

# Media Coverage

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## **Opinion: Private member's bill on patenting of biological materials seeks to trick and confuse with semantics**

Earlier this month a group of Australian senators submitted a private member's bill calling for a ban on patenting of not only genes, but a whole array of different biological materials, citing their concerns that the recommendations of the Senate Inquiry into Gene Patents are too narrow. Doctors Ian Rourke, Karin Innes and Danielle Burns from patent attorneys FB Rice & Co argue that the bill is dishonest to the public and ill thought-out.

Seemingly unhappy with the Recommendations resulting from the Senate Inquiry into Gene Patents, a number of Senators, including Helen Coonan, Bill Heffernan, Rachel Siewert and Nick Xenophon, have introduced a private members Bill into the federal Parliament.

This Bill proposes to amend the Australian Patents Act 1990 to exclude the following as patentable subject matter: "biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature".

Both in the media, and during the Senate Inquiry, the term "gene patents" has been used in a loose and inconsistent manner. Despite much of the attention focusing on human genes and/or genetic diagnostics, the proposed amendments include defining "biological materials" to at least cover "DNA, RNA, proteins, cells and fluids" from any source such as humans, plants, fungi, bacteria or viruses.

In a speech to the Senate on 24 November 2010, Senator Heffernan attempts to justify the Bill. Contrary to what we generally consider to be the logical recommendations of the Senate Committee, many of the arguments presented by Senator Heffernan to support the Bill appear to be confused and misplaced.

### Research Exemptions

Senator Heffernan seems to think that current laws stifle research, however, there are very few examples that suggest this is the case. In a presentation at the Ausbiotech conference in October this year, Dr Julian Clark, the Head of Business Development at the Walter and Eliza Hall Institute of Medical Research Institute, indicated that he was unaware of any patent rights which had hindered basic research at his Institute. As an example, Dr Clark pointed to the over 5,500 global scientific publications relating to the controversial BRCA1 gene (associated with breast and ovarian cancer). Such a massive number of publications clearly do not support Senator Heffernan's assertions that basic research is being hindered.

The focus of some Australian politicians on the patenting of "biological materials" allegedly inhibiting advances in relation to human health is perplexing. The reality is that many other technologies are also essential to medicine. There are large and expensive machines, such as those used in medical imaging, that rely on patented technologies in the fields of electrical and mechanical engineering. So too, there are patents to non-biologically derived compounds used for therapies or reagents for diagnostics.

It has been recognised for some time that current Australian laws regarding research exemptions need clarification (see Recommendation 13 of the Senate Committee), and action on this issue seems to have dragged on for too long. If Senator Heffernan and his colleagues are truly concerned about basic research being stifled by patents, they should have presented proposed amendments focusing on the "broad research exemption" suggested by the Senate Committee.

### International Obligations

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Senator Heffernan appears to recognise that the proposed amendments are contrary to International agreements to which Australia is a party. Like a thief trying to get off a robbery charge on a technicality such as the improper collection of evidence, Senator Heffernan plays semantics with the term "invention". Senator Heffernan tries to mislead the public into believing that centuries ago the patent system was developed to be inflexible and not take into account emerging areas of scientific endeavor that could not have been predicted at the time, such as isolated genes, proteins or cells, nanotechnology, televisions, telephones and computers.

The bottom line is that the patent system is, and should remain, a flexible mechanism for promoting and rewarding scientific innovation. As with "human beings, and biological processes for their generation" already being excluded as patentable subject matter in Australia, Government should be able to decide what technologies can be subject to a temporary monopoly without having to play petty word games with the term "invention". Since the proposed amendments are contrary to International agreements, it is far more appropriate to come to a consensus with our trading partners on this issue and then, if agreement is reached, amend the Australian Patents Act 1990 so it is consistent with our International obligations.

## Practical Implications

In his speech, Senator Heffernan states that the "Bill is very narrow". Whilst the extent of patentable subject matter in the field of biotechnology is significantly reduced by the proposed amendments, there would still seem to be reasonable scope for obtaining at least some patent protection. As noted by Senator Heffernan, "biotechnological inventions which make use of biological materials in such things as new and inventive diagnostics, medicines and treatments will continue to be afforded patent protection just as they are now".

In practical terms, if the amendments are passed by Parliament this would mean that applications for a patent in Australia in the field of biotechnology are more likely to solely have method claims, rather than claims to both the product and methods of using the product. However, the use of the term "medicines" as being patentable in the above quote is confusing. Does it mean that medicines of a non-biological nature are still patentable, or perhaps pharmaceutical formulations containing the biological material will still be patentable? In our opinion, the proposed amendments will make the patent system more expensive. First, phrases such as "derivatives" and "substantially identical" are unclear, meaning that there will be more costs at the patent prosecution stage arguing whether a non-naturally occurring biological material is patentable or not. Second, a well known principle of the patent system is that product claims are easier to enforce than method claims. As a result, patentee's may have to spend more time and money to prove that their rights are being infringed.

## Conclusion

If Senator Heffernan's assertion is correct that the "Bill is very narrow", then what does it really achieve? The answer would seem to be nothing but to add extra expense to the Australian patent system, contradict International agreements, and provide an inadequate solution to the issue of research exemptions which is relevant to all technologies, not just "gene patents".

## What Next?

On 26 November 2010 the Senate referred the Bill for inquiry and report. The Committee is seeking written submissions from interested individuals and organisations. Submissions close 25 February 2011. The Committee is due to report 16 June 2011. During our attendance at the Senate Inquiry into Gene Patents it was noted that our firm was one of the few organisations defending a stance that biological materials, diagnostics and methods of therapy should remain as patentable subject matter in Australia. We strongly urge all interested parties who see the value of the current patent system to provide written submissions to the new Senate Inquiry before the 25 February 2011 deadline.

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*This piece was written and submitted by Doctors Ian Rourke, Karin Innes and Danielle Burns from patent attorneys FB Rice & Co.*