RCPA
The Royal College of Pathologists of Australasia

3 May 2011

Ms Julie Dennett
Committee Secretary
Senate Legal and Constitutional Committee
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Parliament House
Canberra ACT 2600

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Dear Ms Dennett

**RE: Committee Hearing on Patent Amendment (Human Genes & Biological Material) Bill**

Thank you for inviting The Royal College of Pathologists of Australasia (the College) to attend a recent Hearing of the Committee on Patent Amendment (Human Genes & Biological Material) Bill. Senator Susan Boyce asked our representative, Dr Graeme Suthers, two questions on notice:

1. What is the College's view of the proposed amendments to the Patent Act, *"Raising the Bar"*; and
2. Where should a national repository of gene patents relevant to medical genetic testing reside?

I am writing to provide our responses.

**Proposed "Raising the Bar" Legislation**

We note the proposed legislation and its intent to improve the procedures associated with the management of patents. We support proposals which seek to improve the processes of government and regulatory agencies. However, the proposed amendments do not address the more fundamental issue of patentability. The current definition of patentability is in Subsection 18(1) of the Patent Act. This Subsection will not be altered under the proposed legislation, and the distinction between a discovery and an invention will not be clarified by its passage.

The Explanatory Memorandum accompanying the draft legislation addresses the issue of novelty in relation to patentable subject matter, noting that "*It is a fundamental requirement that a patented invention possess an 'inventive step' (in the sense that the new invention adds significantly to what was previously known)*" [p.13]. It is then proposed that the novelty of an application be assessed more broadly than hitherto.

The College is concerned that a more stringent test of novelty is being proposed as a more stringent test of inventiveness. Novelty is an attribute of both discoveries and inventions. Novelty is a necessary but not sufficient attribute to qualify an application as being a new "invention". The distinction between a discovery and an invention is an unresolved issue in the current debate

about gene patenting. In relation to medical testing, the object of analysis (e.g. a gene), the effect of that object (i.e. the patient's genetic disorder), and the association between the two predate the patent holder by many thousands of years. It is difficult to view our understanding of this relationship as anything but a discovery.

The distinction between a discovery and an invention with utility lies at the heart of the test for patentable subject matter and should not be incorporated in the flexible concepts of manner of manufacture or invention as in the current and proposed legislation. As noted by the US Supreme Court, *"The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that E= mc2; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of … nature, free to all men and reserved exclusively to none' "*. The recent decision in the US District Court and the amicus curiae Statement from the US Department of Justice recognise that this logic also applies to human genes.

There should be an explicit, proscriptive test for patentable subject matter that precludes discoveries from consideration, irrespective of the utility of those discoveries. The legislation should be in plain language to ensure that the distinction can be recognised by everyone.

**Repositories for Patent Data**

The responsibility for observing a patent naturally rests with the potential user. Biotechnology patents in general, including gene patents, are frequently transferred between commercial parties. There can also be multiple overlapping patents for the one gene. This makes it challenging for the potential user to identify whether a particular gene is currently patented, who the patent holder is, whether there are competing patents over the same gene, the potential impact of patent claims on the delivery of a diagnostic test, and whether the patent holders are likely to enforce their rights.

In 2006, the College undertook the first (and thus far, only) survey of medical genetic testing nationally. We documented that there were 437 different types of genetic test on offer during that year. This is a dynamic field and laboratories frequently add new tests and allow others to lapse. There is also an increasing move to multiplexing tests (for reasons of efficiency) in which multiple genes are analysed in the one assay. Tests currently available can involve assays of tens of thousands of DNA fragments – each of which may be covered by multiple patents.

If diagnostic laboratories are required to obtain permission from a patent holder prior to establishing a new diagnostic test, there needs to be some easy mechanism for accessing current information regarding each gene. Diagnostic laboratories do not have the expertise to interrogate current IP databases, and are not in a position to broker disputes if multiple parties hold competing claims over the same gene.

At present there is no national repository of information about genetic tests provided by medical laboratories. The College hosts a small database that lists the tests provided by approximately half of the nation's labs, but this is not mandatory and it is up to each lab to keep its own listing current. The TGA will be establishing a national database that will require each medical laboratory to list each test provided by the laboratory. In the case of a genetic test, the laboratory could be required to detail the genes tested. It may then be feasible for the TGA database to incorporate access to relevant patent databases. Alternatively, IP Australia could provide a web-based resource that provides this information.

**Concluding Comments**

The College has made submissions to multiple inquiries into gene patents over the last eight years. We appreciate that members of the current Committee have not necessarily received every submission we have made. For the record:

- The RCPA strongly supports a legal framework which fosters innovation for the benefit of individuals and society. Our medical laboratories are full of patented equipment, and continue to be refreshed with improvements.
- Patents should not extend to discoveries. We take this position on the basis of principle (as above) and the adverse effects of patents and monopolies on the delivery of medical testing.
- In previous submissions we have presented the evidence that patents on genes increase prices for medical tests such that tests are withdrawn. This includes common tests to diagnose leukaemia, liver disorders, and drug responses. No-one benefits from this, neither the patient holder, the patient, nor our society.
- A monopoly on testing is the legitimate and expected consequence of a gene patent.

  In previous submissions we have presented the evidence that:

  - Monopolies limit the training for pathologists and medical scientists
  - Monopolies compromise the quality of medical testing
  - Monopolies block the development of better tests for a gene
  - Monopolies create exclusive databases of genetic knowledge
  - Monopolies dictate inappropriate standards of healthcare
  - Monopolies can impede medical research.

We are grateful that the importance of these issues for the Australian community as a whole is now being considered.

Yours sincerely

A/Prof Paul McKenzie
**President**