Sub 50

15 December 2009

Senator Rachel Siewert
Chair
Community Affairs References Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Dear ~~Senator~~ Rachel Siewert

Thank you for your strong interest in Cancer Council Australia's policy priorities, in your roles as both health spokesperson for the Australian Greens and Chair of the Community Affairs References Committee.

The committee's current inquiry into gene patents is, in Cancer Council Australia's view, among the most important public health policy issues ever reviewed by the Senate.

I understand the committee has recently received submissions from the Chartered Institute of Patent Attorneys (UK) (No 74) and AusBiotech (No 75), which, along with the Institute of Patent and Trade Mark Attorneys' submission, criticise Cancer Council Australia's proposal to amend section 18(2) of the *Patents Act, 1990* ('the Act'). In view of the unsubstantiated claims made in these submissions, it is important to clarify Cancer Council Australia's position.

Claim

The CIPA states that our proposed amendment to the Act to exclude biological materials from patentable subject matter would significantly limit the scope for patenting "key biotechnological inventions"; AusBiotech claims it would "prevent a significant proportion of the Australian biotechnology industry from protecting its innovations".

Cancer Council Australia position

The foundation of our submission is that discoveries of *biological materials that are identical or substantially identical to those that exist in nature* are not innovations or inventions. Patenting of these biological materials, the use of which is essential to innovation, is the real threat to medical research – just as gene patents can restrict the ability of clinicians to use biological materials in diagnostic tests.

Neither the CIPA nor AusBiotech demonstrate how our proposed amendment would adversely impact on Australia's biotechnology industry. Our proposed amendment would simply remove the current ambiguities in patent law, by clarifying that biological materials of this kind, which exist in nature, are not patentable – a legal principle that has eluded the scrutiny of courts in Australia for more than 20 years.

Patent law does not give IP Australia the imprimatur to grant patent monopolies in respect of anything. The subject matter of the grant must be an "invention". This has been the cornerstone of patent law in Anglo-American jurisprudence for hundreds of years and is enshrined in the current Act in s.18(1). However, the application of patent law has not kept pace with technology; this is why we and other organisations concerned about the public interest call for legal reform to ensure the law is applied appropriately.

Claim

AusBiotech claims that our proposed amendment to the Act "may breach" the international Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, while the CIPA suggests our position is "incompatible" with TRIPS; AusBiotech also suggests that excluding genetic products from patentability may be in breach of the US Free Trade Agreement.

Cancer Council Australia position

Our proposed amendments to the Act would not contravene either TRIPS or the US FTA. Both of these international agreements stipulate that patents are only to be granted in respect of "inventions". According to our legal advice, our proposed amendment is entirely consistent with the intent and purpose of the relevant provisions of TRIPS and the US FTA.

Claim

The Institute of Patent and Trade Mark Attorneys claims our proposal is too broad in its definition of "biological materials" and would therefore exclude protection of intellectual property rights over a range of biotechnologies, including vaccines and pharmaceuticals.

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Cancer Council Australia position

The objective of our proposed amendment to the Act is to encourage and reward innovation in the development of vaccines, pharmaceuticals and other biotechnologies, where an "inventive" step is involved.

The materials that should, in our view, be excluded from patentable subject matter are the sequences of naturally occurring genes and proteins that are essentially *information* – which no person conceived of nor invented.

Biological materials (and their sequences) that are identical or substantially identical to what exists in nature are not "inventions". It is to this narrow class of materials that our proposed ban would apply.

We would welcome the opportunity for further discussion on the definition of "biological material" in this context to help allay what we see as unfounded concerns from industry groups about the impact our proposed amendment to the Act would have on genuine innovation.

Claim

The Institute of Patent and Trade Mark Attorneys specifically claims that our proposed amendment would have prevented the development of the cervical cancer vaccine Gardasil.

Cancer Council Australia position

Gardasil's principal developer, Professor Ian Frazer (Cancer Council Australia's president), is a vocal supporter of excluding biological materials from patentable subject matter. Professor Frazer is on record stating:

- "If we allow patenting of genes we're allowing patenting of ourselves. The patent system should protect inventive medicines developed from research using data on gene sequences. But a gene sequence used to develop the invention should not qualify the gene's sequencer to receive benefits;
- "Restricting the research use of a gene sequence could delay the development and testing of truly inventive and practical uses of the gene and its protein product for diagnosis and therapy. This would be to the detriment not only of the wider community, but also of the biotechnology industry itself."

Innovation in the development of vaccines, therapies and other genuine "inventions" would be encouraged by amending the Act as we propose, as the amendment would prevent individual commercial interests from locking up the natural building blocks essential for use in medical and scientific research and clinical applications.

In addition, it is important to redress the perception that an exemption from patent restrictions for "pure" research would prevent monopolisation of genetic materials from impacting on ostensibly non-commercial research in the public interest. As almost all medical research, including that undertaken by academic institutions, involves the potential for some commercial application, opportunities to exempt "pure" research would be extremely limited.

I trust this clarifies our position.

Thank you for again for considering our position. I would be grateful if you could write back, notifying me of your availability for a face-to-face meeting on this issue, perhaps in your parliamentary office some time early next year.

Best wishes for the holiday season.

Yours sincerely

Professor Ian Olver
Chief Executive Officer