The Institute of Patent and Trade Mark Attorneys of Australia
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SENATE LEGAL AND CONSTITUTIONAL COMMITTEE

PATENT AMENDMENT (HUMAN GENES & BIOLOGICAL MATERIALS) BILL 2010

Submission

The Institute of Patent and Trade Marks Attorneys of Australia

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Level 2, 302 Burwood Road, Hawthorn Vic 3122
PO Box 419 Hawthorn Vic 3122 Australia
Tel 613 9819 2004 Fax 613 9819 6002
Email: mail@ipta.org.au Internet: www.ipta.org.au

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1. Introduction

The Institute of Patent and Trade Marks Attorneys of Australia (***IPTA***) is the peak professional body representing 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 marks 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 had been referred to the Senate Community Affairs Committee (***the Senate Committee Inquiry into Gene Patents***), and which related 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 were also 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 filed a further supplementary submission on 6 August 2010 in response to the reforms proposed to the Patents Act by Cancer Council Australia and Clinical Oncology Society of Australia.

The Senate Committee report was handed down on 26 November 2010. However, the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (***the Bill***) was introduced into the Senate, and read a first time, on 24 November 2010. IPTA is surprised that the sponsors of the Bill, two of whom were Members of the Senate Committee, introduced this Bill just two days before the Senate Committee report was tabled and, further, introduced a Bill proposing legislative amendments which are contrary to their Committee's own recommendation not to amend the Patents Act, at this stage, to exclude genes from patentable subject matter.

3. Community Concerns

The issues which underpinned the establishment of the Senate Committee Inquiry into Gene Patents stemmed from Genetic Technologies' (**GTG**) actions in relation to their BRCA diagnostic test patent rights. Specifically, as the exclusive Australian licencee they sought to centralise BRCA diagnostic testing within their own laboratories. This proposal caused much concern within some parts of the community and led to the establishment of the Senate Committee Inquiry into Gene Patents. The main concerns expressed by the community, as determined both from the submissions made to the Senate Committee Inquiry into Gene Patents and the transcripts of its hearings, can be summarised as follows:

(i) *Genes are a discovery and not an invention*

- Genes are a product of nature and belong to humanity.
- The identification of genes is a routine procedure
- Identifying genes is merely a discovery since they are found within the genome and have not been newly created

(ii) *The existence of gene patents stifles research*

- The licence fees which are payable to access patented genes increases research costs and is contrary to the ethos of scientific innovation.
- Research is stopped if licences are not obtained since those genes cannot be used by the research scientist. That is, technology becomes effectively "locked up".
- Excluding genes from patents is the best way of ensuring that medical research is not compromised.

(iii) *The existence of gene patents risks public health and drives up health costs*

- Patenting increases the cost of genetic tests due to the monopolistic behaviour of patentees.
- Monopolies eliminate competition and decrease incentive to find better and more affordable tests.
- Gene patents reduce public access to genetic tests, thereby creating a potential public health crisis.
- A patentee could refuse to make a test available.
- The current legal framework cannot protect the community from these risks.

Other than the element of philosophical objection to the patenting of genes, which is dealt with in more detail below in section 7, the concerns expressed by the community were largely centered on how patent rights are exercised. IPTA believes that the current focus on banning the patenting of biological materials is actually misplaced. The enactment of the Bill would do little to alleviate the concerns which have been expressed by the community and would likely result in consequences which would impact undesirably on the Australian community.

4. Alleviating the Community's Concerns

The concerns expressed by the community in relation to the risk that abusive monopolistic behaviour, stemming from the existence of patent rights, could proceed unchecked are legitimate concerns which must be seriously considered and appropriately addressed. However, dealing effectively with this issue is difficult within the context of the highly charged, emotive debate which has occurred to date. What is therefore now required is a sensible and responsible debate which is followed by a response that is enshrined in law, well understood, based on rational analysis and which will safeguard access to all technologies, including technologies as yet unknown. The concerns which have been expressed in relation to stifling research and public access to medical technology are not unique to gene related technology, or even biological technology generally, but apply equally to all technologies. Accordingly, to propose solutions which are technology specific is to ignore the core issues which have been articulated by the community. Focussing on technology-specific solutions is therefore short-sighted, arbitrarily restrictive and wastes the opportunity to fully address the community's legitimate concerns.

5. Patent Amendment (Human Genes & Biological Materials) Bill 2010

(a) Scope of Bill

The Bill seeks to amend S18(2) of the Patents Act to insert a new exclusion in relation to what subject matter may constitute a patentable invention. Specifically, in addition to the existing exclusions to patentability of human beings and the biological processes for their generation, it is also now proposed that the following would be excluded:

> "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))

A new subsection is also proposed to be inserted which provides 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))

IPTA holds significant concerns in relation to the scope and potential impact of these proposed amendments. The proposed amendments are extremely broad in their scope, unclear in terms of their boundaries, and do little to alleviate the fundamental concerns

underpinning this debate. IPTA provides specific comments below in relation to these issues:

(i) Subject matter falling within the scope of S 18(2)(b) and 18(5)

The language proposed in the Bill is not only extremely broad but unclear in relation to the limits of its scope.

