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The Secretary
Senate Community Affairs Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Sir/Madam

Please find attached a submission from the Victorian Government for consideration by the Senate Community Affairs Committee as part of its *Inquiry into Gene Patents*. This submission, which represents the views of a number of Victorian Government departments, has been endorsed by the Premier, the Hon John Brumby MP.

As the Committee is probably aware, there are many diverse views on the application of patents law to genetic material, including within government. The attached submission provides an integrated, whole-of-government perspective on the issue of gene patents, which I hope the Committee finds useful in its deliberations.

Thank you for providing the Victorian Government with the opportunity to participate in the inquiry.

Yours sincerely

HON DANIEL ANDREWS MP
MINISTER FOR HEALTH

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The Place To Be

Senate Community Affairs Committee Inquiry into Gene Patents

Submission from the Victorian Government

Introduction

Awarding legally enforceable, limited-term patents over new, useful and non-obvious inventions is a key element of the innovation system, providing a level of certainty that encourages significant investment in research and development. Strong protection of intellectual property is as essential in biotechnology as it is in most other cutting-edge fields of endeavour.

The recent scenario involving a private company and its patents for breast cancer (BRCA) gene mutations and associated diagnostic testing has focussed attention on the patenting of genetic materials and particular commercial practices that may impact on the availability and pricing of diagnostic health tests. If more companies holding gene patents were to adopt commercial strategies similar to those contemplated by the company holding the BRCA 1 and 2 gene patents, Victoria would be concerned about the impact on maintaining broadly accessible, publicly funded health services.

Victoria looks forward with interest to the deliberations of the Senate Community Affairs Committee and the review of patentable subject matter currently being undertaken by the Australian Government Advisory Council on Intellectual Property (ACIP). The issues associated with gene patent interpretation and application in Australia need to be clarified and addressed where necessary.

Impact on the provision and costs of healthcare

Genetic testing is an increasingly valuable predictive tool, especially in relation to preventative health care for cancer. While demand to make genetic tests publicly available presents a cost pressure for government, gene technologies may ultimately reduce healthcare costs through earlier and more accurate diagnoses and the ability to determine the suitability of individuals to therapeutic interventions.

For example, Victoria estimated that redirecting predictive gene testing for breast cancer to an exclusive provider would have cost an additional $0.5 million per annum initially (i.e. up 50% on current testing funding). Increased costs would require government to either allocate additional funding to maintain service levels or reduce the number of funded tests, resulting in increased waiting times for public patients and reduced service equity as those able to pay would gain preferential access to private services. The cost implications would increase were this scenario to occur across multiple gene and test patents.

Impact on the provision of training and accreditation for health care professionals

As the current genetics workforce is predicted to be insufficient to meet future demand, Victoria is concerned that an increase in exclusive testing arrangements would reduce the number of public laboratories performing specific tests, and consequently the opportunities for student training and professional accreditation. In that scenario, public laboratories that remained involved in testing could expect to carry higher licensing costs, which may translate into increased course fees and possibly fewer enrolments in genetics courses.

For human genetics services, there are risks in separating diagnostic testing from expert interpretation, counselling and support. All of these functions are critical in ensuring that individuals are accurately and fully informed of the implications of their test results. In addition, clinical geneticists and genetic counsellors need to be aware of test limitations to successfully manage the risks associated with false positive (or negative) results.

Impact on the progress of medical research

Victoria recognises concerns that gene patents may limit further research and the development of new and alternative tests and diagnostic methods. However, it also notes that patents *per se* are not typically restrictive, promoting innovation by encouraging further testing and improvement of the patented innovation. More efficient methods are usually keenly cross-licensed (if they are in fact improvements) by the initial patent holders.

Impact on the health and wellbeing of the Australian people

Earlier and more accurate diagnosis of a disease or health condition and ability to predict individual responsiveness to particular therapeutic interventions is expected to reduce the future need for expensive healthcare, as well as avert undue individual suffering.

The Victorian Government has been implementing a policy of early intervention and prevention to improve health and wellbeing, and to reduce likely future demand for acute health services. Investments by State, Territory and Federal governments in population screening programs for the early detection of disease are consistent with this policy. Increased testing costs associated with restrictive licensing requirements impact on service accessibility and discourage predictive testing, a key factor in prevention and early intervention and better targeting of screening.

Ameliorating adverse impacts arising from the granting of patents

The Australian Law Reform Commission (ALRC) reviewed the area of gene patents and human health in 2004 and made a series of recommendations to update and strengthen:

- patenting law and practice regarding the exploitation of gene patents, and
- government responses to optimise the availability for human health applications and further research.

