

Patent Amendment (Human Genes and Biological Materials) Bill 2010

Victorian Government Response to the Senate Legal and Constitutional Affairs Committee Inquiry into the Patent Amendment Bill

Introduction

The Victorian Government welcomes the opportunity to make a submission to the Senate Legal and Constitutional Affairs Committee in relation to the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (the Amendment Bill).

The Victorian Government previously made a submission to the Senate Community Affairs Committee Inquiry into Gene Patents which was established in November 2008 in response to strong community concerns regarding affordable access to diagnostic gene testing and other core health services. The Senate Community Affairs Committee handed down its final report and recommendations in November 2010.

The Victorian Government supports the Senate Community Affairs Committee's recommendations to clarify and strengthen the operation of the *Patents Act 1990*. Many of these recommendations, including changes to the assessment and description of inventions, provisions for Crown use and compulsory licensing, and the introduction of a research exemption, support earlier findings from the Australian Law Reform Commission (ALRC) and from the review of Australia's patent system by IP Australia.

The Amendment Bill

The Amendment Bill was tabled as a private members' bill in the Senate on 24 November 2010 by Senators Coonan, Heffernan, Siewert and Xenophon. On 21 February 2011, the Bill was introduced as a private members' bill into the House of Representatives.

The Bill seeks to amend the *Patents Act 1990* to reinforce the distinction between discovery and invention and to apply that distinction to prevent the patenting of human genes and biological materials existing in nature. The Explanatory Memorandum notes that the 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 Victorian Government position

The Victorian Government recognises the importance of striking a balance between equitable access to the findings and products of biological research and preserving the right of innovators to patent their inventions.

There are significant public and research benefits to be realised through the wide dissemination of research materials. The development of new medical technologies and pharmaceuticals however, requires commercial input and the right to patent inventions has the effect of encouraging investment in new innovation. The broad ban, as proposed in this Bill, on the patenting of biological materials would render the further development of many research discoveries unsustainable. This would stall innovation in Australia and limit public access to new affordable medications and healthcare.

Given this, the Victorian Government does not support the Amendment Bill in its current form as it does not achieve the best balance for the Australian research community and the

broader Australian community. Victoria's position is based on the following issues involving both process and policy.

Process

The Amendment Bill pre-empts consideration of the findings of the Community Affairs Committee which are based on broad stakeholder consultation.

The Bill directly contradicts the findings of other key inquiries such as the Advisory Council on Intellectual Property (ACIP) Review of Patentable Subject Matter (2010) and the ALRC Report on gene patenting and human health (2004) - none of which recommended that the *Patents Act 1990* be amended to include a specific prohibition on the patenting of human genes and genetic products.

The Victorian Government considers that clear alternatives exist to the proposed legislation that will improve Australia's intellectual property rights system and address the fundamental issues that led to the establishment of the Senate Community Affairs Committee inquiry into Gene Patents. For example, the adoption or development of guidelines, such as the OECD Guidelines for the Licensing of Genetic Inventions (2006), to guide discussions and negotiations in the health area.

Policy

The proposed legislation is broad in scope going beyond genetic materials *per se* which means that it captures many products (medicines, human and animal vaccines and enzymes used in green chemistry and waste-management processes) currently available or in development. This situation creates commercial and legal uncertainty for business with significant consequences for government and the community.

The Victorian Government considers that there has been insufficient evaluation or modelling of the adverse impact of the proposed legislation on the cost and availability within Australia of products based on biological materials. In the absence of such modelling it is not possible to evaluate the full extent of the impact of the Amendment Bill on innovation policy and the Australian economy. However the Bill represents a substantial disincentive to innovate at a time when government is focussed on policy settings to encourage innovation in order to raise productivity and international competitiveness. The uncertainty the Bill creates alone will negate these efforts.

Policy risks associated with the Bill include:

- ***Business uncertainty created***

For local industry, the Bill provides a disincentive to undertake value-adding activity and places local firms in a weaker position to resist international investor efforts to shift activities off-shore to locations where the foundation intellectual property is recognised.

For Victoria, a decline in confidence in the Australian business environment threatens the continued development and economic benefits of a Life Sciences sector which contributes over 22,000 jobs; in 2010 spent \$637 million on research and development (more than \$1 billion in total including research activities of publicly funded research institutions); and has over the past year attracted significant international interest, with two partnering deals (Acrux / Eli Lilly, and Mesoblast / Cephalon) totalling over \$2.16 billion.

For international companies, the Bill weakens the business case for companies to be domiciled in Australia, damaging our international competitiveness resulting in loss of jobs, investment and export opportunities. With the loss of international companies, workforce capability will decline which negatively impacts on Australia's ability to adopt new technologies.

