IPTA

The Institute of
Patent and Trade Mark
Attorneys of Australia

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SENATE COMMUNITY AFFAIRS COMMITTEE

INQUIRY INTO GENE PATENTS

Submission

The Institute of Patent and Trade Mark Attorneys of Australia

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1. Introduction

The Institute of Patent and Trade Mark Attorneys of Australia (***IPTA***) provides the following submission in response to the invitation to comment on the 'inquiry into gene patents' which has been referred to this Senate Community Affairs Committee, and which relates to the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in isolated form.

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

2. Terms of Reference

The Senate has referred the following matter to the Community Affairs Committee for inquiry and report by the last sitting day of 2009:

The impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form, with particular reference to:

(a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:

(i) the provision and costs of healthcare,

(ii) the provision of training and accreditation for healthcare professionals,

(iii) the progress in medical research, and

(iv) the health and wellbeing of the Australian people;

(b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of the any matters identified by the inquiry; and

(c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

3. Background

(a) Technology

IPTA notes the inquiry covers human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form. This technology covers a broad range of medical, veterinary, environmental and industrial applications with potential overlap between healthcare and other areas.

(b) Genes and Ingenuity: Gene Patenting and Human Health (ALRC 99, 2004)

IPTA refers the Community Affairs Committee to the Australian Law Reform Commission Report 99 June 2004 entitled *Genes and Ingenuity: Gene Patenting and Human Health* (***ALRC Report***). On 17 December 2002, the ALRC formally received a reference from the Attorney-General to undertake a review of intellectual property rights over genes and genetic and related technologies, with particular focus on human health issues. Following extensive consultation with health professionals, interested parties and the public, the ALRC Report made important recommendations for reform but it did not suggest any radical overhaul of the Australian patent system. The ALRC did not identify fundamental flaws in patent law or practice and found that the *Patents Act 1990* should *not* be amended to exclude genetic materials and technologies from patentable subject matter. In addition, the ALRC found that the *Patents Act 1990* should *not* be amended to exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter. Rather, social and ethical concerns should be addressed primarily through direct regulation of the use or exploitation of a patented invention and not patentability *per se*.

IPTA recommends the Community Affairs Committee considers the ALRC Report as it provides a comprehensive overview of the technology, details the patenting of the materials in question, and outlines the underlying issues on this emotive subject.

Although the ALRC Report was published in 2004, there have been no significant changes in Australia since publication to warrant any reconsideration or review of the patent system in relation to gene technology.

(c) Patents

A patent is a limited monopoly (up to 20 years for most inventions and extendable for up to a further 5 years for pharmaceutical substances or pharmaceutical substances produced by recombinant DNA technology) granted to a person for a patentable invention. For an invention to be patentable in Australia, it must be a manner of manufacture within the meaning of section 6 of the Statute of Monopolies 1623 (i.e. suitable subject matter), be novel, involve an inventive step, have utility, and not have been secretly used. In return for obtaining a patent, the inventor must fully describe the invention including the best mode for carrying out the invention at the time of filing the patent application. Patent specifications are published and available to the public 18 months from the earliest priority date of the invention. The patent system encourages innovators to apply for patents so the inventions are published to further expand the knowledge in the technical area.

When a patent expires or lapses, any one may use or exploit the invention for commercial gain without regard to the old patent.

It is important to note that the grant of an Australian patent does not give the patentee authorisation to make or use an invention. Rather, the grant of a patent provides the patentee with a negative right. That is, a patentee can exclude third parties from making or using the invention. For example, just because a patentee has a granted Australian patent in respect of a human pharmaceutical does not mean that the patentee is free to market that pharmaceutical in Australia. Before doing so, the patentee must secure marketing approval from the Therapeutic Goods Administration. Thus, the grant of a patent does not constitute Government endorsement as to the legality, safety or morality of a patented product or its use.

(d) Australian Patent Law

The *Patents Act 1990* includes provisions for application, examination, grant, enforcement and use of patented inventions. Importantly, in Chapter 12 of the *Patents Act 1990* there are provisions for the grant of compulsory licences to third parties where the reasonable requirements of the public with respect to a patented invention have not been satisfied; and the patentee has given no satisfactory reason for failing to exploit the patent. Any perceived misuse of patent rights by a patentee can be addressed through the *Patents Act 1990* and other legislative provisions. To restrict patent protection for a class of technology to all innovators on the basis of a perceived misuse by a patentee of its legitimate monopoly rights is unjustified.

(e) International Agreements

Australia is a signatory to the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (***TRIPS***), and therefore bound to comply with the provisions of this Agreement. TRIPS provides minimum standards of IP protection which must be provided by members. The most relevant articles of TRIPS to the present inquiry are Articles 7, 8, 27 and 30.

