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Chapter 5 Domestic Legal Framework

Proposal 5 - 1 IP Australia should regularly review the schedule of patent fees for standard patents and innovation patents to: (a) assess the impact of the fees on the actual term of Australian patents; and (b) ensure that fees are set at a level appropriate to discourage patent holders from maintaining patents that lack real commercial value.

We agree with this Proposal, provided caution is exercised in establishing and maintaining appropriate levels for patent fees. Patent fees are frequently an important consideration for patent holders in determining whether to maintain patents or let them lapse. In many cases, patent holders will maintain valuable patents but let remaining patents lapse prior to their expiry.[1] In this manner, the patent maintenance structure goes some way toward ensuring that only quality patents are maintained for their full twenty-year term. Patent fees have recently seen an increase in the US. The US Biotechnology Industry Organisation (BIO) recently showed support for the passage of the US *Patent and Trademark Fee Modernisation Act* 2003 (HR 1561) on the grounds that the Bill would provide additional resources to the USPTO and allow them to issue quality patents, which are crucial for the biotechnology industry.[2] This support is based primarily on the fact that patent user fees will be fed back into the USPTO as a result of the *Patent and Trademark Fee Modernisation Act,* to hire and train additional examiners.

Patent fees should not, however, be set at a prohibitive level, as this may put the benefits of patent protection out of reach of many smaller players in the biotechnology market. Evidence has consistently suggested that many upstream biotechnology inventions are of limited value in and of themselves. Patent holders rely on being able to recoup the costs of research and development (including patent protection) through licensing arrangements. Excessive patent fees may make obtaining patent protection difficult, threatening the viability of smaller companies in the biotechnology market.

Chapter 6 Patentability of Genetic Materials and Technologies

Proposal 6 - 1 IP Australia should assess patent applications relating to genetic materials and technologies according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology.

We support this Proposal. The same legislative criteria must be applied to all patent applications. To do otherwise would be contrary to Article 27 of the TRIPS Agreement. Whilst there might have been be some scope for defining genetic materials and

[1] See Mark A Lemley, 'Rational Ignorance at the Patent Office' (2001) 95 *Northwestern University Law Review* 1495 at 1503. Note that Lemley's analysis was in respect of patent holders holding United States patents.

[2] Biotechnology Industry Organisation, 'Patent Fee Bill Will Help Ensure Continued Biotech Innovation' *Press Release*, 3 April 2004 at http://www.bio.org/newsroom/newsitem.asp?id=2004_0304_01 at 22 March 2004.

technologies as discoveries rather than inventions, we agree with the ALRC that the time for making such a distinction is long gone. With regard to the novelty and inventive step criteria, we noted that the recent amendments to the *Patents Act* 1990 (Cth) by the *Patents Amendment Act* 2001 (Cth) have significantly increased the stringency of these requirements and recommending any further amendments to the legislation would be inappropriate at this stage.

However, this does not stop the ALRC from recommending changes to the way that these criteria *are applied* in respect of patent applications relating to genetic materials and technologies. We strongly support Proposal 8-4, that IP Australia should provide its examiners with more detailed guidelines to assist them in their examination of these applications. In particular, more guidance should be provided as to the applicability of the novelty and inventive step criteria and the permissible scope of claims. In the Nicol-Nielsen study, we heard repeated criticisms about the breadth of patents that were granted in Australia, when compared with other jurisdictions. We believe that such findings justify modifications to existing practices. At the very least, the ALRC could recommend the undertaking of a comparative analysis of the claims allowed in granted patents in Australia and other jurisdictions. We acknowledge that the study undertaken by Andrew Christie and Melanie Howlett found no significant difference in the types of claims that would be granted by patent offices in Australia, the US, Japan and Europe in hypothetical EST patent applications. A further analysis of actual patent grants, as suggested above, would provide compelling evidence of the need, or lack of need, for Australia to adjust its examination practices to meet international best practice.

Proposal 6 - 2 The responsible Minister should request the Advisory Council on Intellectual Property to review the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law.

We are of the view that a review of this nature is unnecessary. The manner of manufacture test has served us well in the past and continues to provide the necessary flexibility to allow for appropriate responses to be made to new technologies. We support the conclusions of the IPAC and IPCRC inquiries. We are not convinced that an express set of exclusions, as provided in UK and other European legislation, has served these countries in any better way than the manner of manufacture test in Australia.

Proposal 6 - 3 The Commonwealth should amend the Patents Act 1990 (Cth) (Patents Act) to:
(a) include 'usefulness' as a requirement in the assessment of an application for a standard patent and in the certification of an innovation patent;
(b) require the Commissioner of Patents to be satisfied on the balance of probabilities that the criterion of usefulness is made out in order to accept an application for a standard patent or to certify an innovation patent; and
(c) include 'lack of usefulness' as a basis upon which an accepted application for a standard patent may be opposed, in addition to its current role as a ground for revocation.

Proposal 6 - 4 IP Australia should develop guidelines, consistent with the Patents Act, the Patents Regulations 1991 (Cth) and existing case law, to assist patent examiners in applying the 'usefulness' requirement. The guidelines should require that the claimed 'usefulness' must be 'specific, substantial and credible' to a person skilled in the relevant art.

Whilst we agree that the industrial applicability or utility criterion needs to be fully examined in Australian patent applications, we are not convinced that the proposed adaptation of the usefulness requirement is the appropriate way to achieve this end. The usefulness criterion has a distinct meaning in Australian law, as developed in a significant body of case law. We believe that adaptation and extension of the usefulness criterion as proposed is apt to cause confusion. Moreover, the proposed amendment to the *Patents Act* 1990 would also seem to be unnecessary.

We prefer that approach recommended by the IPCRC, that specific, substantial and credible utility should be examined through the manner of manufacture requirement. As noted in Discussion Paper 68, IP Australia states that these requirements are already incorporated into the assessment of manner of manufacture. However, we submit that there is room for a more explicit direction to patent examiners that these inquiries *must* be undertaken. This result could be achieved either by the provision of more detailed guidelines to examiners by IP Australia, or, if greater certainty is required, by making these prescribed matters, as previously suggested by us (and noted in Discussion Paper 68 at 157).

Question 6 - 1 Do the 'fair basis' and 'sufficiency' requirements in s 40 of the Patents Act adequately limit the scope of claims in gene patents? If not, what are the deficiencies in the way these requirements are applied, and what reforms are needed to address these concerns?

These requirements have the capacity to adequately limit the scope of claims in gene patents provided that they are applied with an appropriate level of stringency. We accept the argument that generally patent offices around the world tend to allow of broad claims are in patents relating to all types of new technologies and that this explains why the early gene patents granted in the US were broad in scope. However, the USPTO has now adapted its practice, imposing far more stringent limitations on the breadth of gene patents. The new written description guidelines and the case law have both provided assistance in this regard.

We submit that the fair basing and sufficiency requirements are equally as important as the utility requirement (if not more so). The scope of patent claims should not travel too far beyond the scope of the invention disclosed in the patent application. On the other hand, patent claims should not be narrowed too far, because a large number of narrow patents in an area could be equally as detrimental to innovation as single broad patents.

It is noted in Discussion Paper 68 that, in the US, revisions to the utility and written description requirements were implemented in parallel. We support adoption of the same

approach here. If specific, substantial and credible utility is to be explicitly recognised as a requirement in Australian patent law, then logically the disclosure requirements should be applied with the same level of stringency. We suggest that detailed guidelines should be drawn up with respect to the applicability of fair basing and sufficiency requirements in gene patent applications and that the US written description guidelines could provide assistance in this regard.

Chapter 7 Exclusions from Patentability

Proposal 7 - 1 The Patents Act 1990 (Cth) (Patents Act) should not be amended specifically to exclude genetic materials or technologies from patentable subject matter.

Proposal 7 - 2 The Patents Act should not be amended specifically to exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter.

We agree with both of these Proposals, for the reasons given in support of them in the submissions and by the ALRC itself. In particular, we highlight the importance of keeping Australian patent law on an equal footing with the law in other jurisdictions and uncertainty as to whether the creation of such exclusions would achieve the desired outcomes.

Proposal 7 - 3 The Patents Act should not be amended to expand the circumstances in which social and ethical considerations may be taken into account in decisions about granting patents. Rather, social and ethical concerns should be addressed primarily through direct regulation of the use or exploitation of the patented invention.

We agree that there should be direct regulation to deal with social and ethical concerns relating to the use or exploitation of patented inventions. Nevertheless, there may still be circumstances where patenting of certain inventions would be considered to be outrageous. The ordre public/morality exclusion would cover such circumstances in Europe. We believe that the general inconvenience exclusion could have similar application in Australia. We suggest that the ALRC should make some acknowledgement of the need to make provision for exclusion of morally outrageous patents, and the applicability of the general inconvenience exclusion in this regard.

We also wish to raise two other issues relevant to consideration of social and ethical matters. First, in the ALRC/AHEC inquiry on the protection of human genetic information, considerable emphasis was placed on the need to ensure that research in this area is conducted in accordance with the highest ethical standards. One matter that is particularly contentious is the commercial use of human tissue without the knowledge or consent of the source. As patent law presently stands, there is no requirement on the part of the applicant to verify that research leading to the claimed invention has been conducted in accordance with nationally prescribed standards (we refer specifically to the National Statement on Research Involving Humans and the *Privacy Act* 1988 (Cth)). Nor

is there any requirement to verify that the source of human tissue used in the creation of the invention consented to its use or to patenting of any inventions derived from that use.

