AIPLA
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

15 March 2011

Ms. Julie Dennett
Committee Secretary
Senate Legal and Constitutional Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

By email: legcon.sen@aph.gov.au

Re: Inquiry into The Patent Amendment (Human Genes and Biological Materials) Bill 2010 of the Legal & Constitutional Affairs Legislation Committee

Dear Ms. Dennett:

The American Intellectual Property Law Association ("AIPLA") appreciates the opportunity to comment on The Patent Amendment (Human Genes and Biological Materials) Bill 2010 ("the Bill" or "the Amendment").

AIPLA is a national bar association in the United States of America whose approximately 16,000 members are primarily lawyers in private and corporate practice, in government service, and in the academic community. AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property in the U.S. and in many countries around the world, including Australia. AIPLA's primary objectives are to aid in the improvement of laws relating to intellectual property and in their proper interpretation by the courts, and to provide legal education to the public and to its members on intellectual property issues. Because this Bill raises issues of concern to our members, and the intellectual property that they own and use in Australia, we are providing these comments.

We understand that the Amendment, proposed on 24 November 2010, is intended to prevent the patenting in Australia of any and all "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." This proposal raises grave concerns for health care and biomedical research, and for the reasons explained below, AIPLA urges the Legal & Constitutional Affairs Legislation Committee to resist its enactment.

This proposed legislation, if enacted, could have not only a substantial negative effect on the healthcare, medical research, and well-being of the Australian people. It could also have a similar impact on entities outside of Australia and could erode Australia's position as an international participant in biomedical research and development and in biotechnology industrial activity.

AIPLA has been following the so-called "gene patent" debate in Australia with special interest as similar concerns have been voiced in the United States in a case involving Myriad Genetics, Inc., Genetic Technologies' licensor, and its patents on the BRCA1 and BRCA2 genes. AIPLA sympathizes with people who want second genetic diagnostic tests before making critical decisions about their health and believes that patents do not and should not deter basic scientific research. However, AIPLA also believes that patenting is essential for protecting investments in new products and encouraging the advancement of additional technologies. Considering the costs of developing new diagnostic and new therapeutic biological products, patenting biological materials is particularly critical.

NO EVIDENCE SUPPORTS THE BILL

The Bill was introduced just before the release of the Australian Senate Community Affairs Committee Report (the "Report") on the Senate Gene Patent Inquiry. This careful inquiry spanning several years was directed to the impact of gene patents on healthcare, medical research, and the health and well-being of the Australian people. Not one of the Report's sixteen recommendations includes an express prohibition of patenting genes or any other biological material.

In this regard, the Report is consistent with an earlier inquiry made in 2004, the Genes and Ingenuity, which was held by the Australian Law Reform Commission (ALRC). By contrast, the Bill under consideration, introduced by Senators Coonan, Heffernan, Siewert, and Xenophon, is not supported by any fact-based justification for the proposed ban. The drafters of the Bill state that its purpose is to "advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease." They believe "without patent protections of biological materials that doctors, clinicians, and medical and scientific researchers will gain free and unfettered access to such materials as they exist in nature."

However, there is no evidence that patents stifle research in Australia. As noted in the Report, the Senate Community Affairs Committee was unable to make definitive conclusions and was ultimately "frustrated by the lack of comprehensive, systematic and accessible data in relation to gene patents." As a result, Recommendations 1 and 2 of the Report seek to improve the data and information used to evaluate the quality and impact of gene patents.

Two carefully researched inquiries in Australia were unable to find any evidence to support the proposed ban, which not only would prohibit the patenting of genes but would do so in a sweeping way. The scope of the proposed ban would include all "<u>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</u>."

THE BILL IS VAGUE AND OVERLY BROAD; IT MAY ELIMINATE PATENTS FOR THERAPEUTIC PRODUCTS

As noted above, the Bill seeks to amend Section 18(2) of the *Patents Act 1990* ("Patents Act") to exclude from patent eligibility "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." "Biological materials" would be defined to include "DNA, RNA, proteins and fluids." AIPLA believes that these expansive and indefinite terms could be problematic for patent protection in this technology. In particular, it is unclear what "including their components and derivatives," "substantially identical" and "as they exist in nature" mean.

