Senate inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010

Submission from Cancer Council Australia, Clinical Oncological Society of Australia

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Cancer Council Australia is Australia's peak non-government national cancer control organisation. Its member bodies are the eight state and territory cancer councils, whose views and priorities it represents on a national level.

The Clinical Oncological Society of Australia is the peak multidisciplinary society for health professionals working in cancer research or the treatment, rehabilitation or palliation of cancer patients.

Responsibility for content is taken by the Chief Executive Officer of Cancer Council Australia, Professor Ian Olver, and the President of the Clinical Oncological Society of Australia, Professor Bogda Koczwara.

Overview

Cancer Council Australia/COSA support the Patent Amendment (Human Genes and Biological Materials) Bill 2010, while noting that adjustment to the bill's wording may be required to address concerns among some stakeholders. We also commend Senators Coonan, Heffernan, Siewert and Xenophon for introducing the bill; and MPs Peter Dutton, John Forrest, Rob Oakeshott and Malcolm Turnbull for sponsoring it in the Lower House.

We believe the bill has the potential to prevent monopolisation of genetic sequences and other biological substances that should be freely available for competitive research and to help ensure equitable access to healthcare.

As set out on page 2 of this submission, we recommend specific changes to the bill's wording. We also acknowledge that further subtle changes to the bill's text may be required to address specific concerns among some medical researchers. As recommended below, discussion among professionals from a range of fields and consumers may be required to achieve this.

The bill should also be complemented by implementation of the Senate Community Affairs References Committee's[1] and the Australian Law Reform Commission's[2] recommendations for additional, more specific amendments to the Patents Act, 1990 – particularly a clearer definition of "inventive step".[*] In that context, the focus of this submission is:

- Recommended changes to the bill's wording;
- Why a public hearing or forum is critical to this inquiry;
- Why the law must change;
- Issues that an amended Patents Act must address; and
- The Patent Amendment Bill and the Senate/ALRC recommendations.

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[*] We note that some of these matters are being addressed in current reviews by the Australian Council on Intellectual Property (ACIP).

Recommendations in summary

1. That the Patent Amendment (Human Genes & Biological Materials) Bill be passed but first amended according to the recommended wording set out and explained in Recommendation 1, below.

2. That the committee convene public hearings or a discussion forum comprising professionals from a range of relevant fields and consumers to openly discuss the bill. It is critical that such a forum focus on the bill's specific wording, and not delay its passage by re-examining evidence already scrutinised in the gene patents inquiry.

3. That the Patents Act 1990 be further amended as recommended (recommendations 6-15) by the Senate Community Affairs References Committee in its 2010 report on gene patents and by the Australian Law Reform Commission in 2004, particularly in relation to a clearer definition of "inventive step".

4. That the Senate committee note:

    - Australia's obligations under international arrangements such as the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement would not be compromised by the Patent Amendment Bill, as such agreements include exemptions for signatories to act unilaterally to protect domestic public health interests; and
    - developments in the US and elsewhere signal a global shift towards eliminating patent monopolies based on materials that have been discovered, rather than invented. The BRCA case in the US, where the majority of gene patents are held, presents an instructive precedent, further emphasising the need for change in Australia.

Cancer Council Australia/COSA recommendation 1

That the Patent Amendment (Human Genes & Biological Materials) Bill be passed but first amended as follows.

Recommended amendments

Amendments 1 & 2

Cancer Council Australia/COSA support amendments 1 and 2 of the bill.

Amendment 3

We recommend a change to amendment 3, under Subsection 18(2). Where point (b) currently reads:

> (b) 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.

replace with:

> (b) biological materials whether isolated or purified or not and however made which are identical to such materials as they exist in nature.

Explanation

We recommend a clearer, more concise definition of “biological materials” in this subsection, with a more specific definition of “biological materials” added after Subsection 18(4) as below. This in our view would better clarify the distinction between invention and discovery in the context of biotechnology patents. In addition, the word “derivative” is not required, as such derivatives are more explicitly stated in Amendment 4.

We recommend the removal of “substantially”, in favour of a clearer definition of identity, or “identical”, also included separately after Subsection 18(4) as follows. This in our view would help ensure biological materials that have been structurally and *functionally* altered continue to be patentable (see Amendment 4); it should assure competitive researchers and investors that the patentability of biological materials adapted inventively for industrial use remains a commercial incentive.

Amendment 4

As above, we recommend Subsection 18(4) be expanded to define “biological materials” and “identical” in the context of the bill. Where Subsection 18(4) currently reads:

> (5) In this section:
>
> ***biological materials***, in section 18, includes DNA, RNA, proteins, cells and fluids.

replace with

> (5) In this section:
>
> ***biological materials***, in section 18, includes DNA, RNA, proteins, cells and fluids including their components
>
> ***identical***, in section 18, means a biological material which is structurally and functionally identical and where any structural change or difference is immaterial to its function.

