IPTA

The Institute of
Patent and Trade Mark
Attorneys of Australia

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SENATE COMMUNITY AFFAIRS COMMITTEE

INQUIRY INTO GENE PATENTS

Further 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 (Sub No 31) in response to the invitation to comment on the 'inquiry into gene patents' which has been referred to this Senate Community Affairs Committee (***the Senate Committee***), 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 Committee in Melbourne as part of the inquiry into gene patents.

IPTA filed a supplementary submission on 7 September 2009 (Sub No 31) in response to the supplementary statement of Cancer Council Australia of August 2009 (Sub No 50) proposing amendments to the *Patents Act 1990* (***the Patents Act***) prepared by its consultant Dr Luigi Palombi.

Submissions have also been filed by Senator Heffernan (Sub No 76). A supporting letter for Senator Heffernan's submissions was filed by Cancer Council Australia on 22 April 2010 (Sub No 50).

On 7 May 2010, Cancer Council Australia and Clinical Oncology Society of Australia wrote directly to Senator Humphries providing further proposed reforms to the Patents Act. This correspondence was tabled in the Senate public hearing on 18 May 2010 and subsequently placed on the Senate Committee's website regarding this inquiry (Sub No 50).

IPTA is surprised and concerned that the Senate Committee would rely on Cancer Council Australia, Australia's peak national non-government cancer control organisation, and Clinical Oncology Society of Australia, Australia's peak national body representing health professionals whose main work is cancer control, to provide patent legislation advice and propose patent law amendments.

IPTA notes that the Cancer Council Australia and Clinical Oncology Society of Australia proposals of 7 May 2010 to amend the Patents Act are quite different from the amendments proposed by Cancer Council Australia in August 2009.

3. IPTA Comments

(a) Bilski and Myriad Litigation

Before providing comments in relation to the Cancer Council Australia and Clinical Oncology Society of Australia proposal, we believe it may be worth bringing the Senate Committee up to date in relation to this litigation, particularly as parties opposed to patenting biological innovation have widely touted this litigation as supporting their anti-patenting position and views.

(i) Bilski Litigation – United States of America

The Supreme Court in the United States of America handed down its decision in relation to *In re Bilski* and has upheld the validity of process claims. The Supreme Court left open issues concerning fields such as medical diagnostic testing and therefore diagnostic claims continue to remain patentable and valid in the United States of America. The Supreme Court did have the opportunity to decide against the patentability of diagnostic claims but it chose not to do so and this is a significant outcome.

(ii) Myriad Litigation – United States of America

In contrast to what Cancer Council Australia and Clinical Oncology Society of Australia may indicate, the recent US decision of Judge Robert Sweet of the United States District Court for the Southern District of New York regarding seven US patents relating to human BRCA1 and BRCA2 genes (initiated under US Constitutional grounds and now under appeal to the Federal Circuit) is not directly relevant to considerations on patenting of biological materials in Australia.

The decision of first instance, which did not involve expert scientific evidence and has no relevance Federally, is under appeal. It is important to note that these seven US patents were challenged at two different levels:

(I) In relation to the claims to the isolated proteins and genes, *per se*, these have been challenged on the basis that they are not inventions and therefore not patentable subject matter. All the usual arguments in relation to the identification of these molecules being discoveries rather than inventions were submitted.

(II) In relation to the medical diagnostic claims, which are the claims that have formed the basis of the outcry in Australia in relation to the behaviour of Genetic Technologies Limited (***GTG***) regarding its exclusive rights to exploit the Myriad BRCA patent in Australia (and which underpinned the establishment of the Senate Committee review), were simply challenged on the basis of an application of the Federal Circuit Court *In re Bilski* decision in the context of diagnostics. In light of the Supreme Court *Bilski* decision, the challenge to the diagnostic claims is rendered moot as the original *Bilski* decision has now been overturned. Accordingly, irrespective of what the outcome is with the appeal in relation to

the gene and protein claims, the main basis to challenge the diagnostic claims under US law is gone.

(iii) Myriad Litigation - Australia

The Australian Myriad litigation has been widely touted as mirroring the US litigation. This assertion, however, is misleading.

