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RCPA
The Royal College of Pathologists of Australasia

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Patents Licensing Inquiry
Productivity Commission
Locked Bag 2, Collins St East
Melbourne VIC 8003

Email: patents@pc.gov.au

Dear Sir/Madam

**RE: Compulsory licensing of patents**

Thank you for the opportunity to make a submission to this Inquiry.

The Royal College of Pathologists of Australasia (the College) is the peak body in Australia representing pathology professionals who provide medical tests. We are responsible for the assessment and accreditation of Australia's pathologists, and have a role supporting NATA in the assessment and accreditation of Australia's medical laboratories. We recognize that medical testing involves both scientists and pathologists and, as of 2010, our College membership includes both professions.

We do not have expertise in matters of intellectual property and patent law. However, we do have expertise in the provision of medical testing which is the foundation of health care. The College does not depend on revenue from gene patents, or from ignoring such patents, for its role or viability. Accordingly, we do not have a conflict of interest in stating our views.

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 the terms of reference for this Inquiry into the Compulsory Licensing Provisions of the Patents Act 1990, we note that in conducting the Inquiry the Productivity Commission should have regard to “... affordable and equitable access to health care, including medical treatments and diagnostic tests in Australia". In our submissions to the other Inquiries we have detailed our concerns and documented examples where the patenting of genes has, in our view, compromised the quality and accessibility of medical genetic tests for Australians. Our evidence is readily available (and attached), and we do not propose to reiterate these examples in this submission.

Before providing specific comments, we wish to note that there is a subtle but significant distinction in the perspective of the College versus the Productivity Commission. As noted on page 2 of the Issues Paper, the Productivity Commission is required to "base assessment on what set of arrangements would give the best outcomes for the Australian community **as a whole**" [our emphasis]. We have no dispute with this principle for the Productivity Commission, but it falls short of the professional responsibilities of medical practitioners.

Most clinicians deal with patients on a one-to-one basis, and not with the population as a whole. If legislation or regulation of patents addresses most commercial and social issues surrounding access to a commodity, the relatively small proportion of "problem cases" may be tolerable. But in healthcare, a small proportion of "problem cases" represents discrimination against certain individuals and an abrogation of our communal responsibility to provide equitable access to healthcare. We make no apology for our focus.

Turning to the specific questions presented in the Issues Paper, most of them relate to legal and procedural matters on which we are not competent to comment. However, we have identified specific questions which raise issues of concern for the College.

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*In areas where governments are responsible for service provision, such as healthcare, do the Crown use provisions in the Patents Act provide a means of overcoming concerns about the effectiveness and efficiency of compulsory licensing? How could the Crown use provisions be amended to address any identified limitations?*

We note (page 12 of the Issues Paper) that the Crown use provisions in the Patents Act provide for the Commonwealth or State government to use a patent for the delivery of services by the Commonwealth or that State. In an Australian survey of genetic testing in 2006[1] (attached), less than 5% of the types of genetic test available to medical practitioners were funded by the Commonwealth. The great majority of types of genetic test were funded by State governments for patients residing in their specific jurisdiction. However, 75% of all types of genetic test were only provided by one or two laboratories nationally. This meant that many samples were sent between States for testing, and there are various financial arrangements to reimburse the State providing a specific investigation. For many of these types of test, the number of samples assayed nationally each year is small (less than 100) and it makes sense in terms of both quality and economics to centralise a specific genetic test in one or two "reference laboratories".

It is not clear to us how the Crown use provisions might apply in this situation. If a particular State Government invokes Crown use of a gene patent to provide a particular medical genetic test for its citizens, would the provision for Crown use extend to the testing of samples that had been sent from another State for analysis? If not, each State would need to invoke Crown use of that gene patent and develop its own test to meet the needs of the patients in its own jurisdiction. In contrast to using a limited number of "reference laboratories" nationally for a particular test, we would see an increase in the number of laboratories doing a very small number of assays each year, a move that would compromise both cost effectiveness and quality.

On the other hand, as genetic testing for common disorders becomes more widely available, we are seeing an increasing number of genetic tests that are provided by multiple laboratories across Australia. For example, in 2006, there were 9 public sector laboratories in Australia providing genetic testing of the familial breast cancer genes, BRCA1 and BRCA2. If a particular State government invoked Crown use of a gene patent to provide a particular medical genetic test for its citizens, would the other State governments need to go through the same process to invoke Crown use for provision of testing in their own jurisdictions?

It is not clear to us how the Crown use provisions could be implemented given the dynamic and diverse nature of medical genetic testing in Australia.

[1]The RCPA is currently completing a followup survey of genetic testing activity nationally during the 2011 calendar year.

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*What, if any, changes should be made to the public interest test to make it more efficient and effective?*

Box 3 in the Issues Paper outlines the tests of public interest and competition that the Federal Court applies to any application for compulsory licensing. The public interest requirement includes a reference to the patent holder being ordinarily expected to supply or licence a patented product on reasonable terms.

In medical testing, it is our view that the test of "reasonableness" must include issues of quality, data management, and access that would not typically be considerations of the Federal Court in considering a patent.

