Design and Submission of Somatic-Cell Human Gene Therapy Protocols* (1985); *Points to consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA into the Genome of Human Subjects* (1990).

Subcommittee,[49] as well as the full RAC.[50] Institutional Review Boards and Institutional Biosafety Committees provided the first tier of review at all levels. The US Food and Drug Administration was responsible for tier 2, level 1 review. In total six hearings were required, those of the Human Gene Therapy Subcommittee and RAC being in public and the rest in private. The first review began in 1988, that protocol ultimately being accepted in 1989.

During the first few years in which the approval process for gene therapy trials operated in the USA it became obvious that the process was cumbersome and repetitive. The role of each of the review bodies was never clearly defined. The Human Gene Therapy Subcommittee was, from the outset, thought of as a stop-gap, a mechanism for regulation that could be established quickly and replaced by a more independent body at a later stage. Already in 1991 there were calls for the RAC to streamline its review process,[51] and by 1992 the Human Gene Therapy Subcommittee had been disbanded, leaving the RAC as the principal expert body to vet gene therapy protocols.[52]

The RAC was subjected to considerable scrutiny in 1995. In particular the mandate of the RAC was questioned: should it focus on the safety and ethics of the clinical trial, or the quality of the science?[53] The review process was recognised as being unnecessarily unwieldy, and it was recommended that where protocols were very similar to previously approved trials they should go directly to the FDA after initial screening by the RAC, thereby giving the FDA responsibility for all levels of tier 2 review. New protocols would still receive full public review by the RAC.[54] At that time it was suggested by some that the RAC should not play any further role in the regulation of individual

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49 For tier 2 review at level 3.

50 Tier 2, level 2 review.

51 Gershon, D., "Cracks in the NIH" (1991) 353 *Nature* 591.

52 That is, tier 2 review at both level 2 and level 3. See Gershon, D., "NIH Merger to Shorten Review" (1992) 355 *Nature* 664.

53 Marshall, E., "RAC's Identity Crisis" (1995) 269 *Science* 1054.

54 See for example, Taylor, R., "NIH Review to Suggest Streamlined Handling of Gene Therapy Bids" (1995) 375 *Nature* 713; Marshall, E., "One Less Hoop for Gene Therapy" (1995) 265 *Science* 599.

gene therapy protocols,[55] although RAC members strongly disagreed with this viewpoint.[56] Since the recommended changes were adopted the RAC has found itself with little work to do. In May 1996 the Director of the NIH announced that it would be closed down,[57] although since then that decision has in part been reversed.[58] In future the RAC will exist solely as a forum for public debate on gene therapy, but will not be involved in the approval process.

1.5.2 International Regulation

The RAC type of review process is clearly held in high regard elsewhere. Government reports in a number of other countries have recommended the implementation of similar review mechanisms. Most countries that are undertaking or are likely to undertake somatic cell gene therapy trials now have, or are in the process of creating, national bodies for tier 2 review at level 3. These include Australia,[59] the United Kingdom,[60] Canada,[61] Japan,[62] and countries of the European Community[63] Both the European Medical Research Councils in 1988 and the Council of Europe in 1989 also recommended that national bodies should be established to consider level 3 review of all human gene therapy proposals.[64] In this respect, as with all other aspects of the trialing of somatic cell gene therapy, other countries lag behind the USA. New

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55 McGarrity, G.J. and W.F. Anderson, "Human Gene Therapy Protocols: RAC Review" (1995) 268 *Science* 1261.

56 Chase, G.A. *et al*, "Regulation of Gene Therapy" (1995) 269 *Science* 14.

57 "Gene Panel to be Disbanded" (1996) 381 *Nature* 359.

58 Wadman, M., "Gene Panel Reprieved after Public Outcry ..." (1996) 384 *Nature* 297.

59 See Chalmers, D.R.C. and D. Nicol, "Current Regulation of Human Gene Therapy in Australia" (1997) *Today's Life Science* (in press).

60 Hodgson, J. "UK Rules Out New Gene Therapy Laws" (1993) 366 *Nature* 194.

61 Medical Research Council of Canada, *Guidelines for Research on Somatic Cell Gene Therapy in Humans* (1990).

62 Swinbanks, D. "Japan Reviews First Guidelines for Gene Therapy Trials" (1993) 362 *Nature* 684; Swinbanks, D., "Gene Therapists Face Double Check" (1994) 369 *Nature* 5.

63 GAEIB, *The Ethical Aspects of Gene Therapy. Press Dossier Relative to the Opinion from the GAEIB* (1994), 21.

64 *Ibid.*, at 22.

national bodies are being created for level 3 review at a time when the role of the equivalent US body is seen as unnecessary.

1.5.3 Regulation in Australia

In Australia, the NHMRC established a centralised gene therapy committee (GTC) in 1994.[65] Guidelines for gene therapy protocols have recently been drafted by the GTC, which largely (although not completely) follow those of the RAC and the United Kingdom Gene Therapy Advisory Committee. Generally institutional ethics committees are required to undertake an initial review of gene therapy protocols, the main function of the GTC being to act as an advisory body to institutional ethics committees. The GTC has three other functions:

- to provide advice to researchers to facilitate the design of protocols;
- to act as a source of information to the community; and
- to maintain a register of trials in this country.

Membership of the GTC includes scientists, clinicians, representatives from GMAC and the TGA as well as an ethicist,[66] and a lay person.[67] As such, it can provide broadly based advice over a range of areas. The GTC provides advice to individual chief investigators, institutional ethics committees, and other relevant bodies on the processing of applications. Decisions are relayed to the institutional ethics committee ultimately responsible for the proposal. Modifications may be required to individual protocols before they can be supported by the GTC.[68]

There is considerable overlap in the tasks of the GTC and GMAC with respect to safety issues, and for this reason four individuals are members of both committees, and have been given the mandate to act on behalf of GMAC when reviewing gene therapy proposals. In consequence, the GTC conducts

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65 Professor Ron Trent from the University of Sydney is the chair.

66 Sister Regis Dunne from the Provincial Bioethics Centre in Queensland.

67 Associate Professor Loane Skene from the University of Melbourne.

68 This has been the case for all studies reviewed to date. As of 27 May 1996 three trials have been approved, one has been postponed because insufficient information was given to the GTC and two have been rejected. Personal communication with Professor Ron Trent, 27 May 1996.

tier 2 review for both levels 2 and 3. In addition, the TGA plays only a minor role in level 1 review, because gene therapy trials currently go through the CTN drug safety system. As such, the GTC has primary responsibility for tier 2 review of gene therapy protocols. This is quite different from the USA approach, in which the RAC was only ever given limited jurisdiction over tier 2 review. The changes to the regulatory process in the USA mean that the FDA is now responsible for all tier 2 review.

1.5.4 The Need for Public Access to the Review Process

Few countries other than the USA have opted for public review by bodies equivalent to the RAC. This decision has been seen as regrettable by some. In the United Kingdom Shaw Committee Report the problems of holding meetings in public were recognised. Nevertheless, it was recommended that, at the very least, approved proposals should be available to the public, provided that patients' confidentiality was protected. This was believed to be necessary in order to ensure public support for and alleviate public unease about gene therapy. In the USA this level of review has always been subject to public scrutiny and it could be argued that the main reason for setting up this form of review in the first place was to ensure public input.[69] Indeed, the decision to disband the RAC elicited so much concern because it was seen to be depriving the public of a forum for discussing gene therapy and of access to information about gene therapy trials that ultimately the decision had to be reversed.[70] The rejection of open meetings by other countries could be seen as weakening the process. It may well make the role of the tier 2 body harder to justify, and begs the question of what exactly this body is supposed to achieve. In Australia it appears that the role of the GTC was only ever to be in the provision of expert advice to institutional ethics committees and researchers.[71]

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69 Kaiser, J., "Gene Therapy Panel Gets a Thumbs Up" (1995) 270 *Science* 1287.

70 Wadman, M., "Gene Panel Reprieved after Public Outcry ..." (1996) 384 *Nature* 297.

71 Personal communication from Professor Ron Trent, chair of the Australian Gene Therapy Committee.

1.5.5 *Comment*

In general the national bodies that have been formed to conduct tier 2, level 3 review have been recognised for their effectiveness.[72] In the USA, the review process found favour principally because it was open to the public and consistent nationally.[73] On the other hand, the RAC was a committee of the NIH, the main funding body for this sort of research. This creates three major problems: technically the RAC could only review NIH-funded research; it could only review proposals for funding; and the NIH thus became both the promoter and regulator of such research. Nevertheless, the RAC appears to have fulfilled its role critically, independently and professionally.[74] Furthermore, bodies external to the NIH have been willing to submit their protocols voluntarily to the RAC for review.

The adequacy of the review process in Australia remains to be tested. It can be said with some confidence that to date gene therapy trials in this country are proceeding with deliberative caution. Australia has in place a two-tier system of research review that is consistent with the model "best-practice" of regulation in all countries either currently undertaking gene therapy trials, or likely to undertake them in the future. It is essential that this two-tier review process both displays and is seen to display the three vital characteristics of quality, transparency and efficiency.[75] Some areas warrant attention within the present regulatory system:

- The principle of transparency demands public consultation, because of the perceived social impacts of gene therapy, particularly on human identity

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72 See, for example, para 110 of the United Kingdom House of Commons Science and Technology Committee Report *Human Genetics: The Science and Its Consequences* (1995) HMSO, London (the Shaw Committee Report).

73 Such considerations are discussed in Walters, L., "Human Gene Therapy: Ethics and Public Policy" (1991) 2 *Human Gene Therapy* 115.

74 *Ibid.*, 117.

75 Set out by the European Group of Advisers on Ethical Implications of Biotechnology in its opinion on *The Ethical Implications of Gene Therapy* (1994) GAEIB Opinion No. 4, 13 December 1994.

and human rights.[76] The NHMRC, with its statutory public consultation functions, is perhaps the appropriate body to undertake such work.

- This two-tier review process overlies existing frameworks for oversight of release of genetically modified organisms by GMAC, drug trials by the TGA and institutional ethics committees, and medical practice by the legal system and professional bodies, and may thereby reduce efficiency of the regulatory system. Overlap in the review process is alleviated to a certain extent by exemption of gene therapy from GMAC review and by choice of the CTN scheme. Irrespective of the validity of these efficiency arguments, they should never take precedence over the rights of individual patients or subjects.

- The ethical assessment of human gene therapy requires input from individuals outside the field of human genetics because many of the issues involved have ethical, social and legal as well as scientific dimensions. Through the present system, decisions as to whether to approve a trial ultimately rest with the relevant institutional ethics committee. Impartiality and independence of the institutional ethics committee are of paramount importance in this process.

Part 2: Medical Practice

2.1 Legal Duties and Professional Standards of Practice in Relation to Human Genetics

The cornerstones upon which the legal duty of the medical profession are based are the duty to exercise reasonable skill and care, the requirement of informed consent to the risks and benefits of any proposed treatment, and the duty of confidentiality. Each of these relates directly to the ethical principles outlined at the start of this chapter.

The tendency in the Canadian and US courts has been to require that a doctor generally acts with "utmost good faith and loyalty".[77] The majority in

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76 See Maclean, S.A.M. and D. Giesen, "Legal and Ethical Consideration of the Human Genome Project" (1994) 1 *Medical Law International* 159.

77 Using the words of La Forest J in *McInerney v MacDonald* (1992) 93 DLR (4th) 415, at 423.

the Australian High Court in *Breen v Williams*[78] refused to adopt the notion that the entire doctor-patient relationship should be fiduciary in nature,[79] whilst not denying that some fiduciary-like duties may be imposed on a doctor. These include the duty of confidentiality and the presumption that if the doctor receives substantial benefit in excess of proper remuneration it is a result of undue influence.[80] According to Dawson and Toohey JJ, whether such requirements are classified as fiduciary is open to debate.[81] Gummow J, on the other hand, saw these duties as being more clearly fiduciary in nature.[82]

Specifically, *Breen v Williams* decides that a doctor will not be required to provide access to a patient to the doctor's own medical records compiled in relation to that patient. More generally, it also means that a doctor will not necessarily be liable for "any act that objectively was not in the best interests of the patient".[83] Liability will only arise when there is breach of the duty to exercise reasonable skill and care. This duty arises in both contract and tort.

The contractual duty of the doctor, unless otherwise expressly restricted or expanded, is to exercise reasonable skill and care in the advice and treatment of the patient. According to Brennan CJ, this obligation requires that the doctor act to maintain or improve the health of the patient generally.[84] Gaudron and McHugh JJ give a number of reasons why it is inappropriate to imply a term into all doctor-patient contracts that the doctor should act in the best interests of the patient. In particular, they see that it would be inconsistent with the existing duty in contract and tort to exercise reasonable skill and care.[85]

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78 *Breen v Williams* (1996) 138 ALR 259.

79 Judgments of Dawson and Toohey JJ, at 273; Gaudron and McHugh JJ, at 284, and 287-289. Brennan CJ, at 265-266 and Gummow J at 304-308 were more willing to recognise the fiduciary nature of the relationship between the doctor and patient. It is less clear from their judgments precisely how far they see the fiduciary relationship extending. Note that Kirby J did not sit because he sat on the NSW Court of Appeal decision of the same case: *Breen v Williams* (1994) 35 NSWLR 522.

80 Dawson and Toohey JJ's judgment at 273.

81 *Ibid.*

82 At 306.

83 Gaudron and McHugh JJ's judgment, at 282.

84 Brennan CJ's judgment, at 262.

85 Gaudron and McHugh JJ's judgment, at 282 and 286-287.

Breach of the duty to exercise reasonable skill and care which results in loss or damage to the patient is also actionable in negligence, unless the damage suffered was not actually caused by the breach, or was too remote from the breach.[86] Tortious redress is also available in battery for lack of consent and in negligence for failure of the doctor to fully inform the patient of the risks involved in a proposed treatment.[87] The requirement that the doctor fully inform the patient of the risks operates in both the clinical and research setting. As Professor Dieter Giesen has pointed out,

> "every [research] subject's basic human right to self-determination dictates that he submit to the experiment on a purely voluntary basis and that his consent be fully informed".[88]

Some variation exists between countries as to the exact nature of the requirements for fully informed consent to the risks and benefits of a proposed treatment. In Australia,[89] the patient-oriented principle has been adopted from the USA[90] and Canada,[91] for actions in negligence, whereas in the United Kingdom the *Bolam* test[92] prevails, the focus of inquiry remaining with the responsible body of medical opinion.[93] The patient-oriented approach should apply when the consent sought is to medical research, and arguably there should be an even higher duty of disclosure. According to Hall JA of the Saskatchewan Court of Appeal:

> "The subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent."[94]

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86 *Rogers v Whitaker* (1992) 67 ALJR 47.

87 *Ibid.*

88 Giesen, D., "Civil Liability of Physicians for New Methods of Treatment and Experimentation: A Comparative Examination" (1995) 3 *Medical Law Review* 22.

89 In *Rogers v Whitaker* (1992) 67 ALJR 47. See Chalmers, D.R.C. and R. Schwartz, "*Rogers v Whitaker* Informed Consent in Australia: A Fair Dinkum Duty to Disclose" (1993) 1 *Medical Law Review* 139.

90 *Canterbury v Spence* 464 F.2d 772 (1972).

91 *Reibl v Hughes* (1980) 114 DLR (3d) 1.

92 *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

93 *Sidaway v Governors of Bethlem Royal Hospital* [1985]1 AC 871.

94 *Halushka v University of Saskatchewan* (1965) 53 DLR (2d) 436, 617.

The extent to which consent is required for subsequent use of removed tissue is an area of increasing concern. This issue is discussed in some detail in section 2.4 on use of human tissue.

The legal basis for the duty of confidentiality arises either out of an implied term in the contract between the doctor and patient, or through equitable relief for abuse of confidential information.[95] It may also arise out of a limited fiduciary relationship between the doctor and patient.[96] The duty of confidentiality is particularly relevant with respect to genetic screening and testing, and is discussed in more detail in section 2.3.

The value of peer review and professional standards of practice cannot be discounted in all innovative areas of medical endeavour.[97] In Australia there is in place a whole series of formal review procedures. Medical practitioners are answerable to the relevant state Medical Board. Specialist Colleges apply further specific standards as set out in their Articles. Other bodies, such as the Australian Medical Association, State Health Departments and individual hospitals also supervise and quality audit the conduct of practitioners. Aside from legal proceedings for malpractice, dissatisfied patients have the options of formal or informal complaints procedures. Finally, and most importantly, as a result of the 1992 Medicare Agreement between the federal and state governments, most states either have appointed or are in the process of appointing Health Complaints Commissioners.[98]

Professional self-regulation standards are relevant as they apply to genetic research on humans in the same fashion as for all other forms of medical practice.

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95 Discussed in Abadee, A., "The Medical Duty of Confidentiality and Prospective Duty of Disclosure: Can They Co-exist" (1995) 3 *Journal of Law and Medicine* 75. See *W v Edgell* [1990] Ch 359.

96 *Breen v Williams* (1996) 138 ALR 259, Gaudron and McHugh JJ, at 285.

97 See Giesen (1995) 3 *Medical Law Review* 22.

98 The complaints procedures available in Australia are set out in some detail in Chalmers, D.R.C., *Australian Medical Law.* In: *Encyclopaedia of Medical Law* (1994) Kluwer Press, Belgium, 168p.

2.2 Regulation of Product Development

2.2.1 Registration of Therapeutic Goods

The TGA has set up a system of registration, the Australian Register of Therapeutic Goods, for all therapeutic drugs and devices. The TGA has three further tasks:

- to set standards for drugs and devices and their importation;
- to test function through a drug evaluation branch for prescription drugs, a compliance branch for non-prescription drugs; and a therapeutic devices branch; and
- to set standards for advertising.

Manufacturers of drugs and devices in Australia are required to obtain licences from the TGA.[99] Licences will only be granted to manufacture drugs or devices included on the Register, unless they are exempt from registration.[100] Goods are required to be evaluated and approved before being included on the Register. They will be included if, amongst other things, quality, safety and efficacy of the goods for the purposes for which they are to be used has been satisfactorily established.[101] This will usually be achieved through the clinical trial process, discussed in section 1.2. State *Poisons Acts* and other associated legislation deal with the process of distribution and licence chemists and other drug outlets.

Manufacturers of therapeutic goods are required to follow certain manufacturing principles, including codes of good manufacturing practice.[102] The Code of Good Manufacturing Practice for medicinal products outlines the requirements as to buildings, environment, equipment and procedure for manufacture.[103]

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99 With a few exceptions, see Therapeutic Goods Administration, *What You Need To Know About the Regulatory Requirements for Manufacture and Supply of Medical Products in, or from, Australia* (1992) AGPS, Canberra, at 19.

100 Drugs used for experimental purposes in humans being one notable exemption. These are subject to the CTN and CTX schemes, as outlined in section 1.2, above.

101 Section 25(1)(d) *Therapeutic Goods Act.*

102 Section 36.

103 Therapeutic Goods Administration, *Australian Code of Good Manufacturing Practice for Therapeutic Goods: Medicinal Products* (1990), reprinted in 1996.

2.2.2 *Product Liability*

Despite the detailed requirements for testing and manufacture of new medical products, there will always be some risk to the consumer from side effects associated with the product. The advent of genetic engineering has reduced many of the risks of contamination associated with the use of products that would otherwise have to be obtained from human tissue. One of the more compelling examples of the problems associated with the use of contaminated human tissue is human growth hormone. Human growth hormone was previously extracted from the human pituitary gland and such extracts carried with them the serious risk of contamination with the agents causing Creutzfeldt Jakob disease.[104] Genetically engineered growth hormone is now available and is free of such contaminants. Nevertheless, there may yet be serious defects associated with genetically engineered products and these may become apparent only some years after supply.

Where injury or damage occurs as a result of misdiagnosis or mistranscription, action may be available in negligence for breach of duty of care. Further, an action may be brought to remove a practitioner who has made an error in the transcription of a medical dosage from the register of medical practitioners, but only in circumstances when the mistranscription amounts to misconduct.[105]

A range of options is available to persons who suffer loss or damage as a result of defective products. Foremost amongst these is Part VA of the *Trade Practices Act* (TPA) 1974 (Cth), which was introduced in 1992. This Part creates a right to compensation to persons injured or whose property is damaged by a defective product, as against the manufacturer of the product. This is a form of strict liability, and is a major advance on the common law position, which requires negligence on the part of the manufacturer to be proved by the plaintiff.[106] Section 75AK creates a number of defences, the most relevant of

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104 See the *Inquiry into the Use of Pituitary Drug Hormones in Australia and the Creutzfeldt-Jakob Disease, Report* (1994) AGPS (Chair Dr Margaret Allars).

105 See *Pillai v Messiter (No 2)* (1989) 16 NSWLR 197.

106 The classic formulation of this type of negligence being that in *Donoghue v Stevenson* [1932] AC 562.

which in terms of supply of genetically engineered products is the state of the art defence.[107] This enables the manufacturer to raise as a defence that the state of scientific or technical knowledge at the time of supply of the product was not such as to enable the defect to be discovered. In addition the consumer must bring an action within ten years after supply of the goods.[108] Since defects in genetically engineered products may not yet be part of the state of the art, and may not emerge for many years after supply, the extent to which product liability provisions provide adequate protection of the consumer in this area should be carefully scrutinised.

Other options for legal redress, including contract, negligence and the consumer protection provisions in Part V of the TPA all suffer the same sorts of shortcomings.[109] Moreover, for negligence and consumer protection, fault on the part of the manufacturer must be proved by the consumer. Taking s52 TPA as an example, the consumer has to prove that the manufacturer engaged in misleading and deceptive conduct. Such requirements may be particularly difficult for consumers to prove because a number of intermediaries may be involved in the chain of supply.

2.3 Regulation of Genetic Screening and Testing and Protection of Human Rights

Many of the ethical issues associated with screening and testing are inextricably linked to other major ethical debates associated with reproductive technology, abortion, neonatal euthanasia and care of the disabled. Because some forms of genetic screening have been available for a considerable time, the ethical issues associated with genetic screening have also been extensively debated.

The identification of genes which are supposedly linked to particular traits brings with it the expectation that screening tests will become available almost immediately to test for those traits. Indeed, there would appear to be

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107 Section 75AK(1)(c).

108 Section 75AO(2).

109 Travers, R.C., "A Proposal to Reform Australian Product Liability Law" (1995) 69 *Australian Law Journal* 1006 also lists Division 2A of Part V of the TPA as an alternative option for seeking legal redress.

considerable pressure both from industry and from the general public to market test kits as rapidly as possible. There are many problems associated with this. These include, first, that if kits become available too early the percentages of false positives and false negatives will not have been properly assessed. Secondly, adequate mechanisms for counselling testees both before and after testing may not have been fully implemented. Thirdly, and perhaps most importantly, it cannot be too strongly emphasised that the value of genetic tests is questionable when there is no possibility of curing the exposed defect.

The UK Shaw Committee Report specifically referred to the problems associated with testing for late onset conditions and recommended that extensive counselling and follow up support should be provided for adults coming forward for this testing.[110] The Committee found that such diagnosis is only justifiable if those requesting it have fully considered all its implications.[111] Further, the Committee expressed the belief that children should not have genetic diagnosis for late onset disorders, recommending that: "there should be no mass screening for public health reasons in childhood unless a treatment for the disorder exists".[112]

2.3.1 Protection of Privacy

Unlike other forms of human genetics, some aspects of genetic screening and testing can be considered as mainstream medical practice and therefore will not be required to be subjected to the stringent regulatory requirements of biomedical research, except insofar as they may require clinical trials prior to registration and manufacture of requisite materials. Yet screening, perhaps more than any other aspect of human genetics, creates the most serious ethical problems because of the potential for interference with human rights through invasion of privacy and discrimination. For this reason, the whole gamut of national and state legislation associated with the protection of human rights as well as relevant international instruments may all have a role in the regulatory regime for genetic screening and testing.[113]

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110 Shaw Committee Report para 79.

111 Shaw Committee Report, para 80.

112 Shaw Committee Report, para 92.

113 For a review of Australia's position in relation to human rights see Bailey, P.H., *Human Rights: Australia in an International Context* (1990) Butterworths, Sydney.

Some of the more relevant provisions for the protection of privacy are listed below.

- Where the information is obtained during testing or examination of an individual by a doctor, the traditional duty of confidentiality not to divulge information applies.
- Where the information is in relation to a Commonwealth agency, the Commonwealth *Privacy Act* 1988 applies which only permits information to be divulged in very limited circumstances. Specific requirements in relation to the collection, storage and use of private data are set out in a number of Privacy Principles.
- Other State and Commonwealth Statutes establish further duties of confidentiality. For example, the Commonwealth *Epidemiological Studies (Confidentiality) Act* makes it an offence for a person who has carried out an epidemiological study to divulge personal information. Similarly, State Public Health Legislation places responsibilities and duties on health employees not to disclose information.
- Where the information is gathered in research, the current NHMRC Guidelines on Privacy in Research apply. These Guidelines generally require that researchers have regard and respect for the individual's rights and to take all precautions to protect the person's privacy.
- The NHMRC has issued further guidelines for the use of genetic registers in medical research,[114] which require that keepers of registers follow guidelines set out in the NHMRC Statement on Human Experimentation and Supplementary Note 6, Epidemiological Research (1992).

2.3.2 *Discrimination by Third Parties*

The new genetics has the capacity for greatly increasing the information available about an individual's genetic makeup, which inevitably creates the potential for interference with human rights. Unless that information is protected rigorously, it is possible that some individuals will be discriminated against on the basis of their genetic constitution.[115] There is a real possibility of

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114 NHMRC *Guidelines for the Use of Genetic Registers in Medical Research* (1991) Report to the NHMRC by the Medical Ethics Committee of NHMRC. AGPS, 18p.

115 Note that in the USA a number of states are already attempting to introduce legislation to prevent genetic discrimination in the health insurance arena. See Dotsey, J.,

the creation of a genetic underclass of the uninsurable and unemployable in the future, even though many of these people will show no present physical manifestation of their condition.

It is important to remember that employers, insurers and superannuation providers are already able to "discriminate" without the use of DNA analysis. There are many other ways of tracing the likelihood of predisposition to particular diseases or susceptibility to disease, for example through tracing family histories. Thus the prohibition of DNA analysis will not of itself prevent discrimination. The current attitude of the Life Investment and Superannuation Association of Australia is to require the disclosure of genetic test results consistent with the general "utmost good faith" requirement of disclosure in insurance contracts. However, the Association does not compel individuals to undertake genetic tests.[116]

In the area of employment the terms of the *Disability Discrimination Act* 1992 (Cth) are likely to prevent an employer from selectively testing an individual employee with a susceptibility to a genetic disease. It is further unlikely that a susceptibility to a condition rather than *having the condition* would be a relevant consideration provided the person had the capacity to undertake the job. There is a body of evidence, however, that suggests that when it comes to filling positions, people can be discriminated against on the basis of genetic predisposition, even by Commonwealth agencies.[117] Moreover, there is further evidence that sufferers of genetic disorders and their families perceive that they have suffered the effects of discrimination by health insurers, life insurers and employers.[118] The fear of discrimination may cause a small but significant percentage of the relatives of sufferers of genetic disease

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"Lawmakers Crack Down on Genetic Discrimination: a Legislative Overview" (1996) 10 *Gene Watch* 2.

116 Life, Investment and Superannuation Association of Australia, *Draft Policy Regarding Genetic Testing* (1996).

117 See Taylor, S., "Case Study of Genetic Discrimination in the Context of Huntington's Disease: Some Social Implications of the 'New Genetics' Technologies" (unpublished manuscript).

118 Lapham, E.V., C. Kozma and J.O. Weiss, "Genetic Discrimination: Perspectives of Consumers" (1996) 274 *Science* 621.

to refuse to be tested.[119] Such refusals may ultimately have serious reproductive or psychological consequences.

The United Kingdom Nuffield Council Report of 1993 on *Genetic Screening: Ethical Issues* recommended that the potential use of genetic screening by employers should be kept under review.[120] The Report further recommended that insurers should adhere to their current policy of not requiring any genetic tests as a prerequisite of obtaining insurance, and that pending the outcome of discussions concerning the future use of genetic information, insurance companies should accept a temporary moratorium on requiring the disclosure of genetic data.[121]

2.3.3 *Familial Considerations*

The nature of genetic information requires that some additional considerations are taken into account, principally because of the family implications of genetic screening and testing. The 1993 Nuffield Council Report recommended that the accepted standards of confidentiality with respect to medical information should be followed as far as possible. However, when information is revealed that may have serious implications for relatives of those who have been screened, it was recommended that health professionals should seek to persuade individuals, where necessary, to allow the disclosure of relevant genetic information to other family members.[122] Subsequently, the Shaw Committee Report recommended that if an individual cannot be persuaded to share this information, their right to

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119 *Ibid.*, 9% refusal rates were reported in that study.

120 Nuffield Council on Bioethics, *Genetic Screening: Ethical Issues* (1993), Chapter 6, recommendation 6.27 at p 64.

121 *Ibid.*, recommendations 7.37, 7.38 at p 73. Note, however, the two exceptions to that moratorium:

(i) the moratorium should not apply to individuals with a known family history that can be established by conventional questions;

(ii) the moratorium should only apply to moderately sized policies.

