IPTA

The Institute of
Patent and Trade Mark
Attorneys of Australia

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SENATE COMMUNITY AFFAIRS COMMITTEE

INQUIRY INTO GENE PATENTS

Supplementary Submission

The Institute of Patent and Trade Mark Attorneys of Australia

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1. Introduction

The Institute of Patent and Trade Mark Attorneys of Australia (***IPTA***) represents patent and trade marks attorneys registered in Australia, both in private and corporate practice. Although membership of IPTA is voluntary, over 90% of patent attorneys registered in Australia are members, either as Fellows or as Ordinary Members. Most members are also registered trade marks attorneys in Australia. In addition, the membership of IPTA includes registered trade marks attorneys who are not registered patent attorneys. Many of the patent attorney members are also registered New Zealand patent and trade mark attorneys. Accordingly, it is considered that the views of IPTA are representative of the views of a large proportion of patent and trade marks attorneys registered in Australia.

2. Background

IPTA filed a submission on 19 March 2009 in response to the invitation to comment on the 'inquiry into gene patents' which has been referred to this Senate Community Affairs Committee (Sub No 31), and which relates to the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in isolated form.

On Tuesday 4 August 2009, Dr Trevor Davies, IPTA Councillor, appeared before the Senate Community Affairs Committee (***the Senate Committee***) in Melbourne as part of the inquiry into gene patents.

IPTA notes that representatives of Cancer Council Australia appeared before the Senate Committee in Sydney on 5 August 2009. Following this appearance, Cancer Council Australia has filed a supplementary statement dated August 2009 (Sub No 50) in which it has provided to the Senate Committee a proposal to amend the *Patents Act 1990* (***the Act***) prepared by its consultant Dr Luigi Palombi.

IPTA also notes that the supplementary statement of Cancer Council Australia has been provided in response to the Senate Committee questions on notice asked during the hearing on 5 August 2009.

IPTA is surprised that the Senate Committee would turn to Cancer Council Australia, Australia's peak national non-government cancer control organisation, to provide patent legislation advice and propose patent law amendments.

IPTA is filing a supplementary submission addressing serious issues that may arise from adopting amendments to the Act proposed by Cancer Council Australia.

3. Cancer Council Australia – proposed legislation amendments

The amendments to the relevant sections of the Act proposed by Cancer Council Australia on pages 2 and 6 of its supplementary submissions are set out in the attached Annexure. For completeness, the full text of Section 18 and Section 7 of the Act are provided and proposed changes are indicated by underline and ~~strikethrough~~.

IPTA notes that there is an inconsistency with regard to Cancer Council Australia's proposal for amendments to Section 18 of the Act. The are two suggested changes for Subsection 18(2).

On page 2 the proposed amendment reads:

> (2) The following are not patentable inventions:
>
> (b) Biological materials, including but not limited to their components, parts or derivatives, whether isolated or purified or not and regardless of their state and processes used in their production, which are identical or substantially identical to those that exist in nature.

On page 6 the proposed amendment reads:

> (2) The following are not patentable inventions:
>
> (b) Biological materials, *including recombinant materials (*including but not limited to their components, parts or derivatives, whether isolated or purified or not and regardless of their state and processes used in their production*)* which are identical or substantially identical, *individually or collectively*, to those that exist in nature. (*emphasis added*)

IPTA has taken the amendment on page 6 to be the amendment proposed by Cancer Council Australia to Subsection 18 of the Act.

The following amendment to Section 7 of the Act has also been proposed by Cancer Council Australia:

> (2A) For the purposes of this Act, an invention that includes or makes use of a biological material as a component will be taken to involve an inventive step when compared with the prior art base unless the incorporation or use of that biological material, regardless or whether it is known or unknown, in the manner claimed in the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed any where in the world before the priority date of the relevant claim, whether that knowledge is considered separately or together with either of the kinds of information mentioned in subsection (3).

It is unclear what additional exclusion is contemplated by this amendment to Section 7.

4. IPTA Comments

At page 6 of the proposal referring to the exclusion of patentability of biological materials under Section 18 of the Act, Cancer Council Australia states:

> This amendment merely excludes, as a class, a patent monopoly over naturally occurring biological materials regardless of their actual physical state or their method of production. So long as the biological materials are identical or substantially identical to the naturally occurring biological materials they cannot be the subject of a patent monopoly, even if they are recombined. Accordingly, if the individual parts of a recombined and isolated gene are nothing more than a fusion of genetic parts, each of which are identical to their corresponding natural equivalents, then the recombined product is also excluded.
>
> The purpose of the amendment is to stop the patenting of genetic and protein materials that are rudimentary, in the sense that they are identical or substantially identical to their natural counterparts.
>
> In doing so, it will encourage further downstream innovation which utilizes these biological materials in new, inventive and practically useful ways.

IPTA disagrees with these comments as the proposed amendments to Section 18 of the Act do not just stop 'the patenting of genetic and protein materials that are rudimentary, in the sense that they are identical or substantially identical to their natural counterparts'. The proposed amendments go much further than indicated by Cancer Council Australia.

As there is no definition of 'biological materials' in the proposal, this term is extremely broad and covers a wide range of important classes of inventions including:

- isolated nucleic acids, proteins, peptides, lipids, carbohydrates
- chimeric biomolecules for medical, veterinary and industrial uses
- antibiotics and antivirals
- antibody-based drugs
- cancer treatments and diagnostics
- pharmaceutical formulations
- vaccines
- genetically modified organisms such as plants and bacteria
- biodegradable materials such as bioplastics
- biosensors
- natural products such as pesticides and insecticides
- dairy industry products such as cheese starter cultures and "live" yoghurts
- improved yeasts for brewing, fermenting and baking

- industrial enzymes
- extremophile microbes for use in diverse industries such as oil recovery, paper manufacture and bioremediation
- improved algae for use in the production of biodiesel

IPTA notes that the proposed amendments are extremely broad and, if the Act was amended as proposed by Cancer Council Australia, Australia would potentially exclude the protection of the majority of biotechnology inventions.

