

The Conversation

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Who owns the rights to the human body? It's patently obvious

AUTHOR

1.



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The Bill seeks to close the loophole opened by the US Patent Office 30 years ago. AAP

[Read the argument against the proposed legislation](#)

Patents are only to be for granted inventions – that's the intent of the [Patents Act 1990](#), it has been the law for nearly 400 years, and it's also what [Article 27.1 of TRIPS](#) says in black and white.

About 30 years ago, a new patent office practice was established by the [United States Patent and Trademark Office](#), the [European Patent Office](#) and the [Japan Patent Office](#).

The change essentially meant that naturally occurring biological materials, such as DNA and amino acids or proteins, which have been isolated (removed from their natural environment), could be considered to be inventions.

This practice was subsequently adopted in Australia and its implementation resulted in the granting of thousands of patents over isolated biological materials from a variety of sources, including viruses, bacteria, human genome and plant genomes.

However, the legality of this practice was never tested, either in a United States or Australian court – until 2009 in the former and 2010 in Australia.

This only happened when the legality of patents granted to [Myriad Genetics](#) over the [BRCA 1 and BRCA 2](#) genes and their use in genetic tests were challenged.

In the United States, a Federal Court judge held in March 2010 that the US patents, insofar as they claimed the BRCA 1 and BRCA 2 genes as inventions, were invalid.

The judge held that the isolation of a naturally occurring biological material was not the equivalent of transforming that material from a product of nature into a product of humankind.

His decision has been appealed and the appeal was heard a few weeks ago. You can listen to the legal arguments [here](#).

Whatever the outcome of that appeal, it is likely that the case will go to the US Supreme Court for final determination.

In Australia, a test case is proceeding through the Federal Court and a tentative trial date has been set for September 2011, but there is a strong possibility that that date will change.

Patent Amendment (Human Genes and Biological Materials) Bill 2010

The [Patent Amendment Bill](#) going through the Australian Parliament seeks to define what an invention is in the context of biological materials which are (and this next bit is important) *identical or substantially identical to what exists in nature*.

In other words, it seeks to close the loophole which the US patent office practice opened 30 years ago.

The intent of the Bill is to make it clear that a naturally occurring biological material isolated from its natural environment is not patentable matter, that is, it is not an invention.

This is a scientific fact. As an example, imagine a cotton ball – removing a cotton ball from a cotton plant doesn't make the cotton ball an invention. It is absurd to suggest it does.

The Bill does not prevent the patenting of modified biological materials if they are substantially different to those that exist in nature.

So, the modified protein which is at the heart of the [Gardasil](#) vaccine would not be affected. Neither would the monoclonal antibody which is at the heart of [Herceptin](#), nor the modified human insulin which is at the heart of [NovoLog](#).

These are biological materials but each have been modified so they function in a way that unmodified proteins do not and their enhanced function is sufficient to distinguish them from their naturally occurring parent proteins.

Further, the Bill does not prevent the patenting of vaccines, medicines, diagnostics and therapeutics that use biological materials as their active ingredient.

So, even if the Bill becomes the law, it will still be possible to apply for a patent for a vaccine containing a biological material identical to one existing in nature, such as a vaccine using a live attenuated viral strain.

All the Bill does is prevent the patenting of the naturally occurring biological material itself, not the product which uses such a material to produce a new and inventive efficacious result, which is what a new vaccine does.

Ultimately, the Bill merely applies patent law as it was always intended to be applied.

Even the US government acknowledges the USPTO's practice was wrong in law. In October 2010, the US Department of Justice, on behalf of the US government, filed an [amicus \(friend of the court\) brief](#) in the Myriad BRCA US patent appeal.

The brief said that having reviewed the “longstanding practice of the [U.S.] Patent and Trademark Office” relating to “patents for isolated genomic DNA”, the Department of Justice found the practice to be contrary to “settled principle under [U.S.] Supreme Court precedent”.

The main reason for the opposition to the Bill is that it will achieve its stated aim.

Those who oppose it have either obtained patents on isolated biological materials which are identical or substantially similar to those that exist in nature (pharmaceutical and biotechnology companies, universities and certain research institutions) or have participated in procuring such patents (patent attorneys and intellectual property lawyers) or are financially benefiting from them.

Their opposition is an over reaction because the Bill will not actually stop the patenting of new and inventive diagnostics, medicines and therapeutics which contain or incorporate these biological materials.

It will merely prevent the patenting of the biological materials existing in nature or those derived from such materials that function in exactly the same way.

The argument that this Bill will bring the Australian biotechnology sector to its knees is complete and utter nonsense.

It is regrettable that some of Australia’s leading scientists have publicly opposed it when all it seeks to do is ensure that only true inventions are rewarded with a patent monopoly.

[Read the argument against the proposed legislation](#)

Do you think human genes and other biological materials should be allowed to be patented?

Leave your comments below

3 Comments

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1.



Bruce Arnold

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US law has provided patent-style protection for plants - aka what exists in nature - since 1930. Australian law has provided that protection since 1987. Disregard emotive polemic about "complete and utter nonsense" and the "regrettable" support by "some of Australia's leading scientists" - there is cogent analysis in <http://www.aph.gov.au/library/pubs/bd/2010-11/11bd107.pdf> which highlights flaws in the Bill

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Sean Lamb

US plant patents are not granted for things that "exist in nature", but rather something unique that has been developed or bred under cultivation

<http://www.uspto.gov/web/offices/pac/plant/#1>

Since technology is moving so fast that in the era of whole genome sequencing, to take patent protection to its logical extension when some one has their genome sequenced, the final step would be for laboratory to have to go through the final sequence and hand delete every gene sequence that is under patent.



Anna Lavelle

In my testimony to the public hearing into the Patent Amendment Bill before Parliament, I gave evidence that the proposed Bill fails completely to address any of the valid concerns raised by the community about gene patents and should be rejected.

In this view, AusBiotech is aligned with an overwhelming two-thirds majority of the 114 written submissions made to the Senate Inquiry, including submissions from the Group of Eight, the Peter McCallum Cancer Centre, the Royal College of Pathologists, the Walter and Eliza Hall Institute, Professor Ian Frazer, the Garvan Institute and the Consumers Health Forum.

As the Group of Eight submission notes, the distinction between discovery and invention "is clear from the current wording of the Patents Act 1990 and believe that the Patent Amendment (Human Genes and Biological Materials) Bill is unnecessary."

The Bill does not serve the interests of patients, researchers or industry. In fact, the Bill threatens the very foundations of scientific research and development on biological materials which are built on patents. If this Bill becomes law, it is likely to have far-reaching and serious consequences.

For further information, see AusBiotech's briefing document:

http://www.ausbiotech.org/data/downloads/2010%2022%2011%20-%20Final%20AusBiotech_MP%20Briefing%20on%20Gene%20Patents.pdf

Hansard for the Public hearing can be viewed at:

http://www.aph.gov.au/Senate/committee/legcon_ctte/patent_amendment/hearings/index.htm

AusBiotech's written submission to the Inquiry can be found at:

<http://www.ausbiotech.org/data/downloads/AusBiotech%20Submission%20on%20Patent%20Amendment%20Bill.pdf>