FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INDUSTRIELLE

Julian Crump
Secretary General

24 February 2011 Via electronic filing

Julie Dennett
Committee Secretary
Senate Standing Committees on Legal and Constitutional Affairs
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

Dear Ms Dennett,

Re: Patent Amendment (Human Genes and Biological Materials) Bill 2010

It has come to the attention of FICPI, the International Federation of Intellectual Property Attorneys, (**FICPI**) that the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (the **Bill**) was introduced into the Australian Senate and read for the first time on 24 November 2010.

I have pleasure in attaching FICPI's comments on the aforementioned Bill. FICPI has had the benefit of reviewing a draft of the comprehensive submissions made by IPTA and is in full agreement with those submissions.

Should you have any comments regarding our submission, may I ask you to contact Greg Chambers, the President of FICPI Australia and Australian delegate on FICPI's Executive Committee. His details are:

Correspondence to: Julian Crump
Secretary General of FICPI

Founded over 100 years ago, FICPI represents IP attorneys in private practice internationally with almost 5,000 members in 86 countries, including the US, Japan and Australia, a strong European membership and new sections in India and China.

FICPI aims to enhance international cooperation amongst IP attorneys and promote the training and continuing education of its members and others interested in IP.

FICPI offers well balanced opinions on proposed international, regional and national legislation based on its members' experience with a great diversity of clients having a wide range of different levels of knowledge, experience and business needs of the IP system.

Yours sincerely,

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COMMENTS OF FICPI ON THE *PATENT AMENDMENT (HUMAN GENES AND BIOLOGICAL MATERIALS) BILL 2010*

1. Introduction

It has come to the attention of FICPI, the International Federation of Intellectual Property Attorneys, (***FICPI***) that the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (***the Bill***) was introduced into the Australian Senate and read for the first time on 24 November 2010. FICPI has had the benefit of reviewing a draft of the comprehensive submissions made by IPTA and FICPI and is in full agreement with those submissions. FICPI has significant concerns with regard to the Bill and particularly with regard to the impact that the Bill, if enacted, would have on the fulfilment by Australia of its obligations under international treaties and agreements and on the IP system, the harmonization of which at a global scale is a key of its practicability and success. It is for these reasons that FICPI has decided to make these submissions in relation to the Bill.

FICPI is an international and non-political association of approximately 5,000 intellectual property attorneys from over eighty countries, including Australia. FICPI's members represent individual inventors as well as large, medium and small companies and public research organizations.

2. Background to the Bill

We understand that following on from action by Genetic Technologies Limited (***GTG***) to bring in-house the conduct of the BRCA diagnostic testing that it carries out in Australia under exclusive license of the relevant patents, the Australian Senate established a Senate Committee Inquiry into Gene Patenting. The Bill was introduced just prior to tabling of the Senate Committee Inquiry report, by two members of the Senate Committee. In the various hearings conducted and submissions presented to the Senate Committee there were a range of ethical, legal and economic issues discussed in relation to the granting in Australia of patents relating to genetic technologies. FICPI International does not believe it is appropriate for it to comment upon the ethical and economic considerations arising out of this debate, and specifically in relation to the Bill, as ultimately these are matters for the Australian people to decide upon through their elected representatives. However, an issue debated in the context of the Senate Committee Inquiry, which is relevant in consideration of the Bill, is the question of whether biological materials (and more specifically gene technologies) are a "discovery" or an "invention". This question is central to whether the Bill, if enacted, would impact upon Australia's International treaty obligations, and is one which we believe it is appropriate for FICPI to comment upon from its international perspective.

