

Sensitive to criticism, IP Australia has suggested a modest range of reforms to the patent system. Some of the agency's ideas have merit – such as lifting the threshold for an innovative step; and making utility a standard for an examination. Unfortunately, though, IP Australia's proposal for an experimental use defence is an embarrassing travesty. The sole purpose test would make the experimental use a Clayton's defence of no practical use to anyone. IP Australia, though, has also shied away from reforming the dysfunctional system of compulsory licensing and Crown Use in Australia. Outrageously, the Australian Parliament has still not met its international obligations about establishing an effective mechanism for the export of essential medicines to tackle public health crises.

A number of academics – most notably, Dianne Nicol, Jane Nielsen, Charles Lawson, Joshua Sarnoff, Andrew Christie, and Peter Drahos – have made a range of constructive suggestions as to how to improve the quality of patents granted by IP Australia.

Faced with the polarised opinions of stakeholders, there is a terrible temptation that Australian Parliament will do nothing in respect of patent law reform. That would be a tragedy. There is a great opportunity for the Australian Parliament to reform both the procedure and the substance of the patent system to ensure that IP Australia grants high quality patents. Moreover, there is scope for fixing the dysfunctional public interest mechanisms in the patent system – such as experimental use, compulsory



licensing, and crown use. The patent system needs to be more responsive to public policy concerns about health-care, access to knowledge, climate change, and traditional knowledge.

It will be an important test of the leadership of Prime Minister Kevin Rudd and Innovation Minister Kim Carr to see whether they can modernise Australia's patent system.

**http://obama.3cdn.net/780e0e91ccb6c4bf6e_6udymvin7.pdf*

REJOINDER

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Genetic Technologies no 'rogue' company

In August the ARDR published a commentary 'Human gene patents: we need them...' by Dr Julian Clark from the Walter Eliza and Eliza Hall Institute. In his piece, Dr Clark writes: "No doubt, recent unreasonable actions by companies exercising their patent rights have eroded equity of access to genetic tests. Most prominent and widely reported are the attempts by Australia's Genetic Technologies (GTG) to restrict genetic tests for the BRCA1 mutation patented by US company Myriad. Let's be clear, it is critical that breast cancer patients have fast and cost effective access to such tests. However, Australia's response to the actions of few 'rogue' companies must not jeopardise its standing in the international community and compromise its role in developing new therapies, or ability to access cutting-edge therapies." Below a response by the chief executive officer Genetic Technologies, Paul MacLeman:

In August in the Australian R&D Review Julian Clark of the Walter and Eliza Hall Institute astonishingly called Genetic Technologies a "rogue" company. This was in the context of genetic testing. This cannot be left without a response.

Genetic Technologies is Australia's leading provider of genetic testing, servicing large numbers of physicians, forensics labs and retail consumers.

As part of our oncology service offering, the Company some years ago moved to offer BRCA breast cancer gene testing. As there was a granted patent for BRCA mutation identification and interpretation issued in Australia, Genetic Technologies followed the orthodox procedure and acquired a license to the patents from patent-owner Myriad Corporation. That is, we conformed to existing rules and laws.

Before Genetic Technologies began offering BRCA testing, some medical institutes were taking up to four years to provide results to high risk women patients.

Genetic Technologies entered the market with a turn-around time of 2 weeks. As part of this license Genetic Technologies pays a substantial annual lump sum royalty to Myriad.

Other organisations such as medical institutes are conducting these

tests and choosing to not pay royalties. Most existing test providers are acting as quasi-commercial pathology providers, receiving fees for these services and do not pay royalties. They are charging about the same as Genetic Technologies and so are earning bigger profit margins on the tests.

However the real commercial pathology providers are also operating by the rules and are not blatantly breaching patents. The private sector is playing by the rules and trying to do the right thing.

Hypocritically many of the large publicly funded medical institutes have patents on other biological materials such as antibodies which they rigorously enforce and charge royalties for access.

If the gene patents rights were to be removed in Australia, Genetic Technologies would benefit in not having to make royalty payments to Myriad. We would therefore be on a level competitive playing field with the large medical institutes.

How anyone can judge Genetic Technologies' conduct in all this as "rogue" is hard to comprehend. Conventional use of rogue might more readily apply to those that are flaunting the rules rather than those abiding.