On a plain English interpretation, the phrase "biological materials" extends to any material found in a living organism. This is certainly consistent with the non-limiting definition of "biological material" provided in the Bill, which lists DNA, RNA, proteins, cells and fluids as non-exclusive examples of biological materials. Other materials which would be encompassed by this definition, by virtue of their presence in a living organism, would include chemical messengers, metabolites, peptides, membranes, lipids and carbohydrates. Still further, since the phrase "biological material" is interpreted relative to that which forms part of a living organism, this phrase encompasses not just materials found in the human, but those found in any living organism including all animals (e.g. mammals, marsupials, reptiles, aves), insects, microorganisms (e.g. bacteria, parasites, viruses, fungi), plants (e.g. flowers, shrubs, trees, fruit, vegetables, crops), aquatic organisms (fish, crustaceans, algae, aquatic plants, seaweeds, plankton) and the like.

The active agents of many of the pharmaceutical products we take for granted are in fact biological materials isolated from natural sources or their derivatives. Examples include the statin drugs for lowering cholesterol derived from fungal metabolites, the anticancer drug, Paclitaxel, derived from the bank of the pacific yew tree and the aminoglycoside antibiotics, such as streptomycin, derived from bacteria to name but a few.

In addition to this amendment extending to all biological materials, however, also excluded from patentability are the components and derivatives of these materials.

Reference to "components" would arguably encompass a broad range of molecules which correspond to subunits or subregions of these biological materials. For example, epitopes of allergens or pathogens (such as viruses), receptor/ligand binding sites and other functionally active regions of molecules or cells would fall within the scope of "components". In terms of the impact of this Bill to healthcare, it must be understood that the identification and use of such components in therapeutic and prophylactic medicines, such as vaccines, is widespread since it is generally preferable to administering the biological material in its whole form. By working with components rather than whole molecules, unwanted side effects can often be minimised. The components are also easier to manufacture on a large scale, thereby meeting community demand and reducing cost.

The term "derivative" is of itself a relatively vague term. "Derivatives" of biological materials may include entities directly obtained from an organism or those which are full or partial synthetic analogs of a substance or molecule found in an organism. The term may therefore include modified tissues, engineered cells, mutant or modified proteins, functional molecules or chemicals, biological substances produced using recombinant technology from isolated or manufactured nucleic acids, humanised

antibodies, RNAi molecules, antagonists, agonists or mimetics of a human protein or chemical messenger, heterologous proteins or chimeric proteins. In relation to small molecules, such as chemical metabolites, derivatives could include salts, esters and prodrugs designed to assist bioavailability and efficacy. The list is endless.

Of still further concern is the proposal to exclude from patentability biological materials which are "substantially identical" to the subject material as it exists in nature. It is curious that in the face of a Bill, the stated purpose of which is to reinforce the applicability of the distinction between discovery and invention, this Bill would extend to excluding the patentability of molecules which differ from their naturally occurring counterparts.

The generation of modified molecules which differ in structure from the natural counterpart is a significant area of research since even minor structural modifications can sometimes dramatically alter the functionality of the molecule. This can lead to the development of molecules exhibiting unique functional attributes, even if only minor structural differences are made. The identification of which parts of a molecule should be modified and the nature of that modification are often underpinned by years of research. By any sensible definition, these findings, and the molecules generated thereby, are "made by man" and are therefore not discoveries. Yet, the actual structural difference to the original molecule may be small and would therefore arguably fall within the scope of "substantially identical". Examples of molecules which are envisaged to fall within the scope of "substantially identical" include:

- modified antibodies - an important class of cancer treatments;
- new generation insulin which exhibits improved functionality but differs from native insulin by only one amino acid;
- mutated epitopes of common allergens, such as nuts, grasses and dust mite, which are able to stimulate the T cell immune response but not the B cell response, thereby inducing immunity without stimulating an allergic response;
- mutated viral and bacterial proteins which are designed to be used for immunisation;
- recombinant nucleic acid molecules expressing modified biological materials for use in the manufacture of new cancer treatments;
- genetically modified plants and animals for use in agriculture.

The Bill therefore arguably encompasses virtually all biological materials even where they are structurally different from their native counterparts.

(ii) Uncertainty introduced by the Bill

IPTA believes that of significant relevance to the impact of the Bill is the fact that in most jurisdictions in which Australian biotech innovators file their patent applications, Patent Examiners require the terms "derivative" and "substantially identical", as they are used in the context of claiming biological materials, to be deleted. This request is usually made on the basis that these terms are regarded as vague, have no clear

boundaries and are undefined under local patent jurisprudence. Accordingly, the Bill in fact proposes the use of terms which, in the context of well-established patent practice, are almost universally deemed vague and of unclear and undefinable boundaries.

Still further, although there does exist some general jurisprudence in relation to the meaning of the phrase "substantially identical", this exists only in the context of trade mark law and copyright law. Both these fields of intellectual property are entirely unrelated to patent law and concern the reproduction or use of visual, oral, aural or other types of symbolic representations. In the context of trade marks, these are associated with particular goods or services. Accordingly, this jurisprudence is not applied by Patent Offices in the context of determining the scope of "substantially identical" as it relates to patent applications directed to biological materials. Rather, this phrase simply continues to be deemed undefinable and is routinely required to be deleted.