Secondly, there is extensive debate in various international forums concerning patenting of natural genetic resources. There have been calls for the TRIPS Agreement to be amended to make it mandatory for the country of origin and the access and benefit sharing arrangements required in the Convention on Biological Diversity (CBD) to be disclosed in any patent applications involving natural genetic resources. As the CBD does not apply to human genetic resources, there has not been any consideration of the issues associated with the use of human tissue in this forum. However, we believe that it would be inappropriate and illogical to impose stringent requirements on the use of non-human genetic resources, but not on human tissue. The crucial aspect of the consent requirement for use of human tissue is consent of the source individual, not the source country. Hence, we support the inclusion of a requirement for patent applications to disclose evidence of consent from the source where an invention is based on biological material of human origin or where the invention uses such material, as provided in recital 26 of the European Community Directive on the Legal Protection of Biotechnological Inventions.[3] We acknowledge that this proposal would create more stringent requirements in Australia than in other jurisdictions. However, we believe this is justified. The ALRC/AHEC Report *Essentially Yours* and other ethical statements demonstrate the importance placed on ethical obligations in human genetic research in Australia. A requirement that patent applicants verify that there has been compliance with ethical standards serves to reinforce the value placed on compliance with these standards. This could be achieved through section 29 of the *Patents Act* 1990 and regulation 3.1 in the Patents Regulations 1991.

The fact that it may be difficult for applicants from other jurisdictions to satisfy the requirement that research has been conducted in accordance with ethical standards and that appropriate consent has been obtained should not be a barrier to the implementation of this requirement. Ethical standards in human genetic research are well recognised internationally and consent is a pivotal requirement. Patents relating to such subject matter should not be granted in Australia unless applicants are able to provide appropriate documentation. The onus should be on them to find means of satisfying these requirements.

We recognise that this submission may be fairly controversial. In particular, the imposition of requirements of this nature may reduce the incentive to patent in Australia. Nevertheless, we still believe that it warrants some consideration.

Chapter 8 Patent Office Practices

Proposal 8 - 1 To ensure the on-going competence of Australian patent examiners in assessing patent applications, IP Australia should continue its efforts to provide examiners with continuing education in areas of technology relevant to their particular

[3] 98/44/EC.

specialty. IP Australia should review and update its education programs regularly so that new developments can be incorporated as required.

We agree with this Proposal. However, what is really required is more funding, allowing for more examiners, greater levels of specialisation and more training. If renewal fees are increased for patents in the later years of their lives, as suggested in our response to Proposal 5-2, these increases in revenue could supplement the budget for patent examiners. This was the primary justification for increase in patent fees in the US.

Proposal 8 - 2 The Commonwealth should amend the Patents Act 1990 (Cth) (Patents Act) to authorise IP Australia to establish panels of experts to advise patent examiners in assessing patent applications, as circumstances require.

Proposal 8 - 3 IP Australia should ensure that appointments to the panel of experts reflect a balance of independent scientific and legal expertise, and that they be made only after consultation with relevant industry organisations and other stakeholders. IP Australia should also develop procedures for the operation of the panel, including procedures in relation to confidentiality, conflict of interest, and decision-making by the panel.

We recognise the desirability of establishing a panel of experts and agree that if such a panel were established it should be in the form proposed in Proposal 8-3. However, we do have some concern about the cost of creating and maintaining this panel. We have already mentioned the desirability of directing more revenue into funding for patent examiners. If the panel of experts were to be funded from patent application and renewal fees, the outcome may be counter-productive if this results in decreases to the funding allocated to patent examiners.

Proposal 8 - 4 IP Australia should develop examination guidelines, consistent with the Patents Act, the Patents Regulations 1991 (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving genetic materials and technologies.

We strongly support this Proposal, as we have already noted in our responses to the Proposals in Chapter 6. The reasons for this are obvious. Three are identified below:

- detailed guidance is required in complex areas of technology;
- Article 27 of the TRIPS Agreement does not allow discrimination between fields of technology, but does not prohibit guidance being given as to how the standard patenting criteria apply in specific areas of technology; and
- other jurisdictions have adopted the use of guidelines as the appropriate mechanism for directing patent examiners as to the applicability of the patent criteria in specific areas of technology.

Proposal 8 - 5 The Commonwealth should amend the Patents Act to require patent examiners to be satisfied on the balance of probabilities when assessing all statutory

requirements for patentability that are relevant at the stage of examination. (See also Proposal 6 - 3.)

We agree with this Proposal. Irrespective of how a requirement for specific, substantial and credible utility is ultimately implemented, it should be assessed in accordance with the same standard of proof as novelty and inventive step. Similarly, we can see no justification for allowing a lower standard of proof for the disclosure requirements in section 40.

Chapter 9 Challenging and Enforcing Patent Rights

Proposal 9 - 1 IP Australia should develop and regularly update a searchable online database comprising patents and published patent applications. The database should be accessible to the public through IP Australia's website and should provide user-friendly access and search capabilities on a wide variety of bases. If a fee is charged for use of the database, it should be kept at a level that does not unreasonably limit access.

We are strongly of the view that improvements need to be made to existing patent databases in Australia. We are also strongly of the view that *no* fee should be charged. Any requirement to pay a fee would undermine the public disclosure component of the patent system.

Opposition procedures

Although no specific proposals have been made about the opposition process in Australia, we do have concerns about it. In the Nicol-Nielsen study we heard comments, particularly from research institution participants, that opposition proceedings could be used strategically by more powerful players to block or delay patent grants. We are of the view that it may be more appropriate to provide for a limited post-grant opposition period instead of a pre-grant period. We note that reports in other jurisdictions have recommended the introduction of post-grant opposition procedures. Given that the influential US Federal Trade Commission report was released after the period for submissions on the ALRC Issues Paper had closed, there is some desirability in the ALRC re-considering this issue in its final report.

Chapter 10 Jurisdictional Issues

Proposal 10 - 1 The Commonwealth should amend the Patents Act 1990 (Cth) (Patents Act) to provide that original jurisdiction in matters arising under the Act be conferred exclusively on federal courts. The original jurisdiction presently exercised by state and territory courts under the Act should be abolished. The Federal Court of Australia should continue to exercise appellate jurisdiction in matters arising under the Act, exclusive of all courts other than the High Court of Australia.

We agree with the proposal that the original jurisdiction of the state and territory courts should be abolished. Patent law is a complex and specialised area of law. Patent

applications are drafted by highly trained professionals and patent examiners are individuals with a significant degree of expertise in particular areas. Although many disputes over patents arise, few of these disputes make it through to a litigated conclusion. It is difficult, therefore, for judges to accumulate a level of expertise that aligns with that possessed by others involved in drafting and assessing the validity of patents.

We agree that it would be inappropriate to create a specialist Gene Patent Court, if only for the reason that it would have little or no work to do. We are also of the view that a more broadly based specialist intellectual property court is unnecessary. We believe that the present Federal Court system of nominating a panel of specialist judges to hear intellectual property appeals works well. We agree with the ACIP recommendation that the Federal Court should be encouraged to promote further specialisation of intellectual property judges.

Proposal 10 - 2 Courts exercising jurisdiction under the Patents Act should continue to develop procedures and arrangements, in consultation with relevant stakeholders, to allow judges to benefit from the advice of assessors or scientific advisors in litigation involving patents over genetic materials and technologies.

We agree with this Proposal. The provision of expert assistance to the judiciary in patent litigation is essential in order to ensure that judges without training in fields such as molecular biology are nonetheless able to exercise their judicial function with assured competency in technical cases. Concerns about the role of assessors in relation to the impartiality of judges are ill-founded. On the contrary, judges are more likely to be able to give a reasoned and informed judgment if properly advised on the technical matters inherent in litigation involving gene and biotechnology patents. It is unrealistic to expect judges to be in a position to properly acquaint themselves with the intricacies of particular fields of scientific endeavour in the absence of expert guidance.

Chapter 12 Publicly Funded Research and Intellectual Property

Question 12 - 1 Should the National Principles for Intellectual Property Management for Publicly Funded Research and the National Health and Medical Research Council's Interim Guidelines: Intellectual Property Management for Health and Medical Research be expanded to require research institutions to favour Australian industry when commercialising patented inventions created through the use of public funds? Should the National Principles or the Interim Guidelines include a 'no Australian disadvantage' clause in any sale, licence or partnership arrangement involving patented inventions created through the use of public funds? If so, how should such requirements be implemented?

We have concerns about the imposition of a requirement to favour Australian industry. We do not believe that it is appropriate for public funding to be tied to a requirement to

favour Australian industry when commercialising patented inventions. Similarly we do not agree that the National Principles or Interim Guidelines should include a 'no Australian disadvantage' clause in any sale, licence or partnership arrangement involving such patterns. We provide a number of reasons for these conclusions below.