While most of the recent focus has been on isolated genes and methods of using them for research and diagnosis, other valuable biological materials that have identical or close analogues in nature include engineered organisms (bacterial and mammalian), cell lines, vectors, plasmids, small molecules, vaccines, biologics such as antibodies and proteins, to name a few. Therapeutic antibodies, for example, are on the market or are being developed as treatments for many diseases, including infectious diseases, cancers, rheumatoid arthritis, multiple-sclerosis, Alzheimer's disease, Type I and Type II Diabetes, cardiovascular disease, and musculoskeletal diseases, among others. Many of these antibodies are fully human or humanized, meaning that this type of antibody is derived from human antibody genes. Fully human and humanized antibodies are generally considered to be safer than other types of antibodies. However, because they are derived from human genes, therapeutic human antibodies or the DNA that encodes them could be viewed as "biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to materials as they exist in nature."

Another category of biological medicines that could be impacted by this legislation are analogues of natural human proteins. Such analogues may have structures that are intentionally "substantially identical to proteins as they exist in nature." An example is a class of molecules called "rapid-acting insulin analogues." Such analogues typically differ from natural human insulin as little as possible. Rapid-acting insulin analogues retain substantially all of insulin's structure and its essential activity in controlling blood glucose in people with diabetes, yet precise changes in structure achieve a faster control than insulin.

At least three rapid-acting insulin analogues have been marketed in Australia: insulin lispro (HUMALOG (R), Eli Lilly and Company); insulin aspart (NOVORAPID (R), Novo Nordisk); and insulin glulisine (APIDRA (R), Sanofi-Aventis). The structural differences between insulin, as it exists in nature and the rapid-acting insulin analogues are very minor, as shown in the table below. Yet they each have clinically significant differences compared with natural human insulin.

Molecule	Atomic formula	Molecular weight	Amino acid changes compared with insulin[1]
Natural human insulin	$C_{257}H_{389}N_{65}O_{77}S_6$	5,808	-
Insulin lispro	$C_{257}H_{389}N_{65}O_{77}S_6$	5,808	2
Insulin aspart	$C_{256}H_{381}N_{65}O_{79}S_6$	5,825	1
Insulin glulisine	$C_{258}H_{384}N_{64}O_{78}S_6$	5,823	2

These insulin analogues could be considered "substantially identical" to insulin as it exists in nature and thus unpatentable according to the proposed Amendment.

Beside insulin, many other human proteins or analogues of human proteins have been and are being developed for therapeutic purposes, including: parathyroid hormone, amylin, calcitonin, excendin-4, glucagon-like peptide-1, glucagon, gastric inhibitory peptide, oxyntomodulin, somatostatin, bone morphogenic protein 2, bone morphogenic protein 7, gonadotropin releasing hormone, keratinocyte growth factor, platelet-derived growth factor, follicle stimulating hormone, chorionic gonadotropin, leutinizing hormone, interferon-α, interferon-β, tissue plasminogen activator, growth hormone, insulin-like growth factor 1, Factor VIIa, Factor VIII, Factor IX, Protein C, β-gluco-cerebrosidase, erythropoietin, granulocyte colony stimulating factor, granulocyte-macrophage colony stimulating factor, interleukin, glucosidase-α, and analogues of many of these proteins.[2]

Because the patenting of "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" would be forbidden, the Bill could deny patent protection to these valuable therapeutic human proteins, protein analogues, and humanized antibodies in Australia.

ALTERNATIVES TO ENACTING THE BILL

One of the more emotional motivations for banning patenting of biological materials as they exist in nature is based on the mistaken belief that the patentee of a biological material "owns" part of a human. Section 13(1) of the Patents Act describes the right that a patent provides:

> Subject to this Act, a patent gives the patentee the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention.

[1] Human insulin has 51 amino acids.

[2] See Benjamin Leader, Quentin J. Baca & David E. Golan, "Protein therapeutics: a summary and pharmacological classification," Nature Reviews Drug Discovery 7, 21-39 (January 2008).

The reference to "exclusive rights" means that the patentee could obtain a court order directing an infringer to cease infringing–that is, the patentee would have a right to "exclude." A patent may not be validly exercised against things in existence before the patent is filed because to do so will invalidate the patent for lack of novelty. A patent thus cannot give the patent owner any rights or ownership in relation to any biological material as it exists naturally in the body of any human being. The Bill is not needed to prevent ownership of biological materials as they exist in nature.