IPTA therefore believes that although the significant breadth of this language is self-evident, its full scope and, in particular, its boundaries are undefinable. This introduces into the patent law an unacceptable level of uncertainty in determining what may be patentable in this field of technology.

(iii) Subject matter falling outside the scope of the Bill

The Bill proposes to exclude from patentability biological materials, *per se*. However it does not exclude from patentability therapeutic, prophylactic or diagnostic methods. Accordingly, methods of treatment and diagnosis will continue to be patentable. Even if these methods involve the use of a biological material, the fact that the biological material is not patentable in its own right will not impact on the patentability of the method for using that material.

To this end, it is important that the patient, research and clinical communities understand that the patent rights which exist in relation to diagnostic tests, such as the BRCA diagnostic test, would not be excluded from patentability by the Bill. Although the BRCA patents do contain claims to the isolated BRCA DNA molecules themselves, it is not these claims which protect the diagnostic test. Rather, the diagnostic test is protected by a separate set of claims which is directed to a method of diagnosis based on screening for the existence of the relevant mutations in the BRCA genes of a patient. These types of claims would be unaffected by the Bill and therefore diagnostic tests would continue to be patentable.

Similarly, methods of treatment, whether they be therapeutic or prophylactic, are also separately patentable from the biological molecules which may be used in the context of those treatments. Although the Bill would likely exclude from patentability the molecules themselves, the methods by which the patients are treated would remain eligible for patent protection.

(b) Impact of the Bill relative to community concerns

Ironically, when one considers the subject matter which falls outside the scope of the Bill, it becomes evident that the Bill does not address the community concerns which underpin the present debate. It was GTG's actions in seeking to become the sole provider of the BRCA diagnostic test, by virtue of the existence of its patent rights over this diagnostic method, which led to the current situation.

IPTA is concerned that the patient groups and clinicians who are genuinely concerned about the inappropriate use of patent rights as they relate to diagnostic methods, such as the BRCA diagnostic, will be disappointed to find that the enactment of the Bill will not change the situation with respect to diagnostic methods. These patent rights will continue to be validly granted. As stated earlier, IPTA acknowledges that all of the concerns which have been expressed should be taken seriously and should be carefully considered. However, IPTA believes that there are significantly more effective avenues available to alleviate these concerns and to restore comfort that the inappropriate exercise of patent rights cannot proceed unchecked. These are discussed below in Section 8.

Still further, in addition to the fact that banning the patenting of biological materials will not address the issue of access to diagnostic tests, it also will not address the broader issue of ensuring appropriate community and research access to all technologies, irrespective of whether they are biological products, non-biological products (such as chemotherapy drugs), methods of treatment, methods of prophylaxis (such as vaccination protocols), or diagnostic methods. Quality healthcare in Australia is dependent on significantly more than just access to biological materials.

(c) Unintended consequences of the Bill

In addition to the fact that the Bill does not actually alleviate most of the concerns expressed by the community in relation to clinical and research access to medical technology, it may also unintentionally create a range of new problems. These can be summarised as follows:

(i) As detailed above in Section 5(a) and (b), the Bill has been drafted using broad and vague language. The boundaries of the proposed language are unclear and the community would therefore be reliant on the courts to interpret this language and define these boundaries. This is an extremely undesirable situation. Bearing in mind that, historically, there have been relatively few biotechnology patent cases litigated in Australia, and the fact that the community does not want to be encouraging litigation which is expensive and time consuming, this potentially leaves enormous and indefinite uncertainty in relation to the scope of the Bill.

It should also be remembered that when a biotechnology case is litigated, the clarification which it provides is limited to the scope of the issue which has been brought before the court. For example, even if an issue in relation to the meaning of "components" was tried, this would be unlikely to provide clarification in relation to the meaning of "substantially identical" or "derivative". The community would be, therefore, reliant on the handing down of multiple decisions to bring clarity across the scope of the Bill. Whether or not this would occur is entirely dependent on the willingness of parties to both initiate and then follow through (i.e. not settle) their litigation. Realistically, this process is beyond anyone's control and would likely take decades to resolve, at enormous cost.

In the meantime, in the absence of any jurisprudence, IP Australia would be forced to make its own internal decisions as to how to interpret the Bill. Based on the fact that IP Australia has taken the position that terms such as "derivative" and "substantially identical" lack clarity, uncertainty in the minds of investors and applicants may be created in relation to the scope of molecules falling within the patenting ban, leading to a loss of confidence in the use of the Australian patent system in the context of biotechnology. This could result in the Australian patent system being disregarded when formulating intellectual property strategies, on an International scale, to develop and translate research from bench to bedside.

(ii) Since the language proposed in the Bill encompasses all biological materials, and in light of the uncertainty as to how broadly this language actually extends, any interest in pursuing the patenting of biological materials in Australia may effectively cease. This would place Australia completely at odds with all developed countries and our major trading partners. Australia risks becoming a pariah (and a backwater) within the international biotechnology community of the developed world.