In addition, the Australia-United States Free Trade Agreement (***AUSFTA***) contains provisions relating to patents which reflect the TRIPS provisions with only minor differences. Article 17.9 of the AUSFTA is relevant to this inquiry.

(f) Gene Patents

There are a number of groups in Australia that appear to be philosophically opposed to patenting of gene related technologies. Some of these groups are quite vocal and their activities may have resulted in misinformation on gene patenting being disseminated to the public. Other groups opposed to gene patenting may be self serving in that they wish to provide commercial services in the area of gene testing and healthcare without having to pay royalties or legitimate fees to patent owners and innovators.

In contrast to some assertions, valid patents do not cover naturally occurring genes or biological materials when present in nature. Patents do not result in an individual's genes or genetic makeup being owned or controlled by third parties.

Inventions in the area of biotechnology often come out of extensive research and innovation resulting in patents for new treatments or diagnostics that provide improved clinical outcomes. Biotechnology does not only cover the area of human health. Biotechnology includes innovation in animal health, primary production, crop science, environment and pollution control, industrial applications, and energy production. Preventing patenting in this technology generally may have adverse consequences for many growing technology areas.

A simplistic argument against patenting of biological materials is that isolated biological materials cannot be distinguished from naturally occurring molecules. Although this may be the case for some biopharmaceuticals such as hormones or growth factors, the ability to produce naturally occurring biomolecules on a commercial scale for use in medicine, for example, is clearly useful and potentially patentable. Patentable inventions include modified naturally occurring proteins that have been manipulated to perform under altered conditions (such as different pH or temperature) or have improved biological activity. Such modifications remove any connection with "natural occurrence" and can be clearly useful and beneficial.

(g) Patents filed in Australia

To assist the Community Affairs Committee in appreciating the important use of the patent system in Australia, IPTA offers the following outline of patenting trends and filings in a number of technology areas, including biotechnology, which generally covers inventions for human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form.

The total number of Standard Patent applications filed in Australia by Australian and foreign applicants from 1990 to 2006 (the figures of 3 from 30 Technology Groups in the years 1990 and 2000 – 2006 are summarised in Table 1) has almost doubled. The technology group for which the greatest number of patent applications have been filed (10% of the total applications filed) was organic fine chemicals and filings increased in this group by about 150% over this period. Biotechnology was rated fifth in number of applications filed from 1990 to 2006 and reflects 6% of the total applications filed. However, biotechnology was one of the fastest growing technology groups having an increase of about 300% over this period.

The total number of Standard Patent applications filed by Australian applicants during the same period showed a similar trend (the figures of 3 from 31 Technology Groups in the years 1990 and 2000 – 2006 are summarised in Table 2). Of note, about 90% of Standard Patent applications filed in Australia are owned by foreign companies but the trends in biotechnology patent filings by Australian applicants are similar to foreign derived filings.

Table 1: Standard Patent applications from all applicants*

Technology Group (Ranking)	Year									
	1990	(1991-1999) **	2000	2001	2002	2003	2004	2005	2006	TOTAL (all years 1990-2006)
Organic fine chemicals (1)	1598		1929	2129	2459	2273	2257	2520	2678	**31570**
Pharmaceuticals, cosmetics (2)	673		2209	2405	2352	2398	2821	2838	3449	**29418**
Biotechnology (5)	465		1588	1812	1765	1611	1433	1319	1322	**18376**
TOTAL (all 30 Groups)	14987		22003	22733	22565	21621	22906	23106	26003	**313364**

*adapted from IP Australia sources

**data not shown

Table 2: Standard Patent applications by Australian applicants*

Technology Group (Ranking)	Year									
	1990	(1990 – 1999) **	2000	2001	2002	2003	2004	2005	2006	TOTAL (all years 1990-2006)
Civil engineering, building, mining (1)	278		341	433	321	347	384	393	444	**5852**
Pharmaceuticals, cosmetics (13)	25		61	118	55	65	87	76	99	**973**
Biotechnology (14)	26		63	97	57	65	62	67	66	**898**
TOTAL (All 31 Groups)	1944		2516	3637	2430	2536	2703	2699	2903	**39908**

*adapted from IP Australia sources

**data not shown

As the majority of patent filings are derived from foreign sources, any changes to availability of patent rights for a particular technology in Australia may adversely impact the commercial activities of foreign companies in Australia.

As Australia is the signatory on a number of International Treaties and Conventions (TRIPS, AUSFTA) related to trade and intellectual property, exclusion of patentability for specific technologies may result in Australia breeching some of its international obligations.

There are several factors that have influenced the increase in Australian applicants seeking patent protection for biotechnology inventions. Notably, many public funded research institutes and Universities have included commercialisation as an additional outcome. A critical step in successful commercialisation is the protection of innovation through patenting.