Such an exclusion to patentability would result in Australia breaching its obligations under the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (***TRIPS***) and Australia-United States Free Trade Agreement (***AUSFTA***). TRIPS provides minimum standards of IP protection which must be provided by members and AUSFTA contains provisions relating to patents which reflect the TRIPS provisions with only minor differences.

An exclusion to the patentability of inventions relating to 'biological materials which are identical or substantially identical, individually or collectively, to those that exist in nature' as proposed by Cancer Council Australia would prevent a significant proportion of the Australian biotechnology industry from protecting its innovation. Restricting patent protection in Australia as proposed by Cancer Council Australia would have an adverse impact on potential commercialisation opportunities in Australia and reduce investment in the Australian biotechnology industry.

The inventions 'Gardisil' (vaccine for human papilloma virus), anti-tumour necrosis factor (treatment for inflammatory conditions such as rheumatoid arthritis), and 'Termilone' (a natural product for the control and treatment of termites) are just a few examples of well-known Australian innovation that would not be patentable in Australia under the proposal by Cancer Council Australia.

If there is no opportunity to protect useful and potentially valuable inventions in Australia, development in the area of biotechnology would be greatly reduced, including a reduction in development crucial for bringing a product to market.

Similarly, if international companies and organisations could not protect their biotechnology innovation in Australia, it is quite likely that much of that innovation developed outside of Australia would not be made available to the Australian public. Access to innovation in the areas of medicine, veterinary science, agriculture, food technology, and the environmental could be curtailed, as a consequence.

IPTA submits that the Senate Committee should not adopt or recommend the proposal by Cancer Council Australia to amend the Act.

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Annexure

The full text of Section 18 and Section 7 of the Act are set out below. Cancer Council Australia proposed amendments are indicated by underline and ~~strikethrough~~.

Section 18 Patentable inventions

Patentable inventions for the purposes of a standard patent

(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:

(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an inventive step; and

(c) is useful; and

(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

Patentable inventions for the purposes of an innovation patent

(1A) Subject to subsections (2) and (3), an invention is a patentable invention for the purposes of an innovation patent if the invention, so far as claimed in any claim:

(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an innovative step; and

(c) is useful; and

(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

(2) The following are not patentable inventions:

(a) Human beings, and the biological processes for their generation~~, are not patentable inventions~~.

(b) Biological materials, including recombinant materials (including but not limited to their components, parts or derivatives, whether isolated or purified or not and regardless or [sic] their state and processes used in their production) which are identical or substantially identical, individually or collectively, to those that exist in nature.

Certain inventions not patentable inventions for the purposes of an innovation patent

(3) For the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions.

(4) Subsection (3) does not apply if the invention is a microbiological process or a product of such a process.

Section 7 Novelty and inventive step

Novelty

(1) For the purposes of this Act, an invention is to be taken to be novel when compared with the prior art base unless it is not novel in the light of any one of the following kinds of information, each of which must be considered separately:

(a) prior art information (other than that mentioned in paragraph (c)) made publicly available in a single document or through doing a single act;

(b) prior art information (other than that mentioned in paragraph (c)) made publicly available in 2 or more related documents, or through doing 2 or more related acts, if the relationship between the documents or acts is such that a person skilled in the relevant art would treat them as a single source of that information;

(c) prior art information contained in a single specification of the kind mentioned in subparagraph (b)(ii) of the definition of "prior art base" in Schedule 1.

Inventive step

(2) For the purposes of this Act, an invention is to be taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed ~~in the patent area~~ any where in the world before the priority date of the relevant claim, whether that knowledge is considered separately or together with either of the kinds of information mentioned in subsection (3).

(2A) For the purposes of this Act, an invention that includes or makes use of a biological material as a component will be taken to involve an inventive step when compared with the prior art base unless the incorporation or use of that biological material, regardless or whether it is known or unknown, in the manner claimed in the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed any where in the world before the priority date of the relevant claim, whether that knowledge is considered separately or together with either of the kinds of information mentioned in subsection (3).

(3) The information for the purposes of subsection (2) is:

(a) any single piece of prior art information; or

(b) a combination of any 2 or more pieces of prior art information; being information that the skilled person mentioned in subsection (2) could, before the priority date of the relevant claim, be reasonably expected to have ascertained, understood, regarded as relevant and, in the case of information mentioned in paragraph (b), combined as mentioned in that paragraph.

Innovative step

(4) For the purposes of this Act, an invention is to be taken to involve an innovative step when compared with the prior art base unless the invention would, to a person skilled in the relevant art, in the light of the common general knowledge as it existed in the patent area before the priority date of the relevant claim, only vary from the kinds of information set out in subsection (5) in ways that make no substantial contribution to the working of the invention.

(5) For the purposes of subsection (4), the information is of the following kinds:

(a) prior art information made publicly available in a single document or through doing a single act;

(b) prior art information made publicly available in 2 or more related documents, or through doing 2 or more related acts, if the relationship between the documents or acts is such that a person skilled in the relevant art would treat them as a single source of that information.

(6) For the purposes of subsection (4), each kind of information set out in subsection (5) must be considered separately.

[*Notes: (1) For the meaning of "document" see section 25 of the Acts Interpretation Act 1901.*

(2) See also the definitions of "prior art base" and "prior art information" in Schedule 1: see also paragraph 18(1)(b) and subsection 98(1).]