(iii) Any suggestion that the Bill would only exclude from patentability an isolated biological material but not vaccines or other compounds designed to be administered to a patient is misplaced. Where vaccines and other administrable compounds essentially comprise the biological material itself, they would be arguably excluded by the scope of the Bill. For example, take the following claims:

1. An isolated biological A.

2. An isolated biological A capable of eliciting an immune response in a subject.

3. A vaccine comprising an isolated biological A for eliciting an immune response in a subject.

Despite the difference in language, all three claims effectively relate to the biological material itself. The Bill is a blunt instrument which would arguably exclude all these claims. The words used to describe the form of the biological material (e.g. vaccine, pharmaceutical, composition, compound etc.), would not necessarily alter the outcome under the Bill if a practical interpretation of the claim led to the conclusion that the biological material *per se* was what was effectively covered by the claim. To argue otherwise is to debate semantics and is indicative of the fact that the Bill is shrouded in uncertainty regarding its true scope.

(iv) In the absence of patentability extending to biological materials, the Australian patent system as it applies to biotechnology would be limited to providing patents over methods - such as methods of treatment and methods of diagnosis. The reality is, however, that method claims are significantly less attractive to those investing in and developing biotechnology than claims to a product *per se*. Specifically, method claims are generally significantly more difficult to police and the burdens of proof in the context of infringement situations more onerous to satisfy. Composition patents provide rights over a product which is relatively easily distributed, sold and tracked. However, claims limited to compositions would not allow a patentee to prevent large scale manufacture of the active agent used to make the product. Method based inventions can also often be performed without recourse to the patent holder for

access to products or information since the patent system forces the publication of the details of how to perform the method. Their use may therefore spread unchecked. Accordingly, Australia runs the risk that where the development of a biological material in Australia could only be protected at the level of its method of use, and not at the level of the product itself, the Australian patent system would become viewed internationally as of very limited value.

(v) The absence of a functioning patent system directed to biological materials in Australia is unlikely to impact on the fact that all other developed countries continue to provide for patents over biological materials, particularly in Europe where this is enshrined in legislation. Accordingly, technology will continue to be patentable overseas and may well further encourage the move to translate technology from bench to bedside overseas. Since research is often conveniently centred where development and investment occur, Australia runs the risk that Australian scientists and their research programs will move overseas to where the patenting and commercialisation becomes centred. We also open ourselves to cherry picking of promising Australian research programs by overseas research institutes, companies and investors. This is an extremely undesirable outcome for a country which is trying to promote its intellectual talent, stem the "brain drain" and assert its significance as an important centre for biotechnology development.

(vi) In the absence of a patent system which extends to biological materials, we run the risk of an adverse impact on the importation, and therefore availability, of patented medicines in Australia. Ultimately, the decision of the owners of these medicines as to whether they would invest in pursuing regulatory approval in Australia and thereafter make available these medicines in competition with third parties, such as generic drug manufacturers, will be made on a case by case basis. However, the indication that an adverse outcome is a very real (and not merely a theoretical) risk for the Australian people is evidenced by the statement which appears at page 6 of Amgen's February 2011 submission to the Committee (Submission No. 12):

> *"Without patent protection for our biological medicines, we would be unwilling to sell our therapeutics in the Australian market. Without a sustained sales presence, it would be difficult to maintain a clinical trial presence knowing that Australian patients trialling Amgen medicines would never be able to access them."*

This highlights the fact that these sorts of decisions have moral as well as commercial dimensions, and that the adverse ramifications for Australian healthcare outcomes could be devastating.

The reality is that Australia is a small market when considered on a global scale and enacting legislation which would effectively make us less desirable as a potential market would seem extremely unwise.

(vii) Introducing a ban on the patentability of biological materials will also likely place Australia in breach of its International obligations. This is discussed in more detail below in section 6.

6. International Issues

Australia is an active member of the International intellectual property community and is a signatory to many intellectual property related treaties. However, it is the terms of Trade-Related Aspects of Intellectual Property Rights (***TRIPS***) and the Australia-US Free Trade Agreement which may be threatened if the Bill was to be enacted.

(a) TRIPS

The sections of the TRIPS agreement which are relevant to the present issue are as follows:

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 *order 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.

Some jurisdictions such as Europe, have opted to exclude from patentability diagnostic, therapeutic and surgical methods. However, where this has occurred, an alternative form of claim language has been provided for, based on claiming the use of a compound or reagent relative to a specific application (being the method in issue). Accordingly, from a practical point of view the ability to obtain useful patent rights in the context of the development of novel diagnostic and treatment methods has not been adversely impacted upon.

Biological materials are not listed as subject matter which can be excluded from patentability. In the explanatory memoranda of the Bill, the point is made that biological materials are allegedly discoveries and therefore not patentable inventions. It is on this basis that the architects of the Bill have previously argued that the provisions of TRIPS would not be breached if Australia was to ban the patenting of biological materials. That is, TRIPS only provides that patent protection must be made available for “inventions”.

In fact, IPTA believes that this analysis is not supported by international practice. The notion that discoveries are not patentable is a basic tenet of patent law which is recognised worldwide. If biological materials were merely discoveries, we would expect to have seen more evidence of this view internationally. However, the positions in Europe, the United States of America, Canada, China and Japan, as examples of several major jurisdictions, suggests otherwise.