There is considerable ambit in these exceptions which must bring into question the effectiveness of any such moratorium, were it to be introduced.

122 Chapter 5, recommendations 5.40 and 5.41 at p53.

privacy must be respected.[123] Note, however, that the Australian Medical Association's Code of Ethics, as amended in 1996, refers to the need to:

> "[k]eep in confidence information derived from your patient, or from a colleague regarding your patient, and divulge it only with the patient's permission. Exceptions may arise where the health of others is at risk or you are required by order of a court to breach patient confidentiality."[124]

The first exception may well allow a doctor to divulge confidential genetic information to family members at risk, which may be contrary to the recommendations made by the British committees. The conflict between a doctor's duty to respect the confidentiality of a patient and the duty to inform others of serious risks to life or health is not easily reconciled. Doctors need to be advised of the parameters within which they should make decisions whether to disclose such information.

2.3.4 Recent Australian Analysis

In Australia, the most recent discussion of relevant privacy law has been conducted by the Privacy Commissioner: *The Privacy Implications of Genetic Testing*.[125] The Commissioner analysed privacy concerns in respect of genetic testing and implications of the collection of personal information in the context of employment, insurance, law enforcement and scientific research. Matters listed for further consideration included: the need to conduct a survey to establish the extent of genetic testing; the need for formalising standards as to disclosure of personal genetic information; the lack of desirability of population DNA databases; and the development of standards in insurance, superannuation and employment for use of personal information.

The Cancer Genetics Ethics Committee (CGEC) of the Victorian Anti-Cancer Council has produced comprehensive guidelines on the establishment and use of registers of genetic diseases which are to be referred to the national Australian Health Ethics Committee for public consultation. The CGEC sees that cancer genetic registers differ in a number of ways from the types of registers anticipated in the NHMRC guidelines. It pays particular attention to community concerns regarding the protection of confidentiality and privacy,

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123 Shaw Committee Report, para 228.

124 Australian Medical Association, *AMA Code of Ethics* (1996).

125 Information Paper Number 5 (1996).

consent to identification in a register, possible misuse of information and broader social implications, and admits that it is unlikely that all adverse effects can be completely eliminated.

Work of the kind undertaken by the Privacy Commissioner and the Anti-Cancer Council are valuable starting points both in determining the issues that are likely to arise as genetic tests become more prevalent, and in modifying and expanding the regulatory framework to deal with these issues.

2.3.5 *Public Lack of Interest in Population Screening*

It is becoming apparent that one of the ways that the public has chosen to deal with the negative aspects of screening for genetic disease is simply to refuse to be tested. In the USA clinicians have been surprised by the lack of interest of the public in undergoing screening for hereditary gene defects such as cystic fibrosis.[126] A cystic fibrosis consortium, which was established to assess the social impact of genetic testing and screening, has found that pregnant couples were the only group in which there was significant uptake of freely available tests, and then only if the tests were incorporated into a broader testing program.[127] One of the groups in the consortium concluded that: "[W]e believe that clinicians should not routinely offer carrier screening to nonpregnant individuals who do not have a family history of CF."[128]

2.3.6 *Comment*

The primary justification for patenting of human genetic research is to encourage investment in that research, and the primary justification for funding and conducting human genetic research is that it will ultimately lead to better diagnosis and treatment of genetic diseases and other diseases with genetic components. The manufacture of therapeutic proteins using genetic engineering has made an important contribution to the treatment of disease. The same cannot be said for gene therapy at present. The initial promise of this technique has not yet been fulfilled and it may be many more years before any

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126 See, for example, Coghlan, A., "Public Gives Thumbs Down to Gene Screening" (1996) *New Scientist* 13 April, 8.

127 Marshall, E., "ELSI's Cystic Fibrosis Experiment" (1996) 274 *Science* 489.

128 *Ibid.*

form of gene therapy is part of routine medical practice. On the other hand, developments in the diagnosis of genetic disease are proceeding apace. The difficulties in this area are not so much to do with implementation of the technology as with ensuring that it is implemented in an ethically appropriate fashion. The wide ranging considerations that must be taken into account outside the safety and ethics of the technique itself suggest that great care will have to be taken in the implementation of any genetic testing or screening technology into clinical practice. Moreover, if the public rejection of population-based genetic screening is more widespread then continued public finding of research in this area may need to be reevaluated.

2.4 Regulation of Use of Human Tissue

The Human Genome Diversity Project (HGDP) is a research project and therefore falls under the same regulatory regime as for all biomedical research, as discussed in Part 1. Although similar ethical issues are raised by both the Human Genome project and the HGDP, the HGDP has elicited a more vocal response, particularly from indigenous groups. Unless a great deal of effort is made in the near future to alleviate those concerns, it will be difficult for the project to gain public support. That support is essential because the entire project is premised on the willingness of individuals to voluntarily donate samples. If genetic research involving non-western cultures is to progress in any meaningful way, then it is essential that one of the fundamental norms of conduct of that research be that differing cultural perspectives are taken into account. More generally, the HGDP has also served to highlight the important legal issues associated with the collection and use of human tissue.

2.4.1 Informed Consent to the Collection of Tissue Samples and Ownership of Samples

The law has always denied a property right to the donor of bodily tissues, principally to prevent commercialisation in the use of those tissues. The decision of the Californian Supreme Court in *Moore v Regents of the University of California*[129] makes it clear that, in California at least, there can be no action for conversion of human cells because the donor can have no proprietary interest in those cells. The case arose because John Moore, a

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129 (1990) 51 Cal. 3d 120.

sufferer of hairy cell leukemia, had his spleen removed as part of his treatment. Before that time, his physician, Dr. Golde knew of the research and economic value of Moore's cells but failed to inform him. The Mo cell line, derived from Moore's spleen cells, was subsequently patented and proved to be a commercial success. Moore sued for conversion and for breach of fiduciary duty or lack of informed consent. The majority of the Supreme Court refused to accept the conversion argument, but accepted that there had been a breach of fiduciary duty or lack of informed consent. Golde should have informed Moore of his personal interest, because this may have affected his medical judgment. The outcome was that Moore settled out of court for a small amount but failed to get a share of the profits derived from the patent on the Mo cell line.

In the past the trend has been to presume that human tissues that had been removed for therapeutic or research purposes had been abandoned by the donor once they had given valid informed consent to the proposed removal. There is now growing support for the additional requirement of informed consent to subsequent use. The European Bioethics Convention, for example, requires that separate consent be given to subsequent use of research samples.[130] The Nuffield Council on Bioethics in the United Kingdom addressed this issue in its 1995 report *Human Tissue: Ethical and Legal Issues.* The need to clarify and strengthen the ethical and legal framework associated with clinical and research use of human tissue was recognised as urgent. There was general agreement that human tissue "legally cannot and ethically should not be treated as a commodity."[131] The Report recommended that consent to treatment "should be taken to include consent to subsequent disposal or storage of tissues and further acceptable use provided that it is regulated by appropriate ethical, legal and professional standards."[132] This requirement will generally be satisfied provided that the range of intended uses is explained to the donor. These recommendations largely follow the judgment of the Californian Supreme Court in *Moore:* that the legal use of removed tissue is a

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130 Council of Europe *Draft Convention for the Protection of Human Rights and Dignity of Human Beings with Regard to the Application of Biology and Medicine: Bioethics Convention* (1994) Article 13.

131 Nuffield Council Report (1995) Chapter 13, para 13,9.

132 Nuffield Council Report (1995) Chapter 13, para 13.12.

matter of informed consent, and should not come with in the domains of property law or commercial law.

In Australia, this issue is in the process of being clarified with respect to the use of human tissue for research purposes, following a 1993 discussion paper by the Australian Health Ethics Committee on "Use of Routine Blood and Tissue Samples for Research". That discussion paper was circulated to interested parties and comments elicited. In addition a number of workshops were held in 1993, in which the use of patient tissue was a major topic. Subsequently a notice of intent to issue guidelines was published and information packages were released. The most recent step is a compilation of submissions in response to the information packages.

The need for guidelines on the use of human tissue for research purposes was generally supported in the submissions, although many expressed an opinion that some flexibility should be retained. In relation to informed consent, the general view was that there should be a flexible approach, as determined by institutional ethics committees on a case by case basis. It would seem that there was some consensus that consent to future use may not always be necessary. However, there was support for the view that consent should always be required for research using foetal tissues and placenta and genetic material or cell lines. A number of submissions commented on the uncertainty in Australian law with respect to ownership and commercial exploitation of human tissue.

As with other aspects of the research/therapy dichotomy, requirements are less stringent for matters falling into the category of therapy. There is no requirement for institutional ethics committee oversight of consent procedures for therapeutic interventions, or the need to follow guidelines drafted by the Australian Health Ethics Committee. Its jurisdiction is purely in relation to biomedical research funded by its governing body, the NHMRC. Even so, common law informed consent requirements apply equally to both categories. The need for separate consent to subsequent use remains to be determined in Australia.

2.4.2 *Informed Consent With Respect to Indigenous Peoples*

Different considerations apply when tissue is obtained from indigenous groups. It can be argued that valid informed consent can only be obtained if information is supplied in a culturally appropriate form. In some instances this may require consent from the social group as well as the individual, both because of the dangers of genetic stigmatisation and racism attaching to the whole group, and because of differing beliefs about ownership and rights to consent.

There is some recognition of the unique health needs of Aboriginal and Torres Strait Islander peoples in Australia. It is generally acknowledged that research and clinical practice involving these peoples raises particular concerns.[133] The NHMRC has provided some guidance as to how to conduct research involving indigenous peoples,[134] but no special considerations are explicitly required with regard to clinical practice. NHMRC guidelines are required to be applied by institutional ethics committees in assessing any research proposal involving Aboriginal and Torres Strait Islander people. They address several areas of particular concern, namely consultation and community involvement, consent and ownership and publication of data. Patenting of research material is not expressly prohibited, but separate consents are required for any use of information or blood or tissue samples gathered in the course of research.[135] Abrogation of these guidelines would presumably lead to application of the normal sanctions that are available for breach of research guidelines, including withdrawal of funding and publication of default. This would most probably be sufficient to deter researchers from applying for a patent without obtaining the requisite consent. Nevertheless, it would not affect the validity of any patent granted. Nor do the guidelines apply to non-NHMRC funded research.

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133 See the Council Session of the Aboriginal and Torres Strait Islander Health Standing Committee of NHMRC in June 1995 on Aboriginal and Torres Strait Islander Health.

134 NHMRC, *Interim Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research* (1991).

135 Guideline 9.

The Human Genome Organisation has also recently issued guidelines on the conduct of genetic research.[136] These exemplify the need for communication in a culturally and socially appropriate form, consultation preceding recruitment, informed consent at the appropriate level, and respect for choices made as to use of materials. The guidelines also endorse technology transfer and sharing of profits with the indigenous peoples from whom samples were taken. Those seeking to collect material under the auspices of the HGDP research effort are required to follow the guidelines. It is of vital importance to the success of any research in this area that such guidelines are both respected and seen to be respected by the relevant communities.

2.4.3 *Comment*

If *Moore's case* is good law in Australia, and a person can have no proprietary interest in their own body parts once they have been removed, informed consent remains as the only existing means of protecting the interests of all the parties involved.[137] The adequacy of informed consent provisions is far from certain. I suggest that this aspect of regulation of human genetic research and its clinical application, perhaps than any other, needs greater attention by lawyers and policy makers.[138] Indeed, the problems associated with use of human tissue loom large on any ethical agenda for human genetic research. It may be that legislation is the only means by which the interests of the donor of tissue can be protected. The supply of tissue from willing donors is vital to the continuance of human genetic research. Donors will be loathe to do so if they see researchers benefiting financially from the use of their tissue. It does seem inequitable that the only person who is prohibited from making a profit out of the use of human tissue is the donor of that tissue. On the other hand, the implications that may arise out of making human tissue a subject of commerce are generally recognised as so profound

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136 HUGO Ethical, Legal and Social Issues Committee, *Report to Council, Statement on the Principled Conduct of Genetics Research* (1996) available on the Internet at http://hugo.gdb.org/conduct.htm

137 Note that the decision of the majority in *Moore* has been widely criticised. A number of commentators have suggested that a person should have a property right in their own removed tissues. See, for example, Ducor, P., "The Legal Status of Human Materials" (1996) 44 *Drake Law Review* 195.

138 Save perhaps for the issues associated with use of genetic information.

that commercial transactions between the donor and user of that tissue should be avoided, if at all possible.

In most instances where human tissue is donated for genetic research it will be "generic", in that the identity of the tissue and of the donor are irrelevant. In such cases I would support the view that it is inappropriate for the donor to receive a share of profits arising out of patents for inventions which use the tissue, because it is not the tissue itself that has generated the profit, but the invention. I will recommend that where the donor's tissue is in some way unique, either to that particular individual, or the individual's ethnic group, there is much better justification for allowing them a share in patent profits, particularly if the patented invention could not have been created without the use of that unique tissue.

Conclusion

This analysis has demonstrated that Australia and other countries have a long history of formulating and testing the appropriate regulatory mechanisms to deal with biomedical research, and these apply to human genetic research as much as any other research involving human subjects. This is not to deny that there are some gaps in the regulatory mechanism, particularly with respect to issues of access to genetic information and access to genetic material. It is difficult to see how a ban on patenting might fill the gaps in the regulatory regime in these areas.

The patent system has in the past been used as a device for discouraging immoral inventions, including prohibitions on the patenting of contraceptives and gambling devices.[139] Ethical considerations have also been used to justify the exclusion from patenting of certain items in some jurisdictions, particularly foodstuffs and medicines, on the basis that private property rights should not interfere with the supply of vital goods.[140] For the

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139 A number of examples are listed by Wells, A.J., "Patenting New Life Forms: An Ecological Perspective" [1994] *European Intellectual Property Review* 111.

140 See, for example, Moufang, R., "Patenting of Human Genes, Cells and Parts of the Body? - The Ethical Dimensions of Patent Law" (1994) 25 *IIC* 487, 501. Section 51(1)(b) of the *Patents Act* 1990 (Cth) allows the Commissioner to refuse to accept a patent request for a

most part, however, it is outside the competence of patent officers and judges to decide whether genetic research in itself is ethically acceptable.[141] If objections to patenting of human genetic material are to be given the attention they deserve they must be separated out from objections to the research.[142] I suggest that if a particular piece of research has been vetted and approved by a body which has been given the mandate to consider such issues, and if the research has been carried out in accordance with requisite guidelines, it is entirely inappropriate for patent officials to revisit the question of acceptability of that research.

Human genetic research and its clinical application are monitored and controlled by a wide array of oversight mechanisms. These range from pronouncements of respected international organisations, through research guidelines to legislative requirements and prohibitions. There is little doubt that the existing system has imperfections, although the full extent of those imperfections may only become apparent as the science and medicine progress. The legal, ethical and social issues associated with human genetic research and its clinical applications will require monitoring for the foreseeable future.

In Australia, oversight of the research phase is stringent. It rests on the ability of individual institutional ethics committees (IECs) to perform their duties, which for some committees may be quite onerous. The role of bodies such as the Gene Therapy Committee in providing expert advice to IECs is

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substance which is capable of being used as a food or medicine and is a mere mixture of known ingredients, or for a process producing such a substance by mere admixture.

141 The extent to which they have the competence to address the ethics of patenting such work is less certain, see Chapter 6.

142 The distinction between the two issues may well have been further confused by the decision of the Technical Board of Appeal of the European Patent Office in *Plant Cells/Plant Genetic Systems.* (1995) OJEPO 545. In its consideration of the public order/morality provision in Article 53(a) of the *European Patent Convention,* the Board looked to the appropriateness of the technology employed in the invention itself, and not just to the exploitation of the invention. This would appear to be outside the competence of the Board in its consideration of Article 53(a) exclusions, and, as suggested by Straus, may present an additional requirement of patentability. Straus, J., "Patenting Human Genes in Europe - Past Developments and Prospects for the Future" (1995) 26 *IIC* 920, at 933.

vital to their effectiveness. It also relieves the IECs from having to assess the technical merits of particular protocols so that they can concentrate on their true role of identifying and assessing the risks to the individual patient. At the same time it is unfortunate that the Gene Therapy Committee does not have a wider mandate to provide the public with a forum both for information and for input.

The most important and contentious legal, ethical and social issues related to human genetic research and its applications are those associated with access, either in the form of access to genetic information or access to genetic material, and the role of the principle of informed consent. The concerns associated with these issues are too complex and too far removed from the patenting issue to be discussed further in this thesis. A number of bodies are turning their attention to these topics. These include the Victorian Anti-Cancer Council, the Privacy Commissioner and the Australian Health Ethics Committee, which plans to examine this area for the next three years. This thesis also forms part of a larger project funded by the Australian Research Council which in part will assess these issues. For the remainder of this thesis, the focus is on the extent to which patenting is appropriate in the area of human genetic research and its applications, and not on the appropriateness of that research *per se*.

CHAPTER 5: COMMERCIALISATION OF GENETIC RESEARCH AND PRACTICE

Introduction

In the previous chapter, I argued that the patent system should not be the forum for regulating human genetic research because a number of more appropriate regulatory regimes exist outside the patent system. Once research becomes the domain of the company rather than the public institute, however, the question is again raised whether the patent system has a role in regulating that research, and, if it does, whether it discharges that role adequately. Two of the premises underlying objections to patenting of human genetic material are that patenting is the only means by which companies are regulated and that if we accept patenting of human genetic material, then wholesale commercialisation of all aspects of research and practice is acceptable.

In this chapter I attempt to rebut these premises. First, there are a number of means by which companies are regulated outside the patent system. I will review some of these modes of regulation to demonstrate that companies, just as much as public institutions, are governed by a wide range of codes of practice, research guidelines and legislation. Thus it is appropriate that the patent system retains its dominant role of providing an incentive for innovation rather than regulating that innovation. Secondly, there may be aspects of human genetic research and clinical practice that should be shielded from commercialisation.[1]

The sequence of activities involved in the transition from the pure research phase to the practice phase has been metaphorically described by John Sulston as a flowing stream, with DNA sequencing at the upstream end, flowing downstream to the marketing of diagnostic tools and therapeutics.[2] The sequence of the flow is shown below:

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1 Means could be provided from within the patent system for discouraging those particular aspects of commercialisation. A number of recommendations to this effect are made in Chapter 7.

2 John Sulston is one of the scientists most actively involved in sequencing the human genome. He used this term at the recent *Genome Summit* held by the Human Genome Organisation (HUGO) in Canberra.

- anonymous sequences;
- fragments of genes;
- whole genes of unknown function;
- gene sequences of known function;
- deleterious mutations;
- diagnostic assays; and
- therapies.[3]

In my discussion of the effect of commercialisation I will use Sulston's flow analogy to assess the differing issues associated with upstream research and downstream practice. It must be recognised that commercialisation plays an influential role at both ends of the stream, and that the development of genetic products occurs within a competitive commercial environment. It is neither possible nor desirable to remove all commercial influences from this area. I submit that the more realistic goal that should be pursued is to ensure that there are mechanisms in place to moderate the excesses that might occur in a purely market-driven system.

The influence of commercialisation in human genetic research and its clinical applications cannot be ignored. The pharmaceutical industry has always been very much a commercial venture, and pharmaceutical companies have always conducted their own applied research. The change that genetics has brought is that these companies are also becoming interested in the earlier basic research phase, perhaps because of the perceived need to stake their claims to particular DNA sequences at the outset. The other change that the new genetics has brought is that many of the scientists who are involved in basic research and for whom academic kudos has in the past been sufficient reward are now claiming their share of the profits to be gained through this technology. In the USA in particular a number of geneticists have either joined pharmaceutical or biotechnology companies or have formed their own private companies. The input of the private sector into basic human genetic research is substantial. An estimated $85 million was spent privately in this area in the USA in 1993.[4] Human genetic research conducted in the commercial domain has been along two main lines. First, some companies have become specialised in hunting for specific disease-related genes, locating them within the human

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3 The underlying science from which this flow analogy is derived has been described fully in Chapter 3.

4 Anderson, C. "Genome Project Goes Commercial" (1993) 259 *Science* 300.

genome, isolating them and sequencing their codes and developing diagnostic tests. For a very limited range of genetic diseases therapeutic treatment regimes have also been established. Secondly, other companies have focused on automated sequencing of large numbers of DNA fragments, including expressed sequence tags (ESTs).[5]

A number of government and private studies in the USA have assessed the economics of the biotechnology industry.[6] It is clear from these studies that the cost of developing biotechnology products is high and a large portion of company revenue is spent on research and development.[7] Burk reported on a survey in 1990 which found that of 500 biotechnology companies sampled, only 25% showed a net profit.[8] Other evidence shows that the average cost of producing a new drug in 1990 was around $US 230 million, and it took 12 years to develop.[9] These estimates are likely to be even higher where biotechnology is used.[10] Quite clearly, investors in biotechnology must have some security for their investment, and the patent system would appear to provide an appropriate source for that protection.

The Mandeville survey of 1981 made the suggestion that, in areas of high technology like biotechnology, developments are so rapid that the patent system is bypassed.[11] Quite clearly, this is not the case today. The number of patent applications for biotechnological inventions has risen dramatically. The European Patent Office estimated that patent applications in the area of genetic engineering increased by 600% between 1981 and 1985.[12] More specifically, 1,175

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5 ESTs are cDNA copies of mRNAs extracted from human cells.

6 Reported in Burk, D.L., "Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed" (1990) 17 *Rutgers Computer and Technology Law Journal* 1.

7 40%, on average: *Ibid.*, at 17-18.

8 *Ibid.*, 18.

9 From a study carried out in the United States, cited in Power, P.A., "Interaction Between Biotechnology and the Patent System" (1992) 3 *Australian Intellectual Property Journal* 214, at 220.

10 *Ibid.*

11 Mandeville, T.D., D.M. Lamberton and E.J. Bishop, *Economic Effects of the Australian Patent System* (1982) AGPS.

12 Cited in Commission of the European Communities, *Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions* (1988) at 9.

upstream patents were issued world wide for human DNA sequences between 1981 and 1995.[13] The extent of patenting is also substantial from the downstream perspective. A new patenting category was created in Australia in 1988, covering medical preparations with genetic material and gene therapy.[14] By September, 1994 there had been 160 patent applications in this category. Currently, then, it would appear that patents are actively being sought by biotechnology companies for inventions associated with genetic research and development. From this it can be inferred that patents are also playing a major role in encouraging innovation in biotechnology, perhaps more than in any other industry.

The existing system for commercialisation of recombinant DNA technology has been remarkably successful. Evidence has been presented that 1993 world net sales of human proteins produced by recombinant DNA technology were $US 7.7 billion.[15] On this basis, a sound rationale has to be presented to justify any modification to the existing system.

Part 1: Regulation of Commercialisation

There is a perception in the community that because companies are profit-based they will somehow be more likely to abuse the trust of research subjects and patients in the quest for profit. There are a number of reasons why this may not necessarily be the case.

1.1 Application of Existing Regulatory Principles

Companies, just as much as universities and other government-run research institutes, are subject to many of the regulatory regimes outlined in Chapter 4. The two regimes of legal liability and professional responsibility of the medical profession apply to medical researchers employed by companies where they have direct contact with research subjects. There may be some gaps in these duties when researchers acquire samples from medical intermediaries. The Nuffield Council Report of 1995 recommended that where tissue is of

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13 Thomas, S.M., et al, "Ownership of the Human Genome" (1996) 380 *Nature* 387.

14 Ref A61K 48/00.

15 Straus, J., "Patenting Human Genes in Europe - Past Developments and Prospects for the Future" (1995) 26 *IIC* 920, at 921.

special interest for research or for commercial development, the proposal should be referred to a research ethics committee.[16]

The more stringent form of ethical review that has been developed for biomedical research in Australia is restricted to research that is:

- funded by the NHMRC (although the Australian Research Council also requires institutional ethics committee review and compliance with NHMRC guidelines);
- conducted by an institution that received NHMRC funding; or
- approved under the CTN or CTX schemes.

Thus companies may be able to escape the NHMRC institutional ethics committee system of ethical review. In the USA, however, the trend has been for companies to submit their proposals for ethical approval on a voluntary basis. There is no reason to suppose that Australian companies will be any less willing to subject themselves to the same sort of review process. In addition, the broad definition of therapeutic goods in Australia means that any of the products used in genetic technology will be required to go through the clinical trial process before they can be registered and licensed for manufacture or importation, and thus institutional ethics committees will be guaranteed input at this stage.

In any case, many of the developments arising out of human genetic research already bypass the institutional ethics committee system because they are classified as medical practice rather than research. This is particularly salient in the areas of genetic screening and testing. As has been pointed out in Chapter 4, in many respects this work creates the most troublesome ethical issues, because of its potential effects on fundamental human rights. The exemption from institutional ethics committee review in this area applies equally to government-sponsored and privately-sponsored work. Those with commercial interests in screening technology must take as much account as public institutions of the system currently in place to protect human rights.

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16 Nuffield Council on Bioethics, *Human Tissue Ethical and Legal Issues* (1995) Chapter 13, para 13.38.

1.2 Regulation of Companies

In many ways companies are subjected to more rigorous monitoring than government-sponsored research institutes. A large body of regulation is in place covering consumer protection, restrictive trade practices and product safety. In Australia the *Trade Practices Act* 1974 (Cth) and complementary state legislation provides the bench mark for acceptable standards of practice, part IV covering restrictive trade practices, part IVA covering unconscionable conduct and part V consumer protection, including unfair practices and product liability. In addition, the *Corporations Law* provides the framework around which uniform codes of business ethics are being developed across Australia.

Parts IVA and V of the TPA provide the critical focus on the individual consumer. The product liability provisions have already been discussed in Chapter 4 in relation to product development. It may also be possible to bring the unconscionable conduct and misleading and deceptive conduct provisions[17] to bear on corporations providing genetic services without full evaluation of the risks to the individual consumer. In this respect the provisions of the TPA arguably provide greater protection to the consumer, because they carry legislative force, whereas the institutional ethics committee system only provides guidance. Crucial considerations are:

- whether a company, in engaging in the supply of genetic services is "engaging in trade or commerce";
- whether a patient is a consumer within the definition in section 4(3) of the legislation;[18] and
- the extent to which "unethical" conduct constitutes "misleading and deceptive" or "unconscionable" conduct.

1.3 Research Involving Indigenous Peoples

Perhaps the most troublesome aspect of the commercialisation of human genetics is that it is unclear how it can be ensured that consideration is given to the views of indigenous groups in relation to commercialisation of

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17 Respectively, sections 51AA and 51AB, and section 52 of the TPA.

18 A person will be a consumer if they acquire goods or services for private use or consumption. There seems to be no good reason why a person who participates in a clinical trial cannot be acquiring goods or services for their personal use.

research of the type being conducted under the auspices of the Human Genome Diversity Project.[19] Ethical review could be avoided if the research is not NHMRC funded, and the doctrine of informed consent could be bypassed if companies acquire human tissue second- or third-hand. Companies thereby may be free to patent and commercialise products of or methods using cell lines taken from indigenous peoples, without even requiring their consent. Moreover, there would be no obligation for companies to share the profits from their work with the indigenous groups from whom the cell lines arose.

1.4 Effect of the Biodiversity Convention

Provisions of the Biodiversity Convention may be applicable to human genetic material. The Biodiversity Convention[20] was signed at the Rio Conference on Environment and Development in 1992. The objectives, stated in Article 3, include the conservation of biological diversity, equitable sharing of the benefits from use of genetic resources, including access to and transfer of technology. The provisions relating to rights over genetic material include Articles 15, 16 and 19. Article 15 requires that the provider country of genetic material determines access to that material, but that restrictions on access should not run counter to the Convention. This Article also requires that financial mechanisms should be established with the aim of providing for fair and equitable sharing of research and development and the benefits of commercialisation. Article 16 requires the transfer of technology to developing countries on fair and favourable terms. It further provides that intellectual property rights should be supportive of and not run counter to the objectives of the Convention. Article 19 encourages the participation of provider countries of genetic materials in their subsequent development.[21]

Although the Convention requires that the host country is consulted with respect to acquisition of genetic material and shares in the profits of patenting, the extent to which it could impact on the commercialisation of

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19 The concerns of indigenous groups were discussed in Chapter 1 in section 3.3.

20 Reproduced in: (1992) 31 *International Legal Materials* 818.

21 These Articles are discussed in more detail in Powers, M.A., "The United Nations Framework Convention on Biological Diversity: Will Biodiversity Preservation Be Enhanced Through Its Provisions Concerning Biotechnology Intellectual Property Rights?" (1994) 12 *Wisconsin International Law Journal* 103.

human genetic research is uncertain from the terms of the Convention itself. Human biodiversity was not an issue that was considered at the Rio Conference, and even if the Convention does apply to human genetic material, regard should be had to the fact that the USA has refused to become a signatory because of its objection to these and other provisions.[22] I suggest that since US biotechnology companies are the main players in commercial human genetic research using samples derived from indigenous peoples, the impact of the Biodiversity Convention is likely to be minimal.