A number of models for exploiting biotechnology innovation generated from publicly funded research have been developed. However, all models require intellectual property capture and protection as key for managing risk and achieving outcomes. Sources of income generated from the biotechnology patents include sale, exclusive and non-exclusive licences, research agreements or contracts through to joint ventures and the establishment of spin-off companies.

4. Submissions

As members of IPTA are involved in advising local and foreign entities in obtaining, commercialising and enforcing patent rights in Australia, IPTA provides submissions on a number of the areas canvassed in the inquiry.

(a) Impact of the granting of patent monopolies over such materials

(i) the provision and costs of healthcare

Patents have covered small drug therapies and diagnostics from the outset of the pharmaceutical industry and patents have played an important role in protecting and encouraging exploitation innovation for healthcare. As medical innovation has moved to the exploitation of larger biomolecules, patent protection has been sought to protect this innovation. IPTA is of the view that patents for gene-related technology should not be considered any differently from other non-biological technologies.

The cost of developing new medical treatments has increased greatly. The increase in these costs is not due to patenting of innovation but to the regulatory requirement to approve safe drugs for release to the community. Without the possibility of obtaining limited exclusivity through patents to recoup reasonable returns for investment in developing technology for healthcare, it is likely that new drugs and tests would not be developed and commercialised and many diseases would remain untreatable or not detected.

Innovation in the area of biomolecules has improved the detection and treatment of many diseases.

The global protein therapeutics market was valued at US$57 billion in 2005. Biotechnology has made notable inroads in the field of protein therapeutics, resulting in some of the key products

presently available in the category. (Reported at The Global Protein Therapeutics Market (https://www.leaddiscovery.co.uk/reports/383/The_Global_Protein_Therapeutics_Market)

Key pharmaceutical product classes:

- erythropoietins;
- interferons;
- interleukins;
- insulin;
- monoclonal antibodies;
- blood-clotting factors;
- colony-stimulating factors;
- growth hormones;
- plasminogen activators;
- reproductive hormones;
- therapeutic enzymes; and
- use of biotechnology in pharmaceutical manufacturing.

Monoclonal antibodies are proteins typically made with recombinant technology using microorganisms. Treatments based on monoclonal antibodies currently generate global revenues of around US$20 billion and represent the fastest-growing segment within the pharmaceutical industry. This area of medicine is expected to achieve a compound annual growth rate (CAGR) of 14% between 2006-2012, easily outstripping the growth rate of 0.6% in the more traditional, small molecules market (http://www.drugs.com/news/mab-sector-growth-continue-far-outstrip-small-molecules-7012.html).

Without the availability of sound patent protection, it is doubtful whether the significant investment in research and development would have been committed to develop many of these biological-based therapies or would be committed in the future.

(ii) the provision of training and accreditation for healthcare professionals

IPTA is unable to provide informed submissions on this area but notes that it would be surprising if the grant of patents in respect of genetic materials could have any direct adverse impact on the provision of training and accreditation for healthcare professionals.

(iii) the progress in medical research

Australia has a strong and internationally respected medical research system. Australian innovators in this area have been encouraged by governments to seek return from public funding and research efforts by obtaining patent protection for Australian applied research.

The National Principles of IP Management for Publicly Funded Research (http://www.arc.gov.au/about_arc/principles_ip.htm) were developed to improve the commercial outcomes from publicly funded research where a commercial outcome is appropriate.

To demonstrate the importance of protecting intellectual property (***IP***), the Foreword of the National Principles of IP Management for Publicly Funded Research is set out below:

> Knowledge and research findings have become the most important resources, and the key elements, in the new business paradigm for economic development. The Government's strategic policy direction to reinforce research investment and commercialisation is clearly reflected in a number of reports and discussion papers, including, the *Health and Medical Research Strategic Review* (Wills Report); *Knowledge and Innovation: A policy statement on research and research training* (White Paper); the Science Capability Review *Chance to Change*; and the Innovation Action Plan: *Backing Australia's Ability*. It has become essential, at both institutional and national levels, that appropriate principles and mechanisms are in place to identify, protect, develop and commercialise these resources. To this end, a working party was established that comprises some key organisations involved with, or with an interest in the outcomes from, publicly funded research in Australia: the Australia Research Council (ARC), the Australian Tertiary Institutions Commercial Companies Association (ATICCA), the Australian Vice-Chancellors' Committee (AVCC), the Department of Education, Training and Youth Affairs (DETYA), the Department of Industry, Science and Resources (DISR), IP Australia and the National Health and Medical Research Council (NHMRC). These agencies have worked together to develop a consistent national framework for the management and the exploitation of intellectual property (IP) generated by publicly funded research.
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> The purpose of developing the National Principles of IP Management for Publicly Funded Research is to assist researchers, research managers and their research institutions, in ensuring that they have access to best practices for the identification, protection and management of IP, and therefore, to maximise the national benefits and returns from public investment in research.
>
> It is important to emphasise that the public research funding agencies, including the ARC, the NHMRC and other government agencies, will continue to support the best research in the national interest and will continue to pursue the vision of advancing the nation's capacity for quality research for the economic, social and cultural benefit of the community. The ARC and the NHMRC do not wish to hold a stake in direct ownership of IP nor do they intend to benefit directly from commercial outcomes of the research funded through their financial support. The intention of the National Principles is simply to improve the

commercial outcomes from publicly funded research where a commercial outcome is appropriate.