- Australia is a small, but highly significant international research jurisdiction. However, it relies heavily on collaborative research involvement with the major overseas players of North America, Europe and Japan. Australian researchers also receive direct funding from some overseas organisations. It is inadvisable to introduce such a parochial requirement without careful consideration of the impact on Australian research. It is possible that a requirement of this nature could inhibit collaborative research or overseas funding. In the area of drug discovery, in particular, it is essential to have reasonably unrestricted capacity to work collaboratively with foreign partners. In such instances, the national benefit may well be served better by promoting such collaborations than by insisting on a 'no Australian disadvantage' clause.
- The general commitment of Australia to the World Trade Organisation reforms may prohibit such uncompetitive and restrictive proposals.
- Requirements of this nature would be inconsistent with the declared NHMRC position that opposed a similar type of proposal from the US National Institutes of Health that aimed to favour NIH funded research for the benefit of the US.
- The suggestion that the sales, licences and partnerships include a 'no Australian disadvantage' clause lacks clarity. The expression 'no Australian disadvantage' is imprecise and is likely to cause operational and interpretation difficulties.

As the Prime Minister's Science, Engineering and Innovation Council has noted:

> It is important that in Australia we learn about, accept and apply a range of strategies to achieve maximum financial return on ideas and IP commercialised for overseas markets. For example, some technologies must be licensed to overseas companies, since there is no market or industrial capacity to develop them in Australia. In these cases, we must ask ourselves what the best strategy is for collaborating with the overseas licensor, so we maximise national benefit from the license.[4]
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> …
>
> Outward looking and comprehensive definitions of 'national benefit' should be used in assessing government funding applications for research projects, recognising that international collaboration need not result in Australia losing its IP.

[4] Prime Minister's Science, Engineering and Innovation Council Seventh Meeting 28 June 2001, 'Commercialisation of Public Sector Research'. Available at: http://www.dest.gov.au/science/pmseic/meetings/7thmeeting.htm (last accessed 20 April 2004).

Proposal 12 - 1 The Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) should review their principles and guidelines on intellectual property and research to ensure that publicly funded research, where commercialised, results in appropriate public benefit. (See also Proposal 12 - 2.)

We agree that the ARC/NHMRC National Principles of Intellectual Property Management for Public Funded Research and the NHMRC Interim Guidelines for IP Management for Health and Medical Research should be reviewed.

The commercialisation of research is declared aim of both the Wills Report and the National Biotechnology Strategy. The adjustment from public to mixed public and private funding research has been gradual. This move has required universities and other public funded research institutions to develop policies and practices with respect to patenting, licensing and general IP management.

The revision of these guidelines and principles should try to incorporate the appropriate consideration of public benefit. Various international instruments have referred to the concept of public benefit in an effort to address the need to ensure that the biotechnology revolution achieves benefits for the society as a whole. The National Biotechnology Strategy particularly mentions the aim of achieving a benefit for the community as a whole.

We propose that in reconsideration of the National Principles and Interim Guidelines the following could be assessed:

- whether all grants from NHMRC should include a standard condition that where research is subject to intellectual property protection and subsequent licensing that the NHMRC requires a small percentage in royalty return on the grant. These royalties may be rare in practice but if secured could be paid into the research trust fund and be available for further public research funding; and
- whether NHMRC grants should include a standard condition that that the NHMRC encourages the public disclosure of all research results as a general principle and publication in the public domain. This *soft* response highlights the existing NHMRC policy of the promotion of public benefit from research.

Proposal 12 - 2 As part of the review proposed in Proposal 12 - 1, the ARC and NHMRC should include guidance on what is meant by 'public benefit' in their principles and guidelines on intellectual property and research.

See our comments in relation to Proposal 12-1 above.

Proposal 12 - 3 The principles and guidelines developed in accordance with Proposal 12 - 1 should enable conditions to be attached to the grant of funding for genetic research, to limit the commercialisation of publicly funded research in appropriate circumstances. Such conditions might include a requirement that research results be placed in the public domain, or that a patented invention be widely licensed.

We do not consider the inclusion of conditions requiring some return from commercialisation to the NHMRC is, in principle, objectionable. Similarly we consider that there are circumstances where it is appropriate for conditions to be placed on commercialisation the public funded research. Some guidance can be obtained from the *Research involving Human Embryos Act* 2002 (Cth). It is the role of the Licensing Committee of the NHMRC to impose conditions on license holders under the terms of the Act. The NHMRC Council determined that conditions be applied in some types of embryo research that may lead to commercial outcomes.

Proposal 12 - 4 Universities and other publicly funded research organisations should ensure that their guidelines on intellectual property ownership cover research undertaken by visiting researchers and students, as well as staff—whether undertaken solely within the organisation or jointly with other bodies.

We agree with this Proposal. It is important that all research in Australia is conducted in a responsible and ethical fashion. Currently institutions have the responsibility of ensuring the quality and integrity of research conducted within their institution. Any review of the National Principles and Interim Guidelines should ensure that *all* research, including visiting and student researchers are covered. We also refer to our comments in relation to Chapter 7.

Chapter 13 Patents and Human Genetic Research

Proposal 13 - 1 The Australian Research Council and the National Health and Medical Research Council, as part of the review proposed in Proposal 12 - 1, should develop principles and guidelines for researchers to ensure that the public interest in encouraging commercial exploitation of inventions is balanced with the public interest in the wide dissemination of important research tools.

We agree in principle with this Proposal. We acknowledge that this is an important Proposal for the future development of commercialisation of research in Australia. In the process of developing approaches and responses to commercialisation, it is important that research institutions balance commercialisation with the wider public interest in the dissemination of information. There is a danger that commercialisation may promote a more secret and closed research culture. This is likely, in the long run to produce negative results on the quality and development of research. We agree that this 'balancing' process will be developmental and on-going. It is therefore inappropriate for any regulatory rule to be developed. It is appropriate for these broad aims to be included as principles or guidelines.

In relation to the specific issue of wide dissemination of important research tools, we note that whilst we did not see significant problems relating to enforcement of research tool patents in the Australian industry in the Nicol-Nielsen study, access issues could well emerge in the near future. These issues will be alleviated for some public sector researchers if the non-commercial research exemption that we discuss in response to

Proposal 14-1 is implemented. However, public sector researchers are likely to encounter enforcement of research tool patents in the future, just as much as private sector researchers. They cannot (and should not) shield behind their public sector status if they are conducting research with commercial implications. We respond to Proposals relating to access to research tool patents more fully below.

What we are concerned about here is not so much how public sector researchers deal with research tool patents held by others, but rather the principles and guidelines that the ARC and NHMRC should put in place to direct researchers who develop their own patentable research tools in research funded by those agencies. We agree that guidelines should be developed along the lines of the NIH guidelines. Key features might include directions to engage in non-exclusive licensing in most instances and ensuring that the research community has access to fundamental research resources. However, the guidelines must also reflect commercial realities. For example, in some circumstances broad non-exclusive licensing will not be appropriate. The guidelines should be cast in terms that allow for the best technology transfer options to be pursued, based on all relevant considerations, including the broader public benefit.

Chapter 14 Experimental and Research Use Defences

Proposal 14 - 1 The Commonwealth should amend the Patents Act 1990 (Cth) to establish a new defence to a claim of patent infringement based on the use of a patented invention to study or experiment on the subject matter of the invention; for example, to investigate its properties or improve upon it. The legislation should make it clear that the existence of a commercial purpose or intention does not affect the availability of the defence.

Whilst we see merit in the inclusion of a new exemption based on the use of a patented invention to study or experiment on the subject matter of the invention (we refer to this as the *research on* exemption hereafter), we do not believe that this proposal goes far enough. We see that two distinct exemptions should be introduced. The *research on* exemption should be in the form proposed here. We believe that this exemption should apply irrespective of whether the research is non-commercial or commercial in nature. The crucial limitation is that the use must relate to the subject matter of the patented invention.

We propose that a second exemption should be implemented to protect non-commercial research, irrespective of whether this is *research on* or *research with* the patented invention. This separation of experimental/ research use into two distinct exemptions is recognised in Chapter 14 of the Discussion Paper and can be read into some of the early case law. In the United States, for example, in the old case of *Whittemore v Cutter* a two-limb test was identified by Justice Story:

> It could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments

> [our second exemption] or for the purpose of ascertaining the sufficiency of the machine to produce its described effects [our first exemption].[5]

Similarly, in the United Kingdom, there are also two distinct exemptions, one relating to private, non-commercial use of the invention,[6] the other relating to experimental use of the invention for purposes relating to the subject matter of the invention.[7]

Perhaps surprisingly, most commentators in the area have either focused their attention on the *research on* exemption, or have not made the distinction between the two exemptions. However, there is some commentary that supports the distinction we are attempting to make. Most notably, Katherine Strandburg gives a detailed exposition of the two exemptions. [8] Rochelle Drefyss and others also discuss in some detail the form that a non-commercial research exemption might take.[9]

Justification for the exemptions

We believe that the two exemptions are justified for a number of reasons. The *research on* exemption is justified because this is a logical extension of the disclosure requirement (people should be allowed to test the validity of the patent adequacy of the disclosure) and the incentive goal of the patent system (people should be allowed to improve on the patented invention).