It would be erroneous to paint the picture that all companies seek to exploit indigenous peoples and rob them of their genetic resources. There is a growing willingness on the part of some companies to engage in royalty sharing agreements with countries and communities from whom genetic resources were acquired.[23] Such agreements appear to be consonant with the spirit of the Biodiversity Convention. They should be encouraged, on the condition that any inequality of bargaining power is not exploited.

Part 2: *Commercialisation of Upstream Research*

Patenting of human genetic research does not stand alone as being a unique problem in academic science. It is part of a wider trend favouring science which has commercial applicability. It would be generally accepted by most of the people involved in academic research, whether they be the funders or the researchers, that the emphasis of that research has changed vastly over the last decade. The academy is no longer the ivory tower that it once was. Like every other institution it must justify itself in the language of economic rationalism. As part of this, research that has commercial implications will be favoured by funding agencies over pure science. In the long run, this change may be detrimental in that it will lead to cessation of the basic science from

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22 United States, *Declaration Made at the United Nations Environment Programme Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity.* Reproduced in: (1992) 31 *International Legal Materials* 848.

23 For example, The Crucible Group, *People Plants and Patents: the Impact of Intellectual Property on Biodiversity, Conservation, Trade and Rural Society* (1994) International Development Research Centre, Ottawa, at 11.

which much applied science flows.[24] Nevertheless, it is a fact of academic life that projects must now be justified in terms of their benefit to the nation, and economic benefits will receive favoured consideration.

2.1 Change in Focus of Publicly Funded Research.

As recently as 1981 it was pointed out that although government and higher education sectors carry out the majority of Australia's total research and development effort, these sources only ever provided a small percentage of total domestic patent applications.[25] The patent incentive has in the past largely been avoided by the public sector because of the perceived fear that pursuit of commercial advantage would somehow corrupt pure research.[26] Given the cost of patenting, the nature of academic research and the small role of patents in innovation the Mandeville report concluded that "it is questionable whether it would be economically desirable for universities to emphasise patenting more than they currently do."[27] Since that time, I would argue that the shift in focus in government expectations of the goals of publicly funded research and development in a number of countries has led to a much greater emphasis being placed on patenting and transfer of technology from the public to the private sector in order that it might be commercially exploited.

2.1.1 Patent Policy in US Public Institutions

In the USA collaboration between the private and public sectors has been encouraged much more than elsewhere.[28] In the 1930s a number of universities already had formal patent policies, and in 1974 Stanford University applied for a patent for recombinant DNA technology, invented by

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24 Australia's newest Nobel Prize winner for Physiology or Medicine, Professor Peter Doherty said as much in his opening address at the *Scicomm96 Conference* (1996) University of Melbourne.

25 Less than 3% in 1978: Mandeville survey, at 71.

26 The history of academic attitudes towards patenting is described in Weiner, C., "Universities, Professors and Patents: A Continuing Controversy" [1986] *Technology Review* 33.

27 Mandeville survey, at 95.

28 Other countries are now catching up. See for example, the United Kingdom's Office of Science and Technology White Paper *Realising Our Potential* (1993).

Cohen and Boyer.[29] Since then, a series of legislative enactments have been put in place in the USA to ensure the transfer of technology from government institutes and universities to the private sector.[30] This legislation primarily requires patenting of appropriate research outputs conducted in the public sector, and transfer of this technology to private industry by technology licensing agreements and cooperative research and development agreements. A recent background paper by the US Office of Technology Assessment (OTA) analysed the efficacy of transfer of technology, which it defined as the conversion of scientific knowledge into commercially useful products, with respect to human genetic research.[31] According to the OTA background paper, "the success of the biotechnology sector [in the USA, when compared with other countries] owes much to federal technology transfer and intellectual property policies."[32] The OTA suggested that such policies will prove equally as important in the commercialisation of human genetic research.

2.1.2 Patent Policy in Australian Public Institutions

In Australia, some consideration has also been given to the desirability of patenting inventions developed through publicly funded research, and licensing them to industry.[33] In particular, a report by a working group of the Prime Minister's Science and Engineering Council pointed out that it is generally recognised that Australia fails to exploit adequately publicly funded research and development.[34] A piecemeal approach appears to be favoured in Australia with regard to policy on patenting and subsequent use of inventions derived from publicly funded research, it being left very much to the

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29 Weiner, at 39.

30 These include the Bayh-Dole Act 1980 (US); Stevenson-Wydler Act 1980 (US); Federal Technology Transfer Act 1986 (US).

31 US Congress, Office of Technology Assessment, *Federal Technology Transfer and the Human Genome Project* (1995) Washington DC, US Government Printing Office, Foreword, at iii.

32 *Ibid.*, at 1.

33 Similar considerations have also been raised in Britain. See, for example, Cornish, W.R., "Rights in University Innovations: The Herschel Smith Lecture for 1991" (1992) 1 *European Intellectual Property Review* 13.

34 Working Group of the Prime Minister's Science and Engineering Council, *The Role of Intellectual Property in Innovation. Strategic Overview, Volume 1* (1993) AGPS, at 10.

individual and the institution.[35] Nevertheless, there is no doubt that the culture has changed, with funding agencies now looking very favourably on collaboration with industry and strategic research programs.[36] Patents are now one of the means by which success in research is measured.[37]

2.1.3 *Effect of Patenting on the Culture of Academic Research*

This growing commercialisation is radically altering the culture of research, based as it is on what have been referred to as the norms and rewards of science, namely: universalism, communism, disinterestedness and organised scepticism.[38] The tradition of rapid publication of results in wide-circulation journals is not only the primary reward for academic scientists, but is also the dominant measure of academic excellence. However, there may be valid commercial reasons, including the possibility of patenting, why the early disclosure of results is not always appropriate. As Sherman has pointed out, patents change both the forum and form in which research results are first disclosed.[39] Even so, other evidence indicates that commercialisation *per se* need not ultimately cause a decrease in publication rate. On the contrary, that evidence shows that researchers from those government institutes in the USA

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35 Australian Vice Chancellor's Committee, *Ownership of Intellectual Property in Universities. A Discussion Paper* (1993). This is also the case in Britain. See Office of Science and Technology, *Intellectual Property in the Public Sector Research Base* (1992) HMSO.

36 Two good examples in Australia are Co-operative Research Centres and Australian Research Council Collaborative Research Grants, both of which are funded jointly by government and industry.

37 Concerns have been expressed in some quarters, however, as to the appropriateness of taking the acquisition of intellectual property as an independent measure of academic achievement. See the National Academies Policy Advisory Group, *Intellectual Property and the Academic Community* (1995) Royal Society, London.

38 By Merton, R.K., *The Sociology of Science* (1973) Chicago, University of Chicago Press. See also Drahos, P., "Intellectual Property Law and Basic Science: Extinguishing Prometheus?" (1992) 10(2) *Law in Context* 56.

39 Sherman, B., "Governing Science: Patents and Public Sector Research" (1994) 7 *Science in Context* 515, at 526.

that have formal partnerships with industry tend to have higher publication rates than those from non-industry aligned institutes.[40]

The other option for protection of research data is secrecy. Although the norms and rewards of science may have some congruency with the patent system, they would appear to have nothing in common with secrecy.[41] One of the primary requirements of both publication and patenting is disclosure of information, allowing its subsequent use by others. The main difference is that use follows on immediately after publication, whereas for patenting, disclosure occurs at the start of the patenting period but use is not permitted until the end. Secrecy is premised on the fact that there is no disclosure requirement. Indeed, disclosure puts an end to the protection afforded by secrecy. For this reason the use of secrecy as a means of retaining control over information could create a "destructive, anti-intellectual climate".[42] Although the patenting option also restricts the release of information, its effects are likely to be much less profound.

2.1.4 Patenting in the Post-Academic Era of Science

This new closed research culture poses problems different from those normally associated with research conducted in the public sector. One of the concerns that has been identified in this new "post-academic" era of science is that objectivity will be lost.[43] Objectivity is incorporated into the academic system through the norm of disinterestedness which requires impartiality in the reporting of research results. Whilst it is clear that some form of security for investment in scientific research beyond mere publication rights must be guaranteed to encourage commercial investment to continue, it is vital to the credibility of that science that it continues to be seen as objective. It may be that in some circumstances patents actually play a role in supporting the objectivity of the science on which they are based: a high level of scrutiny is required both of the claims made in the patent and of the prior art to ensure that the

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40 US Congress, Office of Technology Assessment, *Federal Technology Transfer and the Human Genome Project* (1995), at 35.

41 Eisenberg, R., "Proprietary Rights and the Norms of Science in Biotechnology Research" (1987) 97 *Yale Law Journal* 177.

42 Poste, G., "The Case for Genomic Patenting" (1995) 378 *Nature* 534, at 535.

43 Ziman, J., "Is Science Losing Its Objectivity" (1996) 382 *Nature* 751, at 754.

invention claimed is an advance over the prior art. Nevertheless, the issue remains whether patents are appropriate in the area of human genetic research, where the welfare of the individual research subject should override all other considerations.

2.2 Effect of Patenting on Human Genetic Research and Its Applications

It is clearly in Australia's interests to support human genetic research and its clinical application from a number of perspectives:

- direct improvements to health care;
- financial gains in obtaining a share in this huge commercial venture;
- the kudos to be gained internationally from making a contribution to the research; and
- the expertise to make informed choices as to appropriate technology.

That research effort is both costly and risky, and therefore private funding of the research itself, as well as its application into clinical practice, must be seen as having some desirable features. It is another matter to determine whether the option of patenting is an appropriate incentive.

2.2.1 The National Institutes of Health's Upstream Patent Claims

The Human Genome Project has been described as the biggest patenting issue in the USA at present,[44] primarily because in 1991 the US National Institutes of Health (NIH) applied for upstream patents for a large number of expressed sequence tags (ESTs), as well as the complete cDNA sequences that incorporate the ESTs.[45] The EST claims ultimately were rejected for failure to demonstrate the three crucial requirements of novelty, usefulness and non-obviousness,[46] and were subsequently withdrawn. Given that the US Patent Office routinely rejects a large number of applications, however, its rejection in

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44 Maher, L., "The Patent Environment: Domestic and European Community Frameworks for Biotechnology" (1992) 33 *Jurimetrics Journal* 67 at 128.

45 See, for example, Eisenberg, R., "Genes, Patents and Product Development" (1992) 257 *Science* 903.

46 See, for example, "Ethics, Legality of Gene Patenting are Weighed in Senate Subcommittee Hearing" (1992) *BNA Patent, Trademark and Copyright Law Daily* 1 October 1992.

this case should not be seen as fatal.[47] A change in policy means that NIH are no longer pursuing the patent claims. Even so, it seems certain that commercial enterprises have made similar patent claims, and they are likely to appeal against rejection by the Patent Office. The stated aim of the NIH in applying for the EST patents was to encourage product development.[48] Those who oppose EST patents argue that they would have the opposite effect because they may prevent later downstream patent claims which may otherwise have been valid for genes, proteins and diagnostic tools subsequently developed even though the EST information may not have been used in their development. If nothing else, the NIH claims have demonstrated the need for detailed public discussion and clear official guidelines in the general area of patenting of human genes.[49]

The basis of the Human Genome Project as a cooperative international venture may well have been undermined by patent applications for ESTs. Much of the work involved in the Human Genome Project can still be considered to be basic research, a central feature of which should be the free flow of information. At the very least, application for patents could have impeded scientific progress by the inevitable delays resulting from processing of patent claims. Normal delays have been exacerbated of late by the great increase in the number of claims for biotechnology patents. In the USA it has been estimated that by 1988 there was a backlog in processing of patent claims by the Patent and Trademark Office of around two and a half years, and up to a further two years before the final ruling was made.[50] Eisenberg has suggested that greater certainty in the outcome of applications and streamlining

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47 Agence France Presse in its September 24, 1992 issue cites the number of rejected claims as 90%.

48 For example, Healy, B., "Special Report on Gene Patenting" (1992) 327 *New England Journal of Medicine* 664.

49 Such public discussions are already underway. In 1992 a public meeting was called by the Genome Patenting Working Group, Committee on Life Sciences and Health, Federal Coordinating Council for Science, Engineering and Technology (US), *Federally Funded Genome Research Science and Technology Transfer Issues. Proceedings of a Public Meeting, May 21, 1992* and the Patent and Trademark Office has recently given notice of public hearings and request for comments on patent protection for biotechnological inventions.

50 Crawford, "Patent Claims Buildup Haunts Biotechnology" (1988) 238 *Science* 723.

procedures will outweigh problems associated with interim secrecy required whilst patent claims are being processed.[51]

The effect of the refusal of the Patent Office to accept the EST claims initially appeared to be quite serious.[52] Craig Venter, the geneticist who coded the NIH ESTs, became employed by The Institute for Genomic Research (TIGR), a non-profit partner of Human Genome Sciences Inc (HGS), in which SmithKline Beecham has a major equity share. Venter isolated 150,000 ESTs, which were contained in a computer database. TIGR and HGS claimed that they would only grant access to academic institutions to this database on the condition that an "option agreement" was signed, under which HGS would have exclusive option to any patents arising from research using those sequences. A number of academic institutes around the world have since agreed to sign the agreement.

Other groups, including Merck Pharmaceutical Co., contributed EST information to a central public data base known as GenBank at the National Center for Biotechnology Information in the USA to counter TIGR's move. Merck strongly refuted the suggestion that this indicates an anti-patenting stance for biotechnology inventions. Rather, it argued that it demonstrated Merck's commitment to maintain the crucial distinction between patentability of inventions and accessibility of research tools for research purposes.[53] TIGR has since released a large number of its ESTs to add to the database, although some will remain secret.[54]

2.2.2 *Ownership of Sequence Information*

Now that the main focus of research effort in the Human Genome Project is sequencing the human genome, issues associated with ownership and release of sequence information have become a source of concern for the scientists and funding agencies associated with the project. Gene sequence

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51 Eisenberg, R., "Patenting the Human Genome" (1990) 39 *Emory Law Journal* 721.

52 Dickson, D., "HGS Seeks Exclusive Option on all Patents Using its cDNA Sequences" (1994) 371 *Nature* 463.

53 Caskey, C.T. and A.R. Williamson, "Merck, SmithKline and Patents" (1996) 381 *Nature* 360.

54 Coghlan, A., "Minor Genome Secrets Open To All" (1995) *New Scientist* 7 October, 5.

information clearly is of immense value, both in commercial terms and in terms of basic research.

A number of scientists are strongly of the belief that where sequences of nucleotides have not been ascribed function, and are therefore located at the farthest upstream end of Sulston's flow, they are "pre-competitive" and should be made freely available, even when they are likely to contain a gene with high commercial value. One such example is the sequence of nucleotides which is believed to contain BRCA2, the second gene to be identified as having a link to inherited breast cancer. The sequence has been put on the Internet by the Sanger Centre in the United Kingdom and Washington University in the USA in the hope that this will aid in the localisation of the gene.[55] A major trade association in the USA has also endorsed the release of sequence information into the public domain, so that industry may reap the benefit of the "more meaningful and costly scientific work" in ascribing function to the sequence.[56]

2.2.3 The Bermuda Declaration

These views were supported in a recent strategy meeting of Human Genome Project participants in Bermuda, sponsored by the UK Wellcome Trust.[57] A number of principles were endorsed at the Bermuda meeting, including the requirements that primary genomic sequences should remain in the public domain and that they should be rapidly released. As sequences become available, they are now released onto the Internet, and the HUGO website provides the central indexing of all sequence information. By putting this information in the public domain, the patenting option is effectively

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55 Dickson, D., "Open Access To Sequence Data Will Boost Hunt for Breast Cancer Gene" (1995) 378 *Nature* 425.

56 Industrial Biotechnology Association, *Position Paper: Recommended Federal Policy Concerning Human Genetic Sequences Discovered by Federal Researchers, Contractors and Grantees* (1992). Referred to in Eisenberg, R., "Genes, Patents and Product Development" (1992), at 907.

57 "International Strategy Meeting Agrees Principles of Early Data Release for Human Genome Sequencing" (1996), press release by the Wellcome Trust, London, 17 April. Participating countries included the UK, the USA, France, Germany and Japan. See also Bentley, D.R., "Genomic Sequence Information Should Be Released Immediately and Freely in the Public Domain" (1996) 274 *Science* 533.

excluded until some additional step is taken, for example ascribing function to a particular gene sequence.

Some caution may need to be exercised with regard to the rapid release of sequence information, because there is no opportunity for peer review.[58] Nor is there much opportunity for quality control. One example that has been cited is the entry into GenBank of EST sequences supposedly of human origin, which later were found to include yeast and bacterial sequences. It has been claimed that those sequences are still listed in GenBank as being of human origin.[59] Sequence information that is available in public access databases will clearly need continual updating and checking for errors. It may be appropriate for a body such as the Human Genome Organisation to be given the responsibility to undertake this task.

2.2.4 *Patent Law and Upstream Patenting*

Even without the release of gene sequence information into the public domain, there now appears to be some unanimity of opinion that where a gene sequence has not been assigned a particular function it is not patentable under current patent law, because it does not have industrial applicability but is merely a research tool.[60] This clearly appears to be the case under current Australian patent law (see Chapter 6). But that same body of opinion supports patenting of bona fide inventions arising out of human genetic research.[61] Such patents may create less of a problem to scientists than patenting of ESTs and other sequences of unknown function, provided that function has been ascribed, because research effort is less likely to be wasted.

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58 In this regard, see the comments of Adams, M.D. and J.C. Venter, "Should Non-Peer-Reviewed Raw DNA Sequence Data Release Be Forced on the Scientific Community?" (1996) 274 *Science* 534.

59 *Ibid.*

60 Some of the more notable viewpoints include those of the international Human Genome Organisation in Caskey, C.T., R.S. Eisenberg, E.S. Lander and J. Straus, "HUGO Statement on Patenting of DNA Sequences" (1995) *Genome Digest* 6; the British National Academies Policy Advisory Group, *Intellectual Property and the Academic Community* (1995); the House of Commons Science and Technology Committee (the Shaw Committee), *Human Genetics: The Science and Its Consequences* (1995) HMSO, London.

61 *Ibid.*

2.2.5 *Deleterious Effect of Broad Patents*

Another concern of both scientists and industry is related to the breadth of patent protection being claimed in a number of areas of biotechnology, particularly because both the European and US Patent Offices are apparently prepared to accept patent claims having extensive coverage. Examples of patents that could impinge on human genetic research include a patent covering all ex-vivo gene therapy;[62] a patent on the enzyme Taq polymerase, which is required for all polymerase chain reaction work;[63] a patent on one of the genes believed to be linked to inherited breast cancer (BRCA1);[64] a patent on a gene that may play a role in obesity.[65] Such patents may have extraordinary value. The so-called obesity gene patent, for example, has been licensed to the pharmaceutical company Amgen for $20 million, as well as milestone payments and undisclosed future royalty payments. The scientists who sequenced the gene will get a one third share of the $20 million payment.[66]

If patents are too broad it is feared that research will be inhibited, either because it will inevitably lead to patent infringement or it will be unpatentable because it is obvious. The British Court of Appeal and House of Lords decisions in *Biogen v Medeva* suggest that these Courts, at least, may not support broad patent claims.[67] One of the concerns raised by the Shaw Committee in its Report to the House of Commons was that patenting criteria are being applied too loosely by patent examiners, and that such problems are exacerbated by the

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62 Coghlan, A., "Sweeping Patent Shocks Gene Therapists" (1995) *New Scientist* 1 April, 4; Nowak, R., "Patent Award Stirs Controversy" (1995) 267 *Science* 1899; Gavaghan, H., "NIH Wins Patent on Basic technique Covering all *Ex vivo* Gene Therapy" (1995) 374 *Nature* 393.

63 Aldhous, P., "PCR Enzyme Patent Challenged" (1993) 260 *Science* 486.

64 Butler, D., and D. Gershon, "Breast Cancer Discovery Sparks New Debate on Patenting Human Genes" (1994) 371 *Nature* 271.

65 Stone, R., "Rockefeller Strikes Fat Deal with Amgen" (1995) 268 *Science* 631.

66 *Ibid.*

67 *Biogen Inc v Medeva Plc* [1995] FSR 4 (Court of Appeal). The House of Lords judgment was handed down on 31st October 1996, an abridges version of which appeared in *The Times*, 1 November 1996.

fact that the width of patent claims cannot be challenged through the European Patent Convention.[68] Section 40 of the *Patents Act* 1990 (Cth) allows for challenges to be made in Australia on the ground of lack of fair basis. In contrast, the problem in Australia is a lack of parties willing to make such challenges. One of the most likely reasons for this is the small size of Australia's biotechnology industry and the lack of competition for the Australian market.

Part 3: Commercialisation of Downstream Practice

There can be no doubt that the growing commercialisation of genetic research will have serious effects on the distribution of health care resources. To be viable commercially, companies will have to set product prices at the appropriate level both to recoup research costs and to achieve an acceptable profit margin. Patents provide one means by which some of these research costs can be recouped.

3.1 Patenting of Drugs

The impact on health care of commercialisation and patenting of inventions that have clinical application is not a new phenomenon. Patenting did not start with genes, although some of the literature seems to suggest as much. It has been recognised for some time that the ability to patent drugs is crucial to the survival of the Australian pharmaceutical industry. At the same time, pharmaceuticals are obviously key components of the health care system. The total expenditure on pharmaceuticals including prescription payments and over the counter drugs is around 10% of all health expenditure in Australia.[69] The cost of prescription drugs to Australia is substantial. In 1994-95 a total of around $2.33 billion was spent on prescriptions, over $1.88 billion of which was supplied by the federal government.[70] This figure is just over 0.4% of the

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68 House of Commons Science and Technology Committee, *Human Genetics: The Science and Its Consequences* (1995) HMSO, London, paras 208 and 209.

69 Commonwealth Department of Human Services and Health, *Annual Report 1994-95* (1995) AGPS, at 79.

70 See Australian Institute of Health and Welfare, *Australia's Health 1996* (1996) AGPS, at 181.

GDP.[71] The federal government subsidises the cost of pharmaceuticals through the Pharmaceutical Benefits Scheme (PBS).[72] Drugs are listed on the PBS by the Pharmaceutical Benefits Advisory Committee.

The critical issue for policy makers in the area is how to ensure that, on the one hand, as wide a range of drugs are offered to consumers at as reasonable a price as possible, whilst on the other, quality is assured and product development continues. The stated objective of the PBS scheme is: "[t]o enable access to necessary therapeutic substances at the lowest cost to Government and consumers consistent with reliable supply."[73]

Exact details of the extent to which patenting of drugs affects pricing policy is difficult to find. Whatever the precise relationship may be, it would appear to be generally accepted that it is in the public interest for the company that has developed and marketed the drug to be able to price it appropriately in order to recoup the high cost of research and development. It can do so because it has a monopoly during the life of the patent, and is therefore not restricted in its pricing policy by market forces. Since the time taken between invention and marketing of a new drug is usually prolonged because of the requirement for clinical trials, the extent to which patents actually have an effect on the cost of drugs may be less than would otherwise be supposed. If, as reported above in the introduction to this chapter, the time taken to develop a drug is 12 years, exploitation of the patent through product pricing will only produce valuable returns during the last eight years of its life. In the first eight years of the patent's life, costs can only be recovered through licensing arrangements and royalty payments

It is not in the public interest for a patented drug to be overly favoured in the market once the patent has expired. In the past the trend has been for drug prescribers and beneficiaries to favour name brand drugs rather than cheaper generics. Recent changes to the listing system for drugs in Australia may reverse this trend. Since 1987 the Pharmaceutical Benefits Advisory

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71 *Annual Report*, at 78.

72 *Australia's Health 1996*, at 180. The history of Australia's medicinal drug policy is described by Harvey, K. and M. Murray, "Medicinal Drug Policy" (1995) In: H. Gardner (ed) *The Politics of Health*, Churchill Livingstone, Melbourne, second edition, chapter 9.

73 *Annual Report*, at 77.

Committee has been required to consider comparative cost-effectiveness before listing drugs on the PBS. That requirement became mandatory for listing of all new pharmaceuticals in 1993.[74] Prescribers and beneficiaries are deterred from requesting particular brands through the minimum pricing policy, whereby the beneficiary pays any additional cost when the particular brand of prescribed drug costs more than the listed basic price. The rationale for introducing economic considerations in drug listing has been stated to be "the potential to encourage more rational diffusion of new technologies in health".[75] There are some problems in using economic values, the most obvious being in the consideration of new drugs to treat new diseases like AIDS. Harris has pointed out that the decision whether to fund expensive treatments costing in excess of $100,000 per life year saved must ultimately be a political one, and that economic evaluation as yet fails to provide an agreed methodology for such difficult decisions.[76] This issue will become more acute as the supply of diagnostic and therapeutic products of genetic engineering increases. There is little doubt that such products will be expensive because of the costs involved in their development.

3.2 Patenting of Drugs and Genetic Products Compared

There is no clear reason why commercialisation and patenting of human genetic research and its clinical applications should have a different effect on the health care system than patenting of drugs.[77] There is a danger in both cases that the need for commercial enterprises to be profit-based may require them to set prices at such a level that it becomes impossible to deliver some products through the national health system. This runs counter to the fundamental ethical principle of distributive justice.

Genetic products, just as much as any type of drug, need to be made available through the health care system as rapidly as possible after their efficacy and safety have been assured in order to alleviate suffering. Since the

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74 Discussed in Harris, A.H., "Economic Appraisal in the Regulation of Pharmaceuticals in Australia: Its Rationale and Potential Impact" (1994) *The Australian Economic Review* 99.

75 *Ibid.*, at 101.

76 *Ibid.*, at 103.

77 Note, however, that the extent of that effect may be greater as the products developed through gene technology become more readily available.

research and development phase is long and expensive for both types of products, however, it is not inappropriate to provide the same form of incentive to encourage that research to continue. It is likely to take at least as long to market the products of human genetic research as for new drugs, and so in this regard the advantages that a patent offers in terms of product pricing will be equally limited. In order to ensure that effects of patents for genetic products are not felt beyond their lifetime a mechanism must be put in place to level the playing field. Economic cost effectiveness may be an appropriate method of achieving this end, as would appear to be the case for drug-related products. Using this means, previously patented products do not receive favourable treatment over generic products produced by competitors. The aim should be that as soon as the patent period comes to an end the market is freed.

3.3 Case Studies on the Effect of Commercialisation

Potential effects of commercialisation on the delivery of products through the health care system can perhaps best be demonstrated by analysing the sequence of events involved in the delivery of two important products which were both produced using recombinant DNA technology.

3.3.1 The Factor VIII Case Study

Haemophilia A is a disease of the blood in which certain of the vital factors for clotting the blood are absent. In its most severe form, death can result from haemorrhaging. In 1990 there were 1134 sufferers of haemophilia A in Australia, 452 of which manifested the severe form of the disease.[78] Factor VIII is the currently accepted blood clotting treatment for haemophilia A. If it can be delivered in pure form, that is free from viral contaminants such as HIV and Hepatitis C, it has the effect of increasing the life expectancy of sufferers of haemophilia A to an age close to that of the general population.[79] Access to Factor VIII is also vital during childhood to prevent later onset of joint damage, requiring corrective surgery. In 1993 inadequate amounts of Factor

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78 McNeill, J., and M. Sinclair, "Epidemiology of Haemophilia A in Australia and Projection of Factor VIII Requirements" (1993) Australasian Society of Blood Transfusion Inc Conference *Factor VIII: Supply and Demand in the 1990s*, 3, at 4.

79 *Ibid.*, at 3.

VIII were being produced to supply its demand.[80] Consequently a number of haemophiliacs were still suffering from debilitating joint disorders. In addition, as long as Factor VIII is derived from blood products its purity cannot be guaranteed. As a startling example of this, the incidence of HIV infection in Australia is close to 30% of the haemophiliac population and practically all cases arose out of the supply of contaminated blood products.[81]

Factor VIII now exists in two recombinant forms, known as Kogenate and Recombinate.[82] Their production was a feat of genetic engineering. Factor VIII was then and still is the largest human protein produced by recombinant DNA technology. Both products have undergone extensive clinical trials and both have been approved by the Food and Drugs Administration in the USA. They have been available in Australia for the last two years. Both are reported as being extremely effective, highly purified products,[83] although there are still some problems associated with their production and delivery which will need to be rectified. There are therefore forceful reasons why these recombinant forms of Factor VIII should be made available to haemophiliacs as rapidly as possible. The difficulty faced by health service providers is the cost of the recombinant products. Each unit may be up to double the cost of the plasma-derived alternative. It has been estimated that free access to the recombinant products is likely to increase the health budget by some $70 million.

This is a clear example of the tension between an individual's right to the best available treatment, a health care system that is increasingly limited by economic constraints and a commercial enterprise that is required by its

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80 Ekert, H., "Factor VIII: Supply and Demand - the Paediatric Picture" (1993) Australasian Society of Blood Transfusion Inc Conference *Factor VIII: Supply and Demand in the 1990s*, 5.

81 Rickard, K., "Towards Optimal Therapy for People with Haemophilia: A Physician Examines the FVIII Situation in Australia" (1993) Australasian Society of Blood Transfusion Inc Conference *Factor VIII: Supply and Demand in the 1990s*, 6.