European Position

In Europe, confirmation of the fact that biological materials are regarded as inventions exists in the legislation of all countries which form part of the European Union. The provisions which have been enshrined in these domestic laws are the same as those provided for in the European Biotechnology Directive. Specifically, the European Biotechnology Directive expressly states that:

- "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" (A.3(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" (A5(2)).

This is a clear indication that the European Union does not regard biological materials as mere discoveries. Since TRIPS requires Australia to provide patents for inventions without discrimination as to the field of technology, the enactment of the Bill would likely raise serious issues regarding our obligations under TRIPS as they relate to our relationship with Europe.

US Position

The position in the United States of America has been repeatedly raised in the media as providing support for the proposal to amend Australia's laws to exclude the patentability of biological materials. In fact, there have been articles published alleging that the US Government supports banning the patenting of human and other genes[1]. These articles are misleading and are based on the misreporting of the US Department of Justice Amicus Brief filed in respect of the BRCA patents litigation. The situation in the United States currently stands as follows:

(i) Early last year the Southern District Court of NY handed down a decision in the case of *Association for Molecular Pathology and ACLU vs. USPTO and Myriad (SDNY 2010) (Judge Sweet)*. This case had been brought before the Court in relation to the family of patents which claimed the BRCA1 and 2 gene sequences and the methods of diagnosing a predisposition to breast and ovarian cancer based on screening patients for the presence of mutations in these gene sequences. The patents were challenged on the basis that they violated both the patent laws of the US and the US Constitution.

[1] The New York Times (29 October 2010): US says genes should not be eligible for patents; The Age (1 November 2010): In policy reversal, US says genes ineligible for patents.

(ii) The claims to the isolated BRCA DNA molecules which form part of the BRCA patents were held to be unpatentable subject matter under the US Patent Act. However, it must be noted that the decision only held that isolated DNA was not patentable, where it is not markedly different from native DNA, and that the judge drew a distinction between DNA and other types of biological materials. Specifically, the judge held that DNA exhibited unique qualities which are distinct from the essential characteristics found in any other compound in the body. At page 124 of the decision Judge Sweet stated, "the information encoded in DNA is not information about its own molecular structure incidental to its biological function, as is the case with adrenaline or other chemicals found in the body. Rather, the information encoded by DNA reflects its primary biological function: directing synthesis of other molecules in the body - namely, proteins……. DNA, and in particular the ordering of its nucleotides, therefore serves as a physical embodiment of the laws of nature - those that define the construction of the human body. Any "information" that may be embodied by adrenaline and similar molecules serves no comparable function".

In drawing this distinction it is clear that the reasons which the judge gave for the non-patentability of DNA do not apply to non-DNA molecules found in the body. The decision of this court is therefore limited in law to the issue of the patentability of DNA and is based on a very clear distinction that DNA is regarded as having unique characteristics not found in other biological molecules found of the body. This would suggest that the same reasoning cannot be extended to justify banning the patenting of non-DNA molecules and that the basis for denying the patentability of genes in the US is therefore not based on a discovery vs. invention argument, being the argument which is being articulated in Australia.

(iii) This decision is a decision of a single judge and is confined to a small district. It has no authority beyond that district. This decision is currently under appeal and has not led to any change in current Unites States Patent and Trademark Office (***USPTO***) practice in examining applications and granting patents for inventions in the biotechnology field.

(iv) The finding of invalidity of the BRCA diagnostic method claims was based on the application of a US judicial precedent (*In re Bilski*) which has no authority in Australia. *In re Bilski* related to a business method patent and not a biotechnology patent. Nevertheless, due to the reasoning provided in that decision, it was generally believed that the logical extrapolation of that reasoning would render diagnostic methods unpatentable. However, on appeal the original *Bilski* decision was effectively diluted and the impact of this decision was essentially reversed to the extent that it was seen to apply to diagnostic methods. Accordingly, diagnostic claims continue to be patentable in the US and it is expected that the decision in relation to the BRCA diagnostic claims must now be reversed on appeal.

(v) The Department of Justice Amicus Brief has been the source of significant misinformation in our media during the last few months. Both in The New York Times and in The Age it was reported that this Amicus Brief reversed a longstanding policy and that the US Government had now decreed that human and other genes should not be eligible for patents. This is incorrect.

The Department of Justice Amicus Brief in fact effectively recommends *watering down* the SDCNY 2010 decision. Specifically, it states only that claims to isolated naturally occurring *human genomic* DNA should remain invalid. However, it clarifies that any man made constructs such as cDNA, vectors, recombinant plasmids, and "similar fruits" of the manipulation of genetic material should remain as patent eligible subject matter. This is a significant divergence from the decision of the New York judge since in that decision it was expressly stated that cDNA was not regarded as patentable.

Still further, the US Department of Justice Amicus Brief is limited to recommending only isolated *human genomic* DNA sequences. It does not recommend that DNA sequences from any other organism of non-human origin would not be patentable nor does it recommend that anything other than a complete genomic DNA sequence would be ineligible for patent protection.

Accordingly, the suggestions in the media that the US Government has decreed that "human and other genes", generally, should not be eligible for patents is entirely incorrect and completely misleading.