3. The Scope of Bill

The Bill includes a proposal to amend S.18(2) of the Australian Patents Act 1990 to exclude from patentable subject matter:

> "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" (S18(2)(b))

The Bill also includes a definition for "biological materials", as follows:

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

We note that although the language "biological materials including their components" is unclear in scope, it is certainly very broad. This language would appear to have the effect of excluding from patent protection any compound or material (either isolated from nature or artificially produced) that is derived from a living organism, as well as any derivative thereof that is either identical or substantially identical to a naturally occurring material. Even without taking into account the vague term "derivative" it is apparent from the non-exclusive definition of "biological materials" that the term is intended to exclude from patentability far more than simply gene related technologies. However, due to use of the term "derivative" (a term routinely objected to as being unclear during examination of patent claims including it for example in the USA, Europe, Japan, China, Canada and Australia) the actual extent of the exclusion from patent protection cannot be determined.

4. Impact of the Bill on Australia's Obligations under International Treaties/ Agreements

4.1. TRIPS

Amongst many other International treaties relating in one way or another to intellectual property protection, Australia is a signatory to the Trade-Related Aspects of Intellectual Property Rights (***TRIPS***) agreement.

Relevant sections of the TRIPS agreement are the following:

> *"Article 27: Patent subject matter*
>
> 1. *Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*
>
> 2. *Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*
>
> 3. *Members may also exclude from patentability:*
>
>   *(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;*

> *(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes."*

Broadly therefore it appears that under TRIPS there are just four grounds upon which member states can enact legislation to exclude certain technologies from patentability, each of which we will briefly consider below.

(i) Not new, inventive or capable of industrial application

The requirements for newness (novelty), inventive step (non-obviousness) and industrial applicability (utility) are the major criteria for patent protection in virtually all jurisdictions with a patent system. This exclusion therefore does no more than allow countries to exclude from patentability those purported inventions that do not meet the normal requirements for patent protection.

We understand, however, that it has been suggested in the debate in Australia surrounding the Bill that biological materials do not fall outside of this exclusion because they are discoveries and not inventions and therefore do not meet the requirements for novelty or inventive step. Throughout the major industrialised countries of the world the question as to whether biological materials are an invention or a discovery (or more properly whether they meet the requirements of novelty and inventive step) is one for which a legal framework has been developed to provide the answer. The present law in the major jurisdictions involves a case-by-case analysis, so that in some instances a biological material will be found to meet these requirements, while in others it will not. In the opinion of FICPI this is appropriate as it allows the reward of valid patent protection only in the case where the level of innovation justifies it. It is FICPIs position that the blanket exclusion from patent protection of all biological materials would have a very significant adverse effect of not only eliminating patent protection for obvious or minor technological advances in the biological field (which is already addressed in the current law) but also of excluding patent protection for many significant innovations that would benefit society and contribute to economic growth. FICPI believes that without the ability to secure a short term period of market exclusivity for such innovations there will be a significant disincentive for developing new technologies in the biological field and/or transferring such technologies to Australia.

The consideration of novelty in the context of a biological material is a relatively narrow enquiry: have details of the biological material previously been used or disclosed in public? For example, in the case of a naturally occurring protein derived from a fungus that is shown to have activity as an antibiotic, the requirement of novelty would be met if the patent claims are restricted to cover only the protein when either isolated from the fungus or when synthetically produced. The patent claims then would not cover the protein in the form in which it exists in nature.

The consideration of inventive step is not quite so straightforward. Essentially, however, if it can be shown that there was no previous indication provided in the literature that the particular protein claimed could have any useful activity then it is likely that the necessary level of non-obviousness would be fulfilled to meet the requirement for an inventive step. The demonstration that the protein has a useful activity as an antibiotic agent will most likely have involved significant research and development activity and expenditure in isolating and characterising the protein and in conducting detailed experimentation to demonstrate its biological activity.

It is only if the biological material meets the requirements of both novelty and inventive step that a patent office or the courts would consider it to be a patentable invention, rather than a non-patentable discovery. The correct application of these well understood tests provides a clear and relatively predictable basis for distinguishing between the biological materials that meet the requirements for patent protection and those that do not. This system works effectively and is relatively predicable across the major industrialised nations of the world.