82 *Ibid.*

83 *Ibid.*, at 9. See also Bray, G., "Clinical Studies of Recombinant Factor VIII (Recombinate) in Previously Untreated Patients with Severe Haemophilia A" (1993) Australasian Society of Blood Transfusion Inc Conference *Factor VIII: Supply and Demand in the 1990s*, 14; Cochran, M.A., "Recombinant FVIII (Kogenate): Production, Safety and Efficacy" (1993) Australasian Society of Blood Transfusion Inc Conference *Factor VIII: Supply and Demand in the 1990s*, 16.

shareholders to make acceptable profits. In the current economic climate rationing of health care resources is inevitable and the way in which they are rationed is an area of increasing debate. I suggest that it surely would be inappropriate if a patent system, the ultimate aim of which is to provide an economic benefit for the Australian population in general, has the actual effect of causing an adverse economic impact on the provision of health care to that same population.

3.3.2 The Hepatitis C Case Study

Hepatitis is a disease of the liver which has a number of symptoms. Many people who have had hepatitis never fully recover from it and in some it may lead to cirrhosis or liver cancer, both of which can be fatal. In the 1970s it was discovered that one form of hepatitis was caused by the Hepatitis A virus and another form was caused by Hepatitis B. However, there were still more forms of hepatitis, which were termed non-A non-B hepatitis (NANBH). At that stage, it was not known if NANBH was a virus or some other agent, or if it had more than one cause.

From a public health point of view it was important that the cause of NANBH was found as soon as possible. In addition to the obvious costs of treating afflicted individuals, it was known that NANBH could be carried in the blood, and therefore all recipients of donated blood were potentially at risk of receiving the contamination. There were also important commercial reasons for finding the cause of NANBH. Once a diagnostic test for NANBH was available, all blood samples would be required to be tested. Thus the manufacture of a reliable diagnostic test would be a highly lucrative venture. The development of a vaccine would be equally as profitable.

In the early 1980s, a number of biotechnology companies embarked on the task of identifying the cause of NANBH. All of them had expertise in recombinant DNA technology and all had the most up-to-date equipment and teams of highly skilled researchers. Even so, many years of research and dollars were invested in the quest. Chiron Corporation won the race. It identified a third virus, known as Hepatitis C (HCV), and developed a diagnostic test for the presence of the virus in human blood. HCV has been found to cause 90% of

cases of NANBH.[84] In Australia alone at least 100,000 people carry HCV,[85] although many of them will be unaware that they are carriers. Consequently, all donated blood is now routinely tested for the presence of HCV. Chiron's work was therefore a critical breakthrough in combating the spread of hepatitis.

A number of companies subsequently tried to market their own diagnostic kits, but this turned out to be of little value to them, because Chiron had taken out a patent which protected the information that it disclosed about the virus. Chiron could have given licences to its competitors which would allow them to use its invention in return for licence fees, but it chose instead to licence only one company. Using this strategy Chiron controlled the market for HCV diagnostic kits. Companies attempting to market competing kits in Britain were sued by Chiron for infringement of its patent. They counter-claimed that Chiron couldn't enforce its patent, that it was invalid because it covered things that Chiron had not invented.

The claims made by Chiron in its patent were indeed very broad. Chiron's research had given it a detailed knowledge of part of the gene sequence of the virus that it had isolated, yet the patent was wide enough to cover the whole of the virus and every strain of the virus. Chiron's competitors said that it had gone too far. The role of the patent system is supposedly only to exclude others from exploiting an invention. The competitors argued that Chiron's claims were more than mere exclusion from use of the invention; in reality they amounted to ownership of the virus itself. The English courts did not agree, holding that the patent was valid.[86]

The other companies thus lost out on a lucrative market because they could not sell their kits. The public also may have lost out. First, Chiron was not restricted by market forces in its pricing of the kits because it had no competitors to force the prices down. Secondly, because Chiron only had

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84 Data from the National Health and Medical Research Council, *Draft Report on a Strategy for Detection and Management of Hepatitis C in Australia* (1996).

85 *Ibid.*

86 Of a series of cases between Chiron and its competitors, the most relevant are *Chiron Corporation v Organon Teknika Ltd (No. 3)* [1994] FSR 202 before Aldous J in the Patents Court and *Chiron Corp v Murex Diagnostics Ltd(No. 12)* [1996] FSR 153, before Leggatt, Morritt and Schiemann LJJ in the Court of Appeal.

detailed knowledge of one strain of HCV, its kits worked best on that strain and competing kits worked better on other strains. There was a danger that a particular test kit might not show up the presence of a strain to which it was not particularly sensitive. For this reason, the National Health and Medical Research Council in Australia has recommended that every sample that tests positive should be tested again using an alternative kit.[87] But Chiron's patent would be infringed if any kit other than those marketed by Chiron and its licensee were used. It would seem to be contrary to health care policy to restrict the market for diagnostic kits in this way. Thirdly, no one had yet marketed a vaccine for HCV. It makes sense to assume that the more people that are researching in the area, the better the chance that a vaccine will be developed. If some people are excluded from working in that area, the time taken to develop a vaccine will increase.

Some of the companies were not satisfied with the decisions of the English Courts. One of them, Murex Diagnostics Ltd, decided to challenge the validity of the patent under Australian law. The *Murex v Chiron* case was heard by Burchett J in the Federal Court in Sydney.[88] After 40 days of hearings the case was settled out of court.[89] The settlement included the provision of a licence to Murex which enabled it to market its diagnostic kit, and so from its point of view further challenge was unnecessary. Further, we can fairly safely make the assumption that Chiron must have concluded that its patent would be declared invalid if the case had reached the stage of final judgment. On this basis, from a commercial point of view it was better for Chiron to grant Murex a licence than to continue with the case.

Business interests clearly were more important to the parties in the *Murex v Chiron* case than the effect on public health. This is not to say that the out of court settlement necessarily will be detrimental to public health. Competing kits can now be marketed, which will improve the reliability of diagnostic tests and may cause the prices of the test kits to fall. In this case, therefore, the end result was probably favourable in public health terms. But

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87 National Health and Medical Research Council, *Draft Report on a Strategy for Detection and Management of Hepatitis C in Australia* (1996).

88 *Murex Diagnostics Australia Pty Ltd v Chiron Corporation* No. G106 of 1994.

89 In Chapter 6 I will discuss the implications that the *Murex v Chiron* case might have had on Australian patent law, had Burchett J been able to hand down his judgment.

there is no guarantee that this will happen in every case. I argue that if patents are cast in too broad terms they could exclude non-licensed researchers from developing diagnostic or therapeutic tools. Unless licensed researchers are committed to developing those tools in a timely fashion the health care system will suffer.

Conclusion

Where research into or application of genetic technology is institution-based it is subject to a high level of ethical scrutiny, the cornerstone of which is the protection of the individual, which is achieved by an assessment of the risk to that particular individual. As soon as such work moves outside the institution or outside the definition of research it may be beyond the reach of the ethical review system. Arguably existing human rights and consumer protection legislation provides adequate protection of the public, even in the commercial arena. Difficulties will always arise, however, where commercial interests and the welfare of the individual patient or the indigenous group are in conflict. The patent system, designed as it is to encourage innovation, favours commercial interests. In some circumstances the effect of human genetic research on the individual patient or the social group may be so profound that commercial interests should be subsumed to considerations of their needs. If this is the case then the role of the patent system in human genetic research must be limited appropriately (see Chapter 7).

The need for commercial funding of human genetic research and its introduction into clinical practice is beyond question. Commercial funding will inevitably lead to commercialisation of the research or practice itself, and included in this is the need for economic viability. Any debate about the desirability or otherwise of commercialisation of human genetics must acknowledge the reality of the situation. From the upstream perspective, institution-based research that is linked to private industry will be favoured by funding agencies over purely academic research. At the downstream end, provision of health care is required to fit prescribed economic parameters. Products are generally supplied to the health care service by private enterprises. This linkage between the private and public sectors at both the upstream and downstream ends of the flow inevitably leads to the introduction of commercial considerations into academic research and health care, including the need to provide the patent incentive.

Companies may well be willing to invest in research and development without the patent incentive, if by undertaking research they get a sufficient headstart over their competitors to be the first to market the products of that research. There will be little or no advantage over the patent system in terms of public interest, however, if lack of patent protection requires that research results are kept secret until marketable products are available, since this will inevitably lead to prolonged duplication of research effort. In the last year there has been a remarkable change of direction by some of the larger pharmaceutical and biotechnology companies, which are now taking a farsighted approach to investment in research and protection of their research interests. The willingness of a number of companies to invest in a pathogen sequencing consortium[90] is but one example of a realisation of the benefits of collaborative research and release of research results into the public domain so that they can be shared by all. Even so, this willingness is perhaps still premised on the availability of later downstream patents. Companies will always argue that they wouldn't do the research without the patenting option, and there is no way to refute this other than by doing the experiment. It seems hardly likely that a government would be willing to take this risk, because the cost to the nation of companies taking their research elsewhere will be high and it will be difficult to entice them to return.

From both a law and a policy perspective, patents cannot and should not be claimed for DNA sequences of unknown function. The same cannot be said for more downstream inventions, where neither the law nor the policy can be stated with nearly as much certainty. The restrictions that patent law imposes on downstream inventions will be analysed in Chapter 6. There are a number of mitigating provisions, outside the normal patenting criteria, that may ameliorate detrimental effects of upstream and downstream patents. These include, at the upstream end, exclusion from infringement for experimental work and freedom to publish once a provisional application has been lodged, and, at the downstream end, provision of compulsory licences and revocation

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90 The pathogen sequencing consortium is a consortium of scientists and biotechnology/pharmaceutical companies which plans to sequence the fifty most prevalent pathogens. Dr. Michael Morgan of the Wellcome Trust discussed this proposal in his talk "Human Pathogen Sequence Data" given at the HUGO *Genome Summit* in Canberra in October, 1996.

of patents which are not in the public interest. The extent to which these provisions should be made use of is discussed in Chapter 7.

CHAPTER 6: PATENTABILITY OF HUMAN GENETIC MATERIAL

Introduction

The final premise on which many of the objections to patenting human genetic material are based is that if some genetic material is patentable then it necessarily follows that all genetic material is patentable. This is not the case. In Chapter 2 I examined the legislation and case law in Australia that provides certain defined limits on the patentability of inventions. It is not enough for there to be a *bona fide* invention; that invention must demonstrably have commercial application, be new, and involve an inventive step and must be fully disclosed. In this chapter I will analyse how patent law relates to inventions derived from human genetic research with respect to the requirements of manner of manufacture, novelty, inventive step and disclosure.

Given the commercial nature of human genetic research, and the clear economic implications to the nation of alleviating genetic disease, it is unlikely, without express exclusion, that the isolation and subsequent synthetic manufacture of human genes could be considered to be improper subject matter for the letters patent, as expressed in *NRDC*.[1] It clearly belongs to the useful rather than the fine arts. Taken on face value, therefore, the manner of manufacture test will be satisfied for most inventions arising out of human genetic research. The same cannot be said, however, when all that is being claimed is the DNA sequence with no knowledge of its function. Unless information is included as to how to produce that specific sequence or how the sequence may be used, it offers nothing in the way of commercial applicability. In this respect, therefore, concerns about the patenting of DNA sequences of unknown function, including ESTs, are unfounded.

What is of real and particular concern is the extent to which exclusive rights can be claimed over DNA sequences of known function and their applications. Generally the aim of the patentee will be to extend the ambit of the patent as far as possible. This is particularly important in the area of human genetic research for two reasons. First, the unique degeneracy of the genetic code must be taken into account. To recapitulate on the information that was provided in Chapter 3:

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1 *National Research and Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.

- proteins are made by a two step process: messenger RNAs are transcribed from DNA genes and the chains of amino acids that constitute proteins are translated from the messenger RNAs;
- there is a one to one copy of DNA bases to messenger RNA bases;
- each amino acid is translated from a set of three messenger RNA bases, known as a codon;
- there are 64 different codons, based on the various combinations of the four messenger RNA bases;
- there are only 20 amino acids;
- more than one codon can code for a particular amino acid;[2] and
- consequently there can be more than one DNA sequence for a particular protein. This is known as degeneracy of the code.

The effect of degeneracy of the code in terms of patenting is that unless all of the DNA sequences that code for a particular protein are claimed, competitors are not excluded from using a code different from that claimed in the patent to make the same protein. As such, narrow downstream claims often also include broad upstream claims.

Secondly, for many of the claims to human genetic material, the only inventiveness is in the method chosen to produce the sequences. Once the sequence has been produced, the value of the invention is in the disclosed sequence and the method itself becomes redundant. If only the method could be patented it would have little value. Consequently, patent claims often include any method of using or producing those sequences. Here, therefore, patents for narrow upstream inventions include broad downstream claims.

Patent examiners and the courts must ensure that the patents claiming the use of DNA sequences are not impermissibly wide, but at the same time that they have some real value. The focus of this chapter is to assess the extent to which the limitations on patenting presently existing within the *Patents Act* 1990 (Cth) provide appropriate limitations on patenting of human genes and their applications.

There is scant case law on this matter in Australia. The case of *Murex v Chiron* which has recently been settled out of court after 40 days of hearings before

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2 Note that some of the codons are known as start or stop codons, because they signal the start and stop of the translation process. These codons do not code for amino acids.

Burchett J in the Federal Court[3] had the potential to provide the benchmark in interpreting the issues. Realisation of that potential now must await another challenge to a biotechnology patent. For the present, some guidance can be obtained by looking to other jurisdictions. Although there are some differences in the legislation in Australia and Europe, the decisions of the European Patent Office and the English courts provide assistance.[4] The landmark English cases of *Genentech*,[5] *Genentech (Growth Hormone)*,[6] *Asahi*,[7] *Biogen*[8] and *Chiron*[9] as well as the decisions of the European Patent Office in *Onco-mouse* [10] and *Relaxin* [11] all require detailed consideration. Although none of these cases apart from *Relaxin* relates to human genetic research *per se*, the information that they provide about the general area of patentability of biotechnology inventions gives valuable guidance as to how similar issues associated with the particular area of human genetic research may be interpreted by the courts. Finally in this chapter, the specification requirements will be analysed with respect to human genetic research. Again settlement of the *Murex* case means that the standard for future biotechnology

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3 *Murex Diagnostics Australia Pty Ltd v Chiron Corporation* No. G106 of 1994.

4 Note that the divergence between Australian and US patent law is somewhat greater. For this reason, only the most seminal US cases have been called on to provide assistance.

5 *Genentech Inc's Patent* [1987] RPC 553, before Whitford J in the Patents Court; [1989] RPC 147, before Purchas, Dillon and Mustill LJJ in the Court of Appeal.

6 *Genentech Inc's (Human Growth Hormone) Patent* [1989] RPC 613, before Falconer J in the Patents Court.

7 *Asahi Kasei Kogyo KK's Application* [1991] RPC 485, before Falconer J in the Patents Court; Dillon, Ralph Gibson and Stuart-Smith LJJ in the Court of Appeal; Lord Keith of Kinkel, Lord Brandon of Oakbrook, Lord Ackner, Lord Oliver of Aylmerton and Lord Jauncey of Tullychettle in the House of Lords.

8 *Biogen Inc v Medeva Plc* [1995] RPC 25, before Aldous J in the Patents Court; [1995] FSR 4, before Nourse, Peter Gibson and Hobhouse LJJ in the Court of Appeal; the House of Lords handed down its opinions on 31st October 1996. The Law Lords sitting were Lord Goff of Chievely, Lord Browne-Wilkinson, Lord Mustill, Lord Slynn of Hadley and Lord Hoffmann. Lord Hoffmann gave the leading judgment. An abridged version of the judgment was reported in *The Times* on 1 November 1996.

9 *Chiron Corporation v Organon Teknika Ltd (No. 3)* [1994] FSR 202 before Aldous J in the Patents Court; *Chiron Corp v Murex Diagnostics Ltd(No. 12)* [1996] FSR 153, before Leggatt, Morritt and Schiemann LJJ in the Court of Appeal.

10 See particularly the decision of the Technical Board of Appeal, *Re Harvard College (President and Fellows)* (Decision T 19/90) [1990] OJEPO 476.

11 [1995] OJEPO 388.

patent cases in Australia has not yet been set. Assistance can be obtained from the English decisions in *Biogen* and *Chiron.*

It will become apparent that neither the law nor the science in this area is easy. Both are new, and the parameters have not been fully explored for either. In *Genentech* Mustill LJ commented that the problem is exacerbated by the fact that novel patents in this area are frequently drafted in a way that is difficult to comprehend. His Lordship referred to the Genentech claims as being "laconic", and preceded by writings which were "long and diffuse and cast in a most unusual form".[12] The aim of Genentech was for the patent to cover the maximum amount of territory in the general area of the invention. If only the true extent of the invention were claimed, the patent would have little value because it would be too easy for others to invent around it. To achieve this end, the claims in *Genentech* were cast in what Mustill LJ referred to as

> "concentric zones of generality, no doubt in the hope that if one or more claims failed, others would still survive in a form sufficient to give Genentech the commercial advantage which the application was intended to secure."[13]

One of the critical policy issues that the courts are required to determine is how far patent protection should be allowed to extend outside the invention. In *Genentech* the court was in agreement that the claims made were far too wide, yet in other cases, such as *Chiron v Murex,* similar very broad claims were upheld. These cases serve to emphasise the fact that decisions as to the validity of patent claims will often turn on the way the application is drafted and the credibility of the expert witnesses on each side.

Part 1: Manner of Manufacture and Human Genetic Research

Most of the inventions derived from human genetic research and its applications will have the requisite commercial applicability to satisfy the manner of manufacture test. It does not necessarily follow that all will be patentable. The 1984 Report of the Industrial Property Advisory Committee,[14] in recommending that the manner of manufacture test should be retained in the new legislation, rationalised this decision by stating that the application of the test was facilitated by the extensive body of case law. That case law has developed a range of

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12 *Genentech Inc's Patent* [1989] RPC 147, at 252.

13 *Ibid.*

14 *Patents, Innovation and Competition in Australia* (1984) AGPS.

exceptions for material which is considered to be unpatentable because it is not a manner of manufacture. Human genes and their applications potentially may be included within some of the exceptions, which are described below.

1.1 Case Law Exclusions from Patentability

1.1.1. Mere Discoveries: General Considerations

Traditionally, mere discoveries have not been patentable because of the requirement that knowledge and ingenuity are used to produce a new and useful thing.[15] Discoveries are neither new nor useful, first, they are already in existence, and secondly, they do not have the requisite applicability. In *NRDC* the difficulty in distinguishing between discoveries and inventions was pointed out.[16] The High Court insisted that the whole process must be looked at and it was enough to show that there was one inventive step from the prior art.

Even though discoveries are not patentable, patents can be claimed for methods embracing discoveries, or for products of discoveries, provided that they fulfil the other patenting requirements. As such, even if the identification of a naturally occurring gene or gene sequence is classified as a discovery, the utilisation of that knowledge to make a synthetic gene and gene products may be characterised as patentable inventions.[17] The law in Australia at present is unclear as to whether:

- an isolated gene sequence of known function is a patentable invention or a mere discovery; and

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15 See, for example, *Lane-Fox v Kensington & Knightsbridge Electric Lighting Co Ltd* [1892] RPC 413.

16 *National Research and Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, at 264.

17 The Patent Office, in its *Manual of Practice and Procedure*, affirms this view with respect to the patenting of microorganisms and other life forms, stating at 8.1.15.2 c), with reference to the decision in *Rank Hovis*, below, that naturally occurring micro-organisms *per se* are not patentable as they represent a discovery and not an invention, but a claim to a pure culture in the presence of some specified ingredients would satisfy the requirement of a technical intervention, and at 8.1.15.3 that isolation and cultivation of naturally occurring micro-organisms which have some new use satisfy the requirement of technical intervention.

- the novelty and inventive step requirements for a patentable invention can be satisfied through the sequencing of the gene in question, irrespective of whether this is considered to be a discovery or an invention. [18]

These considerations are particularly important in patenting genes because many of the methods employing gene sequence information and the products derived from its use are already known. If gene sequences are classified as inventions or if they are allowed to be used to fulfil the requirements of novelty and inventive step, the extent to which patents can impinge on both applied and basic genetic research may be considerable. Broad patent claims could be encouraged, potentially covering all future use of the gene sequence in issue. This is precisely the issue that was being argued in the *Murex v Chiron* case before Burchett J. The Chiron patent claims the Hepatitis C genome. Murex argued *inter alia* that the genome was a discovery and was therefore not patentable. If Burchett J had been given the opportunity to accept this argument then patentability would have had to be found in the narrower claims to methods employing the genome, or products derived from its use, both of which may have been obvious.

1.1.2. Living Organisms and Products of Nature as Discoveries: Specific Considerations

Both processes involving naturally occurring living organisms and living organisms themselves, provided that they are not naturally occurring, are now considered to be patentable.[19] For many years products of nature were considered to be unpatentable subject matter because they were classified as inherently being discoveries rather than inventions. The watershed for patenting in this area was the US case of *Diamond v Chakrabarty,* [20] which allowed a patent for a genetically modified bacterium that could break down hydrocarbons. The patent was originally refused by the examiner because the bacteria were products of nature

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18 The statutory exclusion of discoveries in the *Patents Act* 1977 (UK) has been interpreted as allowing the discovery to fulfil the novelty and inventive step requirements (see below at 1.3.1).

19 In *Rank Hovis McDougall Ltd's Application* (1976) 46 AOJP 3915 the Assistant Commissioner of Patents granted a patent for a new strain of micro-organism that could be used in a process for the production of an edible protein. The process itself was also patentable but a patent was refused for the original microorganism, because it was naturally occurring. This decision was confirmed by an official notice from the Patent Office in 1980. Public concerns associated with patenting of living organisms were discussed in Chapter 1, in part 1.

20 447 US 303 (1980).

and were living organisms, taking them outside the scope of patentable subject matter. The Supreme Court disagreed, stating that the relevant legislative history supported a broad construction. Burger CJ emphasised that the claim was to a non-naturally occurring manufacture or composition of matter, and that Chakrabarty's work was "not nature's handiwork but his own; accordingly it is patentable subject matter ..."[21] The critical requirement that must be satisfied is that they are made by man, "anything under the sun that is made by man"[22] being inherently patentable.

Since *Chakrabarty* a wide range of biotechnological inventions have received patent protection in the US. The only requirement to bring material that has been isolated or purified under the umbrella of patentable subject matter would seem to be that it offers some material advantage in utility over the naturally occurring material.[23] In effect, there is little difference between this requirement and the Australian manner of manufacture test. Neither the US test, requiring practical utility, nor the Australian test, requiring a manner of manufacture would now appear to create a major barrier to patenting products or processes involving living organisms that have been modified in some way. Patents for genetically engineered bacteria, pigs, mice, and so on, are unlikely to fail on this basis. The same can also be said for DNA sequences which are produced in recombinant form from cDNA copies of messenger RNA, because the sequences lack the introns present in naturally occurring DNA and therefore can be said to be sufficiently different from the natural form to be products of man rather than products of nature.

The situation is different for living organisms that have not been genetically modified. In the Chiron patent for Hepatitis C, one of the claims that Chiron made was to the unmodified virus. Murex may have had a good case for arguing that an unmodified living organism, albeit one which was very difficult to isolate and characterise, was nonetheless nature's handiwork and not man's. It is open to question whether isolation of the virus from nature is sufficient for it to be claimed as an invention.[24] The product of nature argument can also be raised against

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21 *Ibid.*, at 310.

22 *Ibid.*

23 There is an extensive body of case law in this area. See, for example, *Merck & Co v Olin Mathieson Chemical Co* 253 F.2d 156 (1958); *In Re Bergstrom* 427 F.2d 1394 (1970).

24 Note that such arguments will not prevent the process leading to the isolation of a product from nature from being patented, provided that it fulfils the other patenting criteria.

patenting of DNA sequences where the claims are to isolated gene sequences as they exist in nature.

In the USA, patents are allowed for pure cultures of naturally occurring micro-organisms.[25] The position is somewhat less clear in Australia, because the decision of the assistant commissioner in *Rank Hovis* indicates that mere isolation and purification may not be sufficient.[26] The Federal Court is not bound by this decision and may choose not to follow the reasoning therein, should it be given the opportunity to do so. Patent Office practice would now seem to be more closely aligned with the US position. With regard to gene sequences, for example, a Patent Office note on patenting of biotechnology inventions listed as patentable inventions, *inter alia,* the DNA coding sequence for a gene claimed in either isolated or recombinant state.[27] It would appear, therefore, that mere isolation is regarded as sufficient inventiveness by the Patent Office for the grant of a patent. The law on this matter awaits definitive judicial pronouncement. From an international perspective, the US position has some similarities with that in Europe, although there is some indication of a different stance in England.[28]

1.1.3. Methods of Treating the Human Body

Methods of treating the human body have been described as unpatentable in a number of cases, including *NRDC.*[29] A range of developments in human genetic research could be denied patents should this exclusion prevail. If read widely, it could not only cover surgery, but other forms of therapy and even diagnostic testing. The notion that the method of treatment of humans is not patentable is entirely a product of case law in Australia, yet until recently the cases have been vague in defining both the ambit of the exception and the rationale for

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25 For example, *In Re Bergstrom* 427 F.2d 1394 (1970); *In Re Bergy* 596 F.2d 952 (1979).

26 Note that the decision in *Rank Hovis* was made by the assistant commissioner of patents and therefore does not create a binding precedent for the Federal Court.

27 Australian Industrial Property Organisation, *Australian Patents for Genetically Manipulated Organisms* (1994).

28 Discussed in section 1.3.1, below.

29 Objections to the patenting of methods of medical treatment were discussed in part 2 of Chapter 1.

its existence. The recent decisions of Gummow J and the Full Federal Court in the *Rescare* case[30] have considerably clarified the issue.

The exclusion was first pronounced by Lord Buckmaster in *C & W's Application,*[31] where his Lordship stated that the refusal of the Patent Office to patent an invention for the removal of lead from human bodies because it related simply to human bodies was sound. The justification for this conclusion was that such treatment had no reference to any form of manufacture or trade and therefore was not a manner of manufacture. A series of three cases in the 1970s in England confirmed that a method of treating a human ailment with a known substance was not an invention. In summary, the English position would appear to have been that, even though the rationale for the exclusion in *C & W's Application* was no longer tenable after *NRDC,* it could be justified on the basis of ethics, and because the exclusion was well established in the case law, any change should come from the legislature.[32] However, the exclusion was read strictly so that only the medical treatment of ailments was excluded, and not, for example, contraception.[33]

In Australia, the patentability of a new method of conducting an operation on part of the human body was first considered in *Maeder v Busch.*[34] Whilst none of the High Court judges was willing to decide the issue, Latham CJ, Dixon and McTiernan JJ all expressed doubt as to whether such subject matter could be regarded as a "manner of manufacture".[35] That view would seem to have been endorsed in *NRDC,* where it was suggested that methods of surgery and other processes for treating humans "must apparently be put aside".[36]

Barwick CJ further considered the matter in *Joos v Commissioner of Patents.*[37] His Honour rejected the general argument that methods of medical treatment were not forms of manufacture or trade which was presented in *C & W's Application,*

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30 *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205; *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383.

31 (1914) 31 RPC 235.

32 *Schering Aktiengesellschaft's Application* [1971] RPC 337; *Eli Lilley & Co's Application* [1975] RPC 438; *Upjohn Company (Robert's) Application* [1977] RPC 94.

33 *Schering's Application* [1971] RPC 337.

34 (1938) 59 CLR 684.

35 Evatt J seemed to be inclined to the opposite view.

36 *NRDC* (1959) 102 CLR 252, at 270.

37 (1972) 126 CLR 611.

and narrowed the exception to the treatment of diseases, correction of a malfunction or removal or amelioration of an incapacity, if, indeed, it was to be accepted at all. Barwick CJ went on to explain that if the exclusion did exist, then its justification must be based on public policy, using the *Statute of Monopolies* language of being "generally inconvenient".[38] As a consequence of Barwick CJ's judgment in *Joos*, the Patent Office discontinued its prior practice of refusing patents for the medical treatment of humans.[39] The rationale of this decision was that *Joos* cast doubt on the past practice, and it was the duty of the commissioner only to refuse patent applications when they were clearly inappropriate subject matter for patenting.

The validity of the human treatment exception was questioned in the Israeli *Wellcome Foundation* case, where it was proposed that the exception had no basis in law or logic and the subject matter was clearly within the realm of economic endeavour.[40] Subsequently Davison CJ in the New Zealand *Wellcome Foundation* case gave a detailed analysis and critique of the exclusion.[41] His Honour came to the conclusion that there was no satisfactory basis for excluding medical treatment from patenting, and that there was no warrant in law for granting an exclusion based on ethics. Furthermore, it was unrealistic to distinguish between cosmetic and medical treatment. Therefore, using the *NRDC* test, it was possible to patent a process using known compounds for a new purpose in the treatment of meningeal leukemia in the brain. Davison CJ's decision was reversed by the New Zealand Court of Appeal, however, where all three judges rejected the assertion that a method of treatment of human illness or disease was patentable.[42] Somers J commented on the special character of treatment of human ailments and adopted Barwick CJ's view that patent applications in this area should be rejected as being generally inconvenient. McMullin J, whilst realising that there was much to be said for developing the law to allow patents in this area, felt that any major thrust should be left to Parliament. Cooke J commented that there remained a deep-seated sense that the art of the physician or surgeon in alleviating human suffering does not belong to the area of economic endeavour.