The Australian Myriad litigation is limited to challenging the patentability of the isolated gene and protein claims. There is no challenge to the diagnostic claims to BRCA gene mutation testing as there is no sound basis on which to base such a challenge.

The fact that legal advisers on the Australian Myriad litigation have not managed to find a reasonable basis on which to challenge the diagnostic claims in Australia is worth noting and important. Even if the isolated BRCA1 and BRCA2 gene and protein claims were rendered unpatentable in Australia, the diagnostic testing claims in Australia would continue to stand. Thus, the patentees and their Australian licensee would retain legitimate exclusive rights to provide diagnostic services for BRCA gene mutations.

(b) Proposed reforms to the *Patents Act 1990*

From the submissions and proposed amendments to the Patents Act, it would appear that Cancer Council Australia and Clinical Oncology Society of Australia are fundamentally opposed to patent rights being issued to innovators where those rights may prevent members of Cancer Council Australia or Clinical Oncology Society of Australia from gainfully and freely exploiting that third party innovation. In its covering letter to Senator Humphries, Cancer Council Australia and Clinical Oncology Society of Australia requires that diagnostic tests (presumably human genetic tests) be freely available to all its members to exploit in Australia. Importantly, however, the amendments proposed to the Patents Act by Cancer Council Australia and Clinical Oncology Society of Australia are not solely directed at, or limited to, patents in the area of human genetic testing.

Cancer Council Australia and Clinical Oncology Society of Australia furthermore require that biological materials, whether in natural or purified form, are freely available for non-commercial scientific use.

IP Australia has proposed an amendment to the Patents Act to include Experimental Use provisions which should sufficiently clarify that non-commercial scientific use of biological materials (or any other materials or subject matter) in Australia will not be impeded by patents. In the view of IPTA, no further amendment is warranted or required to the Patents Act in this regard.

We provide specific comments below regarding the proposals by Cancer Council Australia and Clinical Oncology Society of Australia.

(i) Amendment 1 - Objects

The proposed amendment to add an object statement in the Patents Act may have no affect on any legal interpretation of the Patents Act, nor assist IP Australia in carrying out its examination of

patent applications under the Patents Act, nor a Court's determination on validity of a patent granted under the Patents Act.

Interestingly, if one of the objectives is to promote greater production, employment and research and development within Australia, destroying the current patent system in the context of biotechnology innovation will not achieve this outcome. It will shift research, development and the application of the technology to other regions such as the United States of America, Europe and China where functional patent systems will continue to exist for the field of biotechnology.

(ii) Amendment 2 – Validity

We note the following amendment to Section 18 of the Patents Act has been proposed:

(2A) 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 proposed amendments are unclear, unduly restrictive, and unnecessary.

It is unclear why there is a distinction between 'manners of manufacture' in 2A of the proposal and 'patentable inventions' in 2B of the proposal.

The notion of introducing a section to the Patents Act which includes the phrase "although not limited thereto" introduces an unacceptable level of uncertainty and cannot be allowed. Such an amendment would make the law insufficiently definitive and would not provide clear guidance.

The term 'component parts' would potentially encompass human body parts, organs, tissues, cells, proteins, glycoproteins, proteolipids, nucleic acids, enzymes and chemical messengers such as hormones and neurotransmitters. The term could also encompass the smaller molecular subunits that make up cells, proteins, nucleic acids, such as peptides, amino acids, nucleotides, carbohydrates, lipids and elemental components such as oxygen, carbon, hydrogen, phosphorous and nitrogen.

The term 'derivatives thereof' may include entities directly obtained from human sources or those which are full or partial synthetic analogs of a substance or molecule found in humans. The term may include modified tissues, engineered cells, mutant or modified proteins, functional molecules or chemicals. Exclusions encompassed by the proposed amendments include current and potential treatments and diagnostics for the benefit of humans and animals. Examples in this regard include biological substances active in humans and animals produced using recombinant technology from isolated or manufactured nucleic acids, antibodies, RNAi molecules, antagonists, agonists or mimetics of a human protein or chemical messengers, heterologous proteins, chimeric

proteins, nucleic acids, and biologicals isolated from other organisms having similarity to a corresponding human substance.