The non-commercial research exemption is justified on the basis that the patent grant only allows the holder to exclude others from *exploitation.* It should not be used in a way that stifles non-commercial research because this could negate the incentive goal of the patent system. We acknowledge that the payment of royalties for off-the-shelf patented products is unlikely to stifle non-commercial research and that there may be no good reason why non-commercial researchers should be exempted from payment of those royalties.[10] However, the situation becomes more problematic if licence negotiations have to be entered into and if refusal to licence is a possibility. This situation is most likely to impede non-commercial research when the patent claims a fundamental research tool. A considerable amount of the research use of a patented research tool is likely to be *research with* rather than *research on* the patented invention. Restrictive licensing of research tool patents could create impediments for both non-commercial and commercial research. We are not suggesting that all such uses of research tools should be exempt,

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[5] Ibid at. 862.
[6] See section 60(5)(a) of the *Patents Act* 1977 (UK).
[7] Section 60(5)(b) of the *Patents Act* 1977 (UK).
[8] Katherine Strandburg, 'What Does the Public Get? Experimental Use and the Patent Bargain' (working draft:16 July 2003). Available at:
http://www.law.berkeley.edu/institutes/bclt/ipsc/papers/attendees/IPSC_2003_Strandburg.pdf
(last accessed 16 April 2004).
[9] Rochelle Cooper Dreyfuss, 'Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course' (April 8, 2003). NYU Law School, Public Law Research Paper No. 59. http://ssrn.com/abstract=394000 (last accessed 16 April 2004). See also an unpublished article by Richard Nelson cited in Strandburg, above n8, at her n199 and her discussion at 79-82.
[10] This issue is explored more fully in Janice Mueller, 'No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools' (2001) 76 *Washington Law Review* 1at 33-35.

because this would effectively reduce the value of research tool patents to zero. We are saying that there is justification for excluding non-commercial research from infringement.

The need for legislative action

We recognise that at present a practice-based non-commercial research exemption appears to be operating in Australia (this became clear to us through the course of the Nicol-Nielsen study), and that this exemption may well be broader than any statutorily enacted exemption. Thus, at present, infringement action against non-commercial users of patented inventions is rarely, if ever, pursued. There is little or no evidence to suggest that the lack of an express exemption is discouraging innovation or significantly affecting the ability of non-commercial users to use patented inventions.

We do not have much concrete empirical evidence as to the impact of the lack of an express *research on* exemption on the incentive/use balance. However, we surmise that again in practice such use would generally be considered to be exempt by participants in the industry, irrespective of whether they are patent holders or users.

Nevertheless, the lack of express exemptions may encourage some patent holders to change their enforcement practices in the future. We are already seeing moves to enforce research tool patents against public sector research institutions involved in research that has commercial links.[11] It is not too fanciful to predict that others may attempt to enforce patents against public sector researchers in accordance with the Madey formulation. If the Australian courts were to create a common law exemption for non-commercial research, but to restrict it by using the narrow Madey version of *philosophical inquiry,* then public sector researchers could be faced with patent infringement actions, irrespective of whether their research is non-commercial or commercial in nature. This could have a stultifying effect on non-commercial research in Australia for various reasons, including:

- the cost and time associated with involvement in patent infringement litigation;
- shifting of research projects away from areas where researchers fear that they may be pursued for infringement; and
- delays and increased costs caused by patent searching and licence negotiation.

The lack of an express *research on* exemption could create similar problems in future.

Form of the exemptions

We see merit in adopting a clear exposition as to the nature of a research/experimental use exemption in Australia, along somewhat similar lines to the UK approach. Experimental use for purposes related to the subject matter of the patented invention should be exempt because there must be legally available avenues for testing and improving on the invention. We agree with the judgment of Dillon LJ in the Monsanto case that for this limb of the exemption there should be no distinction drawn between

[11] See, for example, Australian Broadcasting Corporation Four Corners, 'Patently a Problem' broadcast on 11 August 2003, transcript available at http://www.abc.net.au/4corners/content/2003/transcripts/3922059.htm (accessed 12 August 2003).

non-commercial experimentation and experimentation that may have a commercial end in view.[12] The crucial question in respect of this exemption is whether or not the experimentation relates to the subject matter of the patented invention. In accordance with the views of Dillon LJ, this would include such uses as: 'limited experimentation to establish whether the experimenter could manufacture a quality product commercially in accordance with the specification of a patent'.[13] His Honour went on to explain the distinction further:

> Trials carried out in order to discover something unknown or to test a hypothesis or even in order to find out whether something which is known to work in specific conditions … can fairly, in my judgment, be regarded as experiments. But trials carried out in order to demonstrate to a third party that a product works or, in order to amass information to satisfy a third party, whether a customer or [a regulatory] body … that the product works as its maker claims are not, in my judgment, to be regarded as acts done "for experimental purposes".[14]

We believe that a distinction of this nature may be apt for the Australian situation, provided that other alternatives are explored for other uses, particularly when they relate to research tool patents.

With regard to the non-commercial use component, we believe that the UK approach may be too narrow. The provision in s60(5)(a) of the UK legislation refers to *private* non-commercial use. This provision has not received much judicial attention, as noted by Aldous J in *Smith Kline & French v Evans.*[15] In that case His Honour interpreted 'private' not to mean secret or confidential but 'in the sense of denoting that the act was done for the person's own use'.[16] We submit that the justification for the non-commercial use component of the proposed exemption is its *public* nature both from the perspective of the purpose of the use (for the benefit of the public) and from the perspective of disclosure (disclosing to the public rather than keeping secret or confidential). The justification for the exemption is that it would encourage publicly funded non-commercial research, the results of which should be freely released into the public domain, in accordance with Mertonian norms.

We recognise that the distinction between commercial and non-commercial research is being eroded and the bright line between basic and applied research is becoming decidedly fuzzy. This may make the non-commercial research exemption difficult to apply. One solution that has been proposed in the literature is that researchers could have the option of self-defining as non-commercial users.[17] Public statements have already been made to this effect by various research groups, including, for example, the Human Genome Project through its Bermuda Declaration and the Single Nucleotide

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[12] *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515 at 538.
[13] Ibid, citing *Micro-Chemicals Ltd v Smith Kline & French Inter-American Ltd* (1971) 25 DLR 79 at 89 with approval.
[14] Ibid at 542.
[15] [1989] 1 FSR 513.at 517.
[16] Ibid
[17] See Dreyfuss, above n9 at 9.

Polymorphism (SNP) Project. Dreyfuss and others have suggested more formalized waiver mechanisms to enable reliance on a non-commercial research exemption, which would apply in the following circumstances:

- unwillingness or inability on the part of the patent holder to supply the patented materials on reasonable terms;
- agreement by the researcher to publish the work; and
- agreement by the researcher to refrain from patenting the results of the research, or patenting and non-exclusively licensing on reasonable terms.[18]

We agree that if a non-commercial research exemption is created it will be necessary to provide some formalized structure to identify which research is non-commercial and which has commercial aims. A self-defining option is attractive. It may be appropriate for a waiver provision of this nature to be required for all basic research in addition to the types of hybrid research where the researcher has made a commitment not to commercialise. However, the problem with requiring basic researchers to sign a formal waiver of in the circumstances set out above is that it would require them to conduct patent searches and approach relevant patent holders. Given that the patent landscape is becoming increasingly complex, these obligations may be quite onerous in some areas of research. In our view basic researchers should be freed entirely from obligations of this nature. We suggest that it would be sufficient for researchers to make undertakings to publish their work and to refrain from patenting the results of their research.

Dreyfuss points out that given the nature of this type of research, it may be necessary to provide for a buyout from the waiver to enable patenting and commercial development.[19] We believe that there is merit in this proposition, given the serendipitous nature of basic research.

We submit that both of these exemptions would be allowed under Article 30 of the TRIPS Agreement. As noted by Maureen O'Rourke, Article 30 closely parallels Article 13, which provides for limited exceptions to the rights of copyright holders.[20] It is generally assumed that this provision allows the fair use/dealing provisions found in the copyright laws in most jurisdictions. Hence, O'Rourke concludes that: 'To the extent that Article 30 parallels Article 13, this suggests that some type of patent fair use is not only permissible but also expected under TRIPS.'[21] We agree with this proposition.

[18] Strandburg has isolated these requirements from the work of Rochelle Dreyfuss, above n?? and from Richard Nelson, in an unpublished article. See Strandburg above n8 at 79. See also Mueller, above n10 at 54-66.
[19] Dreyfuss, above n9 at 11.
[20] Maureen O'Rourke, 'Towards a Doctrine of Fair Use in Patent Law' (2000) 100 *Columbia Law Review* 1177.
[21] Ibid at 1202.

Chapter 15 Research Culture, Patents and Commercialisation

Question 15 - 1 In assessing the research record of grant applicants, is sufficient weight given to the applicant's record in applying for and obtaining patents? Are there any other disincentives for researchers to seek patents over genetic research outcomes?

Question 15 - 2 Are any additional strategies or policies required by the National Health and Medical Research Council, the Australian Research Council, universities, or other publicly funded research institutions to encourage researchers to patent and commercialise the outcomes of genetic research?

Question 15 - 3 Do researchers in human genetics possess sufficient expertise to participate in the process of applying for and exploiting gene patents? If not, what measures might be taken to address any lack of expertise?

We believe that the universities have generally moved to acknowledge a grant of a patent as evidence of successful research accomplishment. To the best of our knowledge the NHMRC and ARC both recognise the grants of patents as indicative of standing in the research field.

The Wills Report noted the impressive record of Australian researchers in publishing in recognised international journals. It also noted the current record of Australian researchers and institutions in taking the publication to proof of concept stage and commercialisation of products. The research culture in Australia is changing and the universities are leading this initiative. Universities are developing research plans that often conclude commercialisation games and most universities have commercialisation units within their research offices. It is not clear to us that the NHMRC and ARC need to be involved in the introduction of further commercialisation strategies or policies at this time. These bodies are essentially public funding organisations that administer high quality competitive grants systems. The current competitive peer reviewed process has worked well.