In the opinion of FICPI the blanket exclusion in Australia from patent protection of all biological materials would not only be a retrograde step in comparison with the legal regime currently in place, but would contravene the provisions of TRIPS Article 27(1) which appropriately only excludes inventions which are not novel, inventive or industrially applicable.

(ii) Exclusion necessary to protect order public or morality

The question of what activities may violate *ordre public* or morality is inherently a difficult one to answer. Every individual within a society will have his or her own position with regard to questions of morality. Therefore, without taking a poll of the Australian people on their moral position with respect to the patent protection of biological materials it is difficult to make a clear assessment of the predominant national position. However, what can be said is that patent protection of biological materials is currently allowable (assuming that the normal requirements for patent protection such as those mentioned at item(i) above are met) in all of the major industrialised countries of the world. If one makes the assumption that the laws of a country are reflective of the morality or ethics of the populace then it is reasonable to infer that there is no moral problem associated with the patent protection of biological materials in places such as the USA, Europe, Canada, China and Japan. In this day and age of international communications and travel it would be surprising to find that the moral position on such an issue was significantly out of step in Australia in comparison to other industrialised countries.

It is also important to keep in mind the difference, both legally and practically, between patent rights and rights to actually use a given technology. Patents grant the patent owner only the right to prevent others from using the patented technology. The grant of a patent does not provide the patent owner with any rights to use the technology. Thus, even if one considered, for example, a

particular form of genetic engineering to be immoral, excluding that technology from patenting does nothing to stop persons from using the technology. If the Australian Senate is of the opinion that some form of *ordre public* or morality is being offended, the solution is to create laws addressing the *use* of the particular technology, not to outlaw the patenting of the technology.

(iii) Diagnostic, therapeutic and surgical methods for the treatment of humans or animals

This aspect of the Article 27 exclusion of not relevant to the present consideration as it does not relate to biological materials as such. It is interesting to note, however, that the Bill would not restrict patent protection in relation to diagnostic, therapeutic and surgical methods for the treatment of humans or animals even if such methods involved biological materials.

(iv) Plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes

The significant aspect of this criterion for exclusion provided under Article 27 is that it makes clear that micro-organisms cannot be excluded from patent protection (presumably other than if they do not meet the normal requirements for patent protection). In its current form the Bill includes micro-organisms within the definition of biological materials. The language of the Bill is therefore clearly non-compliant with TRIPS Article 27.

In summary of our discussion at sections (i) to (iv) above, it is the opinion of FICPI that the blanket exclusion now proposed in Australia from patent protection of all biological materials would not only be a retrograde step in comparison with the legal regime currently in place, but would, if enacted, result in non-compliance by Australia with its obligations under TRIPS.

4.2. Australia-US Free Trade Agreement

The Australia – United States Free Trade Agreement (the **Agreement**) entered into force on 1 January 2005. That Agreement including provisions relating to Intellectual Property, including the following provision relating to patents:

Article 17.9 : Patents

1. Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. The Parties confirm that patents shall be available for any new uses or methods of using a known product. For the purposes of this Article, a Party may treat the terms "inventive step" and "capable of industrial application" as synonymous with the terms "non-obvious" and "useful", respectively.

2. Each Party may only exclude from patentability:

(a) inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law; and#

(b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.

The plain language of this provision provides that, except for diagnostic, therapeutic, and surgical methods for the treatment of humans and animals, the Parties to the Agreement "may only exclude from patentability" inventions which must be exploited without limitation "to protect *ordre public* or morality". The exclusions to patentability proposed in the Bill are much broader and cannot be defended as necessary to protect *ordre public* or morality. FICPI is not even aware of any arguments seriously presented to defend the proposed exclusions on the basis of a need to protect *ordre public* or morality.

The Bill (S18(2)(b)) would exclude from patentability "biological materials including their components and derivatives ... which are identical or substantially identical to such materials as they exist in nature". Such an exclusion is much broader than the permitted exclusion in the Agreement for "diagnostic, therapeutic, and surgical methods for the treatment of humans and animals". As such, the proposed exclusions to patentability would be in violation of the Australia – United States Free Trade Agreement.

