**Association of Australian Medical Research Institutes**

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February 25th, 2011

Committee Secretary
Senate Standing Committees on Legal and Constitutional Affairs
PO Box 6100
Parliament House
Canberra ACT 2600 Australia

Dear Secretary,

**RE: Association of Australian Medical Research Institutes Submission to the Senate Legal and constitutional Affairs Committee's Patent Amendment (Human Genes and Biological Materials) Bill 2010 Inquiry**

AAMRI welcomes the opportunity to make a submission to the Senate Standing Committee on Legal and Constitutional Affairs inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010.

The Association of Australian Medical Research Institutes (AAMRI) is the peak body that represents Australia's pre-eminent independent, not-for-profit medical research institutes (MRIs). All 37 AAMRI member institutes are accredited by the National Health and Medical Research Council and are recognised leaders in health and medical research, both in Australia and internationally. Our member institutes engage in a broad spectrum of research from fundamental biomedical discovery through to clinical research. As such, our members use patents to protect the commercial value of the intellectual property generated from their research. The temporary monopoly afforded by a patent is vital for securing the significant investment, both public and private, required to translate research into medical outcomes that benefit the public.

AAMRI contends that the proposed Patent Amendment (Human Genes and Biological Materials) Bill 2010 is legislative reform whose ramifications have not been fully considered. It will have major implications beyond the patenting of biomedical and healthcare innovations and will impact on the patentability of inventions from fields such as biofuel fermentation technology, sewerage treatment process and agricultural biotechnology. The amendment seeks to exclude "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". This is an extremely broad definition, which would exclude many promising genetic and biological therapeutics from being patented and developed into clinical interventions. For example, millions of diabetic patients around the world benefit from human insulin produced through genetic engineering. The human insulin gene is expressed in bacteria to produce vast quantities of

human insulin hormone just as it occurs in nature. Under the proposed amendment, recombinant human insulin would be not be a patentable invention as it involves biological material – this is despite the clear inventive process of using a cloned human gene for the novel application of treating diabetes.

A major concern regarding the proposed amendment is that it does not differentiate genes and biological materials from their potential application. There is little doubt that the isolation of genetic or biological material is not an invention. However, we must acknowledge that the development of a novel and useful application of genetic or biological materials, such as recombinant human insulin above, comprises a patentable invention.

AAMRI is concerned that the Patent Amendment (Human Genes and Biological Materials) Bill 2010 will have unintended negative impacts on Australia's healthcare, research and innovation sectors. Examples of research that would be exempt from patentability include projects that were recently awarded National Health and Medical Research Council (NHMRC) Development Project grants[3]. Funded research activities include the development of:

- a new genetic test for the Fragile X Syndrome in children and newborns (Murdoch Children's Research Institute); and
- a novel, orally administered drug, based on a natural natriuretic peptide isolated from snake venom, to treat congestive heart failure (Baker IDI Heart and Diabetes Institute).

None of the technologies and therapeutics developed through these two projects, both of which are based at AAMRI member institutes, would be patentable under the proposed amendment. As a result, it would highly unlikely that sufficient commercial investment would be secured to progress these technologies to the clinic and approximately $750,000 of public research funding would be wasted.

The debate over gene patents – now expanded considerably with this amendment to include all biological materials – involves many complex legal and scientific issues. AAMRI's position regarding the proposed amendment to the *Patents Act 1990* has been largely informed by the findings and recommendations of the two previous inquires into gene patents: Australian Law Reform Commission (ALRC) report, *Genes and Ingenuity: Gene Patenting and Human Health* (2004)[1] and the Senate Community Affairs Reference Committee report, Gene Patents (2010)[2]. Both reports acknowledged the complexity of reforming the patent system given its fundamental importance to translating biomedical innovations into health interventions. AAMRI asserts that the recommendations delivered by previous inquiries provide a well considered and balanced framework for strengthening the patent system and ensuring the appropriate use and exploitation of patents while maintaining Australia's research and innovation sectors.

The concern surrounding the patenting of human gene sequences was initially prompted by Genetic Technologies attempts in 2002-3 and 2008 to enforce exclusive rights over the breast cancer genes, BRCA1 and BRCA2, within Australia. Both the ALRC and the Senate Standing Committee on Community Affairs noted that there have been limited examples of gene patents having a negative impact on the provision of healthcare or the restriction of medical research progress. This suggests that the problem does not lie with the subject matter of the patent, but with the errant behaviour of a small number of patent holders or licensees. AAMRI supports calls for the Australian Health Minister's Advisory Council (AHMAC) to establish a process to evaluate whether patents involving genes and biological materials are affecting the healthcare delivery costs in Australia. This will be an important

step towards alleviating ongoing community concerns and gathering sufficient data about the presumed economic impact of gene patents on the provisioning of healthcare.

Furthermore, it must be highlighted that gene patents are largely yesterday's problem as most patents have a twenty year term. Many of the early gene sequence patents, or patents with overly broad claims regarding genetic sequences, were issued during the late 1980s to early 1990s, and therefore, have by now either expired or are nearing expiration (if they have not been previously invalidated or lapsed). This led the ALRC to note:
*"The Inquiry ultimately concluded that if there had been a time to recommend that gene sequences should not be patentable, that time had long since passed. Rather, it was preferable to focus on reforms that would make the system work better."* (ALRC99, p. 13)[1]
This refers to the ALRC findings that the issues surrounding gene patents were, in general, not specific to genetic materials or technologies. Instead it was determined that genes and genetic technologies had highlighted deficiencies within the patent system. As a consequence the ALRC report explicitly recommended that the *Patents Act 1990* **should not** be amended to exclude particular genetic materials and technologies from patentable subject matter (see Recommendation 7-1)[1]. The proposed amendment to the *Patents Act 1990* directly opposes this expert recommendation and threatens to smother future biomedical innovation and commercial investment. AAMRI would prefer to see reforms that are directed towards strengthening the patent system and refining the regulation of patent use and exploitation.

The ALRC identified during their inquiry that major scientific innovations, such as the early breakthroughs in genetics, place considerable stress on the patent system[1]. Inevitably, some inappropriate and overly broad patents are granted for the initial applications while examiners come to terms with the emerging science and technology. However, as patent examiners become more expert in understanding the nature, complexities and boundaries of the new field the scope patent claims become more appropriate. This situation has not been limited to genetic technologies but has also been observed with isolated chemical compounds and electronic business systems[1]. AAMRI would recommend that IP Australia enhance efforts to provide training and education to patent examiners in response to emerging areas of technological expertise.

Finally, AAMRI strongly supports the establishment of an experimental or research use exemption from liability for patent infringement. Australian health and medical researchers have long assumed that they are exempt from patent infringement. The implementation of such an exemption would provide AAMRI members with the freedom to conduct their research without any concerns of patent or licence infringement, and ease community concerns that gene and biological materials patents impede health and medical research progress.

Yours sincerely

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President, Association of Australian Medical Research Institutes

**References**


1. Australian Law Reform Commission. *Genes and Ingenuity: Gene Patenting and Human Health.* ALRC Report 99. Commonwealth of Australia. Canberra. 2004.
2. Senate Community Affairs Reference Committee. *Gene Patents*. Commonwealth of Australia. Canberra. 2010.
3. NHMRC Development Grants commencing in 2011. http://www.nhmrc.gov.au/_files_nhmrc/file/grants/funding/funded/development_grants_commencing_2011.pdf. Accessed February 20, 2011.