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38 Section 6, *Statute of Monopolies.*

39 This decision is explained in *Upjohn's Application* (1979) 49 AOJP 382.

40 *Wellcome Foundation Ltd v Plantex Ltd* [1974] RPC 514.

41 *Wellcome Foundation Ltd v Commissioner of Patents* [1979] 2 NZLR 591.

42 (1983) 2 IPR 156.

In the most recent case to address the issue in Australia,[43] Gummow J found that the decision of Davison CJ in *Wellcome Foundation* was more appropriate to the Australian position than the decisions of the Appeal Court judges. His Honour pointed out that it was the practice of the Commissioner of Patents to accept such patents, and this had produced no deleterious consequences. On appeal,[44] all three judges agreed that, unlike England, there was no binding authority in Australia and therefore they were free to decide the matter for themselves. They decided the matter by a majority of 2:1 in favour of patenting, Lockhart J stating that: "I see no reason in principle why a method of treatment of the human body is any less a manner of manufacture than a method of ridding crops of weeds..."[45]

Both Lockhart and Wilcox JJ commented that Parliament had been given the opportunity to create a statutory exception when it enacted the 1990 Act, but failed to do so. This shows a contrary line of reasoning to the English cases, where it was argued that the method of medical treatment exclusion was well established and it was for the legislature to change. I suggest that if the exclusion were as well established in the case law in Australia, then it would be questionable whether it would be appropriate to use the argument that since the exclusion does not appear expressly in the Act it can be ignored. The rationale for keeping the manner of manufacture test in the new legislation was that it should be interpreted using the case law. In the three High Court cases of *Maeder, NRDC* and *Joos,* however, the judges were seemingly very careful to avoid any definitive pronouncement on the issue. Given the lack of justification in law for the exclusion, and the anomalies between cosmetic treatment and medical treatment, and products and processes of medical treatment, the majority decision in *Rescare* would appear appropriate. Nonetheless, the matter is not yet concluded. Sheppard J, in dissent, found that where the treatment and relief of human suffering had direct bearing on the well-being of the nation and involved a life threatening disease patent claims should be rejected on the basis that they are generally inconvenient.

Despite Sheppard J's reticence in the *Rescare* appeal, the authorities indicate that there is now little or no place for the method of medical treatment exclusion to the manner of manufacture test. The Patent Office sees the decision in the *Rescare* appeal as affirming its long established practice following *Joos* not to object to

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43 *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205.

44 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383.

45 *Ibid.*, at 400.

methods of treatment of humans.[46] Furthermore, the Office also sees *Rescare* as establishing that arguments based on ethics or social policy are not relevant in determining whether particular subject matter is patentable.[47]

1.2 Statutory Exclusions

1.2.1 Patents Act 1990

Section 18(2) of the *Patents Act* provides the only express exclusion to patentability, that human beings, and the biological processes for their generation, are not patentable.[48] This provision was introduced into the *Patents Bill* 1989 by Senator Harradine, and agreed to by both houses.[49] Senator Harradine stated his belief that the second half of this amendment would prevent patenting of techniques developed for cloning human embryos at the four cell stage, although Senator Coulter seemed to doubt that it would cover anything more than normal sexual reproduction.[50] Reference to the possible patenting of humans in the first part of the amendment is generally considered to be so contrary to fundamental norms that it goes without saying. This amendment therefore probably has negligible effect.

The Patent Office's note on biotechnology stated that the only limitation that this exclusion would create in the area of genetic research would be that DNA or genes in the human body would not be patentable as such.[51] On the other hand, once a gene sequence has been separated from the human body and manufactured synthetically for reintroduction into the body for therapeutic purposes it would be patentable. The Patent Office went on to list the range of potentially patentable

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46 Australian Industrial Property Organisation, Patent Office *Manual of Practice and Procedure, Volume 2*, section 8.1.14.4.

47 *Ibid.*

48 Note also that in section 51(1) the commissioner has discretion to refuse to accept an application (a) for an invention the use of which would be contrary to law or (b) for a substance which is capable of being used as a food or medicine, but only where the food or medicine is a mere mixture of known ingredients.

49 House of Representatives, *Hansard Parliamentary Debates* 16 October 1990, 2947, at 2955.

50 Senate, *Hansard Parliamentary Debates* 20 September 1990, 2653, at 2653-2655.

51 Australian Industrial Property Organisation, *Australian Patents for Genetically Manipulated Organisms* (1994).

inventions in this area.[52] Although applications in any of these areas are open to challenge in opposition or revocation proceedings, the clear signal from the Patent Office is that there is very little restriction in what it sees as patentable subject matter in this area of research.

1.2.2 Statute of Monopolies

Section 6 of the *Statute of Monopolies* excludes manners of new manufacture which are contrary to law or mischievous to the state by raising prices, hurting trade or being generally inconvenient. It would appear to be accepted by the judiciary that both the 1952 and 1990 *Patents Act* import the whole of this section.[53] In *Joos*, for instance, Barwick CJ referred to the method of medical treatment exclusion being based on public policy using the *Statute of Monopolies* language of being generally inconvenient, and Gummow J confirmed that the question should be framed in this way in *Rescare*. In the *Rescare* appeal Lockhart J would not accede to the appellant's argument that the ground of generally inconvenient was not available. As such, any of these *Statute of Monopolies* arguments could provide an avenue for the judiciary to introduce public policy or ethical considerations in its determination of whether human genes are patentable.

The general inconvenience exclusion has been used a number of times in Australia to deny patent claims for subject matter to which the public expect that they have free access, including purchased computers, lunch boxes and picture frames.[54] Patent claims may also be denied on this basis where there are life threatening consequences, including for methods of medical treatment. In *Rescare*, however, both Gummow J at trial and Lockhart J on appeal rejected the possibility that this exclusion could prevent patenting of methods of medical treatment. Wilcox J went further and stated that the courts should not get involved in matters of ethics or social policy, for which they have no particular expertise. On the other hand, Sheppard J rejected the patent claim on the basis of general inconvenience. As such, it is presently unclear exactly how willing the judiciary will be to use the

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52 *Ibid.*

53 Section 18(1)(a) *Patents Act* 1990 refers to manner of manufacture within the meaning of section 6, *Statute of Monopolies* and the dictionary of terms in Schedule 1 again refers to this section in its definition of 'invention'.

54 See, for example, *Telefon A/B LM Ericssons Application* [1975] FSR 49; *Clayton Furniture Ltd's Application* [1965] AOJP 2303; *Boccari's Application* [1967] AOJP 1380.

general inconvenience argument to exclude from patenting matters which have ethical and social implications.

In *Murex v Chiron,* Burchett J would have been required to consider whether the Chiron invention failed to fulfil the manner of manufacture requirement on the grounds that to grant such a patent would be generally inconvenient or would be mischievous to the state by raising prices. Aside from any ethical arguments against patenting of genes and living organisms, some of which were discussed in Chapter 1, there are strong arguments based on public interest why it may not have been desirable for Chiron to monopolise Hepatitis C testing in Australia.

- A number of strains of Hepatitis C exist throughout the world, and the dominant strains in Australia may not be the same as those in the northern hemisphere. If only one diagnostic test is performed there is a danger of a false negative result if that test is not sensitive to a particular strain. For this reason, the NHMRC has recommended that more than one diagnostic test should be used. A number of test kits are available, but blood banks may not be willing to use them because of the risk of infringement action by Chiron. If a blood bank fails to use more than one test and gives a recipient contaminated blood, then arguably the infected recipient may have a negligence claim against it.
- The Chiron test kits are expensive. The availability of other kits would be likely to have encouraged lower pricing.

Although these arguments are not without foundation, I suggest that it was unlikely that Burchett J would have accepted them, given the clear reticence on the part of judges both in Australia and elsewhere to get involved in public policy and ethical considerations in relation to patenting.[55] From a jurisprudential point of view, one of the main purposes of the law is to set and apply acceptable standards based on these self same issues, particularly in the interpretation of a public interest statute. For the judiciary to claim that it does not have the expertise to consider such difficult questions, even when the legislature has given it the mandate to do so, could be seen as abrogating its legal responsibility. The general inconvenience exclusion provides an important means for the judiciary to consider the policy of patenting. I propose that it is more appropriate to consider such matters here rather than through the other patenting requirements. However, the trend has been in the other direction. The policy of granting or denying broad patent claims tends to have been decided on a case by case basis by either liberal or

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55 See for example the judgments of Lockhart and Wilcox JJ in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383.

strict reading of the novelty and inventive step requirements, as discussed below in Parts 2 and 3. A more overt discussion of these policy issues by the courts may be both more appropriate and more in line with current High Court practice.

1.2.3 *Proposed Amendment to Section 18 Patents Act*

Two attempts have been made by the Australian Democrats to introduce amendments to section 18 *Patents Act* 1990. In 1990 during the parliamentary debate of the *Patents Bill* Senator Coulter sought to add the following amendment to section 18:

> "(2) A patentable invention shall not include the following:
>
> (a) a gene or genes, whether derived from cells or chemically synthesised;
> (b) a genome either complete or one which has genetic material added or deleted;
> (c) the altered organism (human, plant, animal or microorganism) produced by having its genome manipulated, and
> (d) the progeny of the genetically engineered organism which also carry the altered genome.
>
> (3) Sub-section (2) does not limit the patenting of technologies, techniques and processes involved in the carrying out of genetic engineering."[56]

That amendment was rejected by the Senate Standing Committee on Industry, Science and Technology and by the Opposition.[57] In the second reading speech of the *Patents Bill* Mr. Prosser noted that the amendment was too restrictive because it would prevent patenting of vaccines and antibiotics and would create a flow on effect of hindering research and development of new technology in the medical and pharmaceutical fields.[58]

In June 1996 Senator Stott-Despoja of the Australian Democrats introduced an amendment to section 18 as a private member's bill. It states that:

> "(3) The following are not to be regarded as possessing the quality of novelty or inventiveness for the purposes of this section:

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56 Senate Standing Committee on Industry, Science and Technology *Report on the Consideration of the Patents Bill* (1990).

57 Senate, *Hansard Parliamentary Debates* 20 September 1990, 2653; House of Representatives, *Hansard Parliamentary Debates* 16 October 1990, 2947.

58 House of Representatives, *Hansard Parliamentary Debates* 16 October 1990, 2947, at 2948.

(a) naturally occurring genes; or
(b) naturally occurring gene sequences; or
(c) descriptions of the base sequence of a naturally occurring gene or a naturally occurring gene sequence."

In the second reading speech on 27th June 1996 Senator Stott-Despoja commented on the need for urgent action, both in terms of public policy and also for fundamental philosophical and moral reasons.[59] Although most of the concerns outlined by Senator Stott-Despoja relate to patenting of human genes, the amendment covers genes from all species. She justified this on the basis that there is no biological difference between human and other genes, and therefore if the Senate believed that naturally occurring human genes should not be patentable then logically all naturally occurring genes and gene sequences should be excluded.

Given the lack of equivalent provisions in patenting legislation in most other countries,[60] and the perceived need to encourage biotechnology in this country, it is doubtful that Parliament will pass this amendment. It its current form, the amendment is much narrower than the Coulter amendment, including within its ambit only naturally occurring genes and gene sequences and the descriptions of their base sequences. In restricting the amendment in this way, it may well be that if passed it will have as little actual effect on patenting of inventions in this area as Senator Harradine's amendment. For this reason I suggest that there is little justification for the amendment being incorporated into patent law, and to do so would be more likely to cause confusion than benefit.

1.3 Manner of Manufacture v Enumerated Exclusions

The present state of Australian law is such that the manner of manufacture test as interpreted in *NRDC*[61] and subsequent cases is unlikely to create a barrier to

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59 Senate, *Hansard Parliamentary Debates* 27 June 1996, 2332. Note that debate on the Bill was adjourned on the motion of Senator Chee, and that debate has not yet taken place.

60 Note, however, that in 1994 France amended its Intellectual Property Code to declare the human body, its parts and products and the knowledge of the entire or partial structure of the human gene to be inventions, the publication or exploitation of which would be contrary to "ordre publique" or morality, making them unpatentable. Reported in Straus, J., "Patenting Human Genes in Europe - Past Developments and Prospects for the Future" (1995) 26 *IIC* 920, at 922.

61 *National Research and Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.

patenting isolated human gene sequences of known function and other applications derived from those sequences. Furthermore, although some matters could fall within the scope of exclusions to the manner of manufacture test created by the case law, recent interpretation of these exclusions by the judiciary indicates that this may be unlikely. The courts appear reluctant to read the exclusions broadly, or even accept them at all unless they have a firm basis in law. The recent cases of *Rescare*[62] and *CCOM*[63] strongly affirm the interpretation of the manner of manufacture test in *NRDC:* that provided an invention had economically important consequences and there is no justification in law or logic for excluding it, it will satisfy the test. In the area of human genetic research, the test will easily be passed in this form. The courts potentially have the option of introducing ethical and social policy considerations through the "generally inconvenient" and other exclusions derived from the *Statute of Monopolies.* From the comments made in the *Rescare* cases, however, it is clear that counsel would be required to present compelling justification as to why the court and not Parliament should decide such issues. For the present, it is unlikely that Parliament will amend the *Patents Act* to expressly exclude genes and gene sequences from the ambit of section 18.

A different stance has been taken in Europe to the issue of what should be excluded from the reach of the patent system.[64] The manner of manufacture test was the touchstone of patentability in the UK, as in Australia, up to 1977. In 1973 the UK signed the *European Patent Convention* (EPC). Patenting legislation of member states was required to be based on the EPC. A new *Patents Act* was

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62 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383.

63 *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 28 IPR 481.

64 The European patent system has a number of layers of review. Applications can be made for patents in one of two ways.

- Applications can be made through the European Patent Office (EPO), located in Munich. The EPO is able to grant a number of national patents in common form. Opposition proceedings go to the Opposition Division and appeal proceedings are heard by the Technical Board of Appeal. Complex issues of law are passed on to the Enlarged Board of Appeal. Revocation and infringement proceedings are, however, matters of state jurisdiction. In England first instance cases are heard in the Patents Court and applications for leave to appeal may be made to the Court of Appeal and the House of Lords.
- Applications may also be made within individual member states. All decisions and appeals are a matter of state jurisdiction.

See Cornish, W.R., *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (1989) London, Sweet & Maxwell, second edition, at 65.

enacted in 1977, through which manner of manufacture test was replaced by a definition of invention in s1(1) (Article 52 EPC), requiring that it is new, involves an inventive step and is capable of industrial application, and a list of exclusions in s1(2) and (3) (Article 52 and 53 EPC).[65] The requirement of industrial applicability is much the same as the manner of manufacture test, as interpreted in Australian case law. In general inventions associated with human genetic research will satisfy this requirement, the claims for ESTs and other sequences of unknown function being one notable exception. It should be noted, however, that subsection 4(2) (Article 52(4) EPC) provides that a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body is not patentable because it is not capable of industrial application, although a product used in such treatment can be patented, s4(3). As such, the UK *Patents Act* gives statutory recognition of the medical treatment exception outlined above.[66]

Despite the detailed nature of the definition of patentability in the UK and European legislation, it is unclear how much this will actually restrict patenting in the area of human genetics. The matter remains one of statutory interpretation by the judiciary.

1.3.1 Discoveries As Such: Subsection 1(2) Patents Act; Article 52(2) EPC

There has been some debate as to the interpretation of the wording of subsection 1(2) of the *Patents Act* 1977 (UK), although the law now appears settled. Clearly, the exclusions themselves will be excluded from patenting, but the words "only to the extent that" and "relates to the thing as such" indicate that the excluded material can, nevertheless, be used as the substratum of a patentable claim, for example, to a method embracing the excluded material. The critical issue

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65 These exclusions include, in 1(2): (a) a discovery, scientific theory or mathematical method; (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever; (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer; (d) the presentation of information, but only to the extent that the patent relates to the thing as such; and in 1(3): (a) an invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or antisocial behaviour; (b) any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process.

66 Also see White, A.W., "Patentability of Medical Treatment *Wellcome Foundation's (Hitching's) Application* " (1980) *EIPR* 364.

is whether the method is patentable even if the other patenting requirements, principally inventive step and novelty, are only fulfilled by the excluded material itself. Falconer J indicated that patenting should be refused in such cases.[67] His Honour's view was not supported by the majority in *Genentech*[68] and in subsequent cases.[69] Nor would it appear to be the favoured interpretation of the equivalent provision in the EPC.[70]

The interpretation of s1(2) would now appear to be settled that provided there is a new technical result using the excluded matter, and the result itself is not excluded, then that result will be patentable.[71] Furthermore, matter excluded from patentability through s1(2) can contribute to the inventive step required to make the invention patentable. Using this interpretation, things such as gene sequences may be excluded from patenting if they are classified as being discoveries. But if some sort of practical application, which need not of itself be novel or non-obvious, is included, this will be patentable. In *Genentech*, for example, the Court agreed the incorporation of a DNA sequence into an expression vector would have been patentable if the production of the sequence itself was not obvious. The Court was divided, however, on the issue of obviousness.

For Purchas LJ the data on both the DNA and amino acid sequences for human tissue plasminogen activator protein (t-PA) discovered by Genentech were not obvious. Focusing on the total work done, it was outside the capacity of the hypothetical skilled worker. Even so, from Purchas LJ's viewpoint the majority of the claims failed because they related to the discovery as such rather than the method embracing the discovery. Claims to the method embracing a discovery will only succeed where the method is clearly identified and defined, with no speculative element. Genentech attempted to include in their claims methods which had not yet been invented, and as such it was held to be claiming the discovery itself.

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67 In *Merrill Lynch Inc's Application* [1988] RPC 1.

68 *Genentech Inc's Patent* [1989] RPC 147.

69 These include: *Genentech Inc's (Human Growth Hormone) Patent* [1989] RPC 613; *Gale's Application* [1991] RPC 305; *Lux Traffic Controls Ltd v Pike Signals Ltd* [1993] RPC 107; *Merrell Dow Pharmaceuticals Inc v N.H. Norton & Co Ltd* [1994] RPC 1.

70 See, for example, *Vicom's Application* (Decision T208/84) [1987] OJEPO 119, which was used as authority for the interpretation given to s1(2) in *Genentech.*

71 Note that in *Merrill Lynch's Application* and *Gale's Application* both the invention itself and its application were excluded.

Dillon LJ agreed that the nucleotide and amino acid sequences were discoveries not inventions,[72] and also that a patentable invention could be found in the application of a discovery. His Lordship accepted that the inventive step and novelty requirements could reside in the discovery alone. But on the facts of this case it was obvious to the person skilled in the art to set out to produce human t-PA by recombinant DNA technology, and whether the person skilled in the art actually had the ability to perform the task was irrelevant. Consequently there was nothing by way of inventive step to support the claims in the patent.

Mustill LJ also concluded that most of the claims failed. Indeed, for him some failed at the first hurdle because, quite apart from the exclusions in s1(2) they were not inventions, as required in s1(1). His Lordship agreed in part with the judgements of both of the other Lord Justices. Although Mustill LJ preferred the view of Falconer J in *Merrill Lynch* he acceded to the view that a discovery could be the foundation of a patent provided that what was claimed was the embodiment of the discovery. Here Mustill LJ agreed with Purchas LJ that there was no embodiment because the claims included things not yet invented. But he also agreed with Dillon LJ that the discovery of the sequence data did not include an inventive step. Skill and persistence would have been enough.

The one aspect of this case on which all three Lord Justices agreed, with little discussion, was that the sequence data was a discovery and not an invention.[73] In subsequent cases the parties have been willing to concede this point. In the English *Chiron* case, for example, the parties had agreed that included in the discovery in that case was the determination of the genetic sequence of an isolate of the Hepatitis C virus.[74] Arguably parties have little to lose in conceding this issue. Generally patent applicants in this area claim more than just the DNA sequence (the claims for ESTs and other sequences of unknown function providing one exception), and since inventive step and novelty can lie in the discovery of the sequence, there will be negligible effect on the value of the patent in not claiming the sequence as part of the invention. The only danger arises when the claims to methods or products arising out of the discovery are so broad as to be tantamount to claiming the discovery itself.

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72 *Genentech Inc's Patent* [1989] RPC 147, at 237.

73 *Ibid.*, Purchas LJ at 204, Dillon LJ at 237 and Mustill LJ at 256.

74 *Chiron Corp v Murex Diagnostics Ltd* [1996] FSR 153, at 175.

The European Patent Office (EPO) has given a similar interpretation to the equivalent provision in Article 52(2) EPC. According to the Opposition Division in the *Relaxin* case, the long-standing practice of the EPO, as set out in its Guidelines, is to find invention both in the process of isolating a substance found in nature and in the substance itself provided that it can be properly characterised by its structure and that it had no previously recognised existence.[75] Using this interpretation, the new H2-relaxin protein claimed in the patent was classified as an invention and not a discovery. What was required was an industrially applicable technical solution to a technical problem. There was no express reference in this case to the characterisation of DNA sequences isolated from nature as being either discoveries or inventions. The claims in the patent were to DNA fragments encoding for H2-relaxin and its precursors. The sequences of the fragments was not revealed in the claims. What was disclosed was the amino acid sequence of the H2-relaxin molecule and precursors. Claims of this type offer broad protection, covering not only the DNA sequence as it exists in nature, but any DNA sequence which could code for that amino acid sequence. As such, the claims avoid objections based on discovery and lack of novelty. The claims may well lack a fair basis but this is not an opposition ground in Article 100 EPC.

In the earlier European case of *Vicom*, decided before *Genentech*, the EPO also made it clear that the novelty and inventive step requirements can reside in the discovery itself. Similarly, although Purchas LJ in particular referred to the DNA sequences in the Genentech patent as being discoveries, it would appear to be taken for granted in most cases heard by the Technical Board of Appeal of the EPO that genes are patentable subject matter.[76]

The outcome from these cases, that inventive step and novelty can be satisfied by the unpatentable discovery, could be seen as being out of line with the whole notion of patentable inventions. It arises out of a straight exercise in statutory interpretation, the effect of which is to reduce the scope of the exclusion. In Australia, where the exclusions are creations of case law rather than statute, no such formulation has yet been placed on the discovery exclusion. In addition, the conclusion that gene sequences are discoveries cannot be stated with an equal degree of certainty.

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75 *Relaxin* [1995] OJEPO 388.

76 Some twenty decisions to this effect are referred to by Straus, J., "Patenting Human Genes in Europe - Past Developments and Prospects for the Future" (1995) 26 *IIC* 920, at 925.

1.3.2 *Exclusion Based on Method of Medical Treatment: Subsection 4(2) Patents Act, Article 52(4) EPC*

The exclusion in subsection 4(2) has been considered in three cases in England.[77] In each of these, the principal examiner gave a wide meaning to the word therapy, to include preventative as well as curative treatment. As a consequence, some of the claims in each case failed because they were held to fall within the exclusion in subsection 4(2).[78] This broad interpretation of the exclusion could also exclude patent claims for genetic diagnosis and therapy. There is some indication that similar legislation may be interpreted differently elsewhere in Europe. In Germany, for example, a narrow interpretation of therapy has been adopted, thereby allowing claims which were similar to those rejected by the English Court.[79]

Careful drafting of patent claims can avoid altogether the exclusion in s4(2). Subsection 4(3) provides that a product can be treated as being capable of industrial application even though it is invented for use in a s4(2) method. Further, s2(6) allows for novelty to reside in the use. This allows for patenting of purpose-limited product claims to known substances for both first and second (or subsequent) pharmaceutical uses.[80] Just as patents can be claimed for methods embodying excluded discoveries, even when inventive step and novelty reside only in the discovery, so too can patents be claimed for products used in excluded methods of medical treatment, even when novelty resides only in the method of treatment.

In Australia, the decision in *Rescare* means that there is now nothing intrinsically unpatentable about methods of medical treatment. This makes such tortuous leaps of logic as seen in the British legislation and cases unnecessary. The stated purpose of the exclusion in s4(2) *Patents Act* 1977 (UK) is to:

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77 These are: *Unilever Ltd (Davis's) Application* [1983] RPC 219; *Bayer AG (Meyer's) Application* [1984] RPC 11; *John Wyeth & Brother Ltd's Application* [1985] RPC 546.

78 This interpretation was approved on appeal by Falconer J in *Unilever*, [1983] RPC 219 and Falconer and Whitsard JJ in *John Wyeth.* [1985] RPC 546.

79 *Hydropyridine* [1984] OJEPO 26, cited in *John Wyeth* [1985] RPC 546.

80 *John Wyeth* [1985] RPC 546 at 567.

"ensure that the use in practice by practitioners of such methods of medical treatment in treating patients should not be subjected to possible restraint or restriction by reason of any patent monopoly."[81]

By allowing patents for known products used in a new method of treatment (which would be excluded in Australia after *Philips*,[82] unless a new result is created), the effect on practitioners may be felt equally, if not to a greater extent than patenting of the methods of medical treatment themselves.

1.3.3 Exclusion Based on Public Order / Morality: Paragraph 1(3)(a) Patents Act, Article 53(a) EPC

Article 53(a) EPC provides that patents will not be granted where their publication or exploitation would be contrary to "ordre publique" or morality. In its interpretation of this provision, the European Patent Office Board of Appeal has reached a number of favourable decisions for biotechnology patent applicants.[83] The first case to discuss this provision in some detail in relation to biotechnology patents was the application for the Harvard onco-mouse.[84] The application was initially refused by the Examining Division of the EPO.[85] The President and Fellows of Harvard College appealed to the Technical Board of Appeal.[86] The Board considered the grounds of sufficiency of disclosure (Article 83 EPC) and exceptions to patentability under Article 53(a) and 53(b) (discussed below) and concluded that the decision of the Examining Division should be set aside and the case be remitted to that Division for reconsideration. The Board emphasised that any exceptions to the general rule of patentability in Article 52(1) should be narrowly construed.

In its consideration of Article 53(a) the Board recognised the problems associated with genetic manipulation of mammals, particularly in relation to

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81 *Ibid.*, at 565.

82 *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 32 IPR 449.

83 The European Patent Office Board of Appeal's willingness to accept a broad claim in *Polypeptide Expression/Genentech* (Decision T127/85) [1989] OJEPO 275 should be contrasted with the English *Genentech* cases.

84 The application was to patent an entire mouse, which had been genetically altered so that it had a predisposition to cancer.

85 (1989) OJEPO 451.

86 *Re Harvard College (President and Fellows) (Decision T 19/90)* [1990] OJEPO 476.

animal suffering and damage to the environment. The Board concluded that this exception required a careful balancing exercise between benefit to mankind in curing diseases on the one hand and environmental damage and cruelty to animals on the other, and that this balancing exercise was the task of the Examining Division. In the circumstances of the case the Examining Division concluded that the balance swung in favour of benefit to mankind.[87] Opposition hearings are presently being heard by the Opposition Division. Arguments being raised include:

- that higher onco-mammals could suffer considerably;
- that there is considerable risk to the environment; and
- that the balancing act is misconceived it being inherently immoral to subject animals to painful disease.[88]

In *Relaxin*[89] it was pointed out that the provision was likely to be invoked only in rare and extreme cases. Its function was to ensure that patents would not be granted for inventions universally regarded as outrageous, the sort of inventions that, according to EPO Guidelines, were so abhorrent that the grant of patent rights would be inconceivable. One patent application which triggered this exclusion was for a transgenic mouse, the purpose of which was as a research tool in the study of wool growth and human hair production.[90]

The *Relaxin* case makes it clear that for the EPO there is nothing inherently immoral or contrary to public order in the patenting of human genes. The narrow reading of the public order/morality exclusion, and the stated unwillingness of the EPO Divisions to get involved in ethical issues makes it unlikely that this provision will provide an obstacle in the patenting of most biotechnology inventions.

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87 Grant of European patent no. 0 169 672 (Onco-mouse/Harvard) [1992] OJEPO 588.

88 As reported by the Nuffield Council on Bioethics, *Human Tissue Ethical and Legal Issues* (1995) at 90.

89 [1995] OJEPO 388.

90 See Nuffield Council, *op cit*, at 90.

1.3.4 Exclusion Based on Biological Processes or Animal or Plant Varieties: Paragraph 1(3)(b) Patents Act, Article 53(b) EPC

This provision provides that plant or animal varieties or essentially biological processes for the production of plants or animals are not patentable. Microbiological processes, or the product of such a process escape this exclusion.

- Animal or plant varieties:

  Although this exclusion is not directly relevant to the patenting of human genetic material, the cases in which it has been argued demonstrate the difficulties that can arise in interpreting statutory provisions of this nature.

  In the *Onco-mouse* case, the Board of Appeal considered that the animal varieties exclusion was not intended to cover animals as such. It remitted the task of deciding whether the application was for animal varieties to the Examining Division. The Examining Division considered that, since the only aspect of the patent directed to animals was to non-human mammals or to rodents, and since animal variety is a sub-unit of species, Article 53(b) did not apply in this respect. The case is currently before the Opposition Division.

