

**Submission from Bio21 Australia Ltd in response to the Australian Law Reform Commission
Discussion Paper 68: Gene Patenting and Human Health**

1. This response is limited to Chapter 14, Experimental and Research Use Defences
2. Bio21 Australia Ltd is a company of fifteen member institutions all involved in academic research (membership list attached – appendix 1). <http://www.bio21.com.au/>
3. **The key point for Bio21 Australia Ltd member institutions is that it is not clear from the proposed experimental and research use defence (Proposal 14-1) what exactly would be covered by that defence.** If a new experimental use defence becomes law the ALRC should ensure it provides material with the proposal & report, the legislative provision and any explanatory memoranda to give an overview of what it believes is covered by the defence (which we believe should be the items noted in paragraphs 4-6 below) to aid the courts in their interpretation
4. Sections 14.49 – 14.51 discuss a defence specific to gene patents, which is a proposed amendment in the USA. This would appear to provide a greater certainty in the use of genetic sequences. It is not clear if this provision has or will become law in the USA. If covered by the defence, the description provided in 14.103, would give some certainty on the allowable use of genetic sequences, that is “researchers will be able to conduct research on patented DNA sequences without violating that patent if the research relates to improving, further developing or testing the DNA sequence. Research aimed at discovering another function of the DNA sequence, its interrelation with another DNA sequences, or its involvement in the development of disease, for example, all arguably fall within the meaning of improving or further developing the DNA sequence”. However, it is not clear from the Proposal (14-1) that this is in fact the case.
5. The justifications for an experimental or research use defence as outlined in section 14.80 would appear to cover the issues of concern to researchers about their freedom to operate namely:
 - enables the validity of existing patents to be properly tested by experimentation;
 - enables experiments to be conducted to determine whether a patentable invention falls within the scope of an existing patent;
 - promotes attainment of new knowledge about patented inventions;
 - promotes the development of new and improved inventions and reduces the likelihood of monopolisation of a new area of technology by a patent holder;
 - removes a burden on researchers, who might otherwise need to conduct extensive patent searches and obtain advice from lawyers and patent attorneys; and
 - involves minimal interference with the patent holder’s economic interests
6. Similarly the acts as listed in 14.136 viz:
 - testing an invention to determine its sufficiency or to compare it to prior art;
 - tests to determine how the patented invention worked;
 - experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention;
 - experimentation for the purpose of ‘designing around’ a patented invention;
 - testing to determine whether the invention met the tester’s purposes in anticipation of requesting a licence; and
 - academic instructional experimentation with the invention.

- would seem to cover the areas of concern to researchers. **However, it is not clear to members of Bio21 Australia Ltd that the defence proposal as worded would in fact cover these acts or allow the justifications.** Thus, for instance, it is not clear if the issue over use of genetic sequences noted above is, in fact, covered.
7. In the current situation, with no explicit defence, researchers have been conducting research on an implicit assumption that academic research does not infringe patent rights, despite a general awareness of the issues with some high profile reports on patenting of genetic materials. As Professor Nick Nicola, of the Walter and Eliza Hall Institute, points out some of the issues may go back to the initial granting of patents (comments at appendix 2). The amendments to the Patents Act proposed in 6-2 may assist here.
 8. An additional concern would be how any potential free trade agreement with the USA might impact on an exemption for research or experimental use enacted in Australia.
 9. At the current time Bio21 Australia Ltd has received no evidence from its members that their research is impeded by lack of an experimental use defence although as noted above this is most likely due to researchers being unaware if they infringe patent rights. However, this situation may not pertain in the future given the heightened awareness of the issues. There is a concern that within the six-year statute of limitations retrospective claims of infringement may be made, especially where a piece of academic research has subsequently had commercial outcomes. Researchers are concerned that in the extreme, all researchers would need to do patent searches on any reagent, technique, gene sequence, protein or animal they might use, do a freedom to operate analysis and then negotiate licenses whenever there relevant patent is discovered. This would place a huge administrative and financial burden on researchers and research organisations and would essentially stop innovative academic research as we know it. Therefore if researchers are not free to conduct academic research under current Australian patent law some protection is needed.
 10. From a reading of the literature it appears that the EU/UK exemptions when tested in the courts have allowed a wider interpretation of experimental and research use boundaries than has occurred in the USA. We urge that the differences in legislative approach be further analysed, with preference for the EU/UK approach.
 11. Bio21 Members are very concerned that if a defence is enacted as proposed by the ALRC, courts and patent owners will interpret this as meaning that all conduct not clearly and explicitly within the scope of the defence will be an infringement. We are concerned that this will encourage patent owners to enforce their patents more aggressively against researchers, including non-profit and university sector researchers. We suggest that the ALRC final proposal & report, the legislative provision and any explanatory memoranda should make it clear that the defence is not intended to be a codification of the common law, and that it applies *in addition to* any common law defence, and any limits to the concept of "exploitation" of an invention that might exist at common law.
 12. Once a new experimental use defence becomes law the ALRC and other relevant bodies should ensure that there is widespread education of the scientific community, and others, to understand what falls within and what lies outside the scope of the defence.

