Tabled by Senator Humphries at 18/5/10 hearing for Gene Patents Inquiry. Copy provided to IP Australia.

Cancer Council Australia

Clinical Oncological Society of Australia

7 May 2010

Senator the Hon. Gary Humphries
Community Affairs References Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Senator Humphries

With the inquiry into gene patents drawing towards a close, the Senate Community Affairs References Committee has a unique opportunity to recommend legislative changes that could help ensure future accessibility to cancer care in Australia is not compromised by an outdated, inequitable patents system.

As a participating member in the inquiry with a strong interest and a professional legal background, your support for legislative change would be instrumental in the inquiry's report recommending reforms that could have a profoundly beneficial impact on cancer care in Australia.

Enclosed is a summary of changes to the *Patents Act 1990* which we, as cancer clinicians, researchers and heads of Australia's largest allied non-government cancer organisations, believe are fundamental to protecting the public interest from the commercial exploitation of patent law ambiguity. The proposed amendments are tracked against specific sections of the current Act.

At the heart of the gene patent debate is ambiguity between invention and discovery. As cancer scientists with professional interests in genetic technology, we believe the process of isolating or purifying genetic materials is an act of discovery, not invention. The Act urgently requires amending to clarify this key principle; an appropriate form of words for your consideration is included in the enclosed recommendations, under the heading of Validity.

By coincidence, a US court recently ruled the patents for the BRCA1 and BRCA2 gene mutations to be invalid on the basis that their isolation was the discovery of natural phenomena, not an inventive process. Clarifying the Act would prevent similarly invalid patent claims being enforced in Australia; as the technology rapidly advances, the need for such a change to the Act is becoming increasingly urgent.

We believe the Act's function in underpinning economic and social benefits for Australia also needs to be reinforced, along with its capacity to prevent monopolisation of essential services and patent system abuses. The enclosed summary therefore also includes proposed amendments to achieve these ends.

As proposed in our joint submission to the inquiry, such legal changes could be reviewed by a new government multidisciplinary body advising on gene patent policy and comprising scientists, bioethicists, economists and consumers – as well as the patent attorneys who dominate gene patent policy at present.

We strongly believe that the patent system should reward innovation in medical science, not serve as an impediment to competitive research or as the legal means to monopolise diagnostic tests that should be freely available (as almost occurred with BRCA1 and BRCA2 in Australia in 2008).

Exploitation of the current Act's ambiguity could stifle research into cancer diagnostics and treatments in Australia at a time when genetic technology is rapidly accelerating along with the numbers of Australians expected to develop cancer as our population ages.

The Senate inquiry presents a timely opportunity to take important steps towards fundamental changes to patent law to protect the public interest. Your support for our position would be greatly appreciated.

Thank you again for your longstanding support for Cancer Council Australia.

Yours sincerely

Professor Ian Frazer
President
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Proposed reforms to the Patent Act 1990

Cancer Council Australia and the Clinical Oncological Society of Australia call on the Senate to recommend key changes to the Patents Act 1990 to protect the public interest from commercial exploitation of Australia's outdated gene patents law.

Evidence presented to the Senate inquiry into gene patents included a number of examples of the current Act's incapacity to protect the public interest, such as:

- An attempted commercial monopoly over genetic testing for breast and ovarian cancer risk in 2008, demanding that public laboratories cease conducting the tests;
- Monopolisation of erythropoietin medicines and related biological materials, which increased healthcare costs in Australia and could have impeded competitive research into new medicines;
- A patent monopoly over purified hepatitis C polynucleotide and polypeptides, preventing anyone but the patent holder (a US company) from developing or supplying these materials between 1988 and 2008. This resulted in laboratories, including blood banks, relying on an inferior test during the period; and
- Corporate ownership of the human genetic materials that encode proteins linked to a severe form of epilepsy, resulting in restrictions to diagnostic testing. The patent remains in force until 2024.

As genetic technology evolves, such incidents are expected to increase significantly unless the law changes in step with the science. We believe the only way to protect the public interest from the exploitation of outdated patent law is to amend the Patent Act 1990 (the Act) to expressly reward innovation and invention, while ensuring that biological materials, whether in natural or purified form, are freely available for non-commercial scientific use.

A ruling in March 2010 by the US district court of Southern New York provides an international precedent that should guide legal reform in Australia, particularly because the US decision is based on the fundamental principle that biological materials in purified form are discoveries, not inventions.

The evidence overwhelmingly supports the need for legal reform. On this basis we recommend the following key amendments to the Act.

Economic and social objectives

In our view the Act lacks essential economic and social objectives to underpin its intended benefit to the Australian community. (Conversely, limitations and ambiguities in the Act have in effect been detrimental to the public interest in Australia.)

We therefore recommend the following inclusion/amendment to better articulate the Act's function in supporting the public interest.

Amendment 1

3A Objects

(1) The principal object of this Act is to promote the growth of the Australian economy through the development and use of patentable inventions in Australia. Such economic growth should manifest itself through:

(a) greater research and development within Australia;

(b) greater production within Australia; and

(c) the greater employment of Australians.

(2) A further object of this Act is to maximise the social and economic benefits and to minimise the social and economic costs to Australians.

(3) A further object of this Act is to encourage the development in Australia of patentable inventions in all fields of technology.

(4) A further object of this Act is to promote the transfer and dissemination of economic, technical and scientific information within Australia that is transparent, accurate and useful in facilitating the attainment of the principal objective.

These objectives will only be achieved if the Act is further amended along the lines proposed as follows.