  In the interim, the Opposition Division and Board of Appeal has given a different interpretation to the provision with respect to plant varieties, including in the exclusion plants themselves, as well as plant varieties.[91] In a later case, the Opposition Division gave a similar interpretation to this provision.[92] The precise ambit of this new interpretation remains uncertain. It has been suggested that, according to the Technical Board, the plants in question had become a variety because they had been genetically modified to be herbicide resistant and this trait was distinctive and stable in future generations.[93] The patent was not bad because the plants claimed "embraced" varieties, but because they had become a variety. In *Onco-mouse* the Board of Appeal was careful to point out that plant varieties have another form of protection available to them, whereas animal varieties do not. This may be

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91 *Plant Cells/Plant Genetics Systems* (Decision T356/93) and (Decision G3/95) [1995] OJEPO 540. See 374 *Nature* 8.

92 *Lubrizol*, as reported by Abbott A., "Withdrawal of Patent Claim Leaves Position of Plants Unclarified" (1996) 381 *Nature* 178.

93 Roberts, T., "Plant Patent Quagmire" (1996) 381 *Nature* 642.

sufficient to justify a narrower reading of the variety exclusion for animals than for plants.[94] Since it appears that the main justification for this exclusion is the fact that a different form of protection is available for plant varieties, I suggest that it is entirely appropriate that claims involving animals should be interpreted in a different way from claims involving plants.

- Essentially biological processes, not microbiological processes and the products thereof:

  This provision has been given a very narrow interpretation by the Board of Appeal. Technical processes and processes involving microinjection have been held to be non-biological or microbiological processes, thereby avoiding the exclusion. The types of processes that might be included in the exclusion are traditional selective breeding practices.[95] Through this narrow interpretation, a provision that could have had a profound effect on patenting of genetic material in higher organisms will be of minor concern to patentees.

1.4 The European Biotechnology Directive

Differences in the interpretation of legislation derived from the EPC between member countries and difficulties in the interpretation of the exclusion provisions indicate that there is still a great deal of uncertainty and lack of uniformity in the issue of patenting of biotechnological inventions across Europe.[96] In 1988 the European Commission proposed a Directive to establish clear standards for the legal protection of biotechnological inventions.[97] The Commission believed that the proposed Directive was necessary to provide authoritative guidance for the problems presented in national patent law arising with respect to biotechnological inventions and which are not directly addressed by such laws.

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94 Plant varieties are also protected through the UPOV Convention. Note that Australia is a signatory to the *Paris Convention for the Protection of New Varieties of Plants* 1961, and enacted the *Plant Variety Rights Act* in 1987 to satisfy its obligations under that Convention.

95 Nuffield Council, at 93.

96 Some of the implications of this uncertainty and lack of uniformity are discussed by Maher, L. "The Patent Environment: Domestic and European Community Frameworks for Biotechnology" (1992) *33 Jurimetrics Journal* 67-132.

97 Commission of the European Communities, *Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions* (1988).

The main goal of the Directive was harmonisation of standards for protecting biotechnological inventions, but such harmonisation has proved difficult, if not illusory. The issue was complicated by the fact that at the same time as the European Parliament was considering the proposed directive, the EPO was hearing the application for the Harvard onco-mouse as well as a number of other contentious patent claims. The decision of the Board of Appeal in the *Onco-mouse* case provoked outrage in the European Parliament and considerably delayed agreement on the Directive. A common position was reached by the European Commission in February, 1994.[98] Since then a number of reviews of the Directive were made and major changes were proposed, including an absolute ban on patenting human genes and gene therapies on which much current medical/pharmaceutical research is based. Although the biotechnology industry agreed to a number of conditions, it was unwilling to allow terms which would prevent isolated human genes from being patented. Environmental representatives on the European Parliament, in contrast, would not allow the Directive to pass without such provisions. At that stage, a number of commentators expressed doubt that there would ever be a Biotechnology Directive and whether it would be worth having in this form.[99] Their fears were confirmed in 1995, when the European Parliament voted 240 to 180 to abandon the Directive altogether.[100]

Attempts have since been made to resurrect the Directive. The European Commission published an amended version in late 1995. This must be approved by both the Council of Ministers and the European Parliament. The modified Directive still considers isolated genes and living organisms to be patentable.[101] It appears that the process of isolation will be enough to confer the necessary inventiveness, even though the isolated material may be identical to that existing

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98 European Commission, *Common Position of the Council of 7 February 1994 on the Proposal for a Council and European Parliament Directive on the Legal Protection of Biotechnological Inventions, Statement of the Council's Reasons* (1994).

99 Nott, R., "The Proposed EC Directive for Biotechnological Inventions" (1994) 5 *European Intellectual Property Review* 191-194; Dickson, D., "European Patent Directive in Critical Test over Genes" (1994) 372 *Nature* 310; Butler, D., "Patents Stalemate on Biotechnology" (1994) 372 *Nature* 393.

100 Coghlan, A., "Europe Kills of Patents on Life" (1995) *New Scientist* 11 March, 7.

101 Abbott, A., "European Proposal Reopens Debate over Patenting of Human Genes" (1995) 378 *Nature* 756.

in nature.[102] If the Directive is adopted, European law will be parallel with that in the USA, both allowing for patenting of isolated but unmodified natural materials. It is uncertain at present if Australia will take the same position. Given the strong anti-patenting lobby within the European Parliament, it must be seen as unlikely that there will be endorsement of the Directive in its existing form.

The initial rejection of the Directive by the European Parliament was seen by a number of commentators as a rejection of patenting of genes. However, this is not the effect: there is nothing in *European Patent Convention* that explicitly prevents patenting of genes and the interpretation of Article 53(a) in *Relaxin* indicates that nor is there any implicit exclusion. The aim of the Directive is to provide much needed clarification as to the extent to which genes are patentable. It would be unfortunate if this aim could not be achieved.

1.5 The Need for Exclusions in the Australian Legislation

The lack of a unified policy on patenting across the European Community and difficulties in the interpretation of the exclusion provisions makes an analysis of the value of express exclusions difficult. Perhaps the main lesson from the European experience is that if exclusions are to be included in the legislation they must be framed very carefully to avoid ambiguities in their interpretation. The effectiveness of the Australian manner of manufacture test and case law exclusions in dealing with biotechnology patents will only become clear once a number of cases have been decided in the area. There are obvious parallels in the Australian case law and European statutory exclusions. Both offer the possibility of excluding a range of matters associated with human genetic research. In practice, there would appear to be little difference in the interpretation of either form of exclusion, the tendency being to give both a narrow reading. In addition, both the Australian and European legislation include provision for public policy considerations. There is a marked reluctance of the courts and Patent Offices to enter into such debates. As such, current patent law provides little in the way of express impediments to patenting of human genetic information and its applications. However, the other patenting criteria may provide obstacles to patenting that are particularly difficult to overcome in this field.

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102 Grace, M., "A Matter of Life and Death" (1996) *New Scientist* 27 July, 60.

Part 2: *Novelty and Human Genetic Research*

Similar arguments to those raised against the manner of manufacture provision could also be used in relation to lack of novelty: gene sequences form part of the prior art base because they already exist. Generally, this argument has not been held to be sufficient to deny novelty for two main reasons, which are best exemplified by reference to the *Relaxin* case[103]. First, the Opposition Division of the EPO held that, since the DNA fragments claimed in the patent were all cDNAs, they fulfilled the novelty requirement because they were different from the naturally occurring DNA sequences coding for the same polypeptides. Secondly, even if the claim included genomic DNA fragments it was held that the requisite novelty may still be present. Article 54(1) EPC provides that an invention is considered to be new if it does not form part of the state of the art, and Article 45(2) defines the state of the art as comprising everything made available to the public. The parties agreed that even though the form of relaxin claimed in the patent existed in nature it was unknown prior to the invention and therefore had not been made available to the public. Further, it was established patent practice for a natural substance that had been isolated for the first time and was previously unknown to fulfil the novelty requirement.

In many instances, the value of recombinant DNA technology is in producing useable quantities of previously known products. Tissue plasminogen activator, claimed in *Genentech* is but one example.[104] In such situations both the product and the process used to produce it are known. How, then, can the claims be novel? The courts have recognised this difficulty, which particularly pertains to biotechnology patents, and have modified the novelty requirement accordingly. It has been said that to distort the novelty requirement in this way "is arguably to trivialise the concept to the point where it hardly constitutes a credible criterion for

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103 [1995] OJEPO 388.

104 Other notable examples are Factor VIII:C and erythropoietin. The US patents that were claimed for both of these recombinant products have been the subject of extensive litigation because patents already existed for the naturally produced products. The recombinant products were held to infringe the patents on the naturally produced products in *Scripps Clinic and Research Foundation v Genentech* 666 F.Supp. 1379 (1987) and *Amgen Inc v Chugai Pharmaceutical Co* 706 F.Supp.94 (1989), although both of these decisions were subsequently reversed on other grounds.

the grant of patent protection."[105] Ultimately, of course, the judiciary is making a policy decision by weighing the need to encourage investment in this area of research against the need to make that research available to the public. In *Genentech,* Mustill LJ explicitly recognised this tension in patent law, but cautioned the courts against embarking on major judicial legislation.[106] For his Lordship the task was to understand and apply the Act, leaving it to the legislature to repair flaws in the regime. In general, patent legislation appears to have been interpreted to ensure that the balance swings in favour of encouraging investment, unless the monopoly claimed is obviously out of line with the merit of the invention. This was held to be the case in *Genentech,* and in such circumstances the courts have found ways of interpreting the patenting requirements to restrict or deny monopoly rights.

As with the other patenting requirements, it is necessary to look to other jurisdictions to assess how the Australian provisions might apply to biotechnology patents. Again, a number of decisions in the English courts and EPO provide some instructions. The analysis will be framed in the form of two questions: where and how much disclosure?

2.1 Where Should Novelty Reside?

Inroads have been made into the novelty criterion in at least three identifiable areas in Europe, by varying the site of the novelty inquiry. These are: in the discovery or the invention; in the product or the method of medical treatment; and in the product, the process or the purpose.

2.1.1 In the Discovery or the Invention?

Genentech and subsequent cases make it clear that, even though discoveries are not patentable, novelty can reside in the discovery provided that it is the method or product embodying the discovery that is being claimed (see above, at 1.3.1).

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105 Thomson, J.A., *Biopatenting the Splice of Life: A Consideration of the Interface between Biotechnological Inventions and Patent Law* (1994) Ph.D. Thesis, University of Western Australia, at 146.

106 [1989] RPC 147, at 259.

2.1.2 *In the Product or the Method of Medical Treatment?*

Subsection 2(6) *Patents Act* (UK) expressly provides that even if the invention of a substance or composition for use in a method of treatment excluded through s4(2) is part of the state of the art, the invention can still be patented if novelty can be shown to reside in the use (see above at 1.3.2). *John Wyeth* followed the European authority of *Eisai,*[107] in its consideration of the novelty requirement for Swiss-type use claims. These types of claims are framed in such a way to allow for patenting of inventions directed to second or subsequent medical uses of known products.[108] In *Eisai* it was held that the requisite novelty could be found in the new use for product claims to a known substance or composition both when a first therapeutic use is claimed and also when second or subsequent uses are claimed.

2.1.3 *In the Product, the Process or the Purpose?*

In the European case of *Mobil* [109] it was held to be sufficient for novelty to reside in the purpose to which a compound had been put when both the product and the process were already known. According to Lord Hoffmann in *Merrell Dow,* purpose novelty as applied in *Mobil* requires that the new purpose for which an old compound is used in an old way is interpreted as being a "functional technical feature" of the invention. He went on to question whether this part of the decision in *Mobil* applied in the UK.

These three aspects of the "where" question considerably reduce the potency of the novelty criterion, by allowing for novelty to reside in areas of the invention other than the patent claims. In some respects this may have a detrimental effect on research and development, particularly where methods embodying discoveries are framed very broadly, as was attempted in *Genentech.* On the other hand the change in focus of the novelty requirement for inventions embodying second or subsequent therapeutic uses and new purposes arguably may encourage further research because it prevents single patents from dominating entire fields. But this will only be beneficial in terms of encouraging competition if the holder of the product patent is willing to licence its use widely. If the patentee refuses to licence,

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107 *Re Eisai Co Ltd* (Decision G05/83) [1985] OJEPO 64, cited in *John Wyeth* [1985] RPC 546.

108 See *John Wyeth* [1985] RPC 546, at 565.

109 *Mobil/Friction reducing additive* (Decision G02/88) [1990] EPOR 73 referred to in *Merrell Dow Pharmaceuticals Inc v NH Norton & Co Ltd* (1996) 33 IPR 1, at 13.

and continues to carry on research exclusively it will eventually gain patent coverage over the field. This would have been a most effective strategy in the *Merrell Dow* case, discussed below. If Merrell Dow had succeeded in enforcing its patent on the acid metabolite of an antihistamine drug, it would have effectively increased the life of its expired patent on the drug itself, because others using the drug would inevitably have infringed the patent on the metabolite.

It is doubtful whether any of these interpretations would be followed in Australia for a number of reasons:

- the first and second considerations rely very much on statutory interpretation of the specific discovery and medical use provisions in the EPC and *Patents Act* (UK), which have no equivalents in the Australian legislation;
- the decision in *Rescare*[110] indicates that methods of medical treatment are patentable, thereby negating any requirement for Swiss-type claims; and
- it is doubtful whether either the second or third considerations can apply in Australia after the *Philips* case.[111] The High Court made it clear that if, on the face of the specification, the claim is for a new use of an old product, the application will not even pass the first hurdle of being an invention.

Until new interpretations become available, it should be assumed that novelty must reside in the thing being claimed, whether that be a new product or new process. Australian courts may well eventually come up with their own idiosyncratic interpretations of the novelty criterion, based on policy decisions as to the extent to which patenting should be allowed in the area of biotechnology.

2.2 How Much Prior Disclosure Is Required?

The second issue that must be assessed is the extent of prior disclosure that is required to prove want of novelty. Australian law requires that all of the essential integers of the invention are disclosed.[112] According to the decision of the House of Lords in *Asahi*,[113] however, for the prior art to anticipate an invention as required in the *Patents Act* 1977 (UK), a mere disclosure is not enough. The disclosure must be enabling. To understand the holding in *Asahi* it is necessary to explain some of the facts. Asahi claimed a patent for human tissue necrosis factor

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110 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383.

111 *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 32 IPR 449.

112 See Chapter 2, section 4.2.

113 *Asahi Kasei Kogyo KK's Application* [1991] RPC 485.

produced by recombinant DNA technology. It first filed an application in the USA on 6/4/84 and filed in the UK on 4/4/85. It claimed priority from the US application. A competitor had filed an application in Japan on 6/3/84 and a European application on 26/2/85. A number of assumptions were made in the appeal:

- that claims 2 and 3 of the 26/2/85 application disclosed methods of preparing the products claimed by Asahi;
- that the products disclosed in those claims were also disclosed in the 6/3/84 application but the methods for preparing them were not; and
- that the UK application was entitled to the US priority date of 6/4/84.

The court had to decide whether, on the basis of these assumptions, the subject matter disclosed in the claims was part of the state of the art at the US priority date. The relevant prior art base was the 6/3/84 patent, which did not disclose the method for producing the products. Thus the ultimate question was whether, to form part of the state of the art, a disclosure has to include the method of working the invention. If the question was answered affirmatively then the patent would not be bad for want of novelty. Lord Oliver held that the invention was the combination of the formula for the compounds claimed and the means for making them. The 26/2/85 application could not claim the 6/3/84 priority for the totality of the invention claimed, but only for the formula. Lord Oliver made it clear that disclosure of a formula is not enough for a matter to be made available to the public unless the method of working it is so self evident as to require no explanation. Consequently, where the prior art is solely in the form of published information, an enabling disclosure is required.

This decision followed the reasoning of Falconer J in *Genentech Inc's (Human Growth Hormone) Patent.* [114] Falconer J applied the judgments of Lord Westbury in *Hills v Evans* [115] and Lord Reid in *Van der Lely N.V. v Bamfords Ltd* [116] and other recent cases to posit the requirement for an enabling disclosure. Other authorities also supported the contention that the same enabling disclosure requirement applies to claims to new chemical compounds, and hence to proteins and DNA sequences. This decision signifies that for prior disclosure by publication it is not enough that the product is identified, the method of producing it must also be described.

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114 [1989] RPC 613.

115 (1862) 31 LJCh 457.

116 [1963] RPC 61.

A more recent House of Lords decision throws further light on the novelty criterion with respect to anticipation both by publication and by use. In *Merrell Dow v Norton*[117] the patent in issue was for an acid metabolite of an antihistamine drug which was inevitably formed in the patient's liver after taking the drug. Merrell Dow owned the patent on the metabolite and had owned the patent on the drug, but this had expired. It claimed that other companies which had started to manufacture the drug were infringing the patent on the metabolite. At trial Aldous J held that the patent was invalid and this decision was affirmed by both the Court of Appeal and the House of Lords. Counsel opposing the patent argued that the metabolite was anticipated because volunteers in the trial for the drug had taken the drug and therefore made the metabolite inside their own bodies, even though this use did not instruct on the nature of the product or the process for making it. Lord Hoffmann, with whom the other Lords agreed, held that the fact that something had been done before was insufficient to have made the invention available to the public. On the other hand, with respect to disclosure by publication, it was held that the disclosure in the patent for the drug was sufficient to anticipate the claim to the metabolite. This was so even though the chemical structure of the metabolite had not been disclosed. What is required is a description sufficient to work the invention. Where "the recipe which inevitably produces the substance is part of the state of the art, so is the substance as made by that recipe."[118]

Thus, in England, the disclosure must show the method that will inevitably produce the product claimed, but it need not identify the chemical structure of the product. It is not sufficient to identify the chemical structure, without the means for producing it. *Merrell Dow* further denies anticipation by use for the manufacture of a product in the human body without instructions on the method of production. If the Court had decided otherwise a major impediment to biotechnology patents could have been created, in that a patent could not be claimed for a protein or gene isolated from the human body, because it would always have been made before. *Merrell Dow* can therefore be seen as indirectly affirming the proposition that a product of nature isolated for the first time is patentable, because, even though the product existed before, no instructions were available on how to produce it. But it also says that even if the chemical structure of a product is identified for the first time there will be no novelty if the recipe for

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117 *Merrell Dow Pharmaceuticals Inc v NH Norton & Co Ltd* (1996) IPR 1.

118 *Ibid.*, at 11.

producing it is already known. This suggests that identification of the DNA or amino acid sequence required to produce a particular protein will not be patentable if the method of production is already known. At issue is how much of the recipe must be known for it to "inevitably produce" the product. Although standard recombinant DNA techniques are known to those skilled in the art, the particular recipe for producing that specific DNA or amino acid sequence may not be. Slight modifications in the recipe may be enough to create novelty.

In Australia, the language of enabling disclosure rarely appears in decisions addressing the novelty criterion. Even so, *Hills v Evans* and *Van der Lely* appear to have been accepted as good law in Australia, suggesting that the disclosure must not only identify the product but must teach how to produce it.[119] Lockhart J in *Nicaro Holdings* stated that:

> "The prior art must enable the notional skilled addressee at once to perceive and understand and be able practically to apply the discovery without the necessity of making further experiments."[120]

Thus, unlike the "where" question, there is no reason to suppose that the question of how much disclosure is required should be answered differently in Australia than in England.

In summary, on its face, the novelty requirement has the capability of restricting patenting of inventions associated with human genetic research, either because the inventions are products of nature that are already in existence, or because recombinant DNA processes are now standard and well known by those skilled in the field, or because the end products are often already known. On interpretation of the novelty requirement, however, the English and European cases indicate that:

- the requirement for an enabling disclosure means that products of nature, although already in existence, will not destroy the novelty of an invention;
- for a prior publication to destroy novelty it must disclose the method of producing the invention, since disclosure of the formula or sequence of itself is not sufficient either to destroy or to create novelty;
- if novelty is allowed to reside in aspects of the invention other than in the claims themselves, inventions including known products or using known processes can still be novel.

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119 For example, in *Nicaro Holdings Pty Ltd v Martin Engineering Co* (1990) 16 IPR 545.

120 *Ibid.*, at 549.

It is presently unclear whether the novelty criterion will be interpreted in the same way in Australia as in Europe. With respect to the last point, the judgment of the High Court in *Philips*[121] would suggest that a more restrictive interpretation may be imposed, requiring that the things claimed must themselves possess the requisite novelty.

Part 3: Inventive Step and Human Genetic Research

Of all of the patenting criteria, it is most difficult to come to any definitive conclusions as to the patentability of inventions arising out of human genetic research with respect to the inventive step requirement. This is because inventive step is always a question of fact, to be determined with reference to the available evidence. Hunting out genes using recombinant DNA technology will often require a high level of skill and years of dedicated research. At the same time, however, that technology is now the standard method for locating, identifying and synthetically manufacturing genes. It is difficult to say with any degree of certainty what will be required to change a skilful piece of work into an inventive one. Some guidance can be obtained from the judgment of the House of Lords in *Biogen v Medeva.*[122] Lord Hoffmann identified three categories of inventive step which would arise out of the addition of an inventive idea to the existing stock of knowledge:

- using established techniques to do something no one had previously thought of doing, the inventive idea being the doing of the new thing;
- finding a new way of doing something that people had wanted to do but didn't know how, the inventive idea being the way of achieving the goal; or
- solving a particular problem that stood in the way of achieving a known goal by means that were generally known, the inventive idea being in solving the problem.[123]

3.1 Formulation of the Test

There is little uniformity in the cases as to what will constitute an inventive step. Just because an invention is held to be obvious in one case, it does not follow that a similar type of invention will be obvious in subsequent cases. There is

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121 *NV Philips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 32 IPR 449.

122 *Biogen Inc v Medeva Plc* (1996) Unreported Judgment of the House of Lords 31 October 1996.

123 *Ibid.*, at 4-5.

considerable reluctance on the part of the judiciary to lay down a set of fixed criteria with which to assess the inventiveness of a particular claim. Lord Diplock in *Johns-Manville Corp's Patent*,[124] for example, commented on the lack of desirability in formulating a precise definition by which to measure obviousness. There is some justification for this; obviousness is and will always be a jury-type question dependent on the unique facts of the case at hand. Even so, the lack of criteria decreases the certainty of the patent system. Challenges to the validity of patents are expensive. The lack of certainty in the obviousness criteria increases the expense of the process for two reasons. First, this ground is unlikely to be pleaded alone but will have a range of other grounds added to it. Secondly, even where there are other legitimate grounds obviousness will almost invariably be tacked on. The final outcome may be that patentees and competitors come to reasonable licence agreements rather than risking infringement or revocation proceedings. But this does nothing to clarify the law and may allow invalid patents to be enforced.

Various formulations exist to aid the courts in their analysis of the question of obviousness. In England the test was broken down into four factual steps in *Windsurfing International Inc v Tabur Marine (GB) Ltd:*

1. Identify the inventive concept in the patent.
2. Determine the common general knowledge of the normally skilled but unimaginative addressee.
3. Identify what, if any, differences exist between the matter cited as being known or used and the alleged invention.
4. Determine whether, without any knowledge of the alleged invention, the differences constitute inventive or obvious steps to the skilled man.[125]

The *Windsurfing* formulation is still good law in England.[126] The EPO focuses on a slightly different formulation:

1. Identify the closest prior art.
2. Formulate the technical problem which the invention sets out to solve, using objectively established facts derived from the available prior art.

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124 [1967] RPC 479, at 493-494.

125 [1985] RPC 59, at 73-74.

126 See, for example, Aldous J's judgment in *Chiron Corporation v Organon Teknika Ltd (No 3)* [1994] FSR 202.

3. Determine the obviousness or otherwise of the invention.[127]
Whatever formulation is chosen, the last step, although easy to state, is the most difficult for the courts to evaluate.

3.2 Is a New Product Enough?

As with novelty, a patent will not be declared invalid solely because the chemical formula of the product claimed is obvious. It must also be obvious how to produce or obtain the product.[128] At issue is whether non-obviousness of the formula itself will be enough to count as an inventive step. For Lord Diplock in *American Cyanamid*[129] the grant of a temporary monopoly by these means is justified when a new and useful product is made. The outcome may be different when the final product is known to those skilled in the art. This was the situation in *Genentech,* where, according to Purchas LJ:

> "[i]t was certainly obvious that t-PA would consist of a collection of amino acids associated with some kind of defined molecular structure: but it was not known at the material date what that structure was."[130]

A number of decisions of the EPO suggest that novelty of the product is enough to found inventiveness *per se.* In the *Relaxin* case, for example, lack of inventive step was argued in opposition to the grant of the patent on the basis that the claimed DNA fragments were not novel and conventional techniques were used in their isolation. Since the DNA fragments were held to be novel, this was said to be enough to satisfy the inventive step requirement. It was enough to provide "to the public for the first time a product whose existence was previously unknown."[131] The consequence of such decisions is that if a product is found to be novel, it will also be held to be non-obvious. Thomson has questioned whether it could really have been the intention of the legislature that the satisfaction of one patenting criterion should automatically satisfy a second criterion which has

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127 As set out by Leonard, A., "The European Approach to Inventive Step in Pharmaceutical Patents" Internet site: http://biotechlaw.ari.net/leonard.html.

128 *Boehringer Mannheim GmbH v Genzyme Ltd* [1993] FSR 716, at 724.

129 *American Cyanamid Co (Dann's) Patent* [1971] RPC 425.

130 *Genentech Inc's Patent* [1989] RPC 147, at 214.

131 *Relaxin* [1995] OJEPO 388, para 4.6.1.

traditionally been more difficult to satisfy.[132] Such decisions do indeed seem to be relaxing the patenting criteria too far.

It is not at all evident from English decisions that the same leniency will be given to the interpretation of the inventive step requirement. The mere fact that the product claimed in the patent is new will not be sufficient without some clear evidence of inventiveness. In cases like *Genentech* it is always going to be difficult to determine whether the work performed required an inventive step or mere skill and persistence. The requisite person skilled in the art is likely to be a team of highly qualified Ph.D.-level scientists with considerable intellectual capacity. What is inventive to such a team will be quite different from what would normally be inventive to the public, or indeed the judge, who must, nevertheless, place him- or herself in the position of that team. Purchas LJ in *Genentech* commented that this highlighted the artificiality of importing notions of obviousness into areas of high technology. In undertaking the task before him, his Lordship stated that prospects of success or commercial motivation should not be the focus of inquiry. The real question was whether a non-inventive skilled person would have made the discovery within a reasonable time frame. The fact that a number of highly skilled teams had spent a considerable amount of time trying to isolate the data suggested to Purchas LJ that it could not have been obvious. Further, he did not think it fair to the patentee or those in the field to deny the presence of an inventive step.

Dillon and Mustill LJJ did not agree with this reasoning. For Dillon LJ all of the steps taken by Genentech were applications of known technology, none of which was, by itself, inventive. The particular line of research was also obvious. And for Mustill LJ even though the fact that competitors have not been able to produce the invention may strongly suggest that it was not obvious, winning the race was not enough. Nor was a low prospect of success. Mustill LJ considered that on the facts of the case, skill and persistence would have been enough, and skill is not the same as inventiveness.

On the same facts Whitford J at trial and Purchas LJ on appeal held that there was an inventive step. Dillon and Mustill LJJ held that there was not. Can any guidance be obtained from the cases as to how future issues of obviousness may be decided? In many instances the test can be formulated as whether the invention was "obvious to try", but this will not be appropriate in all

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132 Thomson, J., "The Grey Penumbra of Interpretation Surrounding the Obviousness Test for Biotech Patents" [1996] 2 *European Intellectual Property Review* 90, at 91.

circumstances.[133] What is required for something to be "obvious to try" has itself become a matter for conjecture. In *Genentech (Human Growth Hormone)* Falconer J accepted the contention of counsel opposing the patent, that the invention will be obvious if

> "the suitable addressee would consider it worth trying from a number of possible alternatives ... because there is some reasonable expectation that one might get a good result".[134]

On the facts, his Honour held that on this test the necessary scintilla of invention was in fact present.

Biogen adds a further layer to the inventive step requirement. For Hobhouse LJ a mere business assessment to pursue an identified goal by known means is not an inventive step.[135] There must be some element of novel insight or discovery, and in that particular case those elements were lacking. The House of Lords disagreed with the Court of Appeal on this point, stating that it is irrelevant that a commercial decision was made to pursue a particular experimental strategy.[136] Accordingly, "[a]n inventor need not pursue his experiments untouched by thoughts of gain".[137]

Ultimately the matter appears to be decided primarily on the basis of characterisation of the inventive concept in step 1 of the *Windsurfing* test.[138] If the concept is cast in broad terms it may be easy, with the aid of expert witnesses, to prove that it was obvious. If the concept is too narrow, it will not justify the claims made in the patent. The *Biogen* case provides a useful example of these differing effects. Aldous J in the Patents Court defined the inventive concept as the idea "to express a polypeptide displaying antigen specificity in a suitable host". For Hobhouse LJ in the Court of Appeal this broad concept was obvious. Lord Hoffman in the House of Lords agreed that this concept was obvious, but stated that the more accurate concept was to "express unsequenced eukaryotic DNA in a prokaryotic host". This was not obvious, although it was ultimately held to be insufficient to support the claims made in the patent.