The Nicol-Nielsen study provides support for the conclusion that those researchers in human genetics who are interested in the commercialisation process are increasing their level of expertise in patenting and technology transfer and are capable of participating in the process. Other researchers are less interested in the process. Educational programs and support are assisting other researchers in gaining necessary expertise. There will always be some researchers who are not interested in the commercialisation process, and their choices in this regard should be respected.

Proposal 15 - 1 Universities and other publicly-funded research institutions should continue to take steps to raise the awareness of researchers in the health sciences and biotechnology about intellectual property issues and the commercialisation of research, and should provide relevant advice to researchers as required.

We agree with this Proposal. Australian universities have responded to the recommendations of the Wills Report, National Biotechnology Strategy and Innovation Statement. As stated above, most universities are endeavoring to encourage researchers particularly in health sciences, sciences and biotechnology area to commercialise new research where appropriate.

Proposal 15 - 2 Universities should ensure that students undertaking degrees in the health sciences or biotechnology are made familiar with intellectual property issues and the commercialisation of research

We consider that this is a worthwhile Proposal. Some universities are making entrepreneurship or commercialisation required or optional components of degree study. At the University of Tasmania for example the biotechnology degree includes in its curriculum an elective unit addressing core legal, ethical and commercialisation issues.

We note that IP Australia has also taken steps to encourage an understanding of intellectual property and commercialisation issues in research by various means, including the production of their CD *Get Smart with IP: A Quick Guide to Managing Your Intellectual Property.* An awareness of IP commercialisation issues is an important aspect of health, science and biotechnology studies.

Proposal 15 - 3 The responsible Minister should request the Advisory Council on Intellectual Property to review the grace period provisions in the Patents Regulations 1991 (Cth) (Patents Regulations) to ascertain whether these provisions are having an adverse impact on the commercialisation of Australian research in Australia or overseas.

We agree that a review of the grace period provisions is appropriate at this stage.

Proposal 15 - 4 Universities and other publicly funded research organisations should ensure that their researchers are fully informed about the operation of the grace period provisions in the Patents Regulations, particularly in relation to the effect of publication before filing a provisional patent application, and the effect of publication on the patentability of their inventions in countries that do not have equivalent provisions.

We agree with this Proposal.

Chapter 16 Stem Cell Technologies

Proposal 16 - 1 IP Australia should develop examination guidelines, consistent with the Patents Act 1990 (Cth), the Patents Regulations 1991 (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving stem cell technologies. The examination guidelines should address, among other things, the patentability of inventions involving:
(a) totipotent, pluripotent and multipotent cells; and

(b) processes involving stem cell technologies.

We do not believe that this proposal is necessary. Stem cell lines may be created from excess embryos (under the terms of the *Research involving Human Embryos Act* 2002 (Cth)) or adult stem cells. In the case of adult stem cells there is scientific evidence that these cells are not totipotent but more directed in their development. In either case any patent application will be treated on a case-by-case basis. It is not clear whether any researcher will make application to patent a stem cell line itself. It is more likely that the patents may extend to some specific process for extracting, developing and differentiating the stem cell. There do exist guidelines and case law for the availability of patents for biotechnology processes. In summary, we do not see that there is any compelling case for specific guidelines to cover stem cells.

Question 16 - 1 Should specific mechanisms be established to regulate the exploitation of patented stem cell technologies? If so, would any of the following initiatives be desirable:
(a) establishing an Australian stem cell bank or collaborating with existing stem cell banks in other countries;
(b) conferring responsibility on a new or existing body to consider the potential exercise of any patent rights that might arise from research conducted by Australian entities using human stem cell lines; or
(c) developing guidelines and principles by the National Health and Medical Research Council and the Australian Research Council to ensure that the public interest in the commercial exploitation of inventions involving stem cell technologies is balanced with the public interest in dissemination of such technologies?

At this stage, it is not clear how Australia will collaborate in proposals for stem cell banks in other countries. We are aware of a proposal to establish an international publicly available stem cell bank in Paris. In addition, Harvard University has recently announced the availability of seventeen stem cell lines for public research. It is too early to make proposals relating to the establishment of stem cell banks in Australia or collaborative ventures. However, we propose that the HGCA be requested to monitor such development. Similarly the HGCA could monitor the exercise of any patent rights in relation to human stem cell lines and make appropriate recommendations, taking into account the need to balance competing public interests.

Chapter 18 Technology Transfer from Publicly Funded Research Institutions

Proposal 18 - 1 Biotechnology Australia, in consultation with state and territory governments and other relevant stakeholders, should:
(a) continue to develop and implement programs to assist technology transfer offices in universities and publicly-funded research institutions in commercialising inventions involving genetic materials and technologies; and
(b) develop strategies to ensure widespread participation of technology transfer offices in these programs. (See also Proposals 19 - 1 and 23 - 1.)

Proposal 18 - 2 The Australian Research Council and the National Health and Medical Research Council should review their principles and guidelines on intellectual property and research to emphasise the importance of clear ownership of intellectual property resulting from collaborative or jointly funded research. (See also Proposals 12 - 1 to 12 - 3.)

Proposal 18 - 3 Universities and other publicly funded research organisations should ensure that their policies and practices address the problems of ownership of intellectual property resulting from collaborative or jointly funded research. (See also Proposals 12 - 4 and 18 - 2.)

We agree with all of these Proposals. However, we also note that it is important for publicly funded research institutions to have due regard for the norms of science and the importance of free and timely dissemination of research results. They should also be wary of patenting too early and over-valuing their patented inventions. The stark reality is that these institutions must take into account the broader public interest in addition to their own financial self-interest.

We note further that Biotechnology Australia has the responsibility for the implementation and promotion of the National Biotechnology Strategy. It is the appropriate body to continue to develop and implement technology transfer programs and ensure widespread participation in them. However, we note that the resources of Biotechnology Australia are quite limited (a staff of approximately 12 only). It may be desirable to include a proposal to the effect that should Biotechnology Australia accept this increased responsibility then increased funding will be required.

Proposal 18 - 4 Biotechnology Australia, in consultation with state and territory governments and other relevant stakeholders, should develop model materials transfer agreements for use by universities and other publicly funded research institutions, along the lines of the models developed by the United States Association of University Technology Managers.

We agree with this Proposal. We note in our response to Proposal 23-2 that model licensing agreements may be of limited value because of the unique features of individual deals. However, we predict that there may be more uniformity to material transfer agreements and hence model agreements are likely to be of greater value in this area.

Chapter 19 Patents and the Biotechnology Industry

Proposal 19 - 1 Biotechnology Australia, in consultation with State and Territory governments and other relevant stakeholders, should:
(a) develop further programs to assist biotechnology companies in commercialising inventions involving genetic materials and technologies; and

(b) develop strategies to ensure widespread participation of biotechnology companies in these programs. (See also Proposals 18 - 1 and 23 - 1.)

We agree with this Proposal, for the reasons provided in Chapter 19 of the Discussion Paper and identified in the Nicol-Nielsen study.

Chapter 20 Gene Patents and the Healthcare System

Proposal 20 - 1 The Australian Health Ministers' Advisory Council (AHMAC) should establish processes for:
(a) an economic evaluation of medical genetic testing and other new genetic medical technologies; and
(b) an examination of the financial impact of gene patents on the delivery of healthcare services in Australia.

Whilst we strongly support the need to establish processes for economically evaluating genetic testing and other technologies and examining the financial impact of gene patents, we are concerned that this Proposal may be imposing too heavy a responsibility on AHMAC. We note the suggestion in Discussion Paper 68 at 560 that MSAC could assist AHMAC in this assessment. However, the HGSA has pointed out that the MSAC system 'does not have the capacity to undertake the task' (Discussion Paper 68 at 557). We support the suggestion by the HGSA that an Office of Health Technology Assessment could be established within the TGA. We believe that the combined results of this inquiry and the previous ALRC/AHEC inquiry on the Protection of Genetic Information justify a recommendation by the ALRC to the effect that such a body should be created.

Proposal 20 - 2 AHMAC should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare.

We agree with the suggestion that government funding and purchasing power could be used to control the cost of goods and services subject to gene patents. We believe that the ALRC is in a position to make concrete recommendations to this effect. A useful starting point could be a recommendation for more comprehensive and systematic coverage of diagnostic genetic tests through the MBS.

Proposal 20 - 3 Where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, Commonwealth, state and territory health departments should actively consider whether to: request re-examination of a patent; initiate proceedings to oppose a patent; apply for revocation of a patent; apply for the grant of a compulsory licence; or exploit or acquire a patent under the Crown use and acquisition provisions of the Patents Act 1990 (Cth) (Patents Act).

We have two main concerns regarding this Proposal. First, we do not believe it is feasible to impose a responsibility on state and territory health departments to inquire into these matters. A clear distinction needs to be drawn between the centralised health care system in the UK and the federal structure in Australia. The UK Health Department is said to be the third largest organisation in the world, behind the Chinese Peoples' army and the Indian railway.

Health departments in states like Tasmania are already struggling to provide adequate services. It would be inappropriate for them to divert funds to specialist IP divisions. On the other hand, it would be entirely appropriate for such matters to be dealt with by a body such as an Office of Health Technology Assessment mentioned in our response to Proposal 20-1. This body could take advice from state and territory heath departments, but they would not be required to undertake these activities on their own behalf.