The National Principles are expected to evolve over time in the light of the experiences of the funding agencies, research institutions and researchers. Organisations may wish to develop their own detailed IP management strategies within the framework of these principles to best suit their particular environments and needs. The NHMRC recognises that further consideration needs to be given to intellectual property issues in health and medical research involving indigenous people and communities, and where research has the potential to benefit public health in an international context.

Examples of numbers of Australian patent applications filed in the area of biotechnology by Australian research Institutes:

The Walter and Eliza Hall Institute of Medical Research (WEHI) – 74 applications;

Baker Medical Research Institute – 50+ applications;

Peter MacCallum Cancer Institute – 48 applications;

Australian Stem Cell Centre Limited – 25 applications;

Garvan Institute of Medical Research – 20 applications; and

Victor Chang Cardiac Research Institute – 7 applications.

There are a number of well known commercially successful innovations in the area of biotechnology coming from Australian researchers. If it were not for the possibility of obtaining patent protection for these innovations in Australia, it is likely that there would not have been such commercial success.

The vaccine against human papilloma virus (***HPV***) ('Gardasil'), used to immunize young women with the aim to reduce the incidence of cervical cancer, resulted from Australian public funded research and many related patents. The technology behind 'Gardasil' was invented by Professor Ian Frazer (Australian of the Year in 2006) and Jian Zhou at The University of Queensland. 'Gardasil' has been licensed and royalty income is being generated for the University of Queensland and others. IP Australia has published a case study entitled 'Gardasil: The IP Behind World Breakthrough in Women's Health' (http://www.ipaustralia.gov.au/patents/case_gardasil.shtml) highlighting the intellectual property issues that surrounded the development of the vaccine. Without patent protection, the vaccine would not have been available to the public via the Australian Government's HPV vaccination program, which commenced in 2007.

Zanamivir ('Relenza'), developed by Biota, that treats influenza and helps to prevent infection by influenza. Significant patent filings were made to ensure sound protection for this Australian innovation and ultimately resulted in successful commercialisation of this drug.

There are many Australian companies working in the area of biotechnology and patent protection is an important part of securing rights for their innovation and building value of these companies. There are 90 companies listed on the Australian Stock Exchange (***ASX***) which are in the Pharmaceuticals, Biotechnology and Life Sciences Industry Group. Of those 90 companies, 33 companies have applied for, or obtained, patents in the area of biotechnology.

(iv) the health and wellbeing of the Australian people

There has been significant innovation in the area of biotechnology for human health throughout the world which has resulted in numerous new treatments, prevention, diagnostics and health guidance that has had a significant positive impact on the health and wellbeing of the Australian people. Such innovation requires significant human and financial capital and returns for this effort are improved by obtaining patents for this innovation. Australian Research Institutes, Universities and companies have been actively involved in this area.

(b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of the any matters identified by the inquiry

IPTA is of the view that the *Patents Act 1990* does not require amendment and the law as it stands adequately protects innovators and the public in relation to human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form.

(c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials

IPTA is of the view that the *Patents Act 1990* does not require amendment to expressly prohibit the grant of patent monopolies over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form.

Section 18(2) of the *Patents Act 1990* presently excludes human beings, and the biological processes for their generation, from being patentable inventions. For an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions, if the invention is not a microbiological process or a product of such a process (section 18(3) and (4)). No further prohibition of patentable inventions is required.

It is also important to note that in view of the manner of manufacture requirement of the *Patents Act 1990* it is not possible to secure patent protection is respect of technologies such as genes, proteins or non-coding nucleotide sequences, in the form that they exist in nature. In order to secure patent protection in respect of such technologies there must be an artificially created state of affairs established through human intervention, with the result that agents like genes and proteins can only be protected in an isolated or synthetically produced form. The significance of this is that Australia's present patent legislation does not allow institutions or companies to protect genes or proteins as they exist in humans or animals.

5. Summary

IPTA submits that the public, research community, healthcare services and biotechnology industry are well serviced by the current patent system and no changes should be contemplated to the *Patents Act 1990* with regard to human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form.

IPTA would welcome an opportunity to provide evidence at a public hearing held by the Senate Community Affairs Committee.

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