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133 See *Boehringer Mannheim GmbH v Genzyme Ltd* [1993] FSR 716, at 723.

134 *Genentech Inc's (Human Growth Hormone) Patent* [1989] RPC 613, at 671.

135 *Biogen Inc v Medeva Plc* [1995] FSR 4.

136 Unreported judgment of the House of Lords, handed down on 31 October 1996, at 16.

137 *Ibid.*

138 [1985] RPC 59, at 73-74.

3.3 The Position in Australia

In the UK *Chiron* case at first instance[139] Aldous J appeared to place much greater reliance on the expert witnesses for Chiron than on those opposing the patent. This was enough to persuade Aldous J that the invention was not obvious. The matter was not raised on appeal. Given that the invention was held to be non-obvious in England, it seems surprising that Murex raised the same obviousness question in Australia. The solicitor advising Murex believed that it was worthwhile to raise the issue again. The out of court settlement suggests that the patent was likely to have been held to be invalid, and, although the ground for invalidity is unknown, it may well be that Burchett J would have declared the invention to be obvious. Although the patent claims are to the same invention in both cases, the focus of inquiry with respect to the knowledge of the skilled man in the field at the time of the invention is different. The Australian case would have been decided on the basis of obviousness requirements in the 1952 Act. As such, only the common general knowledge is relevant.[140] But it is the common general knowledge of the skilled person in Australia,[141] which may be quite different from the common general knowledge in England. A number of Australian scientists are particularly skilled in this area, and it may be that at the time of the invention their knowledge of the technology was superior to that of the equivalent skilled person in England. Much would have depended on the weight given by Burchett J to the expert evidence of the Chiron and Murex witnesses. On this basis, if the case had gone to a decision, and it had been different from the decisions in England, it would have been because of evidentiary matters and not because of differences in the law itself.

What, then, can be said of the inventive step requirement in relation to human genetic research? The decisions of the EPO that have allowed the inventive step to be satisfied for mere novelty of product stand in stark contrast with the judgment of Dillon LJ in *Genentech*, who refused to accept the presence of an inventive step where the product was known and standard recombinant DNA technology was used. Recombinant DNA technology is now the obvious first choice for the production of all biological products in industrially useful

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139 *Chiron Corporation v Organon Teknika Ltd (No. 3)* [1994] FSR 202.

140 See Chapter 2, section 4.3. In Britain obviousness is assessed on the basis of all information that has been made available to the public.

141 *W.R. Grace v Asahi Kasei Kogyo Kabushiki Kaisha* (1993) AIPC ¶90-974.

quantities. It would hardly be seen as a desirable result if this were to mean that experimental use of this technology to isolate and produce medically and economically important compounds was routinely denied patent protection because the technology of itself was obvious. On the other hand, it is equally as undesirable to grant broad patent protection for the discovery of gene sequences, because all future use of those sequences could fall within the ambit of the patent.

Part 4: Specification Requirements and Human Genetic Research

4.1 Enablement and Living Material

The fact that many inventions involved in human genetic research include living matter create particular problems in relation to specification requirements. These have been solved to a large extent for inventions involving microorganisms as a result of the *Budapest Treaty*[142] and other national provisions. These generally require that microorganisms are deposited in prescribed depositary institutions on or before the date of filing. Section 6 *Patents Act* 1990 sets out the Australian deposit requirements. Provided these are complied with, the invention will be taken to comply with the requirement in paragraph 40 (2) (a) that the specification fully describe the invention, including the best method for performing it.[143] Uncertainties remain, however, as to how the specification requirements are to be fulfilled for inventions involving higher organisms. There is as yet no provision to deposit higher organisms, nor is it clear how they could be stored and maintained.

4.2 Specification Requirements in European Legislation

4.2.1 Fair basis

Caution is required in interpreting European case law because the provisions in relation to specification requirements are substantially different to those in Australia.[144] Section 72 *Patents Act* 1977 (UK) provides the grounds for revocation of a patent. Failure to fulfil specification requirements can only be challenged on ground (1)(c) that "the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a

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142 *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure* 1977.

143 Subsection 41(1).

144 The Australian specification requirements were discussed in Chapter 2 at 4.2.

person skilled in the art."[145] The matters to be considered by the Patent Office at the examination stage are set out in section 14. These include the equivalent of the revocation ground 72(1)(c) in subsection 14(3) and also s14(5)(c), which provides that the claim must be supported by the description. Paragraph 14(5)(c) replaces the old fair basing requirement in the 1949 Act.[146]

Because the examination requirement in s14(5)(c) is not a ground for revocation,[147] it would appear on the face of the statute that a patent cannot be challenged in revocation proceedings on the ground that the claims are not supported by the description in the specification, even if it should have been rejected at the examination stage on this basis.[148] There is some indication, however, that the courts are able to get around this omission, which could otherwise significantly increase the potential for widening patent protection in that if a broad claim survived the examination procedure there could be no further challenge to it on the basis that it was not supported by the description. In *Biogen v Medeva*, the English Court of Appeal referred to a number of provisions in the UK Act, as well as the Protocol attached to the EPC. Paragraph 72(1)(a) provides the ground for revocation that the invention is not a patentable invention, and s125(1) indicates that the invention is that which is specified in the claim as interpreted by the description in the specification. The Protocol requires that, in interpreting Article 69 (the EPC equivalent to s125 in the UK Act), the preferred construction should be that which "combines a fair protection for the patentee with a reasonable degree of certainty for third parties". Accordingly, the Court of Appeal asserted that:

> "These provisions of the Convention and the Act, although directly relating to the ascertainment of the extent of the monopoly granted by a patent, confirm the necessary relationship between the claimed monopoly and the description of the invention and do not support any intent by the draftsman that such considerations should cease to be relevant or that restrictive interpretations should be put on other parts of the Convention or the Act. ... [A]ccount must be taken of the whole of the description in the specification."[149]

In consequence,

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145 Paragraph 72(1)(c): insufficiency.

146 In s32(1)(i).

147 As stated by the Court of Appeal in *Genentech* [1989] RPC 147 and affirmed in *Biogen v Medeva* [1995] FSR 4 and *Chiron v Murex* [1996] FSR 153.

148 See Mustill LJ in *Genentech Inc's Patent* [1989] RPC 147, at 260-261.

149 *Biogen v Medeva* [1995] FSR 4, at 30.

"No claim can be valid unless it is a claim to an invention and the invention has to be an invention described in the specification."[150]

Thus, using all its skills in statutory interpretation the Court of Appeal has found a means to examine the extent to which the description in the specification supports the claims even though there is no express statutory authority to do so. The validity of this interpretation was not discussed in the opinion of the House of Lords. For Lord Hoffmann, the general principle expressed by the notion of fair basis could be given effect to through the sufficiency requirement in s72(1)(c). Therefore it cannot yet be said with certainty that the interpretation of s72 presented by the Court of Appeal is a legitimate form of inquiry under English law.

Resolution of the issue of fair basis was critical to Biogen's case, because it was claiming the priority date of an earlier patent (referred to as Biogen 1). Through its application of the above interpretation the Court was in effect making a determination as to whether the invention claimed in the later patent was fairly based on Biogen 1. The problem faced by Biogen was that it wanted to make a product claim to a recombinant DNA molecule displaying antigen specificity to the hepatitis B virus, but the virus possessed genes for two antigens (HBsAg and HBcAg), not one. If Biogen had been able to make a process claim, this would have covered any product made by the process, but it was held not to have invented a process. What it sought to do instead was to make the product claim as wide as possible by claiming any recombinant DNA molecule displaying antigen specificity to the hepatitis B virus. In doing so it was held to have claimed the two separate inventions, and one of these (for HBsAg) was not supported by the description in Biogen 1.

4.2.2 *Sufficiency*

Even if the above interpretation of the *Patents Act* 1977 (UK) is not accepted by other courts,[151] broad claims can still be challenged through the sufficiency requirement in s14(3). Insufficiency is also a legitimate ground for revocation

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150 *Ibid.*, at 32.

151 This issue of whether the claims were supported by the description was not raised as a ground for revocation in the later Court of Appeal case of *Chiron Corp v Murex Diagnostics Ltd(No. 12)* [1996] FSR 153.

through s72(1)(c). The focus of inquiry is whether the disclosure in the specification was enabling.[152] In the House of Lords decision in *Biogen,* Lord Hoffman saw that the concept of enabling disclosure was central to the law of patents and was crucial at three different levels: determination of priority date; determination of validity of the patent at examination; and as a ground for revocation. Although there is no express requirement for an enabling disclosure in section 72, for his Lordship it is incorporated because it is a matter of substance and not form.[153] Thus the issue for the courts to decide is what constitutes an enabling disclosure.

It was held in *Mölnlycke*[154] that the sufficiency provision does not require that all possible embodiments of the invention can be made by the skilled addressee. In that case Morritt LJ claimed to be affirming the decision of the Technical Board of Appeal of the EPO in *Polypeptide Expression/ Genentech,* that an invention will be sufficiently disclosed if at least one way is indicated which enables a person skilled in the art to carry it out.[155] In *Biogen,* Lord Hoffmann expressly rejected the interpretation of *Polypeptide expression/Genentech* given by Morritt LJ, concluding that the European case was merely applying the long established principle that the specification must enable the invention to be performed across its whole width.[156] The level of disclosure required thus depends on the types of claims being made. Where a principle of general application is disclosed it is appropriate to cast the claims in general terms. But where discrete methods or products are being claimed, there must be an enabling disclosure for each of these. Thus the patentee can legitimately make broad claims either because it is possible to show some common principle which enables all of them to be made or because no other way of achieving the same effect can be envisaged. Biogen failed on the latter basis. A common principle was disclosed, in that both HBcAg and HBsAg could have been made from the disclosure in Biogen 1. But Biogen failed because the results claimed in Biogen 1 could also be produced by means different from those disclosed by Biogen. Lord Hoffmann likened such claims to the Wright brothers, having discovered heavier than air flight, claiming a monopoly on all heavier than air flying machines.

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152 *Biogen v Medeva* (1996) Unreported judgment of the House of Lords, opinion handed down on 31 October 1996, at 20.

153 *Ibid.*

154 *Mölnlycke AB v Proctor and Gamble* [1994] RPC 49.

155 Decision T292/85 [1989] OJEPO 275, at 264.

156 House of Lords opinion, at 21.

Where Biogen failed, Chiron succeeded,[157] yet it is difficult to see how its claims were any less broad than a claim to all heavier than air flying machines. Note that the decision in *Chiron* was handed down after the Court of Appeal decision in *Biogen*, but before the House of Lords and thus some of the findings in *Chiron* should not be used as guidance for future cases. For instance, the claim in question in *Chiron* was also to a class of products, and Murex submitted that a claim of this nature will only be a claim to a single invention if it specifies a novel common feature (the common principle in *Biogen*). Chiron submitted that the test was much more simple: whether the invention of one product is the invention of the others. The Court, after reviewing the authorities, accepted Chiron's formulation, although conceding that if this test is satisfied the Murex test is also likely to be satisfied. The Court did not address the issue of whether the claims covered other ways which could have been envisaged for achieving that result.

According to Chiron, the claim in issue related to the discovery of the Hepatitis C virus (HCV) and genome sequence, the invention being a chemical which contained the antigenic determinants of HCV to which antibodies would bind.[158] Murex argued that the claim was in fact to a group of chemicals which were chemically and biologically different from each other. The Court held that the importance of the discovery of the HCV genome was that it enabled the location of antigenic determinants within the protein expressed by the genome. The antigenic determinants were identified as a sequence of at least 10 amino acids to which a HCV antibody would bind. There was no common formula to identify these sequences of amino acids. Even so, the Court held that this was a claim to a single invention of antigenic determinants to HCV, since the invention of one is the invention of all. The invention in issue looks strikingly similar to the claimed invention in *Biogen*, which was held to be more than one invention. The Court in *Chiron* distinguished the two on the basis that the claim in *Biogen* was to a polypeptide displaying "HBV antigen specificity", whereas the claim in *Chiron* was to a chemical containing antigenic determinants. Since the claim in *Biogen* covered both HBsAg and HBcAg, which had different compositions and bound to different antibodies, it was held to be a claim to two inventions. Although the Court held in *Chiron* that the claim was to a single invention in both substance and form, it is difficult to see how the difference from the *Biogen* claim is anything but semantic. Twenty two percent of the genome for that particular strain of HCV in *Chiron* had

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157 *Chiron v Murex* [1996] FSR 153

158 *Ibid., at* 183.

yet to be sequenced, and yet the claim was broad enough to cover all antigenic determinants, including those for which the DNA sequence had yet to be determined. It was also broad enough to cover antigenic determinants from other strains of HCV, the genomes of which had not been sequenced at all, and could contain substantial differences from the strain sequenced by Chiron. By casting the invention in the form of a chemical which contained the antigenic determinants of HCV, it may be that no other methods could be envisaged for achieving the result claimed, without making use of the invention. If this is the case then all that can be said about this requirement in English law is that clever drafting of patents will enable broad claims to be made.

4.3 Application of European Case Law to Australian Legislation

There are significant differences between the Australian and European legislation. In Australia, patents can be challenged in revocation proceedings on all of the grounds of: insufficiency, lack of definition, lack of clarity and ambiguity, and fair basing. In *Murex v Chiron* all of these grounds had been raised by Murex. A broad summary of the statement of claim and particulars is given below.[159]

4.3.1 Sufficiency s40(2)(a):

Not only does the invention claim all strains of HCV, it includes other viruses which may or may not cause non-A Non-B hepatitis (NANBH), and which may not yet have been identified. Yet the only disclosure is to the cDNA sequence of part of the genome of one strain of HCV and the polypeptide sequence encoded by that cDNA sequence. Accordingly, the specification does not provide sufficient information to enable persons skilled in the art to identify and make the invention for those other strains and species of virus, or indeed for that part of the genome and polypeptide sequence yet to be determined in the identified strain. Further, insufficient information is given as to how to produce epitopes or antigenic determinants of HCV, how to determine whether they will be useful as diagnostic assays, and how to produce those assays.

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159 I would like to thank Luigi Palombi of Banki, Palombi, Haddock and Fiora for providing me with this information.

4.3.2 Definition s40(2)(b), clarity and ambiguity s40(3):

A wide range of the terms used in the claims and specification are alleged to lack clarity and succinctness and to be ambiguous and uncertain.

4.3.3 Fair basing s40(3):

- Of the Australian patent on earlier patents:

  Earlier US patents were claimed by Chiron to give an earlier priority date to the Australian patent. Murex alleges that the Australian patent application is not fairly based on them.

- Of the claims on the specification:

  The claims are too wide because they include other viruses and agents which may or may not cause NANBH. There is no support in the specification for such claims, or to claims including polynucleotides or polypeptides that do not comprise epitopes or antigenic determinants for HCV, or to kits, assays or methods for detecting HCV, or to vaccines for the treatment of HCV infection.

In essence the arguments under each of these heads are the same as those used in the UK *Chiron* case: whether the claim to a chemical containing antigenic determinants for HCV was a claim to more than one invention, in which case it was neither supported by the description in the specification, nor did the specification sufficiently disclose the method for making the invention across the whole width of the claim. The Australian cases in which the interpretation of section 40 has been considered give nothing but the most general guidance as to how Burchett J might have undertaken his task in the *Murex* case. If his Honour had used a similar interpretation to that used in the UK case it would have given a signal that the Federal Court might not look unfavourably on broadly drafted patent claims in this area. Using the rationale of the House of Lords in *Biogen*, however, the claims made by Chiron would appear to be impermissibly broad.

Without denying the necessity of providing appropriate protection to patentees, the deleterious consequences of upholding broadly drafted claims must also be recognised. Those effects could be far reaching and oppressive to researchers, competitors, service providers and consumers alike. Moreover, they could give fuel to those lobbying against patenting on ethical grounds, because the

breadth of such claims is tantamount to claiming ownership of the virus and its genome, the very things that those in favour of patenting argue are not within the ambit of the patent system.

Lord Hoffmann justified his decision in *Biogen* on this basis: that further research and healthy competition should not be stifled by allowing the first person who has achieved a desirable goal to monopolise every other way of doing so. The difficulty with this decision, however, is that patent claims drafted appropriately may have little value. In the case of Biogen's invention, for example, all that Biogen had done was to solve a particular problem that stood in the way of achieving a known goal by means that were generally known, the inventive idea being in solving the problem. As such Biogen could only claim the means by which the problem was solved to achieve the goal. Once the problem was solved, the goal was achievable with or without that particular solution, and therefore if the patent was restricted to that particular solution it could easily be avoided by competitors.

Conclusion

Thia analysis has shown that not all of the inventions associated with human genetic research can be patented and that the existing patent system in Australia has considerable scope for regulating the extent of patenting in this area. The manner of manufacture test and associated case law exclusions, together with the novelty and inventive step requirements and the specification requirements in s40 provide a basis for enabling the courts and the Patent Office to exclude from patenting claims which are cast so broadly as to be tantamount to asserting ownership over entire genes and all subsequent uses of those genes. The lack of case law in Australia and the variability in interpretation of these requirements by different judges in the same courts in England mean that the precise parameters for this regulation remain to be determined. My submission is that because these parameters are presently uncertain the normal patenting criteria cannot be relied on to provide the only limitations on patenting of human genetic material. Therefore it is necessary to ensure that other more clearly defined limitations are also available. I argue in the next chapter that those limitations can be provided within the patent system.

With regard to the normal patenting criteria, the manner of manufacture test ensures that patents are granted only for inventions that have industrial applicability, and together with the discovery exclusion, it prevents patent protection from being claimed too far upstream. DNA sequences of unknown

function lack the requisite applicability and naturally occurring sequences are discoveries par excellence. There is every justification for excluding these from the patent system. Although the statutory exclusion in s18(2) has little application, and the amendment to s18 proposed by the Australian Democrats is unlikely to be adopted by Parliament, the exclusions incorporated through s6 of the *Statute of Monopolies* present a real opportunity to exclude patents for inventions contrary to the public interest, and these provisions should be used accordingly. It can hardly be in the public interest for a single person to be able to exclude all others from all research involving a particular gene sequence. The difficulty will be in determining how far outside the true invention the patent should extend: too narrow and the patent will have little value; too broad and the effect will be equivalent to patenting all future use of the gene sequence.

The parameters of the novelty, inventive step and disclosure requirements are exceedingly flexible, and the courts and the Patent Office must have guidance as to the appropriate extent of those parameters. I argue that there may be some justification for allowing a liberal interpretation. Broad protection is needed for upstream patents if they are to have any value, because it is too easy to invent around narrower claims. The deleterious effects of such broad claims, for example those including all the methods for producing a particular product, can be ameliorated if others are able to continue to work in the general area of the claims and can make downstream claims to patents for new products or processes within that general area. By this means downstream research will not be impeded, rather, there will be continuing incentive to do that research. In this respect, if a restrictive interpretation were given to the novelty and inventive step requirements, it would be more likely to deny patents to downstream inventors than to upstream inventors, because many more aspects of the invention would be already known or thought of. This is inappropriate, because downstream inventions are closer to the stage of clinical application and therefore they are likely to provide greater possible benefit to the public. Nevertheless, there are some potential disadvantages with this suggestion:

- Upstream patentees may claim broad patents and refuse to grant licences;
- Licence fees may be set at unreasonably high levels, which could become excessive for later downstream users who may have to pay fees to a number of patent holders;
- Owners of upstream patents who subsequently claim downstream patents in the same area may be able to extend artificially the life of their upstream patents.

Use of the compulsory licensing provision and establishment of guidelines for setting licence fees may do much to lessen these disadvantages, These provisions are discussed in more detail in the next chapter.

The settlement of the *Murex v Chiron* case out of court has done nothing to improve the certainty of the law. Indeed, it has sent a wave of disappointment through the patent law community. Moreover, it means that a patent which is now generally recognised as being invalid is being enforced. Nothing can be done about this unless another party is willing to challenge the validity of the patent in fresh revocation proceedings. On the other hand, because there is general agreement that the patent would have been susceptible to revocation, this would indicate that similar patents may suffer the same fate. Whether this means that competitors will be more willing to bring revocation proceedings or that patentees will be more willing to grant licences to competitors to avoid the chance of revocation remains to be seen. With respect to the development of patent law, the former option is clearly more favourable, but in terms of commerce, the latter is more likely to eventuate.

CHAPTER 7: STRIKING THE RIGHT BALANCE: IS THERE A NEED FOR REFORM?

Introduction

Human genetic research will have an increasing effect on health care in Australia for many years to come as technologies for delivering diagnostic tests and therapeutic treatments improve and knowledge of genetic disease expands.[1] The biotechnology industry is a major player in human genetic research. It is a recognised fact that this industry protects its investment in research and development through patents.[2] I can see no reason why it should choose another source of protection for its investment in human genetic research.

Inevitably, the effect of patenting of human genetic research will be felt within the health care system. It must be remembered, however, that the health care system has been exposed to the effect of patents in the pharmaceutical industry for some years, and this, together with an increasing requirement to justify its functioning in economic terms, means that economic considerations are not totally alien to it.[3] Perhaps the effects of patenting will be more profoundly felt in academic institutions which, in the past, have been shielded from such commercial influences.[4] The biotechnology industry itself is not immune from the patenting debate. Those companies which are focusing on sequencing the human genome would prefer patent protection to be as far upstream as possible, whereas those companies which are predominantly interested in developing diagnostic and therapeutic techniques prefer more downstream protection.

One major assurance can be made about patenting of human genetic research - that DNA sequences of unknown function are not patentable.[5] In other respects, however, my analysis of the Australian patent legislation and case law has shown that the patentability of human genes and gene sequences

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1 These issues were discussed in detail in Chapter 3.

2 Relevant statistics are presented in the introduction to Chapter 5

3 See Chapter 5, at 3.1.

4 Chapter 5, part 2.

5 See the discussion in the introduction to Chapter 6.

has some uncertainties.[6] The way in which the patent legislation is currently interpreted by patent examiners indicates that, although there is provision in the Australian legislation to exclude from patenting some aspects of human genetic research and its applications in addition to gene sequences of unknown function, those provisions are not being used. It is far more likely that patent issues will be decided in this area on a case by case basis through consideration of the normal patenting criteria, principally novelty and inventive step, as well as the specification requirements.

The main theme that I have tried to present in this thesis is that the debate should not be about whether human genetic material should be patented but about the boundaries within which the patent system should be allowed to function. The difficulties in this area are not with patenting genes and gene sequences *per se* but with broad upstream patents that include all the products and processes of a particular gene sequence or broad downstream patents that include all of the methods of producing a particular product. The novelty, inventive step and specification requirements in patent law provide means by which broad claims can be defeated, although the parameters within which they are to be applied have not yet been explored in Australia. In England these requirements have been decided on an *ad hoc* basis, with no clear guidelines developing from the cases. My submission is that we must look elsewhere to ensure that the detrimental effects of broad claims are minimised.

There is justification for allowing broad upstream and downstream claims for genetic inventions. The unique features of genetic material that have been discussed in previous chapters require that claims extend outside the ambit of the invention if patents are to have any real value. I suggest that it is generally appropriate for the first invention in a particular area to be allowed broad coverage, provided that mechanisms are in place to allow others to work the invention in exchange for reasonable licence fees and provided that those other workers can acquire the benefits of more limited secondary patents. In some circumstances, however, it will not be in the public interest to allow broad patents, and in these cases it should be possible to challenge the validity of patents on the basis of the public interest.

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6 See generally Chapters 2 and 6.

The patent system requires that the Patent Office gives the patentee the benefit of the doubt when the patentability of a given invention is open to question.[7] The rationale for this is that the validity of the patent can be challenged at any time during its 20 year life. The Patent Office then adapts its practice in accordance with judicial rulings. Although in principle sound, this system fails if there are insufficient challenges to the validity of patents in a given area. This is precisely the problem being encountered for biotechnology patents in Australia. There have been no cases in which judicial rulings have been made as to the patentability of genes and gene sequences. The *Murex v Chiron* case offered the first opportunity for such a ruling, but out of court settlement prevented this. Challenges to the validity of patents are generally made by competitors in Australia.[8] The public interest is of minor importance to the parties in such challenges, commercial success being the prime consideration. It is easy to see why parties to such litigation would be tempted to reach out of court settlements. Even if the public interest is put in issue by the parties, the judiciary has shown a reluctance to decide matters on the basis of ethics alone when there is no firm foundation for such considerations in law.

The patent system can be changed, either by lobbying Parliament to modify the legislation or by bringing legal action in order to obtain a judicial ruling on the interpretation of the legislation. In proposing any solution to the patenting question it is essential to bear in mind the stance of the government on this issue and the influence of the international debate. Proposed solutions are only of value if there is a possibility that they will be implemented. The following statement is particularly pertinent:

> "it is in our national interest that we [inter alia] resist attempts to restrict patents in sensitive areas where we are proficient, particularly in the areas of computer programs, biotechnology, life forms and plant genetics. Restrictions on the patenting of inventions relating to higher non-human organisms and methods of medical treatment contained in the European Patent Convention can operate to the disadvantage of Australia which is a significant contributor to inventions in this field. Australia should endeavour to exert diplomatic pressure to reduce the influence

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7 See Chapter 2 at 3.6.

8 Note that this is not always the case in Europe: a range of interest groups opposed the Onco-mouse patent; Greenpeace opposed the Plant Genetic Systems patent and the European Greens challenged the H2-relaxin patent (see Chapter 6, section 1.3).

of these restrictions internationally and should be resistant to political pressure to introduce such restrictions in Australia."[9]

This statement is a good indicator of the federal government's position in relation to patenting of human genetic research. The government will be unwilling to impose restrictions which may impede Australia's contribution to the research effort unless there is adequate justification to do so. With this in mind, I will first assess the options for removing some aspects of human genetic research and its applications from the reach of the patent system and for giving them alternative sources of protection. It is my view that none of these options are appropriate at the present time. It is more appropriate to level the playing field of the existing patent system to better protect academic research and the public interest from its excesses. Options to do so will be discussed later in this chapter. The chapter ends with a series of key conclusions which follow from my analysis in the preceding chapters.

Part 1: Specific Legislative Exclusions

One of the immediate responses to the problems associated with patenting is to suggest ways in which certain aspects of human genetic research should be removed from the ambit of the patent system. Such suggestions imply that the patent system itself is inadequate and unable to meet the needs of new technology. There is no evidence that this is the case for other new technologies. Indeed, the patent system has proved itself to be quite capable of adapting. It may be an old system, but it does not necessarily follow that it is out of date. Human genetic technology is perhaps advancing at a greater rate than most other new technologies and the issues associated with it may be of more pressing concern. Whether this means that immediate action should be taken to rectify shortfalls in the patent system is an open question. What can be said with some certainty is that such action should be taken only if it will actually ameliorate the problems.

1.1 All Biotechnological Inventions

The removal of all biotechnology inventions from the ambit of the patent system has been advocated. But to do so without providing some other

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9 Working Group of the Prime Minister's Science and Engineering Council, *The Role of Intellectual Property in Innovation. Strategic Overview, Volume 2* (1993) AGPS, 64.

form of protection for investment is likely to be detrimental to health care in Australia. Companies are unlikely to be willing to invest in biotechnology research without some guarantee of recouping that investment. One of the problems with this particular type of research is that the initial phase of identifying and sequencing genes is especially cost and labour intensive. Once a gene has been identified and its function determined, competitors can adopt the benefits of that knowledge unless it is either kept secret or protected by a patent or by some other form of protection. Of the alternatives suggested below in Part 2, it is difficult to see how any would provide a better balance than that currently available through the patent system.

1.2 Gene Sequences of Unknown Function

Accepting that it is inappropriate to deny protection to all forms of biotechnology inventions (unless a better system of protection is introduced), there may still be specific areas that should be excluded. The patent claims that elicited most concern throughout the world were the NIH claims to DNA fragments of unknown function (ESTs). The fears raised by those claims are illusory. It is most doubtful that ESTs or other sequences of unknown function would be patentable in Australia, or in any other jurisdiction. Indeed, the argument that gene sequences are pre-patentable until function is ascribed is sound. The patent system as it stands accommodates this argument by requiring that the invention is industrially useful (a manner of manufacture in Australia), novel and non-obvious.

1.3 Gene Sequences of Known Function

There are obvious problems to society with patent claims to particular genes both for moral reasons and because patents could effectively exclude all future use of those genes by competitors. This may be detrimental to the health care system because it could impede the production of diagnostic tests and therapeutic treatments for particular genetic diseases. Companies will be likely to target genes which are responsible for the most prevalent genetic diseases because there the economic rewards will be greatest. Yet these are the same diseases for which there is the greatest need for medical intervention. A framework should be put in place to encourage individuals to carry out research on these genes, but at the same time it should not exclude other

individuals from that research. One possible option is the exclusion of genes and gene sequences from the ambit of patent law.