Although the Bill proposes to exclude from patentability biological materials, *per se*, it does not exclude therapeutic, prophylactic, or diagnostic methods from patentability. Thus, methods for diagnosis of genetic disease risk will continue to be patentable in Australia, even if those methods involve the use of a biological material. As a result, the proposed Amendment appears to do little to address the fundamental concerns underpinning the debate on access to genetic testing in Australia.

More importantly, however, the primary issue that is underlying the gene patent debate is access to the available advancements in medical technologies and the potentially abusive monopolistic behaviour that can stem from the existence of patent rights to genetic materials. Banning the patenting of biological materials is unnecessary as such a ban does not address the concerns of access to patented technology. Moreover, this issue is not addressed by selectively excluding certain subject matter from the patent laws, but rather by safeguarding the public from misguided and self-serving abuses of a viable patent system.

Concern about research uses of patented biological materials and ability to obtain second diagnostic opinions could be dealt with by narrowly-tailored legislation. For example, an amendment to the Patents Act to introduce a research use exemption could alleviate concerns over access of such materials to researchers. A research exemption was supported by the Report. Concerns that valuable research involving biological materials could be prevented by patents and concerns that owners of patents covering diagnostic tests could prevent obtaining second opinions should be dealt with by narrowly tailored exemptions from patent infringement, not by wholesale exclusions from patent eligibility. By crafting solutions to specific situations, scientists could conduct research freely, companies could provide patients with second opinions in limited circumstances even when the diagnostic product or service is patented by a third party, and investments in new products and services would be protected and incentivized. The proposed Bill does not achieve these objectives.

On the other hand, we agree with many of the other considerations that persuaded the Committee against recommending that the Patents Act be amended. These considerations include: (1) a level of uncertainty around the potential effectiveness and effect of such a prohibition; (2) reforms to the manner of manufacture test which will clarify the application of the invention-discovery distinction; and (3) the desired high degree of conformity between Australia's patent system and jurisdictions such as the U.S.

UNIFORMITY OF THE WORLD'S PATENT SYSTEMS IS VITAL TO THE WELL-BEING OF A GLOBAL ECONOMY

With so very many countries having made decades of efforts and strides towards harmonization of intellectual property systems, AIPLA believes that the proposal could be at odds with the protections afforded by the rest of the world and may be dangerously inconsistent with the patent systems of others. Australia is a party to a number of international agreements related to intellectual property including the General Agreement on Tariffs and Trade 1994 ("GATT"), the Trade-Related Aspects of Intellectual Property Rights 1995 ("TRIPS"), and the Australia-United States Free Trade Agreement ("AUSFTA").

Banning patents on biological materials could conflict with Australia's international obligations under TRIPS and the AUSFTA. Specifically, the AUSFTA, Section 17.9.2 states that each party may only exclude from patentability:

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

Furthermore, Article 27, paragraph 1 of TRIPS, to which Australia has acceded, requires Australia to afford patent protection "enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

Finally, the proposed legislation would be inconsistent with the expansive patent protection afforded to biological materials in all other industrialized countries, as under the European Union Biotechnology Directive, for example. The purpose for these treaties is to provide a uniform set of intellectual property protections across the globe in order to facilitate economic stability and strong vigorous international economic relations. The proposed Amendment could contravene both the AUSFTA and TRIPS by barring patents in an entire technological field, namely, biological materials.

To the extent that the Bill responds to events in the United States, such a response is unwarranted. Contrary to press reports, the U.S. Government does not support banning the patenting of human and other genes. Those reports appear to be based on the U.S. Department of Justice Amicus Brief filed in the appeal of the *Myriad* decision, *Association for Molecular Pathology v. U.S. Patent and Trademark Office,* Fed. Cir. App. No. 2010-1426.

In fact, that brief takes a position far narrower than the proposed ban on patenting biological materials. Currently, no legislation is proposed by the U.S. Government to ban the patenting of genes or biological materials. In addition, the United States Patent and Trademark Office ("USPTO") has not altered its patent examination guidelines regarding patent applications directed to biological materials. The position in the U.S. remains that all biological materials, including genes, are patentable subject matter. The USPTO continues to issue gene patents.

In short, at this juncture, the U.S. district court opinion in the *Myriad* case should not be a basis for changing Australian patent law.

AIPLA appreciates the thoughtful consideration being given to the important issue of encouraging and protecting innovations, including the development of biomedical diagnostic and therapeutic inventions. We recommend preserving patent protection for biological materials to ensure continued development and access to such innovations for future generations.

Sincerely,

David W. Hill
AIPLA President