Implementing all the exclusions relating to the processes for the manufacture of biological products together with diagnostic, therapeutic and surgical methods would prevent a significant proportion of the Australian biotechnology industry from protecting important innovation. Without adequate patent protection in these areas, it would be difficult to attract investment and commercial support.

Although it is unclear from the submissions as to what Cancer Council Australia and Clinical Oncology Society of Australia envisaged by proposing the term 'component parts and any derivatives thereof', it is surprising that these organizations would be recommending exclusion from patent protection of modified antibodies, one of the fastest growing and important classes of cancer treatments. It is also unclear why Cancer Council Australia and Clinical Oncology Society of Australia would be encouraging the Senate Committee to propose limitations to the Patents Act that that would potentially harm the Australian biotechnology industry (and potentially the pharmaceutical and agricultural industries, more broadly). Precluding from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals may limit new technologies and treatments from being introduced into Australia.

(iii) Amendment 3 - Abuse of patent system

The proposed amendment to add a definition of an 'abusive patent claim' is unclear, redundant, not workable, probably not enforceable by a Court and therefore should be disregarded.

(iv) Amendment 4 - Abusive patents

The proposed amendment regarding examination or enforcement of an 'abusive patent claim' is unclear, redundant, not workable, probably not enforceable by a Court and therefore should be disregarded.

The amendments which are proposed in relation to the abuse of the patent system are an inappropriate way of approaching this issue. Either a patent claim is allowable under the law or it is not. If a claim is not allowable then it will be deemed non-allowable by the Commissioner of Patents or by a Court in a challenge during revocation proceedings. If a patent claim is allowable under the law then it cannot be regarded as abusive. The legality of a patent claim should not be based on some vague notion of what is socially or economically desirable to some.

The notion that the Commissioner of Patents be required not to accept a patent application containing an 'abusive' patent claim introduces such a level of uncertainty into the Australian patent system as to make it potentially unworkable.

(v) Amendment 5 – Relief for infringement of patent

This proposal relates to injunctions and it recommends the Patents Act be amended to include provisions to protect essential products and services from commercial monopolisation through limiting the grant of injunctions. The principles which govern the grant of an injunction were outlined in the High Court decision in Castlemaine Tooheys Ltd and South Australia (1986). In order to obtain an injunction, the applicant must show that there is a serious question to be tried,

the applicant will suffer irreparable injury for which damages will not be an adequate compensation, and the balance of convenience favours the granting of an injunction. Weighing the balance of convenience involves a consideration as to whether the detriment that would be caused to an applicant by not granting the interlocutory injunction is greater than the detriment that would be caused to a respondent by granting the injunction. The applicant bears the onus of persuading the Court that the balance of convenience favours the granting of the injunction.

The proposed amendments would not be workable and are not required.

(vi) Amendment 6 – Essential product

The proposed amendment to add definitions of 'essential product' and 'essential service' is unclear, not workable and therefore should be disregarded.

(vii) Amendment 7 – Grant and term of patents

The proposed amendment to require annual updating of patent information for the life of a patent is unrealistic and not workable. The proposal would be onerous upon the applicant/patentee and encompasses all technologies, not just life sciences. As there are only 12 months between renewals of a patent, there would not be enough time to conduct the proposed experimentation and investigations to meet the obligations to update the patent disclosure.

The proposal suggests that there is insufficient transparency and accountability and that greater disclosure will add rigour to the awarding of patents and uses of genetic materials. The proposal fails to acknowledge that at the time of a patent application is filed there may be no closest commercially available equivalent. This is particularly the case for pioneering inventions in any technology. The proposed changes set a moving disclosure standard over the life of a 20 year patent that has to be assessed for grant and then annually at each renewal.

Apart from the increase in compliance obligations and costs, the moving disclosure standard is most troubling as it fails to recognize commercial reality. A patent owner would also be forced to reveal all improvements that are made through the life of the patent and therefore take away any competitive advantage and remove incentive to develop technology and protect innovation.

4. Summary

IPTA submits that the Senate Committee should not adopt or recommend any of the proposals made by Cancer Council Australia Clinical Oncology Society of Australia to amend the Patents Act.

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