Membership of Bio21 Australia Ltd

As at January 2004

Founding Members:

- Melbourne Health
- University of Melbourne
- Walter and Eliza Hall Institute of Medical Research

Joining Members:

- Austin Biomedical Alliance
- CSIRO Health Sciences & Nutrition
- Howard Florey Institute
- Ludwig Institute for Cancer Research
- Murdoch Children's Research Institute
- Peter MacCallum Cancer Centre
- St Vincent's Health
- St Vincent's Institute of Medical Research
- Women's & Children's Health

Associate Members:

- Cancer Trials Australia
- Neurosciences Victoria Ltd
- Victorian College of Pharmacy, Monash University

Comments from Professor Nick Nicola

Walter and Eliza Hall Institute of Medical Research

Some of the questions are technical relating to patent laws and I do not feel competent to comment on legal issues. My general comments however are the following:

My understanding of patents are that they are awarded by governments to inventors as an incentive to replace commercial secrecy with public disclosure of the invention so that it can contribute to further economic developments in the future. The incentive is a limited monopoly right to make use of the invention for commercial purposes (or more correctly a right to exclude others from making commercial use). The invention is defined by the claims, which demonstrate the actual commercial utility.

If this is correct then it must have been intended that the invention could be used for further research (regardless of whether the research is commercial or not) so long as the user does not sell the invention (ie compete against the monopoly rights).

In some cases this is quite straightforward. If someone invents a new mass spectrometer others cannot make and sell it but, after they buy it, they can use it to produce an improved mass spectrometer or to identify a new drug. In the former case they may need licensing if the new spectrometer contains a substantial embodiment of the old one but in the latter case no license would be required.

The problem arises when the invention itself is a research tool or reagent that is being sold. Use of the invention (without buying it) would then be a violation of the monopoly right even if it is not sold to others because the user(s) would be eliminating the potential market for the invention. One example is a database. If a subscription is bought and it is used to discover a new product there should be no license required unless this was an explicit condition of the sale. On the other hand the database (or any improvement that incorporates the original database) cannot be on-sold without a license. Another example is PCR. If PCR is used to identify a new gene there should be no license fee. However, a diagnostic kit that incorporates a PCR reaction would require a license before it is sold. A real problem is a research procedure that is patented but is not an entity that can itself be sold (eg animal breeding protocols, GTG patent etc). In this case it is difficult to see how such patent applications passed the industrial utility requirement since they do not represent something that can be sold (ie once it has been disclosed). The claims should have indicated the commercial utility, which would then make it clear if a particular use of the invention impinges on the monopoly right or not.

In short I think it should be an obligation of a patent examination to define the commercial uses and market that an invention covers so as to define exactly the monopoly right. Research on the invention should then be exempt if it does not impinge on the commercial monopoly right as described and granted.