

MEDIA RELEASE

Raising the bar on patents

Canberra 22 February 2011: Abandon patentable subject matter amendments in favour of the Intellectual Property Laws Amendments, The Institute of Patent and Trade Mark Attorneys of Australia (IPTA) and AusBiotech are urging the Senate Legal and Constitutional Committee.

In submissions to the Committee, AusBiotech and IPTA will make the point that pursuing the *Patent Amendment (Human Genes & Biological Materials) Bill 2010* will be detrimental to a country endeavouring to promote its intellectual talent, retain its best and brightest, and establish its footprint as an important centre for biotechnology development.

The focus should be on the *Intellectual Property Laws Amendment (Raising the bar) Bill 2011* which is far more comprehensive in terms of Australian patent law.

By way of background, after 20 months of deliberation and considering over 200 submissions, the findings of the *Senate Committee Inquiry into Gene Patents* released in November 2010 should have put an end to a highly-charged and emotive debate and paved the way for a legislative response based on rational analysis.

However, it didn't. A Private Members' Bill was introduced in November 2010. This Bill seeks to ban the patenting of all biological materials (not just genes) even where they exhibit differences to the original form. This is of great concern to both IPTA and AusBiotech. The Bill goes far beyond the terms of reference of the Senate Committee Inquiry and seeks to exclude from patentability all biological materials. It would have huge ramifications across the entire field of medical research in this country and on the future of the Australian biotechnology and medicines industry.

"This debate, which has been constantly fuelled by misinformation, should never have been about the existence or not of patents on genes or other biological materials. It should have been about regulating how patent rights are exercised across all technologies," says Dr Tania Obranovich, of IPTA.

No-one disputes that identifying the existence of a gene is not a discovery. The mere identification of a new gene does not produce technology and does not provide any basis for securing a patent. However, the act of determining its function and usefulness and achieving isolation from its natural environment produces technology that can be used for the benefit of

mankind and can provide the basis for securing a patent," Dr Obranovich says.

Of concern is the fact that it has not been understood that the absence of patents on biological materials will not make any difference to the patent rights that exist in relation to tests such as the BRCA breast cancer diagnostic. These diagnostic methods are separately patented and are entirely unrelated to the patenting of genes or other biological materials *per se*. Yet access to this diagnostic was the very basis of the establishment of the Senate Inquiry.

The real issue is how a patent right is exercised. It is a much broader issue than just biological materials and applies to all areas of technology. A greater service to the Australian community would be to ensure the existence and functionality of proper safeguards in relation to the exercise of patent rights across all technologies. The emotionally reactive and piecemeal banning of patenting of biological materials does nothing to help the public in terms of other technologies they want to access, such as diagnostics.

"The bottom line is that if the Government wants or needs to access a technology to meet the needs of the Australian public, it has power to do so through the Crown Use provisions," explains Dr Obranovich. "A member of the general public can apply to the courts to obtain a licence where the needs of the public are not being met and it has not been possible to negotiate a reasonable outcome with the patent owner. We would be better to focus on the effectiveness and accessibility of these safeguards."

There is also no evidence that patenting of biological materials is stopping or compromising research. In fact, up until 2004 it was generally believed that a research use exemption existed. It has since been determined that the law underpinning this belief was weak and IP Australia is now drafting an amendment to the Patents Act to bring in such an exemption. Importantly, this amendment will apply across all technologies.

"Nor is there any doubt that the current legislation should be re-examined, particularly in relation to how a patent right is exercised. However, there is no compelling case to ban the patenting of biological materials. The Senate Committee Inquiry has acknowledged this and recommends that the focus should be on the proper working of these safeguards across all technologies," AusBiotech's Chief Executive Dr Anna Lavelle commented.

What is fast getting lost in this highly charged and emotive debate is the need for a sensible legislative response that is enshrined in law, well understood, based on rational analysis and that will safeguard all technologies, including technologies that have not even been thought of yet.

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