Some English cases indicate that patentees are willing to accept that gene sequences, even when they have known function, are unpatentable discoveries.[10] But given that novelty and inventive step can still reside in the discovery, very little ground is actually being conceded.[11] The only things that are prevented are claims to inventive methods using the discovery that are cast in such broad terms as to become, in effect, claims to the discovery itself. Provisions of this type may provide a check on broad claims which attempt to exclude all subsequent use of a particular gene or gene sequence. They will only be of practical value, however, if guidelines can be prepared for Patent Office examiners as to the acceptable breadth of patent claims in this area. Unless this can be done, judicial consideration will be required of the breadth of claims made in the patent on a case by case basis. This is both costly and time consuming. Patentees will be encouraged to cast their claims as broadly as possible, and competitors may decide to accept broad claims in return for suitable licensing arrangements.

The amendment to the *Patents Act* 1990 proposed by the Australian Democrats seeks to remove naturally occurring genes and gene sequences from the ambit of the patent system.[12] If this amendment were interpreted as denying patent protection for all genes and gene sequences, inventors in the area would have to rely on patents claiming protection for processes using the genes and gene sequences or products resulting from their use, which appears to be the position in England. On its face, this form of protection would be narrower than patents on the genes themselves and there may be a greater chance that such claims would be held to lack novelty and inventive step. Much would depend on the extent to which the Patent Office and judiciary would allow patent claims to extend outside the scope of the invention, and whether novelty and inventive step could reside in the discovery from which the invention arose, as in England.

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10 See particularly *Chiron Corp v Murex Diagnostics Ltd(No. 12)* [1996] FSR 153.

11 See Chapter 6 at 1.3.1.

12 See Chapter 6 at 1.2.3.

The more likely interpretation of the Democrats' provision is that it would be strictly applied, only preventing the patenting of genes and gene sequences in their natural state. It is generally recognised that exceptions to patenting should be given a narrow reading. Given the current state of gene technology, any gene or gene sequence would have to be isolated and capable of production in its recombinant state to be industrially useful and therefore patentable. As such it would not run foul of the first two parts of the Democrats' amendment. The third part excludes the description of the base sequence of the naturally occurring gene or gene sequence. If the base sequence is the same for the gene in its natural and recombinant state then arguably the sequence could not be claimed. Since recombinant genes are generally produced as cDNA copies of mRNA, however, the base sequences will not be the same as for their naturally occurring counterparts. Hence such claims will not fail on the basis that they are discoveries or that they lack novelty.

Existing patent legislation probably already prevents the patenting of naturally occurring genes and gene sequences because they are discoveries, although the line between discoveries and inventions is very blurred in this area.[13] The Patent Office presently accepts claims to gene sequences, but only in their isolated or recombinant state. The Patent Office would, of course, have to change this practice if the courts decide otherwise or if the legislation was amended. It would take an amendment of the type proposed by Senator Coulter in 1990, which included in its prohibition from patenting "a gene or genes, whether derived from cells or chemically synthesised" or a judicial ruling expressed in similar terms to have any real effect on current Patent Office practice. The desirability of such a broad prohibition would have to be carefully weighed. It may be appropriate to exclude some, but not all genes, the appropriate focus being what is in the public interest. The issue of patenting in the public interest is more fully explored in Part 4.

1.4 Methods of Medical Treatment

Following the decisions of Gummow J and the majority of the Full Federal Court in the *Rescare* case,[14] methods of medical treatment are not

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13 The discovery/invention dichotomy is discussed in Chapter 6 at 1.1.1.

14 *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1993) 25 IPR 119; *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 28 IPR 383. See Chapter 6 at 1.1.3.

excluded from patenting in Australia on the basis that they are not manners of manufacture. This is inconsistent with Europe, where the exclusion has legislative force,[15] and disregards the provision in the GATT TRIPS Agreement which specifically allows for such exclusions. Given that products used in medical treatment can be patented, it is difficult to see why the methods themselves should be singled out for exclusion, particularly when the product claims can be drafted in such a way as to be tantamount to claiming the method as well. Unless the legislature is prepared to exclude both the products and the processes involved in medical treatment, and this must be seen as being highly unlikely and not necessarily desirable, I suggest that there is little justification for excluding only the processes.

Part 2: Other Forms of Protection

Suggestions have been made in the literature for a number of forms of protection outside the patent system which might better achieve a balance between the conflicting interests of society, academic researchers and the health care system on the one hand and the biotechnology industry on the other (if indeed such a conflict exists and if the camps are so obviously in opposition). The main focus of attention has been in providing for the protection of sequence information. Forms of protection that have been suggested include:

2.1 Copyright Protection

The fact that the information in gene sequences can be recorded in a simple sequence of letters (for example, ATTTCCGGAA, etc.) has led some to suggest that copyright may be a more appropriate form of protection than patenting. This option was raised some years ago[16] and has recently been revived in Britain following the new edition of *The Modern Law of Copyright and Design*.[17] It has been suggested that the sequence of letters constitutes a

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15 Discussed in Chapter 6 at 1.3.2.

16 For example, Burk, D., "Copyrightability of Recombinant DNA Sequences" (1989) 29 *Jurimetrics Journal* 469.

17 By Laddie, H., P. Prescott and M. Vitoria, (1994) Butterworths, London, second edition. The issues raised in the book have been discussed in two recent articles: Speck, A., "Genetic Copyright" (1995) (5) *EIPR* 171; Karnell, G.W.G., "Protection of Results of Genetic Research by Copyright or Design Rights?" (1995) (8) *EIPR* 355.

literary work and that the use of this published sequence to make a DNA sequence or protein constitutes infringement. Copyright lawyers would appear to be willing to accept that the sequence of letters may be a literary work, but are less willing to concede that the use outlined above does in fact constitute infringement.[18] Copyright protection only extends to protection of the originality of the work, and the only things that could be described as original are the elucidation of the sequence and its transcription into understandable language. Accordingly, it has been argued that the DNA sequence is not part of the original work and copyright will only protect against copying the sequence of letters and not copying of the DNA sequence itself.[19] As such, copyright does not provide an appropriate form of protection.

The are other policy reasons why the copyright alternative is not acceptable. In particular the length of copyright protection, the life time of the author plus fifty years, is far longer than what is reasonably required.

2.2 Sequence Rights

Some people, including Luigi Palombi who was the solicitor for Murex in the *Murex v Chiron* case, have suggested that a new form of protection should be developed which would provide certain rights over particular gene sequences.[20] Those rights would not be akin to ownership, but would provide acknowledgment and remuneration for valuable work.

The state of play has changed considerably since those suggestions were made. It has recently been agreed within the community of scientists who contribute to the human genome project that all sequence data should be released as rapidly as possible onto a publicly accessible database.[21] In coming to these agreements the parties have effectively given up any opportunity to claim rights to those sequences. Claims to genes or gene sequences must therefore now include information as to a new method of sequencing a particular sequence or as to its function, since otherwise they will not possess any of the

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18 *Ibid.*

19 *Ibid.*

20 Personal communication with Luigi Palombi of Banki, Palombi, Haddock and Fiora, 23 July 1996.

21 See Chapter 5 at 2.2.3.

requisite novelty or inventive step. Now that DNA sequences are publicly accessible, it would be most inappropriate to provide an additional form of protection.

2.3 A New Biopatenting System

One of the other, more broadly ranging reforms that has been suggested is the creation of an entirely new system for the protection of biotechnology inventions. Thomson, for example, has proposed such a system on the basis that the patent system has inadequacies and none of the other existing systems provide a suitable alternative.[22] Her system would create the same rights in the patentee as the patent system does, namely the exclusive right to exploit the invention and to licence others to exploit it. It could include staged forms of protection to take account of differences between improvement patents and patents for new inventions.[23] The biopatent system would give three different types of protection for products, processes and products from processes. One of the more radical changes that Thomson has proposed is the possibility of a one-off payment to the patentee by the government in return for disclosure and tendering of the invention by the government to biotechnology companies. She has also included mechanisms for clarifying the novelty and inventive step requirements.

Although such proposals are not without merit, I think that it is highly unlikely that government will have the motivation to provide such a system unless the patent system is seen as being totally inadequate. There may be some problems with the patent system in its present form, but it is certainly not failing completely. Moreover, I doubt that Thomson's biopatenting system offers sufficiently radical changes to justify its implementation. Slight modifications to the existing patent system may provide many of the same features.

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22 Thomson, J.A., *Biopatenting the Splice of Life: A Consideration of the Interface between Biotechnological Inventions and Patent Law* (1994) Ph.D. Thesis, University of Western Australia, Chapter 10.

23 *Ibid.*, at 408.

Part 3: Ameliorating the Effect on Academic Science

Academic researchers will inevitably feel the effects of the patent system in the future, if indeed they have not done so already. From one side, funding agencies are likely to pressure them to patent inventions arising out of their work and transfer technology to industry. And from the other side, scientists may be exposed to infringement proceedings or demands for royalty payments or licence fees for the use of patented material. If we continue to value this type of research then it is necessary to provide some sort of shield from the potential detriment that patenting may create.

3.1 Grace Period

One of the difficulties that patenting creates for researchers is that they cannot publish research results as early as they would otherwise do because publication may destroy the novelty of an invention arising out of their research. In many circumstances, material will be ready for publication some time before it is in patentable form. Since the sharing of the results of research through publication in peer-reviewed journals is a requisite component of the culture of science, any restrictions on the freedom to publish are undesirable. If the patenting option is to be accepted by academic researchers a mechanism must be put in place to minimise any restrictions on the freedom to publish.

In the USA, novelty is not measured at the time that the patent application is submitted but one year prior to claiming. This one year "grace period" enables researchers to publish their research results up to one year before submitting the patent application without risking loss to novelty. Further, and as a necessary corollary to this requirement, it is the first to invent and not the first to claim who takes priority. The one year grace period is one way of reconciling the conflicting goals of academia and the patent system because it allows scientists to publish in a timely fashion and to continue to refine the research results in such a way as to be able to claim inventor's rights up to one year later. Joseph Straus, who chairs the HUGO Intellectual Property

sub-committee has strongly endorsed world-wide adoption of the grace period provision.[24]

In Australia, two advantages akin to the one year grace period are already available in existing legislation. First, in determining novelty and inventive step, section 24 of the *Patents Act* 1990 provides that validity of a patent is not affected by publications or use in certain prescribed circumstances.[25] This provision is more limited than the US grace period, both in extent and duration. Nevertheless, it does provide the inventor with some capacity to discuss research results in public before submitting a patent application. Secondly, section 38 of the *Patents Act* 1990 allows for completed applications to be associated with provisional applications at any time during the prescribed period of 12 months.[26] Where this is the case, the complete application acquires the priority date of the provisional application. The provisional application is required only to describe generally the nature of the invention.[27] The priority date of the provisional application can be claimed provided that the complete application is fairly based on the provisional application. By these means the inventor can submit a general overview of the invention to the Patent Office and then is free to publish the invention prior to submitting the more detailed claims and specification. These two provisions may provide sufficiently similar advantages to the US grace period that no changes to the Australia patent system are required in this respect.

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24 See, for example, Straus, J., "Intellectual Property Issues in Genomic Research" (1996) 3(3) *Genome Digest* 1. Professor Straus strongly affirmed this view at the recent *Genome Summit* of the Human Genome Organisation (1996) 16-18 October, Canberra.

25 The circumstances that are prescribed are set out in the Patents Regulations 1991, regulation 2.2(2). They include (a) showing or using the invention at recognised exhibitions, (b) publication of the invention at recognised exhibitions, (c) publication of the invention in papers read before learned societies or published by or on behalf of learned societies and (d) working in public of the invention within 12 months of the priority date for reasonable trial of the nature of the invention requires this. Regulation 2.3 provides that the prescribed period for (a), (b) and (c) is 6 months, and 12 months for (d).

26 Patents Regulations 1991, regulation 3.10.

27 See Chapter 2 at 4.2.3.

3.2 Exemption from Patent Infringement for Academic Research

According to section 13(1)*Patents Act* 1990,

> "... a patent gives the patentee the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention."

The word "exploit" is defined in Schedule 1:

> "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;"

The patent will be infringed whenever a person without licence does an act in relation to the patent which only the patentee or licensee has the exclusive right to do through section 13. Accordingly, pure research could be considered to be exploitation and as such it would be susceptible to infringement proceedings through section 120. There is no provision for exemptions from infringement for acts done for non-commercial research purposes under existing Australian legislation, and neither the *Patent Regulations* 1991 nor the Practice Notes 1991 provide guidance as to the extent to which acts of this type constitute infringement. Furthermore, there has been no judicial consideration in Australia of the extent to which research is exempt from infringement proceedings. It has for some time been accepted in the case law in other jurisdictions, however, that where acts are done solely for the purpose of *bona fide* experiments they will not constitute infringement.[28]

In Europe, the *European Patent Convention* provides express exemption from infringement for experimental purposes,[29] and in the USA, a case law defence of experimental exemption from liability is also available against patent infringement. Until recently, the US exemption has been read narrowly.[30]

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28 See, for example, *Frearson v Loe* (1878) 9 ChD 48.

29 For example, see section 60(5)(b) *Patents Act* 1977 (UK).

30 For example in *Roche Products Inc v Bolar Pharmaceutical Co* 733 F 2d (1984) the court characterised the exemption as being truly narrow.

Eisenberg has suggested that there is some indication in more recent cases of a willingness to extend the ambit of the defence.[31]

Presently there is very little indication that patentees are generally enforcing their patent rights against academic researchers. If they were to do so in any systematic way, much of the research conducted in the academic arena could at the very least become more expensive through payment of licence fees and more time consuming through licence applications. At the worst, some research may actually be prevented if licensing was refused by the patentee. For such reasons, there is some justification for an explicit research exemption in the patenting legislation to ensure that research having no commercial implications is not impeded.

Many of the potential hardships to scientists created by the patent system could be softened if this defence was more clearly stated in Australia and elsewhere, and even given statutory recognition. On the one hand, it may be appropriate to allow all forms of basic research exemption from liability. On the other hand, however, where research has an ultimate commercial purpose there may be legitimate reasons for insisting on enforcement of patent rights. The issue then becomes how far downstream must the commercial purpose be realisable. It was held in a New Zealand case that field trials of a herbicide were a stepping stone to a full commercial launch and hence constituted infringement.[32] On this basis, clinical trials for gene therapy or genetic screening tests could be infringing acts. It could be argued even more broadly that all human genetic research has an ultimate commercial purpose. Difficulties will inevitably arise in setting the limits on the types of research that have no commercial implications. It should also be pointed out that the commercial applicability requirement of some inventions lies in their use as research tools. Eisenberg has pointed out that it is not in the public interest for research exemptions to be claimed against these types of inventions, because to do otherwise would defeat the purpose of granting a patent.[33] Any provision

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31 Eisenberg, R.S., "Patents and the Progress of Science: Exclusive Rights and Experimental Use" (1989) 56 *University of Chicago Law Review* 1017, at 1018.

32 *Monsanto Co v Stauffer Chemical Co (NZ)* [1984] FSR 559.

33 Eisenberg, R.S., "Patents and the Progress of Science: Exclusive Rights and Experimental Use" (1989) 56 *University of Chicago Law Review* 1017, at 1078.

allowing for exemption from infringement will require very careful formulation.

3.3 Release of Sequence Information and Broad Patent Claims

By the year 2005 it appears likely that the entire sequence of the human genome will be available on the Internet. Release of sequence information into the public domain will ensure that patents cannot be claimed for DNA sequences of unknown function because they will lack the requisite novelty, as well as commercial applicability. The release of sequence information may also have an effect on more downstream claims to patents for genes and gene sequences of known function, although the House of Lords decision in *Asahi Kasei Kogyo KK's Application*[34] makes it clear that in that jurisdiction an invention will not lose its novelty merely because its formula is already known since the method of making it must also have been made available to the public. It must be remembered, however, that the methods of making particular gene sequences are now fairly routine. As such, the novelty and inventive step requirements may be denied satisfaction if both the method of making the sequence and the description of the sequence are known. Where this is the case, the novelty and inventive step requirements would have to reside in the use of the sequence, either in the form of a particular product or a particular process. This will considerably decrease the scope of patent claims because it will be outside the ambit of the invention to claim all subsequent use of a particular gene.

This valuable contribution of scientists to the public domain should not be underestimated, even though it is not strictly necessary in terms of patent law, since DNA sequences of unknown function are unpatentable. Its primary benefit is that it may renew public faith in scientists as working for the public good rather than for their own gain. It may also curtail speculative patent claims to gene sequences encompassing all future uses. If the value of this offering is to be secured, it is vital that patent examiners vigilantly monitor the ambit of patent claims. In this respect Australian legislation is much more satisfactory than existing European legislation because it enables challenges to be made to broad patent claims at the opposition and revocation stages on the

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34 [1991] RPC 485.

basis that they are not fairly based on the description of the invention in the specification.[35]

In interpreting the specification provisions and other patenting requirements, however, it is important that the Patent Office and the courts should not restrict patent claims to such an extent that they become valueless. In this regard, it may be appropriate for these bodies to allow claims to extend outside the true limits of the invention, particularly where the invention is a new product or process. The detrimental effect on future research in the general area of the claims can be ameliorated first by allowing new and subsequent uses of previously claimed inventions to be patented, provided that this does not enable patentees to artificially extend the life of exhausted patents; secondly, by allowing compulsory licensing of certain patents; and thirdly, by preventing anti-competitive licensing agreements through Part IV of the *Trade Practices Act* 1974 (Cth).[36]

Part 4: Patenting in the Public Interest

4.1 A Morality Clause

The *European Patent Convention* and mirror State legislation provide the only statutory recognition of the need to address morality issues in the patenting of some inventions.[37] Provisions of this nature may be justified solely on the basis of public concern about patenting in some areas and the need to provide a forum to debate such issues. On the other hand, patent examiners have expressed concern that they simply do not have the expertise to adequately assess ethical concerns.[38] What, then, is the appropriate forum? Clearly the ethical appropriateness of the research leading towards the invention and the application of the inventive idea into practice are matters for government regulation, either in the form of research guidelines or legislation. What of patenting such inventions? Are we to assume that if the research and practice themselves are ethically appropriate then so too is their patenting?

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35 See Chapter 2 at 4.2.3 and Chapter 6 at 4.2 and 4.3.

36 The compulsory licensing and TPA options are discussed below at 4.2 and 4.3.

37 Discussed in Chapter 6 at 1.3.3.

38 One famous comment rumoured to be made by an examiner at the European Patent Office was that they wished for a transgenic cat to eat the transgenic mouse.

With respect to patenting of genes there are competing ethical considerations focusing on the desire to alleviate suffering versus the desire to keep things that are common to all mankind as part of the common heritage of mankind. Clearly no one person should be able to assert ownership rights over the entire human genome. It is quite another matter whether an individual can claim an exclusive right to exploit a particular gene or gene product for a limited time. In many circumstances it may be ethically appropriate to grant such exclusive rights if it ensures that research of this nature continues. In others, however, particularly where exploitation rights are being claimed to genes which play a role in common and/or severe diseases, it may be more appropriate to retain open access. In these circumstances value judgments must be made on a case by case basis. It may be appropriate for Parliament to provide guidance as to the factors that should be taken into account in reaching such decisions, but ultimately it will be for the courts or the Patent Office to address these issues. This could be effected in one of a number of ways:

- through compulsory licence applications in section 133 of the *Patents Act* 1990 (Cth);
- through applications under Part IV of the TPA to have anti-competitive licensing conditions set aside; or
- through revocation proceedings based on the "general inconvenience" provision from the *Statute of Monopolies.*

Each of these options is discussed below.

4.2 Compulsory Licensing in the Public Interest

At present the compulsory licensing provisions in the Australian *Patents Act* are rarely used.[39] In some circumstances it may be appropriate for these provisions to be given greater force. The hepatitis C scenario is an obvious example of a situation where it would be in the public interest to encourage further research into the production of diagnostic tests and vaccines.[40] It may well be in the public interest for compulsory licences to be granted to enable extensive research into some of the more prevalent genetic diseases and diseases with genetic components. Potential licensees should be encouraged to

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39 See Chapter 2 at 2.1.1.

40 The hepatitis C scenario was discussed more fully in Chapter 5 at 3.3.2.

apply to the courts for compulsory licences in such areas of research whenever patentees express reluctance to provide licences voluntarily.

The combination of broad primary patents, narrower secondary claims and compulsory licensing will enable those who are successful in the early research and development phase to be rewarded for their inventiveness, but not at the risk of closing off the opportunity for subsequent research to others. It should be noted, however, that this may be detrimental to downstream licensees who will be required to pay licence fees to a chain of inventors as initial inventions become more refined and sophisticated through subsequent inventions in the same area.

4.3 Anti-Competitive Licensing and the *Trade Practices Act* 1974 (Cth)

The aim of Part IV of the TPA is to prevent abuse of market power, although section 51(3) gives patentees some protection from the full rigours of Part IV.[41] It is not in the public interest for patentees to be allowed to impose licence conditions that are overly harsh on licensees. In particular, it is inappropriate for patentees to set licence fees at such high levels that they have the effect of excluding potential licensees who have the ability to make valuable contributions to the research effort. It would seem to be more appropriate in these circumstances that the Patent Office sets, collects and distributes licence fees. Further, the full force of Part IV of the TPA should be available against licensing agreements that are not in the public interest. This may require removal of s51(3). The extent to which s51(3) prevents challenges to licence agreements which are not in the public interest must be examined.

4.4 Defending the Public Interest

The fact that the whole of section 6 of the *Statute of Monopolies* is incorporated into the *Patents Act* 1990[42] means that the focus of inquiry into the validity of a particular patent does not rest solely on satisfaction of the patenting criteria. An investigation can also be made into the appropriateness of granting monopoly rights for that particular invention. There is no reason why the general inconvenience exclusion cannot be raised against the patenting

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41 Discussed in Chapter 2 at 2.1.2.

42 See Chapter 6 at 1.2.2.

of certain genes. The benefit of inquiries of this nature is that patent examiners and judges need not base their assessments of the merits of the arguments solely on ethical considerations. Some of the issues that should be taken into account in determining the balance between providing the patent incentive against the incentive of free access may include:

- present costs to society of the disease in question;
- the likelihood that treatments will eventuate more rapidly if more research teams are working in the area;
- the amount of time and effort already dedicated to the research effort both by the patentee and by competitors; and
- charges made by the patentee for use of the invention.

The *Patents Act* gives jurisdiction to make challenges to the validity of patents based on the general inconvenience provision at both the opposition and revocation stages. The issue remains as to who might bring such challenges. It is doubtful that it would necessarily be in competitors' interests to focus on this public interest provision.[43] Although public interest bodies have not made challenges to patents in Australia in the past, there is nothing preventing them from doing so. Sections 59 and 138 allow the Minister "or any other person" to apply for opposition or revocation of a patent. As such, there is no requirement that the person making the challenge has an interest greater than an ordinary member of the public.[44]

The problem with any public interest litigation is its cost. Even if the challenge is successful and costs are awarded against the patentee, full recovery is unlikely. Most other public interest litigation has the advantage of the possibility of a damages award. The only thing to be gained by challenging the validity of a patent is that it will be revoked, unless an account of profits is ordered. On the other hand, it will only take one or two successful challenges on the basis of general inconvenience for the Patent Office to be required to modify its practice and make specific provision for consideration of the public interest. This feature of the Australian patent system makes it worthwhile to

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43 Note that one of the grounds for revocation raised by Murex in the *Murex v Chiron* case was that the invention was generally inconvenient.

44 As required when standing is limited to "interested persons": *Boyce v Paddington Borough Council* [1903] 1 Ch 109; *Australian Conservation Foundation Inc v Commonwealth* (1980) 146 CLR 493.

bring a small number of test cases before the courts. Public interest bodies such as the Environmental Defenders Offices may well be the appropriate parties to initiate such actions. They should be encouraged to look into the possibility of constructing challenges to patents for inventions which have clear public interest components to them. Funding could be sought from a number of arenas, including medical, scientific and government sources.

4.5 Compulsory Royalty Payments for Research Subjects

The most clear connection between the issues associated with the science of genetic research and those associated with the patenting of that research is in the area of access to human tissue. The law in this area is by no means clear in that it has yet to be determined whether use of the tissue should be contingent on informed consent to that specific use by the donor.[45] It does seem unfair that the only person who is prevented from making a profit out of the use of human tissue is the donor. For this reason it may be appropriate to provide for royalty payments to donors in certain prescribed circumstances. In particular, where that tissue is in some way unique to that donor (as was the case for John Moore[46]) and the patentable invention would not have been achieved without that tissue, there is every reason to provide the donor with a share of the profits from the patent. Where tissue is donated by indigenous groups the provisions of the *Biodiversity Convention*[47] should apply. It is appropriate that indigenous groups are provided with some remuneration, whether it be through monetary reward or more indirect reward in the form of improved medical and other services. At the same time, it is most important that such remuneration is not seen as a form of bribery, used to ensure cooperation.

Conclusions

My aim in this chapter has been to synthesise my analyses in each of the preceding chapters and to suggest means by which shortfalls in the existing patent system with regard to patenting of human genetic material can be rectified. Fourteen key conclusions flow from this synthesis:

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45 Discussed in Chapter 4 at 2.4.1.

46 See *Moore v Regents of the University of California* 51 Cal.3d 120 (1990).

47 Discussed in Chapter 5 at 1.4.

1. Inventions arising out of human genetic research should continue to be patented.

- The patent system plays an important role in encouraging investment in research and practice of human genetics. There is no justification for removing human genetic research and its applications from the ambit of the patent system.

2. No specific exclusions related to genes, gene sequences or methods of medical treatment should be inserted into the *Patents Act* 1990.

- Gene sequences of unknown function are not patentable, nor are naturally occurring genes or gene sequences. These exclusions are adequate. There is little justification for excluding methods of medical treatment without also excluding products used in medical treatment.

3. It does not appear appropriate at present to provide additional protection for investment in human genetic research outside the existing patent system.

- The suggested alternative forms of protection either do not apply, or provide rights in excess of requirements, or provide for a system that would be costly to implement and may provide small benefit over the existing patent system.

4. The adequacy of the provisions in the Australian legislation that allow for publications or use in certain prescribed circumstances and for complete applications to be associated with provisional applications should be compared with the provision in US legislation for a one year grace period.

- A provision which enables scientists to publish their research results before submitting detailed patent applications will aid in maintaining the culture of science.

5. Provision should be made for an express research exemption in the *Patents Act* 1990.

- Arguably the use of a patented invention for non-commercial research purposes is not exploitation of the invention and therefore does not constitute infringement. It would seem far more satisfactory, however, that if research exemptions are deemed appropriate in Australia, a specific provision is provided in the *Patents Act* to facilitate their application.

6. Patent examiners should be encouraged to be vigilant in ensuring that patent claims do not extend too far beyond the true extent of the invention.

- Whilst the patentee needs to acquire protection in an area greater than the extent of the invention because of the degeneracy of the genetic code, it would be inappropriate to allow the patentee to exclude all future use of a particular gene.

7. Second and subsequent licences should be allowed in the general area of a primary patent.

- Incentives should be available to both upstream and downstream inventors to ensure that research tools evolve into diagnostic and therapeutic treatments.

8. A morality clause is not recommended.

- Patent examiners lack expertise in assessing ethical issues. As such they are unlikely to be willing to make use of the provision in all but the most exceptional circumstances, and when they do so they likely to make assessments on the basis of set criteria rather than taking a flexible approach. On this basis, the value of such a provision is questionable.

9. The possibility that the compulsory licensing provisions should be relaxed should be explored.

- It is undesirable in areas that will lead to improvements in public health that a patentee should be allowed to close off whole areas of research. Compulsory licensing would enable widespread research into prevalent genetic diseases or diseases with genetic components. This may be necessary when the patentee is unable or unwilling to exploit the patent with all due haste, and is reluctant to come to voluntary licensing arrangements.

10. Licence fees should be set and monitored by the Patent Office.

- Every effort should be made in the area of human genetic research to ensure that products reach the stage of clinical application. It is inappropriate that patentees should be allowed to impose licence conditions that are excessive or onerous.

11. The need for removal of section 51(3) of the *Trade Practices Act* 1974 (Cth) should be examined.

- With or without s51(3), patent licences will not breach Part IV of the TPA if the public benefit in allowing the patentee to recover the costs of his or her invention outweighs the anti-competitive effect of the licence. Once this is recognised, the need for s51(3) is questionable.

12. Testing in the courts of the ambit of the general inconvenience exclusion from patenting is recommended.

- Bodies such as the Environmental Defenders Offices should look into the possibility of bringing opposition or revocation proceedings on this basis. The ideal test case would require that the patentee was only narrowly ahead of competitors in creating the invention, made broad claims in the patent and imposed onerous licence conditions where it was clearly in the public interest for further downstream research to be done using the invention.

13. Where a person donates unique tissue that is essential to the development of the patentable invention they should be given a share of the patent profits.

- Bearing in mind that the patent is granted for the invention and not for the tangible object that is used in creating the invention, there may be circumstances in which it is appropriate for the donor of the tissue to be given just reward.

14. Indigenous groups should share in the profits of inventions derived from use of their donated tissues.

- Where this is the case, consent requirements must be very carefully framed so that true consent is given, with not even the slightest hint of compulsion to donate tissue.

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