



**Deputy Premier of Western Australia
Minister for Health; Indigenous Affairs**

Our Ref: 25-02694

Senator Clair Moore
Chair
Senate Community Affairs Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600



Dear Senator Moore

Thank you for the opportunity to comment on the Inquiry into Gene Patents.

In preparing this response, my officers have been mindful of the role that the patent system has played in driving innovation in clinical medicine, particularly in regard to pharmaceuticals, medical devices and diagnostic assays.

One of the roles of the Western Australian Department of Health is to ensure that publicly funded genetic testing laboratories continue to provide a service to the Western Australian community that is comprehensive, accessible and economically sustainable. It is therefore important that mechanisms are in place to protect the rights of the Australian community, particularly those individuals and families living with genetic conditions.

I hope the outcome of this inquiry will be to provide a safeguard for the Australian public that allows fair access and affordable health services into the future. I welcome the opportunity to contribute to the inquiry and look forward to the outcomes.

Yours sincerely

Dr Kim Hames MLA
DEPUTY PREMIER
MINISTER FOR HEALTH

Att:

13 MAR 2009

Department of Health

Western Australia

A submission to Senate Community Affairs Committee

Inquiry into Gene Patents

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Opening Comments

This paper was prepared by The Office of Population Health Genomics at the Department of Health WA.

In preparing this response, we are mindful of the role that the patent system has played in driving innovation in clinical medicine, particularly in regard to pharmaceuticals, medical devices and diagnostic assays. It is not our intention to hinder the progress of the biotechnology industry in this country or to exclude patent holders from the financial rewards of inventiveness and innovation. However, one of the roles of the Western Australian Health Department is to ensure that publicly funded genetic testing laboratories continue to provide a service to the WA community that is comprehensive, accessible and economically sustainable. Our response to the inquiry is driven by our concern that patents on genes and genetic sequences have the potential to compromise the delivery of an efficient and coordinated genetic health program.

While a number of our stakeholders object to the patenting of genetic sequences on ethical grounds, it seems their main concerns relate to:

- the overly broad scope of the claims of the early gene patents;
- exclusive licensing practices and the ability of patent holders to restrict access to genetic technologies; and
- the potential for unreasonably high licensing fees to undermine the cost effective provision of genetic testing services.

It may be true that evidence of a negative impact of patents on genetic technologies on research and healthcare is not well documented in Australia. We have so far been spared the problems encountered in other countries, such as the UK, France, Canada and the US. However, it would be foolish to consider Australia immune from the commercial realities of international pharmaceutical and biotechnology industries. It is therefore important that mechanisms are in place to protect the rights of the Australian community, particularly those individuals and families living with genetic conditions.

We hope that the outcome of this inquiry will be to provide a safeguard for the Australian public that allows fair access and affordable health services into the future. We welcome the opportunity to contribute to the inquiry and look forward to the outcomes.

Responses for the Inquiry into Gene Patents

The impact of granting patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form, with particular reference to:

a) The impact granting patent monopolies over such materials has had, is having, and may have had on:

i) the provision and costs of healthcare,

Many disease-causing genes have been discovered, patented and/or published. Publication of the gene sequence and gene marker data has led to the development of in-house assays in clinical research laboratories. Many of these procedures are now validated analytical methods used for predictive and diagnostic genetic tests. Publicly funded hospitals and institutions provide these genetic tests to the community through an integrated clinical framework that ensures they are offered equally to everyone.

Commercial involvement and patenting is well established in health care. The patent system is a government intervention into the commercial free-market designed to prevent market failure and foster innovation. This system has for many years been seen as a critical factor driving innovation in clinical medicine, particularly in the fields of medical devices and diagnostic assays. Without the protection afforded by the international patent system, public benefit arising from such developments would be much less (1). Increasing commercial pressure is leading patent holders to develop new strategies and business models, specifically designed to take maximum advantage from the commercial exploitation of the often broad claims included in patents, particularly those filed in the early days of gene discovery. It is some of these new strategies and business models that more directly threaten the optimal provision of genetic health care and the integrated clinical service through which it is currently provided (2-4) rather than the patents *per se*.

ii) the provision of training and accreditation for healthcare professionals,

No comment.

iii) the progress in medical research, and

Genomic technologies have the potential to decrease the burden of disease through preventive and early intervention strategies. These strategies will largely result from research and development innovations within the publicly funded and not-for-profit biomedical and biotechnology sectors. Patents could restrict this research by limiting access to new discoveries. In response to concerns about this negative impact the Advisory Council on Intellectual Property (ACIP) Options Paper, Patents and Experimental Use (5), along with the recent Australian Law Reform Commission (ALRC) Inquiry, Gene Patenting and Human Health (6), recommended amending the Patents Act 1990 (Cth) to establish an exemption from patent infringement for experimental use.

Providing an exemption for experimental use to researchers is one option for modifying the patent system that will facilitate research. After taking a perspective that values high standards and equitable access to healthcare, the anecdotal evidence obtained from ACIP's inquiry, the ALRC inquiry and our own previous consultations with researchers and scientists, it is the WA government's belief that clarification of an experimental use exemption is required.

Another proposal that may assist research is for research leaders, when they become aware of a patent over a particular tool or technology that may be important to their research, to notify the owners/licensees of the patented invention of their research and research objectives. Such a notification system would offer excellent opportunities for contact and collaboration between innovators. It would probably not be possible to enforce mandatory response by patent owners but it may prove a useful way of encouraging a collaborative approach in the intellectual property arena in Australia.

iv) the health and wellbeing of the Australian people.

The patent system encourages innovation in two distinct ways. First, by providing patentees with a strictly limited period of monopoly, protecting them from imitation and forcing potential competitors to improve on and "invent around" existing patents. Second, by making publicly available the details of all patented inventions researchers and potential competitors are provided with an extensive database of relevant information from which to pursue further innovation.

As such the international patent system offers substantial public benefits and can lead to a welfare enhancing effect. But, as a Canadian study shows (7), it is often a second best instrument, at least in part because of opportunistic behaviour, such as the use of blocking patents and restrictive licensing terms, on the part of patentees. This study also shows that the welfare gains associated with the patent system can be increased if the system incorporates effective research exemptions and related freedom to operate provisions.

The public policy objective underlying the establishment of the Australian public health system was the provision of equitable access to health care for all Australians. It is therefore a concern if restrictive licensing terms are enforced by patent holders (1).

b) Identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the Patents Act 1990 should be amended, in light of any matters identified by the inquiry.

The WA government recognises that the patent system is designed to be technology neutral so that it remains applicable to all emerging technologies. We believe any changes to the Patents Act 1990 specifically addressing patents on genes and genetic technologies are unnecessary, and may create an undesirable precedent with regard to future technologies. The problems encountered in patenting genes and genetic technologies have, generally speaking, been related to the unsustainably broad scope of the claims in some of the early gene patents and the manner in which the patent rights are exploited. This is where reforms to the Patents Act 1990 are required.

c) Whether the Patents Act 1990 should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

Not supported for same reasons as mentioned above in Question b).

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