It is therefore clear that at this stage there has been no change of law in the United States. At best there is a low level judicial decision which has invalidated the gene claims only - not claims to biological materials generally. The US Department of Justice has itself recommended watering down this decision to, at most, apply only to human genomic sequences and to no other DNA sequences nor to any other biological material. There is currently no legislation proposed by the US Government to ban the patenting of genes or biological materials and the USPTO has not altered its patent examination guidelines. Accordingly, for all intents and purposes the position in the United States as it currently stands remains that all biological materials, including genes, are patentable subject matter. For Australia to propose the banning of patenting of all biological materials would put us directly at odds, in the context of TRIPS, with the United States.

(b) Australia – US Free Trade Agreement

In addition to TRIPS, Australia is also a signatory to a US Free Trade Agreement. This Agreement includes provisions with respect to patents, as follows:

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

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.

Again, under the terms of this agreement, both Australia and the US are required to make patents available in all fields of technology. The express exclusions do not state that biological materials are not patentable. There is an exclusion permissible in relation to inventions which one would want to prevent commercialisation of due to the protection of *ordre public* or morality. However, bearing in mind that there is no precedent in any developed country to ban the patenting of biological materials, this would suggest that such patents are not generally regarded as either contrary to morality or *ordre public*.

However, of particular relevance to the present situation is the fact that the countries which are part of the Andean community did enact, as part of the Decision 486: Common Intellectual Property Regime (Title II on Patents), that the following would not be considered an invention:

> Article 15(b): Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing.

The countries that are members of the Andean Pact are Bolivia, Columbia, Ecuador and Peru. In enacting this provision to ban the patenting of biological material, only Bolivia, Columbia and Ecuador were able to do so. Due to the fact that Peru had enacted a Free Trade Agreement with the US, their domestic law was required to maintain the patentability of isolated biological materials. Accordingly, this is arguably currently the most tangible evidence of the impact of a US Free Trade Agreement and, in particular, the position which the US Government takes in relation to the patentability of biological material.

(c) Other Jurisdictions

As mentioned above, there are countries which currently exclude the patentability of biological materials, for example, Bolivia, Colombia and Ecuador. However, they are few in number. Significantly, there are no developed countr jurisdictions which have enacted such exclusions.

Surely it is not desirable to effectively model the future of the Australian patent system on that of undeveloped or developing countries with entirely different economic and Governmental structures to Australia.

It seems clear that the established and best practice of developed countries is to continue to regard biological materials as patentable and to deal with issues of public health and the like from the point of view of ensuring that undesirable monopolistic behaviour cannot proceed unchecked. This approach would be far more advantageous for Australia and far more closely aligned with international best practice, than the arbitrary and piecemeal exclusion of subject matter from the Patents Act.

7. Philosophical Issues

The issues which have been raised by the community are complex and IPTA believes that there does exist an underlying philosophical issue which is apparent when reading the submissions made to the Senate Inquiry into Gene Patents. There are some who believe that the patenting of a gene is tantamount to patenting of the human body while others are not quite so extreme in their view and hold the view that genes are discoveries and not inventions.

It is difficult to discuss issues of philosophy and morality since these are personal issues which are held for many different reasons and which change over time. However, in terms of the view which is currently held in developed countries internationally, biological materials which are isolated from the human body or otherwise recombinantly or synthetically produced are regarded as an invention, rather than a discovery. The rational for this position is as follows:

(i) The mere identification of the existence of a new gene, protein or other biological material is not sufficient to secure a patent and does amount to a discovery.

(ii) It is only the isolated or artificially generated molecule, the utility of which has been established, that can be made the subject of a valid patent.

(iii) A granted patent does not give the patent owner any rights in relation to the molecule which exists in the body.

(iv) The issue of the complexity of the technology used to identify and isolate the gene or other molecule is irrelevant to the issue of patentable subject matter but is highly relevant to other patentability thresholds (i.e. novelty and inventive step).

The fact is that identifying a biological molecule and establishing a utility for it is like finding a needle in a haystack and, in fact, is sometimes tantamount to finding a needle in the haystack when you neither knew that the needle existed nor what it looked like. To attempt to become prescriptive in relation to defining the line between discovery and invention in this field will likely create more problems than it solves.

8. Alternative Options for Dealing with the Community Concerns

IPTA believes that the Bill is an ineffective mechanism for dealing with the concerns which have underpinned the present debate. Still further, and as detailed earlier, IPTA believes that in addition to the fact that the current concerns are not alleviated, the Bill will in fact act to create new problems and lead to undesirable, albeit presumably unintentional, consequences.

If one is concerned about undesirable monopolistic behaviour both at the level of public access to technology and facilitating ongoing research, then those concerns apply to all technologies and not merely to the very specific field of gene technology or, even, biological materials more generally. For example, monopolies can equally be exercised inappropriately

at the level of diagnostic or therapeutic methods or in relation to non-biological compositions which are crucial to delivery of diagnostics, therapeutics and surgery. That being the case, to alleviate the community concern, and to provide comfort to the public, it is necessary to provide an approach which is technology neutral and which relates to regulating the exercise of patent rights generally, rather than a subject matter specific approach which dictates only the existence or not of a patent right. These safeguards also provide a safety net for the exercise of rights in relation to technologies which may not even exist yet, this being a significant consideration when one bears in mind the speed of technological evolution.