Explanation

As above, a clearer definition of “biological materials” would assist in applying the fundamental distinction between invention and discovery to patent claims. In particular, a more detailed definition of “identical” would add clarity. Thus, the critical definitive additions above apply to *structural* identity and *functional* identity. In other words, biological materials that have not been altered in an inventive way would be excluded from the definition of patentable subject matter.

Biological materials whose function has changed as a result of human invention, however, would remain patentable. On the same basis, a structural change to biological material that creates no change in function should not be patented, as it would not be deemed inventive or industrially applicable.

We believe these recommended changes to Subsections 18(2) and 18(4) could address concerns about "unintended consequences" – i.e. a view among some stakeholders, arguably exaggerated, that a broader but clearer definition of biological materials could be a disincentive to research investment.

This is a critical consideration. An examination of the criteria for a number of existing patents shows that amendments to the Patents Act 1990 as proposed in the Patent Amendment (Human Genes & Biological Materials) Bill would not prevent the patenting of inventive uses of biological materials for the development of products such as vaccines and other medicines. Functional change in biological materials should be pivotal to the development of patentable products.

The definition of "biological" in Subsection 18(4) protects the commercial interests of inventive research and, on that basis, should encourage research investment. Moreover, greater clarity in patent law should be a fillip to competitive research generally, by protecting natural biological materials from commercial monopoly.

The definition of method of manufacture and inventive steps elsewhere in the Patents Act 1990 – which would be strengthened if the ALRC's and the Senate's proposed amendments were also passed – would further ensure that novel and industrially applicable uses of biological materials remain patentable, while those that are neither novel nor have an industrial application are not patentable

If some stakeholders remain reserved about these proposed amendments, their concerns should be aired openly in a public forum where supporters of the bill could respond on the basis of the evidence.

Benefits of a public hearing or discussion forum

We understand that the decision to hold public hearings for this inquiry may depend on the volume and content of submissions received. Cancer Council Australia/COSA urge the committee to either convene public hearings or a one-off discussion forum to discuss the bill, even if relatively few submissions are received.

While there is broad consensus among the medical researchers, cancer care professionals and consumers for legal reform to prevent gene monopolies and other risks to the public interest, views on how the *Patents Act 1990* should be amended to achieve this shared objective are expected to vary widely. A live discussion may be more effective in tuning amendments to the act than relying entirely on written submissions. We therefore recommend that the committee either convene public hearings or a group discussion forum comprising professionals from a range of relative fields and consumers.

Cancer Council Australia/COSA recommendation 2

That the committee convene public hearings or a discussion forum comprising professionals from a range of relevant fields and consumers to openly discuss the bill. It is critical that such a forum focus on the bill's specific wording, and not delay its passage by re-examining evidence already scrutinised in the gene patents inquiry.

The bill and the Senate recommendations

Cancer Council Australia/COSA support both the intent of the Patents Act Amendment Bill as well as the separate recommendations of the Senate Community Affairs Committee on gene patents.[1]

The bill calls for a fundamental change to the act which, while arguably requiring some fine-tuning (as this submission notes), has the potential to broadly protect the use of human biological materials from commercial monopoly.

The Senate recommendations are by contrast more specific and narrow, as such providing an effective complement to the intent of the bill. The potential for this complementary function is set out in this submission.

Cancer Council Australia/COSA recommendation 3

That the Patent Act 1990 be amended as recommended (recommendations 6-15) by the Senate Community Affairs References Committee in its 2010 report on gene patents and by the Australian Law Reform Commission in 2004, particularly in relation to a clearer definition of "inventive step".

Why the law needs changing

Problems with Australia's gene patent legal framework are well documented. Most prominently, in 2008 there was a commercial attempt to monopolise genetic tests for breast and ovarian cancer risk through the enforcement of a patent licence. Of great concern is that, while the matter was resolved by the company's voluntary withdrawal of the claim – following sustained public outcry and negative publicity – there was nothing in the law that could have protected Australian women's access to testing in public laboratories.

While Crown Use provisions – introduced in the 19th century to override patents in the interests of the public or the Crown – were mooted as a mechanism to resolve the BRCA impasse, the inability or reluctance of jurisdictions to invoke the provisions underscored their limitations as a feasible legal instrument to protect the public interest from gene patent exploitation. (The provisions' use appears so infrequent that it is difficult to list and comment on specific cases.[3]) So we do not see Crown Use provisions as an effective mechanism. Given the uncertainty about Crown Use provisions, we support the Senate Community Affairs Committee's Recommendations 11 (5.185), that the *Patents Act 1990* be amended to clarify the circumstances in which Crown use provisions might be employed (see Recommendation 2).

The BRCA1 and BRCA2 case alone should stand as a compelling example of how the current system cannot protect the public interest if exploited by a commercial entity. There are a number of other recent examples of research and healthcare being compromised by patent exploitation, including:

- Patents on epilepsy gene mutations (patents 2001265698 and 2004200978), whose enforcement saw restrictions in access to diagnostic testing;
- A patent (624105) on hepatitis C polynucleotides and polypeptides, which compromised progress in the development of diagnostics and vaccines; and

- A commercial monopoly over polypeptides of erythropoietin (patent 600650) and the natural biological matter from which they were derived, which inflated healthcare costs and threatened to impede competitive research.[4]

There are other examples.

