Submission to the Senate Legal and Constitutional Affairs Committee inquiry regarding the Patent Amendment (Human Gene and Biological Materials) Bill 2010

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Summary

It is imperative that legislation be as clear and unambiguous as possible. This is particularly important in Australia where patent litigation is less common than in other parts of the world. The current scope of the Bill is unclear, and is likely to cause uncertainty for future patent applicants and those investing in the biotechnology sector.

The Bill may not achieve its proposed ambition and may cause other undesirable consequences that are contrary to the aims of the Bill. Alternative superior mechanisms are either already in place or have previously been recommended by the Australian Law Reform Commission. These measures should be taken up in preference to the amendments proposed by the Bill. Although the aims of the Bill are well meaning, the Bill cannot be supported in its current form.

La Trobe University

La Trobe University has a focus on research of the highest academic quality and on making a difference in society through its research. Of particular relevance are the key research strengths of Agribioscience, and Environment and Molecular Science encompassing the disciplines of botany, zoology, microbiology, geospace, agricultural science, environmental management, ecology, biochemistry, chemistry and physics.

At La Trobe University, the La Trobe Institute for Molecular Science (LIMS) has been funded by the Commonwealth government with $64.1 million to pursue basic research with a view to successful translation into commercial products such as therapeutic and diagnostic reagents for the treatment of cancer and autoimmune diseases. Additionally, the Bioscience Research Centre project is a $288m partnership with the Victorian government leading to AgriBio, the Centre for AgriBioscience which will help to protect Victoria's $11.8 billion agricultural sector from disease and strengthen Victoria's international reputation for agricultural research and diagnostics.

One of the mechanisms through which La Trobe University can translate research outcomes for the benefit of society is through the patent system. La Trobe University is therefore an active and regular participant in the patenting process, both on its own and along with many other academic, government and commercial collaborators. The subject matter of the University's patent portfolio encompasses a range of technologies including biological materials.

The purpose of this submission is to contribute to the debate about the potential impact of the changes proposed by the Bill.

Patent Amendment (Human Genes and Biological Materials) Bill 2010

The stated purpose of the Bill is "to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature."

The Explanatory memorandum accompanying the Bill also provides that one of the aims of the Bill is to "reinforce the applicability of the distinction between discovery and invention by excluding from patentability, biological materials which are identical or substantially identical to such materials as they exist in nature".

The mechanism provided within the Bill to reinforce the distinction between discovery and invention is , in part, to invoke the proviso of the Statute of Monopolies in which matters were patentable provided that were not "contrary to the law, nor mischievous to the State, by raising prices of commodities at home or hurt of trade, or generally inconvenient".

Additionally, the Bill seeks to exclude from patentability "biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature".

Clarity of the Amendments

The introduction of the proviso of the Statute of Monopolies provides no clarity or certainty that the resultant interpretation will in fact be to exclude discoveries from patentability. Moreover, the Bill does not link the introduction of the proviso with the restriction of biological materials. The applicability of the proviso to the other branches of science and engineering is therefore uncertain and should be clarified. Discoveries and inventions are not restricted to the field of biology.

Unclear legislation should be avoided at all costs. In its current form, the Bill would result in uncertainty for patent applicants and investors in scientific research and ultimately cause unnecessary litigation.

Recommendation: That if the intention of the Bill is to restrict discoveries from patentability then this should be stated in clear language, and if the restriction is to apply to all fields of technology then this should be stated explicitly in the Bill.

Scope of the Amendments

The Bill proposes that the exclusion from patentability should extend to "components and derivatives" of biological materials as well as to "substantially identical" materials. The scope of these phrases is not further elucidated within the Bill or the explanatory memorandum. It is not clear, for example, whether a diagnostic test that uses a biological component would be included. It is also well known that the alteration of a single amino acid in a protein can have a significant impact on its activity. Such alterations may be enormously beneficial and their invention should be encouraged. Would such a modification be "substantially identical"? The Bill should be limited to naturally occurring materials and should not overstep the boundary to artificially created materials. A clearer wording would be "biological material *per se*".