The second issue that we have with this Proposal is that an appropriate balance must be maintained between the public interest in access to healthcare and the public interest in providing an incentive to innovate. We note GTG's concerns noted on page 558 of Discussion Paper 68 that economic evaluation of gene patents and healthcare could be hijacked and politicised. Whilst appropriate evaluation of gene patents and their impact on health care is important, challenges and oppositions should only be considered where the validity of such patents is clearly questionable.

Proposal 20 - 4 Commonwealth, state and territory health departments should establish specialist offices to monitor and manage intellectual property issues relating to genetic materials and technologies. The offices should be staffed by qualified individuals who are capable of giving specialist legal and policy advice about intellectual property, biotechnology and human health. Health departments should also establish mechanisms to enable them to draw on expertise in other government departments and agencies to advise and assist them in dealing with intellectual property issues arising from gene patents.

We refer to our comments in relation to Proposal 20-3. We do not believe that it is feasible for most if not all state and territory health departments to allocate resources to specialist IP offices. If such offices were to be created, they may well be ineffective because they are likely to be under-resourced.

Proposal 20 - 5 The proposed Human Genetics Commission of Australia (HGCA) should monitor the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases. In conducting such monitoring, the HGCA should have the following functions:
(a) providing information to IP Australia during the examination of a patent about the proper scope of the patent, in appropriate cases;
(b) liaising with AHMAC, health departments, and other relevant stakeholders about the advisability of opposition, re-examination or revocation of a patent under the Patents Act, and about who might take such action and in what circumstances; and

(c) liaising with AHMAC, health departments, and other relevant stakeholders about whether access to patented genetic inventions should be obtained under the Crown use, Crown acquisition or compulsory licensing provisions of the Patents Act.

We agree in principle with this Proposal, at least in part. We are not convinced that the HGCA would have sufficient expertise to provide information to IP Australia on the proper scope of particular patents. These are specialist issues, which could only properly be assessed by examiners who are immersed in claims evaluation on a day-to-day basis. We believe that it would be more appropriate to designate to HGCA a policy role, providing general advice to IP Australia on the scope of biotechnology patents.

We also refer to our response to Proposal 20-3. If an Office of Health Technology Assessment were established then it would be appropriate for the HGCA to liaise with this organisation.

Proposal 20 - 6 Pending the establishment of the HGCA, AHMAC should establish a mechanism for monitoring the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases.

We accept this Proposal.

Chapter 22 Medical Treatment Defence

Question 22 - 1 In the absence of a general defence relating to medical treatment, should the Patents Act 1990 (Cth) be amended to enact a new defence to claims of patent infringement based on the use of genetic materials and technologies in diagnostic or therapeutic treatment?

We agree that there are serious issues associated with the potential for enforcement of gene patents against diagnostic service providers, as already discussed in the Nicol-Nielsen study and other articles by Dianne Nicol. However, we do not believe that enactment of a new defence as provided in this Proposal would provide an ideal solution. In part, this is because such a defence would have a major impact on the patent incentive, both in terms of the incentive to innovate and the incentive to disclose.

Chapter 23 Licensing of Patent Rights

Proposal 23 - 1 Biotechnology Australia, in consultation with state and territory governments and other relevant stakeholders, should continue to develop and implement education programs to assist research institutions and biotechnology companies in licensing and commercialising inventions involving genetic materials and technologies. (See also Proposals 18 - 1 and 19 - 1.)

We agree with this Proposal.

Proposal 23 - 2 AusBiotech Ltd should develop model agreements and interpretative guidelines for patent licences involving genetic materials and technologies. The model agreements should be developed in consultation with Biotechnology Australia, state and territory governments, and other relevant stakeholders as a non-binding model of desirable licensing practices. (See also Proposals 13 - 1 and 18 - 4.)

Despite being the peak industry body in the Australian biotechnology sector, AusBiotech Ltd (AusBiotech) is not, in our view, an appropriate body to be involved in the development of model agreements and guidelines, or the examination of licensing initiatives in biotechnology. There are a number of reasons for this view:

- while AusBiotech is the principal body representing biotechnology companies in Australia, it is not the sole body. As such, AusBiotech may not be representative of biotechnology companies as a whole;
- the biotechnology industry in Australia comprises a diverse range of players, ranging from government funded research institutions and enterprises, through to private and publicly funded companies. When the totality of the industry is taken into account, AusBiotech represents only a portion of industry stakeholders; and
- as such, an industry organisation such as AusBiotech is unlikely to speak for all of these industry sectors, and may not possess the necessary expertise to be involved in drafting standard licensing agreements, which frequently involve considerable complexity.

It is more appropriate for a government body, specifically Biotechnology Australia, to be involved in the development of licensing best practice. A better alternative, therefore, might be to recruit the services of the Licensing Executives Society (LES), to assist Biotechnology Australia in compiling a list of standard terms involved in biotechnology licensing agreements. The LES is a body that is likely to possess the necessary expertise. The involvement of a government body would also assist in ensuring that the interests of a multiplicity of stakeholders are represented. Similarly, drafting of guidelines by Biotechnology Australia is likely to lead to impartial guidelines and lend credence to any guidelines developed.

In any case, the drafting of licensing standards and guidelines is an ambitious undertaking, particularly given the range of participants in the biotechnology industry. In many cases, the necessity to bargain arises due to the different outcomes desired by the various parties to a licensing agreement. International attempts to develop guidelines have met with limited success.[22] Although particular terms in licence agreements appear to be problematic on a recurring basis, in many cases flexibility in drafting licence agreements is necessary in order to enable the particular characteristics of the products or technologies involved to be taken into account. A huge volume of licence agreements involving patented biotechnology inventions is entered into every week. These inventions are diverse and ever evolving. Any attempt to circumscribe the terms on which licences

[22] For example, the NIH Principles and Guidelines have not been widely utilised.

are entered may be useful in some cases, but is unlikely to be universally adopted. This is particularly the case given that many licence transactions entered into by Australian companies and institutions involve international parties. Bargaining inequalities further complicate matters where particular parties insist on the inclusion of various terms in licence agreements.

Proposal 23-3 AusBiotech Ltd should consider ways in which industry initiatives can facilitate the licensing of patent rights over genetic materials and technologies, for example through the establishment of patent pools or patent clearinghouses.

We agree that these options warrant detailed consideration. Again, we suggest that Biotechnology Australia and LES may be the appropriate bodies to consider them. The proposed HGCA could also investigate these matters.

Patent pools have been used successfully in a number of industries to overcome issues relating to access to core patents. In some cases, government imposed patent pooling arrangements have been successfully implemented. In others, industry pools have developed in response to patent hold-ups in a particular area of research. In a vast majority of these cases, entering into a patent pool was necessary and beneficial for all parties concerned in that they each held particular blocking positions. Where this is not the case, a patent pool is unlikely to be a desirable option. There may be a number of reasons why players in the biotechnology industry will be reluctant to enter into patent pooling arrangements and these were canvassed briefly in the Discussion Paper at 635-6. The results of the Nicol-Nielsen study offer support to this in that levels of cross licensing within the industry were revealed by the survey results to be relatively low. Caution should therefore be exercised in imposing a pooling arrangement within a particular area of the industry. This is not to say that the feasibility of patent pooling arrangements should not be considered by an appropriate body.

We suggest that it may be particularly useful to explore the option of using clearinghouse mechanisms to reduce the transaction costs in licensing research tools, particularly between research organisations. A clearinghouse could perform one or more of the following functions: facilitating the search for technology that is available for licensing or free use; smoothing the progress of negotiations; and monitoring or enforcing negotiated agreements.[23] Clearinghouses are already being established. In the US, for example, the Public Intellectual Property Resource for Agriculture (PIPRA) facilitates sharing of access to agricultural technologies by US-based public-sector agricultural research institutions.[24]

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[23] G. Graff and D. Zilberman 'Towards an Intellectual Property Clearinghouse for Agricultural Biotechnology (2001) 3 *Intellectual Property Strategy Today* 1; G. Graff, A. Bennett, B. Wright, and D. Zilberman 'Intellectual Property Clearinghouse Mechanisms for Agriculture: Summary of an Industry, Academia, and International Development Round Table' (2001) 3 *Intellectual Property Strategy Today* 15 both available at:
http://www.biodevelopments.org/ip/ (accessed 20 September 2003).

[24] R. Atkinson *et al,* 'Public Sector Collaboration for Agricultural IP Management' (2003) 301 *Science* 174-5.

We also believe that it may also be appropriate for the ALRC to canvass the adoption of open source principles in some areas of gene patenting. We acknowledge that open source principles are being applied with some significant success in relation to copyright in particularly in software applications. There is a growing body of commentary exploring whether these open source principles could be applied in other areas. One of our colleagues, Janet Hope, is exploring the applicability of open source principles in the biotechnology industry for her PhD thesis at the ANU. We believe that open source principles warrant consideration, particularly in relation to information-based patents. However, we do have some reservations as to the extent to which open source principles could provide broadly applicable alternative patent use strategies. One of the major problems in the area of patent law is that significant expenditure is involved in obtaining and maintaining patents. Unless there is some mechanism for recovering these costs, people will be unwilling to embark on the patenting process. Other alternatives to patenting are public disclosure and contracting. The difficulty with public disclosure is that once research results have been disclosed the researcher has no control over downstream uses. Whilst conditions can be imposed on downstream use by contracting, the difficulty here is that such contracts are only of value whilst the research results remain secret, which is the antithesis of open source principles.

