The Royal College of Pathologists of Australasia
ABN 52 000 173 231

Durham Hall 207 Albion Street Surry Hills NSW 2010 Australia
Telephone 61 2 8356 5858 Facsimile 61 2 8356 5828

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Committee Secretary
Senate Legal and Constitutional Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Sir

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

Thank you for the opportunity to make a submission regarding this proposed legislation.

The Royal College of Pathologists Australasia is the peak body in Australia representing professionals who provide medical tests. We are responsible for the assessment and accreditation of Australia's pathologists, and share the responsibility for the assessment and accreditation of Australia's medical laboratories with a regulatory body. We recognize that medical testing involves both scientists and pathologists and, as of 2010, our College represents both professions. For patients of all ages, most clinical decisions that are made by their doctors and nurses are based on the tests provided by members of this College. Our vocation is the delivery of consistent, accurate, useful, and efficient medical testing to benefit the Australian community.

Genetic testing is an increasingly important component of the services we deliver. Genetic testing is used to make diagnoses, to guide the selection of treatment, to monitor the progression of disease, and to determine the risk of disease among relatives. We have taken a keen interest in the Inquiries into genetic testing undertaken by the Australian Law Reform Commission, the Australian Council on Intellectual Property, and the Australian Senate. In this submission, we do not propose to reiterate the arguments and examples that have been provided previously.

At the outset, we do not profess to have expertise in matters of intellectual property and law. However, we do have expertise in the provision of medical testing which is the foundation stone of health care. Nor do we have a conflict of interest in stating our view. The College does not depend on revenue from gene patents, or from ignoring such patents, for its role or viability. We speak as healthcare professionals on behalf of Australian patients and their families.

From this perspective, we have grave reservations with the stated position of IP Australia, the regulatory agency responsible for the management of intellectual property in this country. In its submission to the recent Senate Inquiry into gene patents, IP Australia stated, *"A patent over a gene sequence does not equate to ownership of that sequence. A patent is a right to restrain others from using or exploiting the claimed invention without the patentee's permission"* [page 23]. This means that a person with a patent over a gene sequence can restrain another person from using that sequence to make a medical diagnosis. The patent holder did not create the gene, the mutation, or the disease - but the patent holder can restrict a doctor's freedom to make a diagnosis. This restriction is not based on the machine or process by which the doctor might make the diagnosis, but is focused on the biological basis of the disease itself. The power of the patent holder in this situation compromises the

very foundation of health care in this country. Such a restriction should have no place in our society. If the current legislation and regulations allow this state of affairs, then they must be changed.

A monopoly is the legitimate consequence of a patent. Monopolies have serious consequences for the training, delivery, quality, and reliability of medical testing. They also have the potential to compromise research into better genetic tests. We provided details of this, with examples, in our submission to the Senate Inquiry (attached). We recognize that, thus far, most gene patents have not resulted in a monopoly on genetic testing. It has been argued that the adverse consequences that have arisen from restrictive licensing represent rare exceptions, and that these exceptions should not be the basis on which current practice is changed. If we were dealing with a tradable commodity, such as manufactured item, it may be acceptable to tolerate occasional episodes of restrictive licensing. However, gene patents can and do compromise the equitable delivery of health care. We do not accept that the care of some patients, who have the misfortune to develop a specific disease, should be compromised at the whim of a patent holder who may legally restrict a doctor's freedom to make a diagnosis. If the current legislation and regulations allow this state of affairs, then they must be changed.

The question then arises as to whether the proposed legislation is the most appropriate change. During the recent Senate enquiry, we stated our view that the wording of the current legislation, taken at face value, precludes the patenting of discoveries such as genes. We did not seek to make genes a "special case" that required specific consideration in patent legislation. Human genes are a natural phenomenon and, on that basis alone, should not be patentable.

We remain of the view that it is preferable to avoid making any "special cases" regarding patentability, and that the patent legislation should be expressed in precise yet general language that meets the objectives of the legislators. Nonetheless, we currently have a situation in which genes have been patented under Australian law despite these genes clearly being discoveries, not inventions. It may be that changes to the regulations and to the training of assessors could correct this situation without amending the underlying legislation. However, specific amendments to the *Patents Act* have been proposed and we now turn to address these proposals.

Amendment 1: Paragraph 18(1)(a)

This section currently reads:

> *(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:*
>
> *(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and*

It is proposed that paragraph (1)(a) be repealed, and substituted as follows:

> *(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:*
>
> *(a) is a manner of manufacture within the **full** meaning, **including the proviso**, of section 6 of the Statute of Monopolies; and*

The significance of this amendment rests in the wording of Section 6 of the Statute of Monopolies. The wording of this text (from 1623) is as follows:

> *6 (a) Provided also, that any declaration before mentioned shall not extend to any letters patents (b) and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of <u>any manner of new manufactures within this realm</u> (c) to the true and first inventor (d) and*

inventors of such manufactures, which others at the time of making such letters patents and grants shall not use (e), so as also they be not contrary to the law nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient (f):the same fourteen years to be accounted from the date of the first letters patents or grant of such privilege hereafter to be made, but that the same shall be of such force as they should be if this act had never been made, and of none other (g).

Under the current legislation, this Section is used to define the concept of "manner of manufacture". However, there is only limited reference to this concept in this Section (the relevant phrase is underlined). The bulk of the Section refers to the operation of monopolies, including limits on such operations. The proposed amendment seeks to bring consideration of the operation of monopolies, and limits on such monopolies, into the definition of what constitutes a "manner of manufacture".

