

March 1 2005

Mr Sean Applegate
ACIP Secretariat

By email: sean.applegate@ipaaustralia.gov.au

Dear Sean,

Re: Bio21 Australia Ltd response to ACIP Patents & Experimental Use Options Paper

Bio21 Australia Ltd is a company of fifteen member institutions, all involved in academic biomedical research (membership list attached – Appendix 1) www.bio21.com.au. Bio21 welcomes the opportunity to comment on this paper.

We wish to record the following response to the preferred options listed by ACIP on page 17.

Option B – no change

Bio21 believes that as there has been extensive discussion around the issue in the last 12-18 months, this is no longer a viable option. For instance, the issue has been discussed at meetings of the Bio21 Scientific Advisory Council and Bio21 Business Development Managers (at both meetings all Members are represented), by the Knowledge Commercialisation Professionals group that comprises members from a wide range of research entities in Melbourne, and it was raised at a specific session at the BIO 2004 meeting (San Francisco, June 2004) particularly related to law in the USA and EU but the Australian perspective was also mentioned. In addition, an article “Patent Shakeup Looks Likely” was printed on the front page of the February 18 edition of Australian Biotechnology News. A great deal of uncertainty has been created and this needs to be resolved. There is a risk that if there is no change and a case is brought which results in a very narrow interpretation of experimental use this would have a serious impact on Australia’s research capabilities. However, Option B would be better than a narrow exception that did not cover the activities which researchers actually do.

Bio21 understands that the patent system was intended to provide to an inventor protection of markets and of the commercial value of an invention in return for making the details of an invention publicly available to further enable the research and innovation system for economic benefit. There is a *quid pro quo* in the system. If that is the case then an experimental exemption would appear necessary to allow for that further research.

Options in Part C

Two preliminary points should be made. First, the recent ALRC report 99, “Genes and Ingenuity” suggested an experimental use exemption which included “study” as well as experimentation. We suggest the ACIP recommendation should also include the term “study”.

Second, the ALRC recommendation also has the additional proviso that "the existence of a commercial purpose or objective does not preclude the application of the exemption" ie including the second part of ACIP option C3. Bio21 supports this inclusion. As argued by the ALRC (paragraphs 13.48- 13.53) it is increasingly difficult to distinguish when research is purely for knowledge acquisition alone and when it has a more applied and therefore potentially commercial purpose. In addition, the requirement of many public funding agencies such as NHMRC or ARC for an indication of the commercial potential of a research project would place researchers in a difficult situation in claiming an experimental use exemption without this proviso.

The more important issue is which Option will best enable the research effort to continue without unnecessary impediment.

Bio21 considers that the use of *examples* of legitimate activities, in Options C7 and C8, is helpful to researchers.

We consider, however, that the language of **Option C8**, by referring to experimentation 'on the subject matter of the invention' is too narrow. For example C8 would allow experimentation on say a mass spectrometer to improve its performance, but would not allow the use of a mass spectrometer for the discovery of a new drug completely unrelated to the commercial monopoly granted for making and selling mass spectrometers. Similar restrictions would apply to all scientific instruments and tools.

Of the available options, Bio21 is most inclined to support **Option C7 – Exemption for fair experimentation with inclusive permitted uses**. This exception, with its accompanying details provides an option that could be fair to both inventors and experimenters. It is appropriate to allow experimentation which is *fair*, and which, importantly, does not interfere with the market for the inventor's product.

However, we consider that C7 would be more effective if it referred, instead, to experimentation "with an invention". Such a phrase would cover what researchers actually do. They work with one or more inventions to discover something new and beyond the scope and imaginings of those inventions – this is the creative process.

One objection to an exception covering experimentation with an invention might be that it would render patents on research tools worthless. However, it is our view that these concerns are dealt with by the requirement that the experimentation be fair, taking into account the "commercial effect of the act upon the patent holder". Researchers who refused to purchase PCR kits, or mass spectrometers, would not be engaging in 'fair' experimentation, once the commercial effect is taken into account. However, researchers use for experimental purposes many different inventions a day and, in general, these experiments in no way impinge on the commercial interests of the inventor. If researchers are required to (i) establish whether any and every part of their experiment is covered by a patent and (ii) apply for a licence to use that invention, the entire research effort will grind to a halt.

Bio21 members believe that if an exception is created for *fair* experimentation, researchers would have some protection from unreasonable demands or interferences in the research process, without having to go to all the trouble, and expense, of challenging the validity of the patent or patent claims – a process which is not viable for most of our members. Bio21 therefore favours an option which will allow the maximum scope for research to continue, while still protecting the legitimate commercial interests of inventors. We consider that, of the current options, **Option C7** offers the best chance for such a balancing of interests.

Broader issues that should not be ignored

Bio21 is of the view that patent granting processes are closely related to the issue of the experimental use exemption being considered by ACIP. Researchers at institutions which are members of Bio21 are aware of situations in which patentees have asserted not only rights in their own invention, but also rights in things discovered *using* their invention: for example, recent patent applications in Australia relate to animal breeding protocols that could be used to identify mutated genes. These patents would appear to have little commercial value except to the extent that they would require a license for others to use them in their research, i.e. their commercial value is based on the premise that there is no experimental use exemption. This contrasts with an experimental tool that can be manufactured and sold and for which we believe it is appropriate to give patent protection. We believe these kinds of demands, whether included in the patent claims or otherwise asserted, are inappropriate and can hamper the research process. In particular, when it comes to the process of granting patents, it is vitally important that overreaching claims are not allowed. We also consider that there should be an obligation, at the time a patent is applied for, to define the commercial uses and market that an invention covers so as to define exactly the monopoly right. Research with the invention should then be exempt if it does not impinge on the commercial monopoly right as described and granted. It appears that some patents have no commercial utility but are perhaps a way to generate income simply by blocking the research process. These issues are related to the question of the research exception. The system of examination is inevitably imperfect and the existence of overreaching patent claims, and patents where specific utilities are not identified or described makes the inclusion of a research exception all the more important. However, the creation of a research exception should not be considered a complete answer to these problems, and these other issues should not be ignored.

We would be happy to meet with the ACIP committee at any time to elaborate further on any of the issues raised.

Yours sincerely

A handwritten signature in black ink that reads "Stella Clark".

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Membership of Bio21 Australia Ltd

As at February 2005

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
- Royal Women's Hospital
- St Vincent's Health
- St Vincent's Institute of Medical Research

Associate Members:

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