Chapter 24 Patents and Competition Law

Proposal 24 - 1 The Australian Competition and Consumer Commission (ACCC) should develop guidelines regarding the relationship between Part IV of the Trade Practices Act 1974 (Cth) and intellectual property, with particular regard to patented genetic materials and technologies. The guidelines should extend to patent pools and cross-licensing involving patented genetic materials and technologies.

Whilst it may be desirable for the ACCC to focus on patented genetic materials and technologies in developing guidelines regarding the relationship between Part IV of the *Trade Practices Act* 1974 (Cth) and intellectual property, it is questionable whether this would be feasible in reality. We welcome the recommendation made by the IPCRC that general guidelines be produced to clarify the relationship between s51(3) of the Trade Practices Act and terms in intellectual property licensing agreements.[25] We also welcome the Federal Government's acceptance of this particular recommendation, and understand that ACCC guidelines will follow the amendments to 51(3). The development of guidelines by the ACCC is likely to be a challenging process, and there are many areas of technology in which they will potentially operate. The guidelines will, therefore, need to be correspondingly general to take into account the multitude of technologies that may come within their ambit. Making specific reference to genetic materials and technologies will therefore be very difficult.

An additional difficulty is that many dealings in patented genetic technologies involve considerable complexity. Many of these difficulties have not been considered or resolved

[25] IPCRC Report at 215.

at an international level. We would suggest that while guidelines will undoubtedly assist industry in delineating the reach of competition law with respect to intellectual property dealings, attempting to be too prescriptive might have an adverse effect on the operation of the industry. It is unlikely that guidelines referring specifically to patented genetic materials and technologies will offer any advantage over and above general guidelines as recommended by the IPCRC.

General problems with the Government's response to the IPCRC's recommendation in relation to amending s51(3) were canvassed in Discussion Paper 68. It is our view that the Government's response ameliorates the full force of the recommendation made by the IPCRC, which would have gone some way toward strengthening the exemption contained in s51(3).

Proposal 24 - 2 The ACCC should review the conduct of firms dealing with patented genetic materials and technologies, as the need arises, to determine whether their conduct is anti-competitive within the meaning of Part IV of the Trade Practices Act. The ACCC should liaise, on an ongoing basis, with Commonwealth, state and territory health departments and other stakeholders to identify and assess any emerging competition concerns in this field.

We agree in principle with this Proposal, but recognise that it will be difficult to monitor all potentially anti-competitive dealings (particularly licence dealings) given their commercial nature. Nevertheless, there is certainly room for the ACCC to take a facilitative stance and monitor the conduct of intellectual property owners within the industry on a broad basis.

In our view this Proposal adds little to the current state of competition regulation in Australia. The ACCC is presently responsible for enforcing contraventions of the anti-competitive conduct rules, and this proposal merely reiterates this in the context of patented genetic materials and technologies. The difficulty lies in the discovery of the anti-competitive conduct, its investigation and enforcement. To this extent, it is suggested that the ACCC be provided with the sufficient resources to allow this area to be identified as an enforcement priority, so as to ensure that the market structure is appropriately competitive.

Chapter 25 Prices Surveillance

Proposal 25 - 1 The Australian Competition and Consumer Commission should conduct informal price monitoring of patented medical genetic tests and other genetic inventions involved in the provision of healthcare services if evidence emerges that such prices are having an adverse impact healthcare services.

Given that the ACCC itself could see no reason for it to have a specific role in monitoring prices, this Proposal in isolation achieves little. Informal monitoring would be marginalised within the regulator and unlikely to be given sufficient resources to enable it to be carried out in any useful or substantive manner. The role of the ACCC is to see that

the market structure within the community is one that allows the competitive processes to interact. It should not be the role, nor is it presently the position, that monopoly prices are outlawed. The law should simply allow an appropriate market structure to be in place to allow effective, workable competition. If the market is competitive, and the monopoly prices are being added, then the government should not interfere. It is only where the monopoly prices can be found, and the market itself permits no competition that regulation is necessary. If evidence is available that competitive structure associated with patented healthcare genetic tests and other genetic inventions is monopolistic, then the role of the government should be in ending this monopoly and allowing competitive conditions to evolve (eg, telecommunications).

Chapter 26 Crown Use and Acquisition

Proposal 26 - 1 The Australian Health Ministers' Advisory Council should develop a policy regarding the circumstances in which it is appropriate for the Commonwealth or a State to exploit a patented invention under the Crown use provisions of the Patents Act 1990 (Cth) (Patents Act) for the purposes of promoting human health. Similarly, the Commonwealth Department of Health and Ageing should develop a policy regarding the circumstances in which it is appropriate for the Commonwealth to acquire a patent for the purposes of promoting human health.

Proposal 26 - 2 The Commonwealth should amend the Patents Act to clarify that, for the purposes of the Crown use provisions, an invention is exploited 'for the services of the Commonwealth or the State' if the exploitation of the invention is for the provision of healthcare services or products to members of the public.

Proposal 26 - 3 The Commonwealth should amend the Patents Act to provide that when a patent is exploited or acquired under the Crown use or Crown acquisition provisions of the Patents Act, the Crown must pay such remuneration or compensation as is:
(a) agreed between the parties; or
(b) determined by a prescribed court to be just and reasonable having regard to the economic value of the patent.

Whilst we agree generally with these Proposals, we are not in a position to comment further.

Chapter 27 Compulsory Licensing

Question 27 - 1 Should the Commonwealth amend the Patents Act 1990 (Cth) to clarify the test for the grant of a compulsory licence? If so, should the Commonwealth
(a) clarify the circumstances in which the 'reasonable requirements of the public' will not have been satisfied; or
(b) specify that s 135 is not an exhaustive list of the circumstances in which a patented invention would fail to satisfy the 'reasonable requirements of the public'?

It would certainly be desirable to clarify the compulsory licensing provisions contained in the Patents Act. There are a number of difficulties with the test contained in s133(2), including uncertainty as to the meaning of 'reasonable requirements of the public', and the level of remuneration payable to the patent holder. It is also not clear what a 'reasonable period' of time within the context of s133(3A) means. Any attempt to more clearly circumscribe the circumstances in which the reasonable requirements of the public test have not been satisfied is prone to the same difficulties that currently exist. It would be difficult to delineate with any precision the circumstances in which this test has not been met.

Specifying that s135 is not an exhaustive list of the circumstances in which a patented invention would not satisfy the test has its own difficulties. It assumes of course, that there are additional grounds on which the test could apply, and it does not clarify the existing components of the test. There are a multitude of bases contained in national legislation that may ground applications for compulsory licences.[26] Stating that s135 is not an exhaustive list is sure to give rise to interpretational difficulties, as the bounds of the test will become increasingly unclear.

Settling on a solution to the problems raised by the section is therefore challenging. It is hard to see how the section itself could be amended to provide any level of certainty on the scope of the reasonable requirements of the public provision. Despite these difficulties, we conclude that it would be preferable to attempt to set out more clearly the circumstances in which the reasonable requirements of the public test have been satisfied, paying close attention to the grounds in national legislations of other countries for the issue of compulsory licences.

Proposal 27 - 1 The Commonwealth should amend the Patents Act 1990 (Cth) (Patents Act) to insert the competition-based test that was recommended by the Intellectual Property and Competition Review Committee as an additional ground for the grant of a compulsory licence. The amendment should also provide for an independent review of the operation of the compulsory licensing provisions in addressing competition concerns arising in relation to patented inventions. This review should be conducted five years after the new test commences operation.

We agree with this Proposal. We note, however, that the IPCRC recommended repeal of s135 of the Patents Act and the amendment of s133(2) to include a competition test.[27] This amendment would effectively remove a ground (that is, the 'reasonable requirements of the public' ground) for issue of a compulsory licence. Instead, we would support the adoption of the Government's response to the IPCRC Report, that a competition based test be an additional ground for the grant of a compulsory licence. Despite the fact that the provisions are, at present, cumbersome, there is desirability in retaining (and clarifying in line with Question 27-1) the reasonable requirements of the public test.

[26] See Jane Nielsen and Dianne Nicol, 'Pharmaceutical Patents and Developing Countries: The Conundrum of Access and Incentive' (2002) 13 *Australian Intellectual Property Journal* 21 at 32-33.
[27] IPCRC Report at 162-3.

There is certainly a risk of anti-competitive conduct with respect to the use of gene patents. Adding a competition-based test to the compulsory licensing provisions would provide a ground for addressing anti-competitive conduct, Particular issues for this industry may be misuse of market power, the defensive use of patents by oligopolies so that they constitute a barrier to entry to non-oligopoly members.[28] Many compulsory licences have been issued in the United States to remedy anti-competitive conduct.[29]

We would emphasise, however, that the compulsory licensing provisions are fairly unworkable at present. The unwieldy procedure for obtaining a compulsory licence makes it unlikely that the provisions would be frequently utilised. Without streamlining the process for application for a compulsory licence, the provisions are unlikely to be effective. Few applicants will have the resources or the time to pursue an application. Further, the threat of utilising compulsory licensing provisions may act as a spur to negotiations for voluntary licences in some instances. This threat is likely, however, to be largely non-existent in Australia given the under-utilisation of the Australian scheme. The inequality in bargaining power between many companies, particularly where those companies are start-ups, reinforces this problem.

We agree that a review of the operation of the provisions should be conducted within five years of the amendment of the provision.