4.3. US Perspective

Arguments in support of the Bill have cited pending litigation in the United States in the case of *Association for Molecular Pathology and ACLU v. USPTO and Myriad Genetics* (**the Myriad case**) in which a decision was issued by a District Court on March 29, 2010. That decision, however, does not support the proponents of the exclusions to patentability in the Bill, even if the *Myriad* case is considered in the "light" most favourable to those proponents.

(a) The only court decision at this point in the case is that by a single judge in a lower court. No other courts or judges have followed the decision by similarly invalidating patent claims.

(b) The USPTO has not changed its policy or practice in light of the district court decision. Indeed, the USPTO has continued granting patents with claims similar in type to those granted to Myriad.

(c) The district court decision is under appeal to the Court of Appeals for the Federal Circuit, which court may well reverse the district court decision.

(d) The US Justice Department has filed a brief in connection with the appeal. But even that brief is not in full support of the district court decision. That brief specifically concludes that the Appeals Court "should reverse the district court's invalidation of the composition claims that are limited to cDNA's and similar man-made constructs, but affirm the district court's conclusion that the claims encompassing isolated human genomic DNA are invalid." (Page 37 of Brief for the United States as Amicus Curiae in Support of Neither Party, filed October 29, 2010). Thus, even this brief only offers a narrow support for the district court's position only on *genomic* DNA. (It is also of interest to note that the filing of this brief by the Justice Department suggests a significant division within the US government on the issue, in that the Commerce Department and USPTO were apparently not permitted by the US administration to submit a brief in support of the patent granted by the USPTO, the administration reportedly refusing to sign the brief submitted by the Justice Department.)

As a result, the exclusion to patentability proposed in the Bill is much broader in scope than even the position taken by the one district court judge in the *Myriad* case and much broader that the position taken by the Justice Department's amicus brief. Passage of the exclusionary provisions in the Bill, therefore, would be inconsistent with current US law and patent practice and inconsistent with even the broadest possible outcome of the *Myriad* case. Even complete affirmance of the Myriad district court decision would not exclude from patentability a variety of non-DNA molecules and substances, such as, antibodies, antibiotics derived from bacteria, anti-cancer drugs extracted from plants, and derivatives of such substances, all of which would apparently be excluded from patentability by the proposals in the Bill.

4.4. European Perspective

The exclusions to patentability proposed in the Bill would also be in contradiction to the patentability of such subject matter in Europe. Years of debate on the topic ultimately culminated in passage of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. As of January 15, 2007, all of the 27 EU member states had implemented the Directive. That directive provides in relevant part:

Article 3

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 4

1. The following shall not be patentable:

(a) plant and animal varieties;

(b) essentially biological processes for the production of plants or animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Implementation of the Directive by the European Patent Convention resulted in changes to the relevant Articles of the EPC.

Articles 52 and 53(b) EPC say what can and what cannot be patented. Biotechnical inventions are basically patentable, but with the following exceptions:

- **methods for treatment** of the **human or animal body** by surgery or therapy, and diagnostic methods practiced on the human or animal body
- **plant** and **animal varieties**
- **essentially biological** processes for the production of plants and animals.

Article 53(a) also prohibits the patenting of any invention whose commercial exploitation would be contrary to public order or morality.

It can be seen that while the European Directive and the EPC provide certain exclusions to patentability, those exclusions are much more narrowly tailored than the broad exclusion proposed in the Bill.

Conclusion

The above explanations refer to three major sets of rules and practices which have been developed and finely tuned over the last decades to ensure a generally appropriate balance between what should be patentable and what should not be in this field of technology. They show that the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* introduced into the Australian Senate, if enacted, would bring a strong local disharmony in this landscape, both from the standpoints of legitimacy and of the useability of the patent system for all users in this field.