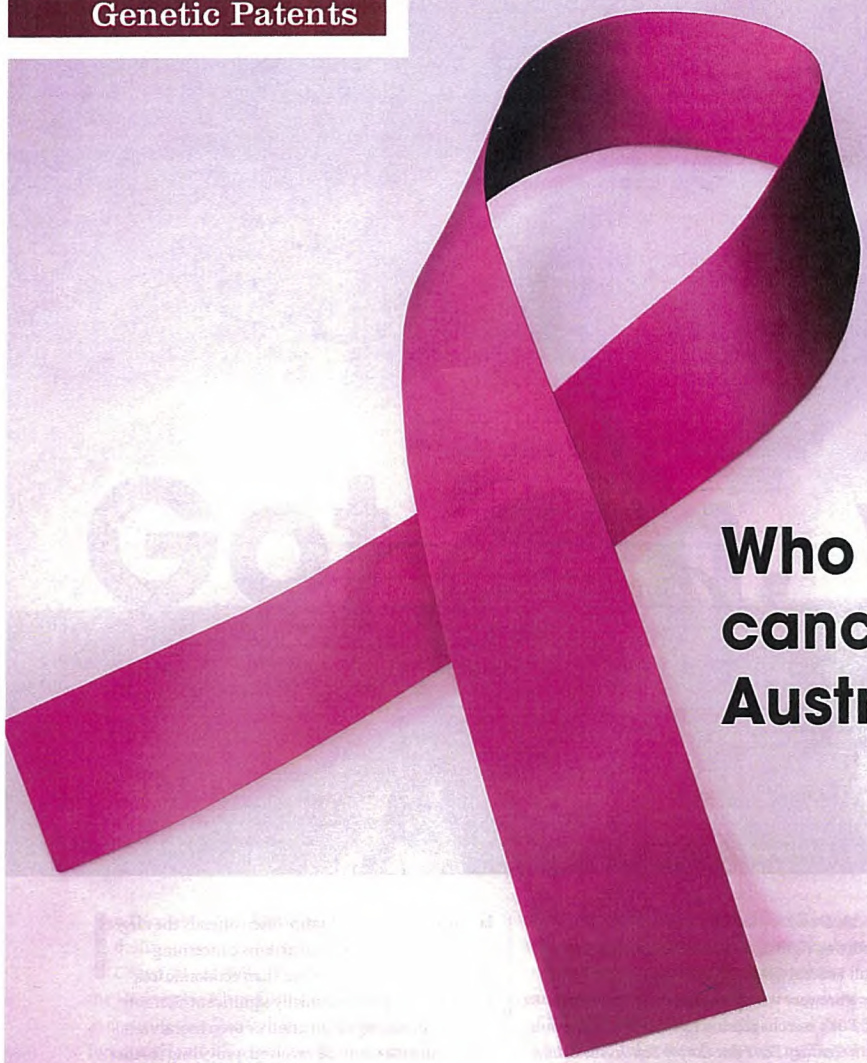
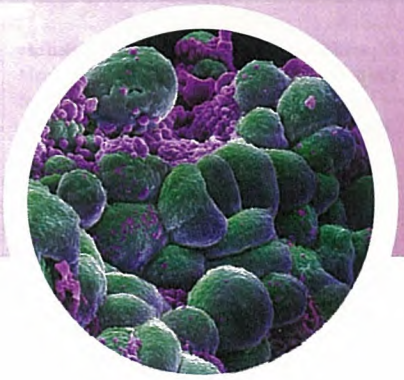


# Who owns the breast cancer gene in Australia?



**Bianca Mueller** takes a look at a recent case involving the patentability of gene sequences

In February 2013, the Australian Federal Court decided that an isolated breast cancer gene is patentable. This judgment is the first adjudication in Australia on the patentability of genes and gene sequences that have been removed from their natural cellular environment: *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 (13 February 2013). The case has been closely followed due to its far-reaching ramifications both in Australia and internationally.

BRCA1 is a human breast and ovarian cancer-disposing gene. Mutations of the gene predispose an individual to develop hereditary breast and/or ovarian cancer. According to the disputed patent, carriers of the breast cancer gene BRCA1 are exposed to a 45 per cent higher risk of developing hereditary breast cancer, and at least an 80 per cent risk of hereditary cancer involving both breast and ovarian cancers. Men too can carry the gene which raises their risk of prostate, pancreatic, and other types of cancer.

Myriad Genetics (Myriad) was granted a patent over the isolated BRCA1 gene, protein, and associated mutations and holds exclusive rights over their use (priority date 12 August 1994). Myriad also holds the rights to the genetic test that can detect the breast cancer gene. Hence, if a patient wants to be tested to determine whether she has the gene, she has to pay Myriad a hefty sum.

## The issue

The underlying question of the case is: should a patent be granted over isolated naturally occurring genes? The answer to that question depends on where one draws the line between a mere discovery and a patentable invention.

Cancer Voices Australia and Mrs D'Arcy, a woman who had breast cancer, sought to invalidate Myriad's patents over the breast cancer gene BRCA1. They argued that the isolated breast cancer gene is not patentable because it occurred in nature and there is no material difference between the genes in their natural and isolated states.

Myriad argued that the isolated breast cancer genes found in human cells differ from the isolated breast cancer gene in the patent. Myriad also argued that the isolated gene is the result of a manner of manufacture because it involved breaking covalent bonds, resulting in an artificially created state of affairs providing a new and useful effect that is of economic significance.

