

Reform the patent system

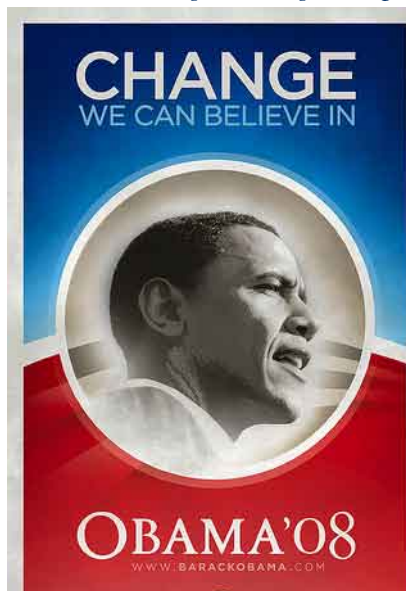
Campaigning to become United States President, Barack Obama vowed to 'Reform the Patent System'. He pledged:

"A system that produces timely, high-quality patents is essential for global competitiveness in the 21st century. By improving predictability and clarity in our patent system, we will help foster an environment that encourages innovation. Giving the Patent and Trademark Office (PTO) the resources to improve patent quality and opening up the patent process to citizen review will reduce the uncertainty and wasteful litigation that is currently a significant drag on innovation. As president, Barack Obama will ensure that our patent laws protect legitimate rights while not

*stifling innovation and collaboration."**

It will be interesting to see whether Obama can realise this platform of 'Change', now that he is an occupant of the White House.

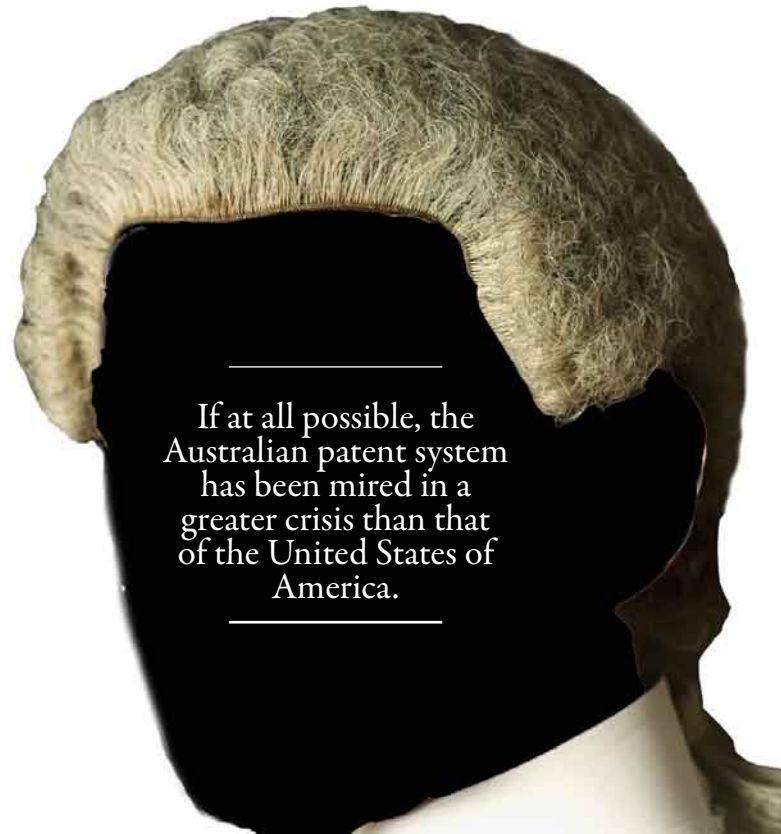
In their recent book, *The Patent Crisis and How the Courts Can Solve It*, Dan Burk and Mark Lemley lament that attempts to reform the patent system in the United States have foundered, partly because of the intervention of various special interest groups:



"Congress has spent the last four years, from 2005 to 2008, in an ultimately futile effort to reform the patent system." The pair lament: "Reform proposals have come and gone; advanced and retreated; merged and coalesced; multiplied, divided, and vanished at every conceivable stage of the legislative process'. Burk and Lemley note the highly politicised nature of the legislative conflicts over patent law reform: "The debates between protagonists and opponents of various amendments have been fierce and protracted."

In the face of such legislative gridlock in patent law reform, the Supreme Court of the United States has been a saving grace, with a number of decisions to improve the operation of the patent system. This year, the Supreme Court is reviewing the scope of patentable subject matter in the matter of *In Re Bilski*. The 2007 Supreme Court ruling in *KSR Inc. v Teleflex Inc.* raised the threshold for the test of an inventive step, emphasizing the need to attribute creative and innovative abilities to a person skilled in the art. This decision has since been applied productively in the context of biotechnology patent applications by the Court of Appeals for the Federal Circuit in the matter of *In Re Kubin*.

The 2006 Supreme Court decision in *eBay v. MercExchange* on the need for discretion in the grant of injunctions has been a useful policy tool in responding to the threat of patent trolls.



If at all possible, the Australian patent system has been mired in a greater crisis than that of the United States of America.

If at all possible, the Australian patent system has been mired in a greater crisis than that of the United States of America. IP Australia has tended to be insular in respect of public policy issues – such as those relating to public health, access to knowledge, climate change, and traditional knowledge. The agency has been slow to respond to public controversies over the quality of granted patents – such as the controversial non-coding DNA patents held by Genetic Technologies Limited.

The Australian Law Reform Commission's minimalist recommendations on gene patents have gone unheeded. The Advisory Council on Intellectual Property has proven to be ineffectual at initiating patent law reform. In contrast to the Supreme Court of the United States, the High Court of Australia has been largely indifferent to the pathologies of the patent system.

Five years after the report of the Australian Law Reform Commission inquiry into gene patents and human health, the Senate Community Affairs Committee has been prompted to investigate gene patents by further controversies over Genetic Technologies Limited. The inquiry has attracted a moderation of attention – with 69 submissions, and 6 days of hearings. The Committee will report back to Parliament on the 26th November 2009.

The Senate Community Affairs Committee has received a spectrum of submissions. At one extreme, abolitionists such as Luigi Palombi and his legislative ally, Senator Heffernan, have demanded a prohibition on the patenting of human genes. At the other extreme, companies like Pfizer and Genetic Technologies Limited have denied that there is anything like a crisis in patent law, and have sought to ward off calls for reform.

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/780e0e91ccb6cdbl6e_6udymvin7.pdf*

REJOINDER

Paul D. R. MacLeman
CHIEF EXECUTIVE OFFICER, GENETIC TECHNOLOGIES LIMITED

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.