(a) Safeguards

Compulsory Licences and Crown Use

The Patents Act already provides two safeguards which are designed to regulate the exercise of patent rights, these being the compulsory licencing provisions (which are also provided for in the context of the TRIPS agreement) and the Crown use provisions. The compulsory licence provisions enable anyone to apply to the courts for a licence to be compulsorily granted to them in relation to any patented technology. This application can be made where the applicant believes the reasonable requirements of the public are not being met with regard to access to the technology and has been unable to negotiate a licence on reasonable terms with the patentee. The Crown use provisions enable the State and Federal governments to compulsorily access patented technology where they believe that it is necessary for the public good. The exercise by the Crown of this right is also dependent on payment of a reasonable royalty to the patentee. Both of these provisions already exist in the Patents Act but could be reviewed to examine their effectiveness and accessibility.

Although these provisions have never been used in the context of biotechnology, that is not to say that the spectre of their existence in the Patents Act has not succeeded in forcing patent right owners to responsibly exercise their patent rights. The reality is that there has never been a health crisis in Australia and even GTG's actions in threatening to centralise all BRCA diagnostic testing in their own laboratories was not followed through. This would suggest that there do exist pressures which act to regulate the behaviour of patentees.

Nevertheless, just because there has never been a public health crisis based on inappropriate monopolistic behaviour of patentees or exclusive licensees in Australia does not mean that we should not review the existence and accessibility of these safeguards and ensure that they are optimal.

Research Use

In addition to public access to technology in the clinical sense, the other concern expressed by virtually all parties was that research activity should not be compromised due to the existence of patented technology.

To date there has not been any significant evidence presented of a systemic inhibition of research programs due to the existence of patents. Of some relevance to this issue may be the fact that, up until 2004, it was believed that a judicial research use exemption existed in Australia . However, an Advisory Council on Intellectual Property ***(ACIP)*** inquiry conducted at about that time reviewed this particular issue and determined that in fact the interpretation of the judicial decision which underpinned this belief was too generous and that this case did

not stand for a wide reaching research use exemption. In light of this determination, however, the codification of a research use exemption was immediately called for. This matter has, for some reason, been slow to be dealt with but is now under consideration. Draft language to codify a research use exemption in fact forms part of the *Intellectual Property Laws Amendment (Raising the bar) Bill 2011* (***Raising the Bar Bill***).

As with compulsory licences and Crown Use, the research use exemption is technology neutral and thereby provides security for researchers across all technologies. Accordingly, rather than arbitrarily carving out genes or biological materials from the patent system, but otherwise maintaining the currently perceived research "problems" in relation to accessing other types of patented technology, the issue is dealt with across the board.

(b) Raising the Bar

Much of the criticism which was made, during the Senate Inquiry into Gene Patents, in relation to gene patents which have previously been granted in the US and Australia, related to both their breadth and the apparent weakness of the data underpinning the claims. IPTA believes that it is important that a distinction is drawn between misapplication of patent law or lax patent examination procedures versus a problem inherent in the law itself.

By and large the patents which have repeatedly been cited by way of example during this debate were filed more than 20 years ago. Just because these broad gene patents were granted, this did not mean that they were necessarily valid and had they been challenged they may well have been revoked. Nevertheless, over the last decade the issue of thorough patent examination procedure has been reconsidered. Patent examination has been progressively tightened and it is now rare to find such broad patents being granted.

IPTA is concerned that what has been lost in this debate is that patent laws are more complex than merely the issue of what subject matter is patentable. Just because subject matter is "patentable" (i.e. it is not expressly excluded from patentability under the Patents Act) does not mean that a patent will necessarily be granted. Although biological material is regarded as subject matter in respect of which a patent can be applied for, unless that subject matter also meets the thresholds of novelty, inventive step and utility, a patent will not be granted. It is for this very reason that gene patents are now rarely granted. Specifically, despite the fact that genes are still patentable subject matter, in light of the publication of the human genome sequence and the fact that the technology for isolating and cloning genes has become significantly more routine than it was in the 1980s, genes per se which are now identified are rarely regarded as either novel or inventive.

The issue of the routine nature of isolating new genes was repeatedly articulated during the Senate Committee Inquiry into Gene Patents and is certainly highly relevant. However, its relevance lies not with whether or not genes or other biological materials are patentable subject matter but whether or not, even if they are, their identification is inventive. By way of direct analogy, patents that were legitimately granted even with broad claims in the field of, say, electronics 20 years ago would not be granted today. This is not because electronics have been excluded from the definition of patentable subject matter, but simply because the technology has advanced and what constituted a genuine inventive breakthrough, following painstaking research and development 20 years ago, would be regarded as routine and entirely non-inventive today. The current patent law naturally adapts as the base of "prior

art" in each field evolves. The beauty of this is that arbitrary or *ad hoc* interventions and exclusions in particular technologies are not needed.

In terms of the specific issue of genes, there is in fact little to be achieved in banning gene patents. These patents are dying a natural death due to the fact that the patent laws are working correctly. Nevertheless, the proposed Raising the Bar Bill focuses on amending the Patents Act to ensure that the thresholds of novelty, inventive step and utility are appropriate for 2011 and beyond, across all fields of technology and that the changes will be implemented stringently by IP Australia.

