Compulsory Licensing of Patents
Productivity Commission
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3 October 2012

Submission re Compulsory Licensing of Patents

Thank you for the opportunity to make a submission regarding Compulsory Licensing under ss. 133 – 140 of the *Patents Act 1990* (Cwlth). These provisions allow an application to the Federal Court to grant a licence to work a patented invention if satisfying a public interest or competition test.

Background

The National Coalition of Public Pathology (NCOPP) represents the values and issues of relevance to public pathology services throughout Australia. Our members are the major publicly owned and operated pathology services in each State and Territory. They provide the majority of pathology services in Australia's public hospitals, in some private hospitals and operate some community collection services for community based doctors and their patients. Their laboratory testing and consultation services play a crucial role in timely clinical diagnosis, in monitoring therapy and in prevention of disease in individuals and the community.

NCOPP members play an important role in teaching undergraduate medical students, and in training current and future cohorts of pathologists and medical scientists. They conduct research into new and existing diseases, diagnostic tests and treatments and collaborate closely with colleagues in all areas of patient care, with many pathologists also performing clinical roles.

NCOPP does not have a conflict of interest in stating our view. NCOPP does not depend on revenue from gene patents, or from ignoring such patents, for its role or viability.

Response to the Commission's terms of inquiry

NCOPP does not profess to be an expert in patents and acknowledges that the compulsory licensing provisions have application to all patents. However, our submission focuses on genetic testing which is an increasingly important component of the services delivered by public pathology. 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.

NCOPP recognises the benefits in patenting a novel treatment based on genetic knowledge or patenting a new technique for genetic analysis. This must be balanced against the overwhelming public interest consideration for access to quality healthcare.

NCOPP would like to iterate that genes and associated proteins should not be able to be patented as they are naturally occurring substances, which are themselves not an invention or innovation under the criteria of the Patents Act. However, some gene sequences have already been patented.

NCOPP acknowledges and refers to the previous submissions made by the Royal College of Pathologists Australasia in the area of genetic patents, to the Australian Law Reform Commission, the Australian Council on Intellectual Property and the Australian Senate Legal and Constitutional Committee.

Whether the current compulsory licensing provisions can be invoked efficiently and effectively

It would be impractical to invoke compulsory licensing provisions in the area of genetic patents. There are approximately 25,000 genes, 5 transcripts from each gene and 100,000 proteins that may be the subject of patents. There are over 400 genetic tests and approximately 200 genes routinely tested in public pathology laboratories. Not every public pathology laboratory conducts the full range of genetic testing, as samples may be referred to specialist laboratories where the demand for a particular test is low. Notwithstanding, it would be a costly and time consuming exercise for each public laboratory or laboratory network to apply to the Federal Court for compulsory licences for the myriad of genes, proteins and genetic techniques in existence.

It is also difficult for a pathologist to determine whether a genetic test may infringe a patent. There are competing and overlapping patents in various stages of approval. If multiple licences whether privately or by application to the Federal Court under compulsory licencing provisions, were required by all public laboratories, the cost of testing could increase dramatically, and development of tests may decline. This may inhibit innovation and good clinical practice.

Furthermore, the public interest test in s. 133(2(a) of the *Patents Act 1990* (Cwlth) requires clarification. How long is a 'reasonable period' of unsuccessfully seeking authorisation? Is this appropriate in a healthcare situation where diagnosis and treatment may be time sensitive?

Frequency, and impact, of compulsory licences in comparable markets and the common features of such licences

Compulsory licensing provisions are generally not invoked for genetic patents. In Australia, patent holders have been less assertive in enforcing patent rights, possibly because the market is so much smaller and testing would be likely to decline sharply. However, the risk of possible patent right enforcement and protracted negotiation of licences has the risk of stifling innovation, and prohibiting or delaying medical testing and treatment.

Measures that may be required to efficiently and effectively exercise Australia's compulsory licensing provisions

In order to efficiently and effectively exercise compulsory licence provisions for genetic patents, sustainability, security, privacy and confidentiality of genetic information must be assured. The quality of patents granted must also be improved.

There is an appropriate exception for research freedom under the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cwlth). However, there should be a mandatory provision for genetic sequences to be stored in a publically available yet secure database for research purposes under licensing provisions on the grounds of public interest in improving genetic research.

There should be an examination as to whether a distinction should be made between utilisation of patents for diagnostic purposes and treatment purposes.

Alternative mechanisms to ensure that the balance between incentives to innovate and to access technology that best reflects the objectives of reasonable access to health care, maximising economic growth and growing the Australian manufacturing industry

Patent monopolies lead to restrictions in the provision of healthcare, and increased healthcare costs, through:

- not permitting testing outside a particular laboratory;
- not permitting modification of a test (e.g. for ethnic differences);
- requiring that a commercial test kit be used that is more expensive than the in-house equivalent;
- limiting the opportunity for training of pathologists and scientists, reducing the specialist knowledge required for the diagnosis and management of at-risk patients and compromising the operation and sustainability of public sector laboratories;
- precluding benchmarking performance against peers and having an independent assessment of external quality assurance;
- precluding fundamental research into the discovered gene, and from accessing databases of gene variants that could inform research and provide useful information to clinicians and patients.

Compulsory licences have not been utilised to overcome these issues.

A way of overcoming the need for multiple laboratories to apply for compulsory licences could be via Crown Licenses or Ex Officio Licensing.

Crown Use provisions (under ss 163 – 170 *Patents Act 1990* (Cwlth)) allow a Commonwealth or a State to use a patent with protection from legal action for patent infringement. This avoids an application to the Federal Court. These provisions have rarely been invoked. It is not clear how these provisions sit with the Agreement on Trade Related Aspects of Intellectual Property Rights 1994 (TRIPS Agreement).

Under an Ex Officio arrangement, the Health Minister could be granted the power to grant a licence where there are important public health reasons (which should be explicitly defined). Clear legislation should be developed about what an important public health reason is.

To avoid every State and Territory Health Minister from having to grant a licence for every applicable patent on public health grounds, their powers may have to be referred to the Federal Health Minister on this matter.

Unlike the public interest exception under compulsory licensing provisions, there should be no need for public laboratories to enter into negotiations with the patent holder, as this is more likely to protract the matter. There should be a register that lists which patents that Minister has granted a licence to use and which are pending consideration, to avoid multiple laboratories having to make a request to the Minister.

Measures to raise awareness of the compulsory licensing provisions
If the compulsory licencing provisions were amended in a way that was more practicable for the public pathology sector, or Crown Use or Ex Officio Licences were invoked or available, there would need to be clear communication around the application processes and the protection provided.

NCOPP hopes that the Government takes this opportunity to improve the quality of patents, and streamlines the licensing application processes in light of the need for accessible, quality healthcare and the sustainability of the public pathology sector.

We trust you will find these comments of assistance and would be happy to discuss the issues further with you as required. Please contact Ms Jenny Sikorski, NCOPP Chief Executive Officer, if you would like to discuss any aspect of our submission further.

Yours sincerely

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CEO NCOPP