Validity

Part 3 of the Act aims to underpin the validity of a patent claim; the Act should therefore be able to resolve ambiguities in the definition of patentable subject matter. However, the ongoing debate about whether isolated/purified biological materials are patentable shows that the Act urgently requires amendment to clarify the distinction between discovery and invention in respect of validity.

Method, as part of patentability, also requires clarification.

In this context, the US court ruling that the BRCA1 and BRCA2 patents are invalid provides definitive guidance.

Discovery v invention

The committee will be aware that the non-commercial scientific community makes a strong case that sequencing genetic material is an act of discovery and does not involve an inventive step. In its 2004 review, the Australian Law Reform Commission was also supportive of this view.

The US district court ruling that the BRCA1 and BRCA2 patents are invalid was based on this principle. After reviewing precedents in the US Supreme Court, the judge dismissed the arguments of the patent owner, Myriad, on the basis that patentable subject matter "must possess a new or distinctive form, quality, or property". The court found that even in purified form, sequencing DNA to identify the BRCA1 and BRCA2 gene mutations was an act of discovery, not of invention.

In concluding, the judge determined that, because "the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter under [the US Patent Act]".

Method

The US court also found that the act of analysing and comparing DNA to isolate gene sequences was not a method of invention, but of "data gathering" and was therefore "not central to a patentable process".

These determinations, viewed in the context of the evidence presented to the committee, indicate the need to clarify Australian patent law accordingly, particularly in respect of "manners of manufacture". We therefore recommend the following definitive amendment to the Act (under Part 3 – Validity, Division 1 – Validity, S18 Patentable inventions):

Amendment 2

> **2A Validity**
>
> The following, although not limited thereto, are not manners of manufacture:
>
> (a) human beings, their component parts and any derivatives thereof, howsoever derived, and whether isolated or purified.
>
> (2B) The following, although not limited thereto, are not patentable inventions:
>
> (a) processes for the reproduction or generation of human beings, their component parts and any derivatives thereof.
>
> (b) diagnostic, therapeutic and surgical methods* for the treatment of humans or animals.

The Act should also be amended to ensure patents are only awarded for inventions and innovations that have an immediate practical application. This would help to protect against the practice of awarding patents for junk DNA. These are sequences of no immediate practical use that are patented by commercial interests on speculation that an application may be developed – possibly by a competitor or not-for-profit researcher, after which a monopoly over the natural materials could be established.

Prohibiting abuse of the patents system

Legal instruments that are out-of-date or lack sufficient rigour to protect the public interest may be exploited by lawyers acting on behalf of commercial or other vested interests. This is demonstrably the case with gene patent law. A number of cases of the patent system being legally exploited at a cost to the community were submitted as evidence to the Senate committee (four examples are highlighted in the introduction of this summary).

We therefore contend that, if the Act is to meet the general objects recommended in amendment 1 and provide clarity on patent claim validity as proposed in amendment 2, it requires an inclusion to prevent abuses of the patent system. We propose the following amendment to the Act, in a specific chapter for protecting against patent system abuses.

* "Method" does not include products such as pharmaceutical innovations etc.

Amendment 3

> **3A Abuse of Patent System**
>
> Definitions
>
> In Chapter 3 [of the Act], 'abusive patent claim' means a claim which may undermine or may have the effect of undermining:
>
> (i) the Objects in section 3A; or
>
> (ii) the patentability parameters in section 18.

Amendment 4

> **52C Abusive Patents**
>
> (1) The Commissioner must not accept a patent application nor grant a patent containing an abusive patent claim.
>
> (2) A prescribed court must, if asked to do so and after due process, revoke a patent containing an abusive patent claim.

Protection of essential products and services

The demand that public laboratories cease conducting life-saving genetic tests for breast and ovarian cancers in 2008 could have been legally dismissed if the Act contained a provision to protect essential products and services from commercial monopolisation. There are a number of other examples, submitted as evidence to the committee, of gene patent abuses that could have been avoided if the Act protected the public interest in this way.

We therefore propose that the Act be amended so that an injunction cannot be granted if the effect is to restrict access to an essential service or product.

Amendment 5

> **122 Relief for infringement of patent**
>
> No injunction may be granted if the product, process or method, the subject of the patent claim in issue, is an essential service or product.

This amendment needs to be supported by a definition of essential product/service in Schedule 1, dictionary:

Amendment 6

> **Schedule 1, dictionary**
>
> *essential product* means a product, or a process for the production of a product, that is used (inter alia) in: the provision of public health services (including hospital or medical services); the provision of ambulance services; and the production, supply or distribution of pharmaceutical products.

essential service means a service in relation to (inter alia) the provision of public health services (including hospital or medical services); the provision of ambulance services; and the production, supply or distribution of pharmaceutical products.

Disclosure

Lack of transparency and accountability are significant problems under the Act. Greater disclosure will add rigour to the awarding of patents for inventive/innovative uses of genetic materials. To this end, we propose the following amendment under Chapter 6:

Amendment 7

Chapter 6 – Grant and term of patents

62A Public Disclosure of Information Relevant to Commercial Production of Patented Invention

A patent cannot be granted or its term renewed unless the patentee has publicly disclosed information sufficient to enable, without undue experimentation:

(a) the replication of the invention to the same or higher standard as its closest commercially available equivalent at the time of grant or renewal, and

(b) to the extent that the scope of the monopoly covers more than one embodiment of the invention, the disclosure in (a) include each and every embodiment.

Conclusion

As the Senate inquiry draws towards a close, we seek the Committee's support in recommending amendments to the Patents Act 1990 along the lines proposed above, to bring patent policy into line with advances in genetic technology.

Amendments to this effect are, in our view, essential to protect the public interest as the evolution of genetic technology accelerates.