- **Recommendation: The reference to "components and derivatives" and "substantially identical materials" should be deleted.**

Effectiveness of the Amendments

One of the aims of the Bill is to prevent the future patenting of human genes, it does not act retrospectively on existing patents. The Human Genome Sequencing Project was completed in 2003[1]. It is therefore likely that the effect of the Bill would be to shut the gate after the horse has bolted, since the genes discovered by the project are already either patented or in the public domain and therefore not able to be patented.

It should also be noted that the ALRC has previously concluded that "there is limited evidence to date that gene patents or licensing practises have had any significant adverse impact on the conduct of genetic research or on healthcare provision in Australia".

- **Recommendation: Seek more effective alternate means of achieving the aims of the Bill**

[1] International Consortium Completes Human Genome Project: http://www.genome.gov/11006929

The Provision of Public Access to Patented Inventions

Alternative options are available to meet the aims of the Bill and avoid its shortcomings. In line with the National Medicines Policy, the Pharmaceutical Benefits Scheme provides Australia with a robust and flexible mechanism by which the public may gain affordable access to otherwise expensive patented pharmaceutical and biological medication while maintaining a viable pharmaceutical research and development industry. An advantage of this approach is that it can be invoked after the patent has been granted. Biological materials are already included within the PBS, for instance, the biological Ranibizumab is currently the 8th highest cost PBS drug, costing the Commonwealth $123 million on its own in the year ended June 2009 at an average price of $2,084 per prescription.

Access to the recent, well-publicised Genetic Technologies Breast cancer patents had the potential to cost millions of dollars. However, the magnitude of this figure should be viewed in light of the $7.6 billion currently paid by the Commonwealth Government through the PBS for access to patented pharmaceuticals[2].

An additional alternative existing mechanism to provide public access to patented inventions lies in section 163 of the Patents Act 1990: Exploitation of Inventions by the Crown. The ALRC has already recommended that the Australian Health Minister's Advisory Council and the Department of Health and Ageing should develop policies regarding the circumstances in which it may be appropriate for the Commonwealth or a State to exploit a patented invention "for the purposes of promoting human health.[3]

- **Recommendation: Make use of the superior existing mechanisms available to achieve the aims of the Bill.**

Experimental Use Exemption

One of the aims of the Bill is to advance medical and scientific research. The Australian Law Reform Commission has previously recommended a robust mechanism to achieve this aim. An Experimental Use Exemption would provide "an exemption from patent infringement for acts done to study or experiment on the subject matter of the patented invention". This approach would be preferable to the Bill since it would apply broadly to researchers in all fields of technology and not be limited to the field of biological research.

- **Recommendation: Introduce the Experimental Use Exemption previously recommended by the ALRC.**

[2] PBS Expenditure and prescriptions twelve months to 30 June 2009
http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs_expenditure_prescriptions-copy1

[3] http://www.austlii.edu.au/au/other/alrc/publiations/reports/99/_4.html

University Collaboration with Industry and the Commonwealth Funding of Research

Recent trends have seen the reduction of Commonwealth funding for University research. Universities have now forged stronger links with Industry collaborators. The protection provided by the patent system to the investment by Industry partners in the university research is critical to the maintenance of this ongoing financial input to the University. Since much of the research undertaken at universities is at an early stage, these industry partners typically do not simply acquire the patent rights but contribute significant financial and in-kind resources in return for future patent rights to the research outcomes.

As mentioned above, La Trobe University has a research focus in biological sciences and agricultural biology. Through industry interaction, La Trobe receives significant industry financial contributions toward biological research. La Trobe has also been a long-standing participant in the Collaborative Research Centre (CRC) program and is currently a member of the CRC for Biomarker Translation. These forms of scientific advancement would otherwise not occur if it were not for industry support and patent protection.

The purpose of the patent system is to encourage innovation. In the absence of the protection provided by the system much high-cost research would not be undertaken and the public would not benefit from the existence of the research outcomes. Lack of funding is a more significant impediment to scientific research than patent litigation in Australian.

The current Bill would significantly impair the La Trobe University's ability to attract industry partners in the biological technologies and cause a reduction in this basic research – an opposite effect to its intended aims.

Recommendation: The Bill should not be implemented in its current form