We agree that the operation of monopolies deserves close scrutiny to ensure that societal benefits, including the freedom of a doctor to make a diagnosis, are not compromised. But we do not see that the various considerations included in Section 6 of the Statute of Monopolies can be condensed to constitute the definition of a "manner of manufacture" in one brief paragraph of our patent legislation. In other words, we support the intent of this amendment, but **the College does not support this proposed amendment** as it stands.

Amendment 2: Paragraph 18(1A)(a)

In the current legislation, Paragraph 18(1)(a) refers to standard patents. The wording is repeated in Paragraph 18(1A)(a) in relation to innovation patents. The same amendment is proposed, and our comments and conclusion are the same as above.

Amendment 3: Paragraph 18(2)

In the current legislation, this paragraph reads:

(2) Human beings, and the biological processes for their generation, are not patentable inventions.

According to the Explanatory Memorandum accompanying the draft legislation, this paragraph had been included in the *Patents Act 1990* to prevent the patenting of inventions "which would transgress socially acceptable norms" [page 2]. This is the only specific exclusion in the *Act* that is based on societal considerations. We have noted above that the current application of the *Act* has resulted in important limitations on the freedoms in our society i.e. legal restrictions on a doctor's ability to make a diagnosis.

It is proposed that this paragraph be repealed and substituted with

(2) The following are not patentable inventions:

(a) human beings, and the biological processes for their generation; and

(b) ***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 proposed amendment seeks to address the important societal consequences of gene patents by explicitly excluding all biological materials as patentable. Whilst this proposal would address our principal concerns about gene patents, we have reservations.

We agree with the proposers that biological materials which are "identical or substantially identical to such materials as they exist in nature" should not be patentable. We would go further, arguing that any substance which is identical to that found in nature should not be patentable. Such substances are discoveries, not inventions. The patenting of discoveries

should be precluded by appropriate general definitions in the legislation. It should not be necessary to make a "special case" of naturally-occurring biological materials by deeming them non-patentable on societal grounds.

We note that the various enquiries by the Australian Law Reform Commission, the Australian Council on Intellectual Property, and the recent Senate Inquiry have not yielded any change to the patent legislation which addresses the fundamental concern we have i.e. that under current Australian legislation and regulations, gene patents have been approved and have restricted doctors' ability to make diagnoses in Australian patients. Given the failure of these previous inquiries to resolve this issue, it is tempting to support this proposed amendment because it directly, albeit imperfectly, address our fundamental concern.

Whilst we agree with the intent of the proposal, it would be more appropriate to amend the legislation to define precisely the distinction between an invention and a discovery. The patentability of a class of materials should be determined on principles laid down in the *Act*, not on the basis of case-by-case exclusions. **The College does not support this proposed amendment**.

Amendment 4: Paragraph 18(4)

The third amendment proposed above includes the phrase "biological materials". The fourth amendment provides a non-exclusive definition of what constitutes "biological materials". It is proposed that an additional paragraph be added after Paragraph 18 (4):

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

The purpose of this amendment is to ensure that certain substances are included in the definition of "biological materials". We question whether such a definition is necessary. First, the list is by no means complete. There are many naturally-occurring substances in humans which do not fall into the five categories listed, including fats, cholesterol, vitamins etc. it is essential that these naturally-occurring substances are not deemed patentable by implication because they are not included in this list.

Second, each of the items on this list can be synthesised or manufactured *de novo*, without being naturally occurring. This possibility is addressed in the third amendment proposed above which only excludes biological materials which are "identical to such materials as they exist in nature". In other words, this list provides no additional definition beyond that already included in the third amendment.

The College does not support this proposed amendment.

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In addressing the specifics of these proposed amendments, it is essential that the Committee remain focused on the goal of the legislation i.e. to ensure that legal constructs designed to promote innovation do not compromise fundamental societal goals such as access to healthcare.

The application of the current legislation can and has restricted the ability of doctors to make diagnoses. This restriction has not been based on technology or innovation; it is a restriction of knowledge. A patent holder can restrain a doctor from making a genetic diagnosis by any means. Any amendment – or lack of amendment – which fails to resolve this issue represents a failure to maintain the foundation of healthcare in a free society.

As we have noted above, the proposed amendments are imperfect and may not be the best means of ensuring equitable access for patients and families to high quality genetic testing. Other strategies could be considered. We will briefly consider other strategies below and would be pleased to discuss this further should the opportunity arise.

There are two issues to be addressed. First, many genes have already been patented under the current legislation and regulations. Any amendment to the *Patent Act* would not address these extant patents. In the US, the Secretary's Advisory Committee on Genetics Health & Society [report attached] has proposed the creation of a statutory *"exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient-care purposes"*. They have also proposed the creation of an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research. The College recognises the importance of research in the development of better medical tests.

We recognize that the creation of a specific exemption means that genes are being considered "exceptional" rather than the matter being resolved on first principles. Nonetheless, this is a necessary interim measure to address the issue of extant gene patents.

The second issue which must be addressed is the patentability of genes in the future. As noted above, the College considers that any naturally occurring substance should not be patentable. The distinction between a discovery and an invention should be described in precise yet general terms in the legislation, and this would constitute a suitable and sustainable amendment to the *Patent Act*.

Yours sincerely,

Professor Paul McKenzie
President