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BioMelbourne Network
Progressing BioIndustry

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

25 February 2011

Dear Ms Dennett

Submission to Senate Standing Committee on Legal and Constitutional Affairs - Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010

The BioMelbourne Network (Network) welcomes the opportunity to provide this submission to the Senate Standing Committee on Legal and Constitutional Affairs' (*Committee*) inquiry into the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (the Bill).

The Network was established in 2001 as an independent Victorian biotechnology industry association and represents some 160 organisations. The Victorian biotechnology sector is the largest biotechnology community in Australia.

This submission is made on behalf of the Network's membership which comprises predominately private sector biotechnology companies and service providers to the sector. Medical research institutes, public sector research organisations and universities also contribute to the Network's membership profile.

The Network asks that this submission be considered in the context of the effects that the Bill would have on Australian research and the biotechnology and pharmaceutical industries.

The Bill proposes to exclude the patenting of the following under Australian law:

> '*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.*'

The Network believes the effects of the proposed amendments to ban the patenting of all biological materials are extremely broad with serious consequences for the Australian biotechnology and pharmaceutical industries, and for research and development in this country more generally.

The Network draws the Committee's attention to the follow issues:

1. Patentable Inventions

- In order to be patentable, existing legislation requires (among other things) that inventions must be demonstrably novel, involve an inventive step and have a useful market purpose.
- The mere identification of a gene or a gene sequence provides no basis for securing a patent under current legislation. For example, simply removing biological material from its natural environment alone does not make that material eligible to be patented.
- The proposed amendments to the *Patent Act (1990)* may deny Australians access to the types of drugs currently listed on the Pharmaceuticals Benefit Scheme.
- Importantly, the proposed ban on all biological materials would impact on a diverse range of sectors including:
  - healthcare (e.g. vaccines, diagnostics and biopharmaceuticals)
  - agriculture, and
  - animal production.

2. Attracting Investment

- The average cost of discovering and developing a new medicine is more than AUD$1 billion. The average development time for new medicines is 12-15 years.
- Numerous studies highlight the fact that patent protection provides incentive for investment in R&D and provides investors a limited but guaranteed period of time to recoup their investment.
- In return for protection, the patent holder must disclose the details underpinning the invention. Disclosing this information in turn stimulates innovation and provides a critical pathway to translate R&D activity to market driven products and services.
- The proposed amendments will significantly diminish the ability for biotechnology and pharmaceutical companies to attract investors to take on risk and invest in product development. The flow on effects will result in fewer medicines and diagnostic tests being made available to Australians.
- In addition the Victorian biotechnology sector is fortunate to be well served by a highly skilled services sector with specific expertise in biological patenting. The Network is concerned that the banning of all biological materials would result in Australia losing the capabilities and skills of these service providers, coupled with a reduction in the support, peer learning and investment that they provide to the biotechnology and research sectors.

3. Equitable Access to Healthcare & Adverse Impact on Medical Research

- It is imperative that the Committee notes that patient access to a diagnostic test and the cost of that access will not be affected at all by the proposed amendments.
- The Network believes there are adequate and appropriate safeguards available to protect public interest from the undesirable behaviours of patent owners that may adversely impact on medical research &/or the cost of effective and equitable provision of healthcare.
- The Australian Law Reform Commission's (ALRC) report *Genes and Ingenuity: gene patenting and human health* (2004) specifically examined the impact of current patent laws related to genetic materials and technologies in the healthcare system.
- Recommendation 19.3 of the ALRC report is relevant to this issue and notes that Commonwealth, state and territory health departments should consider exercising existing legal options to facilitate access to these inventions. Legal options highlighted in Recommendation 19.3 include:
  - refer the issue to the Australian Competition and Consumer Commission where evidence arises of a potential breach of Part IV of the *Trade Practices Act 1974*
  - challenge a patent application or granted patent by initiating proceedings to oppose a patent application, requesting re-examination of a patent or applying for revocation of a patent under the *Patents Act 1990*
  - exploiting or acquiring a patent under the Crown use and acquisition provisions of the *Patent Act 1990*, and
  - applying for the granting of a compulsory licence under the *Patent Act 1990*.
- As noted by the Advisory Council on Intellectual Property in its recent report *Patentable Subject Matter* (2011), where patents on genes, genetic material and related technologies unduly restrict access to diagnostics and or medical treatment, "the Australian experience with pharmaceuticals (and medical treatment) suggests that the remedy to the access problem lies with a pricing mechanism, not with removing patent protection for these inventions." (page 7)
- Clinicians and researchers already have free and unfettered access to patented technologies for research purposes. Confidence that clinicians and researchers do not face the threat of patent infringement can be provided by the inclusion of a research-use exemption in the *Patent Act 1990*.

4. International Trading Obligations

- By discriminating against a field of technology (e.g. biological materials) for patent protection, Australia will contravene its Trade-Related aspects of Intellectual Property Rights (TRIPS) obligations (Article 27).
- Australia will also contravene Free Trade Agreements which mirror our TRIPs obligations (e.g. Australia-United States Free Trade Agreement, Article 17.9).

For the reasons outlined above, we strongly urge the Committee to recommend that the Bill be rejected. The Network lends its full support to the submission made to the Committee by AusBiotech, the national biotechnology industry association.

The Network recommends that any proposed reforms of Australia's patent laws are best considered by the review currently underway by IP Australia.

The core issues purported to be addressed by the proposed Bill (as articulated in the Explanatory Memorandum) have previously been fully considered and recommendations formulated by the ALRC (June 2004) and also by the Senate Committee into Gene (November 2010). In order to best serve the concerns of all Australians. The Network recommends that these findings and recommendations are fully considered by Government and a formal response provided.

The contact person for this submission is Ms Michelle Gallaher, Chief Executive Officer, BioMelbourne Network on

Yours sincerely

Michelle Gallaher
Chief Executive Officer