(c) Intellectual Property Law (Raising the Bar) Amendment Bill 2011

IPTA believes that the better way to move forward in the context of the current debate is not to pursue the *Patent Amendment (Human Genes & Biological Materials) Bill 2010* and to, instead, focus on the *Intellectual Property Laws Amendment (Raising the bar) Bill 2011*. The Raising the Bar Bill is significantly more comprehensive in relation to its consideration of the Australian patent law. Its focus is consistent with the recommendations of virtually all of the previous inquiries which have been conducted in relation to patentable subject matter and experimental use (these are discussed further in the next section). In short, all of these inquiries have generally consistently made the same recommendations, being that the scope of patentable subject matter should not be altered and is not the correct focus to achieve alleviation of community concerns regarding undesirable monopolistic behaviour. Largely, these reports have consistently recommended that the safeguards present in the Patents Act to control such behaviour should be reviewed, that an experimental research use exemption should be codified and that the Patents Act should be reviewed to ensure that patentability thresholds (in terms of novelty and inventiveness) are appropriately set and properly implemented. IPTA believes that the Raising the Bar Bill is consistent with these recommendations and provides a more appropriate avenue of review and potential implementation of changes which would effectively address the community's concerns, in a consistent manner across all technologies.

9. Other Enquiries

There have been a number of recent enquiries in relation to the issues of patentable subject matter and experimental use. These are as follows:

- Australian Law Reform Commission 2004 - Gene patenting and human health
- ACIP 2005 - Patents and experimental use
- ACIP 2008 - Patentable subject matter
- 2010 Senate Community Affairs Committee Inquiry into gene patenting
- ACIP 2010 - Patentable subject matter

All of the reports from these enquiries have consistently made essentially the same recommendations, being that patentable subject matter provisions should not be changed but that any review of the law should focus on the application and working of the safeguards

which appear in the Patents Act, codification of a research use exemption and ensuring that patentability thresholds are appropriately set and properly implemented.

For example, the ACIP 2010 report states at page 7 of the report:

> *Improving access to beneficial patented technology is better dealt with through mechanisms other than the test for patentable subject matter. These other mechanisms include providing efficient compulsory licensing and crown use provisions, allowing experimental use of patented inventions, non-legislative mechanisms such as patent pools, and other targeted government programs.*

IPTA believes that regard should be had to these recent enquiries, the outcomes of which have consistently shared this fundamental core of recommendations.

10. Conclusion

There have been many reviews in relation to the issue of the patentability of biological materials and time and again the outcomes of these reviews have consistently held that isolated biological materials should remain as patentable subject matter. In IPTA's opinion, issues based on philosophical and moral views are very difficult to resolve to everyone's satisfaction. Any outcomes which are pursued from that perspective are unlikely to satisfy all of the interested stakeholders.

In addition to the fact that the Bill does not, in fact, alleviate the specific concerns in relation to access to clinical technology and research use, it also potentially creates a significant number of new problems. To the extent that these problems are created, they are in fact not limited to human health and research but will extend to technology as it relates to biological materials derived from any living organism including all animals (eg. mammals, marsupials, reptiles, aves), insects, microorganisms (eg. bacteria, parasites, viruses, preons), plants (eg. flowers, shrubs, trees, fruit, vegetables, crops), aquatic organisms (fish, crustaceans, algae, aquatic plants, seaweeds, plankton) and the like. Accordingly, the potential detrimental outcomes of the enactment of this legislation would be felt not only in healthcare but also in agriculture, food technology, animal husbandry, the cut flower industry and any other industry which benefits from non-human sources of biological materials. The Bill is too blunt an instrument which is not characterised by the sophistication required to navigate wide ranging community concerns and to provide solutions in the context of a complex legal framework.

The danger posed by banning the patenting of biological materials across all of these species is arguably particularly unwarranted when one considers that it is, in fact, possible to resolve the community's practical concerns by focussing on the issue of regulating the exercise of all patent rights rather than proceeding down the road of selectively banning biological materials from patentability - which, ironically, will do nothing to alleviate the current concerns as they exist in relation to accessing genetic diagnostics. Still further, by focussing on how patent rights are exercised, a solution is designed which applies to all technologies, whether medical or not, which fall outside the realm of biological products, *per se*.

It therefore seems that a more sensible way forward is to discontinue consideration of the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* and, instead, to focus on the *Intellectual Property Laws Amendment (Raising the bar) Bill 2011*. The Raising the Bar Bill is a significantly more detailed and effective piece of legislation which seeks to deal with the community's concerns at the level of introducing an experimental use exemption in addition to tightening the currently applicable patentability thresholds such that they are appropriately set and properly implemented. The Raising the Bar Bill could be used as the vehicle to further investigate and implement any changes necessary to the compulsory licencing and Crown Use provisions, as have been consistently recommended in previous inquiries in relation to the issue of patentable subject matter.

Ultimately, this approach would be of significantly more benefit in terms of the outcomes which are actually sought by the wider community, while avoiding the raft of unintentional but highly detrimental consequences that would inevitably flow from the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*.

Dr Tania Obranovich
The Institute of Patent and Trade Mark Attorneys of Australia (IPTA)