Question 27 - 2 Should the Patents Act be amended to allow a compulsory licence to be granted to a patent holder who cannot work his or her patent without using another patent for which authorised use cannot be obtained? If so, in what circumstances?

Unfortunately s133 fails to provide relief to holders of dependant patents in the form of a ground for application for a compulsory licence.[30] For the reasons outlined in Discussion Paper 68 at 726-8 and in the Nicol-Nielsen study at 239, we are strongly of the view that the position in relation to dependent patents requires clarification and legislative amendment. Given the cumulative nature of biotechnology research, cases of dependent patents are very likely to arise in the context of gene patents. This is therefore a ground that should be provided for in s133. In many cases, owners of dependent patents will be able to obtain a voluntary licence. But if negotiations prove to be unsuccessful, a dependant patent holder should not be precluded from seeking a compulsory licence. We agree that s133(3B) gives rise to considerable illogicality.

A dependant patent may constitute a new application, or a minor improvement over an original invention. Original patents may facilitate follow-on invention in that they may

[28] See generally John H Barton, Antitrust Treatment of Oligopolies with Mutually Blocking Patent Portfolios (2002) 69 *Antitrust Law Journal* 851.
[29] Frederic M Scherer, 'Comment' in Robert Anderson and Nancy Gallini (eds), *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (1998: University of Calgary Press, Calgary) 104 at 108.
[30] It may be that the reasonable requirements of the public test could be relied on by the owner of a dependent patent.

make follow-on research possible. In other cases, follow-on research would simply be slowed or only possible at greater cost if the follow-on researcher did not have the prior research to build on.[31] There are therefore differing degrees of follow-on invention and dependency. We are not suggesting that an application for a compulsory licence should be available to every holder of a dependent patent.

We propose therefore, that the existing test contained in s133(3A) be utilised in formulating a ground in s133 for the issue of a compulsory licence in circumstances of dependency. An application should therefore be available to a holder of a dependent patent where the dependent patent involves an 'important technical advance of considerable economic significance' over the invention for which the compulsory licence is sought, as noted in the Nicol- Nielsen study at 239. Such an amendment would ensure that a compulsory licence is not available for every instance of dependency. Indeed, only holders of patents for new and important applications would be likely to fall within the ambit of such a test. It is likely that only patent holders whose patented inventions fell into such a category would go to the trouble of applying for a compulsory licence in any event.

Question 27 - 3 Given the provision in the Patents Act for Crown use of patented inventions, should the Act also make provision for the grant of a compulsory licence over a patented invention in circumstances of 'a national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use'? If so, should a compulsory licence be available whether or not the applicant has tried for a reasonable period to obtain a licence from the patent holder?

For the reasons outlined in Discussion Paper 68, we would agree that it would be appropriate to make an amendment to the Patents Act to allow a compulsory licence in situations of 'national emergency or other circumstances of extreme urgency', or cases of public non-commercial use. The requirement for reasonable efforts to obtain a licence should be waived in such an instance. Such an amendment would be consistent with Article 31 of TRIPs.

We recommend that the ALRC should go further than merely recommending that the compulsory licensing provisions should be amended to cover national emergency and other like situations in Australia. We believe that the compulsory licensing provisions should be amended more fully, to reflect the Doha Declaration on the TRIPS Agreement and Public Health in its entirety, including the agreed paragraph 6 mechanisms to enable supply of drugs manufactured under a compulsory licence to countries that lack manufacturing capabilities.[32] Implementation of provisions of this nature in the *Patents Act* 1990 would reflect well on Australia's role as a good international citizen.

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[31] See Frederic M Scherer, 'The Economics of Human Gene Patents' (2002) 77 *Academic Medicine* 1348 (Scherer 2003) at 1361-2; Suzanne Scotchmer 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law' 5 *The Journal of Economic Perspectives* (1991) 29 at 31.

[32] TRIPS Council (2003) Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (last accessed 26 September 2003).

Question 27 - 4 Should the Commonwealth amend the Patents Act to authorise a prescribed court, when granting a compulsory licence, to require the transfer of 'know-how' relating to the patented product or process?

We agree that in many cases associated know-how will be required in order to allow the exploitation of a licensed invention. We make no submissions on how frequently this is likely to be the case, as we have no evidence on this fact. If, however, it becomes apparent that know-how is required in a considerable number of cases, the compulsory licensing provisions should be amended to require the transfer of know-how along with a patented product or process.

Chapter 28 A Statutory Licensing Scheme

Question 28 - 1 Should the Commonwealth amend the Patents Act 1990 (Cth) to include a statutory licensing scheme for patented inventions? If so:
(a) should the scheme be available only to a limited class of patents or a limited class of users;
(b) should the scheme be voluntary or compulsory in nature; and
(c) how should a reasonable royalty for the scheme be determined and who should administer the scheme?

There has been extensive commentary on the compulsory licensing option as an alternative to an experimental use exemption, particularly in biomedical research. Strandburg, for example, proposes a two-tier scheme in which research tool patent holders have a period of complete exclusivity followed by a period during which compulsory licences become available.[33] In our view the type of compulsory licensing generally referred to in this literature is not the sort of licensing provided for in the *Patents Act,* where one-off applications are made to the court or the patent office and decided on case-by-case basis, following full hearing on the merits.

We refer to the type of licensing referred to in the literature as statutory licensing, to distinguish it from existing compulsory licensing provisions. We note that the ALRC has also adopted this terminology. In our view, there is some attraction in creating a statutory licensing scheme for some types of patents, particularly research tool patents in hybrid and applied research.[34] Strandburg's two-tier scheme may well be an appropriate additional mechanism for ensuring that research tool patent holders secure appropriate benefits from their patents.

At present we still are leaning towards the view that a voluntary scheme would be most appropriate, at least in the first instance. As noted in Discussion Paper 68 at 750-752, a voluntary scheme would be least likely to offend against the provisions of the TRIPS

[33] See, for example, Strandburg, above n8 at 67-77.
[34] We note that if a non-commercial research exemption is implemented, the statutory licensing scheme would only need to operate for research with commercial aims.

Agreement. In effect, a voluntary scheme would give statutory force to the type of clearinghouse mechanisms discussed by us in response to Proposal 23-3, in much the same way as the voluntary licensing schemes apply under the *Copyright Act* 1968.

We are pleased to see that the ALRC received in principle support for statutory licensing in some of its consultations. Whilst we are not in a position to present further details of out preferred option for statutory licensing at this stage, we believe that there is scope for the ALRC to consider it further in the Final Report to this Inquiry.

Chapter 29 Copyright, Trade Secrets and Designs

Proposal 29 - 1 The Commonwealth should amend the Copyright Act 1968 (Cth) to clarify the extent to which 'fair dealing for the purpose of research or study' applies to commercial genetic research.

We agree with the views of ACIPA and others that that copyright law should promote the free flow of scientific information and that the fair dealing defences in their current form have deficiencies. However, this is a matter that requires comprehensive amendment rather than sui generis amendment only in respect of commercial genetic research.

We agree with the views of Professor Ricketson that there is nothing on the face of the *Copyright Act* to limit research and study fair dealing to non-commercial research.

We submit that copyright law is only likely to have a minor role in commercial genetic research. Whilst copyright may exist in gene sequence information, it only provides the limited right to prevent actual copying, as opposed to the monopoly right granted to patent holders. This means that gene sequence information can be independently generated by another researcher without the risk of copyright infringement. Where gene sequence information is accessed from a database it is likely that contractual principles will prevail. Arguably, if gene sequence information placed in the public domain is protected by copyright, the owner could impose limitations on the downstream use of the information. In such circumstances research and study fair dealing becomes a relevant consideration. Given that the information has been placed in the public domain, however, it is unlikely that the copyright holder would want to impose significant limitations on research use. Open source principles also become relevant.

Chapter 30 Protection of Genetic Databases

Question 30 - 1 Should the Commonwealth amend the Copyright Act 1968 (Cth) to provide that, in relation to genetic databases protected by copyright, the operation of the provisions for fair dealing for the purpose of research or study must not be excluded or modified by contract or technological protection measures?

The issue of whether these provisions can or cannot be excluded by contract has been the subject of a major review by the Copyright Law Review Committee. Whilst there is some

desirability in amending the *Copyright Act* 1968 (Cth) to ensure that there provisions cannot be excluded, our view is that it would be inappropriate to make specific recommendations dealing only with genetic databases.

Question 30 - 2 Should the Commonwealth amend the Copyright Act to establish a statutory licensing scheme in relation to genetic databases protected by copyright?

We do not consider that it is necessary at this stage to introduce a specific statutory licensing scheme for genetic databases.

Question 30 - 3 Does the new Celera subscription agreement cause any significant concerns for public research institutions or researchers engaging in publicly funded research? If so, what are these concerns?

We are not aware of any significant concerns caused by the new Celera subscription.

Question 30 - 4 Should the National Health and Medical Research Council, or another Commonwealth body, have responsibility for monitoring the operation of agreements between genetic database owners and publicly funded research institutions within Australia?

The NHMRC will review the *National Statement for Research For Ethical Conduct in Research Involving Humans* with a view to including a new set of principles governing human genetic databases (recommendation 18-1 report 96, 2003). It is appropriate that the new guidelines include a requirement for those responsible for the genetic database to complete reports on databases as part of the annual compliance system for human research ethics committees. In addition, it may be desirable for the proposed HGCA to monitor the operation of genetic databases and their relation with public funded institutions.