In summary, where business environments are unsupportive, human resource talent will migrate to jurisdictions where innovation is recognised, our companies will lose access to skills and the ability to innovate within their own organisation. The net result will be a loss of productivity and Australia's international competitiveness will decline.

- ***Government innovation policy not delivered, benefits not realised***

Innovation is widely recognised as a means to manage the challenges of an ageing population, food security and environmental management. This is why both the Victorian and Australian Governments have a longstanding commitment to innovation.

Patents are an important part of the innovation process providing an incentive to invest in activities where the outcome is uncertain.

Patents on genetic materials and biologicals underpin business research and development (R&D) investment across a broad range of sectors – health, agriculture, environment, industrial manufacturing and the resources sector where biologicals are increasingly used for waste and site management.

Business R&D investment is essential for the translation of discoveries to the marketplace across all sectors. Patents provide a means to create a return on an investment which in many cases exceeds \$100 million. Business confidence to make R&D investments in Australia will be adversely impacted by legislation such as the Patent Amendment Bill which removes the incentive to invest. As a result new ideas emerging from our publicly-funded research organisations (and companies) will not have the funds to progress into development and Australia will fail to capture the benefit of substantial public investment in research (as demonstrated in the case study below).

Translating Australian research to the clinic - ovarian cancer

Ovarian cancer is the fifth largest killer of women in Australia with approximately 2,000 new cases each year. There is no reliable early detection test for ovarian cancer which means that when most women are diagnosed, the cancer is already at an advanced stage where it has spread and is difficult to treat successfully.

The Victorian Cancer Biologics Consortium led by Australian biotechnology company, Avipep Pty Ltd, represents a Victorian public-private partnership to progress Avibody™ technology from Avipep toward human clinical trials. Initial pre-clinical animal testing has shown promising results. The consortium has been able to raise \$5 million (including \$2 million from the Victorian Government) to undertake a program of activity to translate this discovery into the clinical setting. Clinical trials are scheduled to commence in the second half of 2011 to test these novel antibody-based targeted therapeutics in ovarian cancer.

Avipep and the Consortium would not have been able to raise this funding without an intellectual property strategy that seeks to patent the core technology which involves biological material.

Benefits from landmark life sciences infrastructure projects such as the expansion of the Walter and Eliza Hall Institute, the Victorian Comprehensive Cancer Centre (VCCC) and the Victorian AgriBiosciences Centre which collectively represents more than \$1.5 billion of investment in public research infrastructure will similarly not be realised.

The opportunity for health and economic outcomes arising from such projects is exemplified by the discovery by the Walter and Eliza Hall Institute, Ludwig Institute and Royal Melbourne Hospital (now partners in the VCCC) of colony stimulating factors. The colony stimulating factors have become a vital component of cancer treatment regimes. Evidence of improved patient outcomes by reducing complications of cancer treatment (such as infection rates) and improving economic outcomes (reduced stay in hospital for thousands of patients within Australia) have been accepted by regulatory authorities.

- ***Trade and International obligations not met***

The breadth of the Bill is likely to raise issues with Australia's international intellectual property and trade obligations. At present, the *Patents Act 1990* is technology neutral. Consistent with the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Australia's intellectual property system allows patent rights without discrimination as to the field of technology.

- ***Potential impact on population health and wellbeing***

Exclusion of genetic material from patentable subject matter as proposed by the Patent Amendment Bill is one way of addressing community concerns over affordability and accessibility of health services. Genetic technologies will play an increasing role in health practice, and the commercialisation practices adopted by the companies responsible for these inventions will clearly have an effect on pricing, further research and development, and patient access. Any changes to policy and practice in this area need to carefully consider the balance between public accessibility to new diagnostics and other health inventions and the broader innovation context.

Concluding remarks

Victoria understands the importance of a strong, enforceable, accessible and workable intellectual property regime. It also understands community concerns regarding the potential for restrictive access to some healthcare services.

Alternatives to the Patent Amendment Bill exist, many of which were recommended by the Senate Community Affairs Committee and the ALRC. These alternatives, which aim to enhance Australia's patent system whilst promoting research and the translation of innovations to the benefit of the community, provide a means to achieve a balance between commercial investment and public health and wellbeing.

Victoria's view is as iterated in its submission to the Senate Community Affairs Committee Inquiry into Gene Patents, that is:

- The ALRC, Senate Community Affairs Committee and ACIP were clear in their positions that the *Patents Act 1990* should not be amended to exclude genetic materials from patentable subject matter.
- Measures to ameliorate any adverse impacts arising from the granting of gene patents were recommended in the various reports and consideration should be given to adopting those interventions best suited to Australia's circumstances and position within intellectual property conventions and international trade obligations.

- Australian biotechnology companies should operate on an effective commercial basis, enabling them to progress innovations to market for the benefit of Australia and the international community. Similarly, the Australian public should be able to access health care innovations in a cost-effective manner.