An extensive review of the system by the Australian Law Reform Commission from 2002-04 produced 70 recommendations for reform.[2] However, there has been no government response to these recommendations.

For almost two years, the Senate Community Affairs References Committee inquired into gene patents, tabling a report in November 2010 with 16 recommendations for change.[1] A government response is awaited.

As the use of genetic and other human biological material becomes increasingly integral to cancer diagnostic and therapeutic technology, the need for change highlighted by these cases and activities grows in urgency.

Why go beyond genes?

Since the ALRC inquiry of 2002-04, the focus of our advocacy has been gene patents; the BRCA case in 2008 shows why this is critical.

However, genes are not the only natural biological materials fundamental to medical research and healthcare services that can be locked up by commercial monopolisation. There is a valid view that excluding only genetic products from patentability would not protect from monopoly other biological materials integral to competitive medical research, such as proteins and peptides.

For these reasons we support a broader approach than just prohibiting patents on genetic sequences.

Complementary measures may be required to extend the reach of an amended act to protect diagnostic tests for cancer risk from commercial monopoly.

Protecting diagnostic tests from monopoly

There is a view that the bill in its current form would not amend the Patents Act 1990 sufficiently to prevent monopolisation of genetic tests for cancer risk, such as the tests for diagnosing the BRCA1 and BRCA2 mutations, held by US company Myriad and licensed in Australia to Genetic Technologies.

However, it should be noted that the New York District Court ruling that invalidated patent claims for BRCA1 and BRCA2 gene mutations[5] did so on the basis that neither the genetic sequence for the mutations, nor the test adapted to identify them (ruled an “abstract mental process”, rather than an invention), were inventive. Therefore, amendments to the Patent Act 1990 as set out in the bill (with Cancer Council/COSA’s recommended amendments) would on the same basis prevent invalid patent claims such as those on BRCA1 and BRCA2 being henceforth granted.

Tightening the act further, as per the Senate Community Affairs Committee’s recommendations, would prevent non-inventive genetic tests from being patented and potentially monopolised. To this end, the Government should review the operation of the competition based test for the grant of a compulsory licence as also recommended by the

Senate (see Recommendation 2). The Australian Law Reform Commission also recommended such a test in its 2004 report.[2]

International developments

It should be noted that a small number of foreign jurisdictions with emerging market economies such as Brazil have introduced legislation similar to the Patents Act Amendment Bill. The Senate could investigate how the legislation has affected medical research and healthcare in those countries, to help address concerns about "unintended consequences".

Cancer Council Australia/COSA recommendation 4

That the Senate committee note:

- Australia's obligations under international arrangements such as the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement would not be compromised by the Patents Act Amendment Bill, as such agreements include exemptions for signatories to act unilaterally to protect domestic public health interests; and
- developments in the US and elsewhere signal a global shift towards eliminating patent monopolies based on materials that have been discovered, rather than invented. The BRCA case in the US, where the majority of gene patents are held, presents an instructive precedent, further emphasising the need for change in Australia.

International developments should be a key consideration in deliberations on the bill. It is critical that the committee understand that Australia is not beholden to any international obligations in relation to domestic gene patent policy; the public interest, particularly public health and access to healthcare, should be the priority.

Moreover, recent developments in the US (discussed above), where gene patents have been invalidated for not satisfying inventiveness criteria, reflect a trend towards seeking greater rigour in the awarding of patents on natural biological materials.

The Australian Government has a timely opportunity to contribute to this global shift towards equity and access by amending the Patents Act 1990 along the lines recommended in this submission, through the passage of an amended Patent Amendment (Human Genes and Biological Materials) Bill 2010.

References

[1] Senate report on gene patents, Commonwealth of Australia November 2010: http://www.aph.gov.au/Senate/committee/clac_ctte/gene_patents_43/report/index.htm

[2] Australian Law Reform Commission, Genes and ingenuity: gene patents and human health, 2004: http://www.austlii.edu.au/au/other/alrc/publications/reports/99/

[3] In a 1997 report to the TRIPS Council, Australia stated 'it is difficult to determine the frequency of [Crown] use, though we expect this has been minimal': *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and*

Control of Anti-competitive Practices in Contractual Licences: Australia, 22 October 1997 (1997) World Trade Organisation.

[4] Background on each of these cases is outlined in Senator Bill Heffernan's submission (no.76) to the Senate inquiry into gene patents: http://www.aph.gov.au/Senate/committee/clac_ctte/gene_patents_43/submissions/index.htm

[5] Association for Molecular Pathology, et al., v. United States Patent and Trademark Office, et al, No. 09 Civ. 4515. (Southern District of New York March 29, 2010).