Under the Australian *Patents Act* 1990, human beings, plants, animals and the biological processes of their generation are not patentable inventions. Beyond that, the *Patents Act* does not include any specific prohibition on the grant of a patent for an isolated DNA or RNA sequence. The law leaves the matter to rest with section 18(1)(a) of the *Patents Act* which requires that for an invention to be patentable it must be of 'manner of manufacture within the meaning of section 6 of the *Statute of Monopolies* – a statute that was passed by the English Parliament in 1623. In *National Research Development Corporation v Commissioner of Patents* [1959] HCA 67 (*NRDC*)

the Australian High Court enunciated that a product that consists of an artificially created state of affairs that has economic significance would constitute a manner of manufacture.

## The decision

In applying the broad principles set out in *NRDC*, the Court in *Cancer Voices Australia* had to determine whether the removal of the biological material from its in-situ environment, and its separation from other cellular components, gives rise to an artificial state of affairs that has economic significance.

The Federal Court found that isolated genes - either deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) – are a patentable subject matter. The Court held at [136] that while "there is no doubt that naturally occurring DNA and RNA as they exist inside the cells of the human body cannot be the subject of a valid patent", the present dispute does not involve naturally occurring genes in the way that they exist in their natural environment. Instead, this claim extended "only to naturally occurring DNA and RNA which have been extracted from cells obtained from the human body and purged of other biological materials with which they were associated".

The removal of the genetic material from its natural environment is the result of human intervention involving the extraction and purification of the nucleic acid. This, the Court reasoned, created an artificially created state of affairs even if the isolated BRCA1 gene has precisely the same chemical composition and structure as that found in the cells of some humans.

Extraction and purification of the BRCA1 gene requires skill, labour, and significant monetary investment. According to the Court it would be "odd" if the skill and effort invested in the isolation of a microorganism could not be rewarded by the grant of a patent. The court therefore concluded that the artificially created state of affairs is of economic significance.

The Court inferred from the absence of a prohibition to patent isolated DNA or RNA, the legislative intent to allow for isolated nucleoid acids to be patentable.

The decision is in line with international developments on the matter. In 2011, a US court upheld Myriad's patent claim in the breast cancer gene BRCA1 (although that decision has been appealed to the US Supreme Court). In the UK and in many other parts of Europe, isolated DNA and isolated RNA may be patentable even though they are identical in their chemical composition to DNA and RNA found in a human cell.

## Recent attempts to amend the *Patents Act*

Australia has struggled with this matter for a while and has undertaken many attempts to legislate on the matter. The Australian Law Reform Commission (ALRC) issued a report dated 29 June 2004 entitled *Genes and Ingenuity: Gene patenting and human health* (ALRC Report 99). The report found that the 'manner of manufacture' test used in Australia to determine patentability was ambiguous and obscure.

The Australian Government responded to the 50 recommendations of the ALRC in its *Gene Patents Report*. Beginning in 2009, the Australian Senate carried out two inquiries into gene patents, but decided not to amend the *Patents Act*.

In 2011, the Legal and Constitutional Affairs Legislation Committee recommended not to pass the Patent Amendment (Human Genes and Biological Materials) Bill 2010 because "there was no evidence received by the committee that patents on human genes or biological materials are systematically leading to adverse impacts in the provision of healthcare in Australia". The Bill sought to exclude patents of "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". The Bill eventually lapsed.

Australia is set for implementing wide-ranging reforms of its patent law. The *Intellectual Property Laws Amendment (Raising the Bar) Act* 2012 has passed into law with the Governor General's assent on 15 April 2012. Most provisions of the Act come into effect on 15 April 2013. The Act does not address the issue of what is a patentable subject matter. It provides however for a research use exemption regarding patented DNA and RNA, although presumably not for diagnostic testing itself.

## Implications for New Zealand

The Intellectual Property Office of New Zealand routinely grants patents in relation to isolated DNA and RNA. Unlike in Australia, the patentability of isolated nucleoid acids of claims has never been challenged in the court.

The key considerations that influenced the Australian decision are equally relevant in the New Zealand context. As in Australia, the New Zealand patent law does not expressly exclude isolated genes from patentability. The New Zealand patent law is currently being reviewed. The Patents Bill was introduced to Parliament in 2008 and does not exclude isolated genes from patentability.

The NDRC principles relating to the definition of a patentable invention in section 6 of the *Statute of Monopolies* are equally applicable in New Zealand: *Swift and Company v Commissioner of Patents* [1960] NZLR 775 (SC), *Wellcome Foundation Ltd v Commissioner of Patents* [1983] NZLR 385 (CA), *Pfizer Inc v Commissioner of Patents* [2005] 1 NZLR 362 (CA).

The New Zealand Court of Appeal has excluded methods of medical treatment of humans from patentability based on policy grounds: *Pfizer Inc.*. The Court acknowledged that Australian courts have accepted the patentability of methods of medical treatment. However, while conformity of law in New Zealand and Australia may be a desirable policy objective in matters of commerce, this could not be determinative of the issue.

In the meantime, the Australian and New Zealand governments actively work towards a trans-Tasman patent harmonisation.

A further reason why the determination of the patentability of genes in New Zealand might be different is because the Waitangi Tribunal considered the concerns of Māori in regard to the granting of patents involving the genetic material of taonga species. The Tribunal made various recommendations to provide for a reasonable degree of protection of the kaitiaki relationship with taonga species.

## Conclusion

In the absence of legislative intervention, isolated genes are a patentable subject matter in Australia. However, a patent cannot be obtained over a human, a human body part, or a human gene in its natural host, a human.

The matter continues to be a sensitive topic for the public in general and for cancer sufferers and their families in particular. Cancer Voices Australia has appealed the decision to the Full Federal Court and has launched a petition to the Australian Parliament.

Biotechnology, which is already intrinsically challenging, becomes more so when combined with a patent law system that is based on a statute from 1623 that contains an ambiguous and obscure provision as to what an invention is. This has not made the law easy to understand or even practical to use in this environment.

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