Victoria recommends that the feasibility of implementing the ALRC recommendations be pursued, including a broader statutory exemption for patent infringement in the case of non-commercial experimental use (as applies in some jurisdictions internationally).

In considering appropriate strategies to ameliorate any adverse impact arising from the granting of gene patents, it is important to separate the issues of patenting, the commercial exploitation of the intellectual property, and the public funding of patented genetic tests, either by the State or under Federally subsidised programs.

Assessment of patent applications
There may be opportunities for developing or better utilising existing Australian Government guidelines that aim to improve assessment of patent applications to more clearly demonstrate the novelty and application of the invention.

Managing the implications of patents
Alternative methods for managing the implications of the patenting of genetic material should be investigated and applied where this is necessary for public health and research outcomes.

Guidelines should be available to provide clarity to patent owners and licensees on what action and under what circumstances government may intervene following granting of a patent. For example, consideration could be given to adopting or developing guidelines, such as the OECD Guidelines for the Licensing of Genetic Inventions (2006) that guide discussions and negotiations in the health area to achieve strong public healthcare outcomes.

Mitigation strategies could include:

- challenging a patent application or granted patent
- making a complaint under anti-competition laws
- exploiting or acquiring a patent under Crown use and acquisition provisions, and
- applying for a grant of a compulsory licence.

Effective communication between regulators, government departments and companies to achieve an agreeable negotiated position is preferred prior to enforcing provisions such as compulsory licensing.

Where public access to a patented invention becomes an issue due to restrictive licensing practices, recourse to alternative mechanisms (such as compulsory licensing) should be considered in a broader government context. This should take into account the innovation sector and the potential for such developments to ultimately reduce healthcare costs, as well as immediate public healthcare needs.

Prohibiting monopolies or amending the *Patents Act 1990*

In response to issues raised in the ALRC review, the Australian Advisory Council on Intellectual Property (ACIP) has been charged with reviewing patentable subject matter and this review is proceeding. The deliberations of this inquiry into gene patents should take into account the ACIP review.

Victoria supports the ALRC's recommendation that the *Patents Act* should not be amended to exclude from patentability genetic materials or technologies, or new medical treatment, nor to expand the circumstances in which social and ethical considerations are taken into account in decisions about granting patents. The health care industry relies on a range of technologies that are underpinned by patents, and it is not appropriate to target a subclass of patents, such as gene technologies, for differential treatment by government.

It should be noted that organisations such as the Centre for Law and Genetics, University of Tasmania, in its submission to the ALRC, did not support prohibition of patents on gene sequences on the grounds that there is apparent consensus internationally that patents on such matter should be allowable, that there is a significant number of patents already granted in this area, and that this type of prohibition would not provide a complete solution to the problem and has not been effective when applied in other jurisdictions. Victoria notes that any changes proposed to Australian patent law and practice would need to consider issues around harmonisation with international patent law and Australia's obligations under existing international intellectual property and trade conventions.

Strong government support for patents underpins innovation and commercialisation and Victoria's aim to be a leader in biotechnology and to develop as a 'Bioeconomy'. Gene patents underpin the $50 billion biotechnology industry world-wide. Australia's patent laws should support reciprocal international acknowledgement of intellectual property.

Other relevant matters for consideration

It should be noted that both the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Australia-United States Free Trade Agreement provide member countries with the ability to exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'.[1,2]

Furthermore, a joint study by the World Health Organization and the World Trade Organization secretariat on World Trade Organization agreements and public health, and the *Doha declaration on the TRIPS Agreement and Public Health* provide clarity regarding trade agreements, patents, and public health.[3,4]

Any decisions to be made regarding gene patents that may impact on Australian patent legislation and supporting documentation should involve representatives from key stakeholder areas such as research and public health, as well as economics and industry to ensure that any proposed changes adequately meet the needs of all parties.

In conclusion

Victoria would like to emphasise the following key points:

- The ALRC was clear in its position that the *Patents Act 1990* should not be amended to exclude genetic materials from patentable subject matter. The current ACIP review may help to further clarify these issues.

- 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.

- Measures to ameliorate any adverse impacts arising from the granting of gene patents were identified in the ALRC report of 2004 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.

- Any changes to policy and practice in this area need to carefully consider the balance between public accessibility to new diagnostics and other inventions and the broader innovation context. 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.

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[1] Article 27 of the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights.
[2] Article 17.9 of the Australia-United States Free Trade Agreement.
[3] WTO agreements and public health: a joint study by the WHO and the WTO Secretariat (2002). The World Trade Organization/World Health Organization.
[4] Doha Declaration on the TRIPS Agreement and Public Health (2001) World Trade Organisation.