In support of this view, we note the following examples:

*Quality-*
It is our understanding that in the US, the biotech company, Myriad Genetics, held the patents for the BRCA1 and BRCA2 genes (which are responsible for many instances of familial breast and ovarian cancer). Myriad Genetics retained the exclusive right to provide medical testing of these genes in the USA i.e. for a population of 300 million. However, their test methodology initially missed approximately 15% of the mutations that can occur in these genes. European medical laboratories implemented a second tier of testing to identify these additional mutations, and similar steps were taken in Australian laboratories. It was a number of years before Myriad Genetics altered its own testing method to encompass these mutations. This sequence of events meant that Myriad Genetics may have provided "reasonable" access to its test but, in our view, the quality of this test was both compromised and unchallengeable within the US patents system.

*Data Management-*
It is our understanding that Myriad Genetics has developed an exclusive database of the variations which occur in the BRCA1 and BRCA2 genes in the North American population. The confidentiality of this dataset is governed by privacy legislation. However, this compilation also represents an important resource to assist in the scientific and medical understanding of these genes and their role in health and disease. There are well-established mechanisms for providing such data to assist other clinical or research laboratories testing these genes without breaching patient confidentiality. Myriad Genetics has, to its credit, placed much of this data in the public domain (whilst protecting patient confidentiality). However, they are under no obligation to do so and the public database does not comply with international recommendations regarding the naming of mutations. There is no mechanism for enforcing appropriate nomenclature or release of data because this large dataset is privately owned.

*Access-*
We draw your attention to an instance cited in the Secretary's Advisory Committee on Genetics Health and Society (SACGHS) report (p. F-38; attached). The report noted that a company which holds the IP rights in the US for the major genes causing a serious familial heart disorder has a monopoly on testing and does not offer prenatal genetic diagnosis. This makes such testing unavailable in the U.S. The company claims that there are technical difficulties in distinguishing maternal from foetal DNA. This is difficult to understand as there are well-established techniques for managing genetic testing in this situation. Irrespective of one’s views about the ethics of prenatal diagnosis and termination of pregnancy, it is of great concern to the College that a patent holder can control this issue for an individual or a society.

The guidance provided to the Federal Court regarding public interest tests is couched (understandably) in commercial terms. However, in considering public interest issues in relation to medical testing, the term "reasonable" must include characteristics of test quality, peer

accountability, and access consistent with societal norms. These issues largely reflect the consequences of there being a monopoly on testing, and could be addressed by broad unrestricted licensing of gene patents.

In addition to these considerations about the management of the test process, in our view, there is another important attribute of testing as a healthcare service that must be considered i.e. the security of the service.

In support of this view, we note the following:

> For example, in Australia and New Zealand, testing of the BRCA1 and BRCA2 genes was introduced by public sector laboratories in most States in the 1990s. In 2002, Myriad Genetics provided an exclusive licence for testing of these genes to the Melbourne-based company, Genetic Technologies (GTG). GTG initially sought to enforce its rights against the public laboratories, a move which prompted vocal opposition. In May 2003 the company announced to the Australian Stock Exchange that it would not be enforcing its IP rights for breast cancer susceptibility testing in Australia and New Zealand, and that these rights "were a gift from GTG to the people of Australia and New Zealand."
>
> In July 2008, we understand that GTG wrote to public sector laboratories performing these tests, stating that it would now seek to enforce its licence rights; however the company subsequently decided to reinstate its gift and not seek to enforce these rights.
>
> This experience with breast cancer susceptibility testing highlights that having a single service provider potentially exposes the delivery of health services to the risk of instability. The fact that one company could have such a significant and potentially destabilising influence on the delivery of breast cancer susceptibility testing in Australia is of concern for laboratories performing these tests, for breast cancer health care programs and, most importantly, for patients.

We submit that consideration of the pros and cons of Crown use versus compulsory licensing in the case of medical testing needs to include an assessment of the security of service provision for patients.

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*Should the Patents Act be amended to include a statement of objectives? What are the main objectives that should be included in the statement?*

In considering the overarching purpose and role of the *Patents Act*, legislators and regulators must 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. 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.

There may indeed be merit in including a statement of objectives in the *Patents Act*. But we are concerned that such a statement does not necessarily ensure appropriate application of the legislation. In 2004, the Australian Law Reform Commission's review of gene patenting noted that:

*"Isolated biological materials may, in some cases, replicate exactly the composition and characteristics of material that occurs in nature. Although one cannot deny the legitimacy of patenting processes for isolating and purifying naturally occurring materials, or the legitimacy of patenting new chemical substances that are the product of human ingenuity, there are attractive*

*arguments for the view that such materials should not have been treated as patentable subject matter.*

*However,* ***the time for taking this approach to the patenting of products and materials has long since passed****."* [ALRC99 p 130; our emphasis].

The inclusion of a statement of objectives in the *Patents Act* will be useful only if the principles that are clarified in the statement of objectives are translated into provisions allowing appropriate decision-making to be made by patent examiners.

Thank you for the opportunity to make this submission. We would be pleased to discuss this and related matters should the opportunity arise.

Prof T Y Khong
**President**

Att

1. RCPA submission to the Australian Law Reform Commission
2. RCPA submission to the Australian Council on Intellectual Property
3. RCPA submission to the Australian Senate
4. RCPA Genetic Testing Survey (2006)
5. Report of the Secretary's Advisory Committee on Genetics Health and Society (SACGHS)