

*Because the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter under 35 USC § 101.*

That, however, only loosened Myriad's stranglehold on BRCA testing slightly.

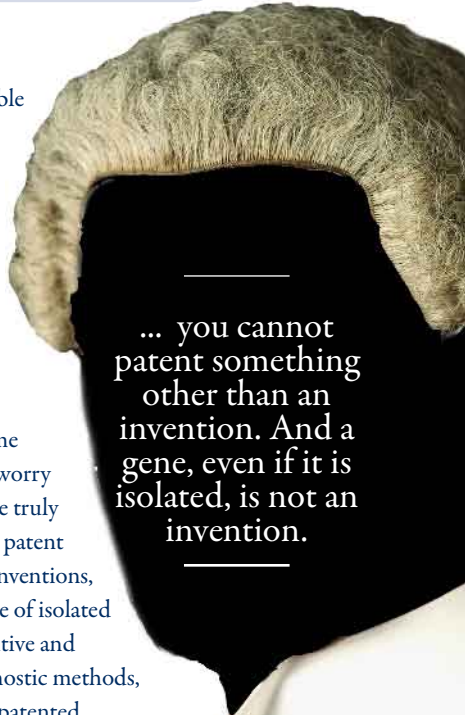
The decisive blow came when Judge Sweet held that the use of these biological materials in diagnostic tests was also not patentable subject matter for two reasons. First, the method claims were "nothing more than data-gathering steps to obtain the DNA sequence information on which to perform the claimed comparison or analysis". Second, "in the absence of a specified method for isolating and sequencing DNA" the method claims were "meaningless" and would "fail the 'machine and transformation' test under § 101".

Finally, he hammered the last nail in the BRCA patent coffin by invalidating the claims directed to "comparing" the growth rates of cells in the presence or absence of a potential cancer therapeutic". In his opinion the method claims sought to monopolise "a basic scientific principle: that a slower rate of cell growth in the presence of a compound indicates that the compound may be a cancer therapeutic" and therefore they too failed for the reason that they "represent nothing more than preparatory, data-gathering steps to obtain growth rate information".

Myriad has announced that the decision will be appealed to the US Court of Appeals for the Federal Circuit (CAFC). And whatever the

outcome it is reasonably foreseeable that the CAFC's decision will be appealed to the US Supreme Court. A final determination is many years away. However, Judge Sweet's decision now represents the law in the United States and will continue doing so until it is overturned (if it is ever overturned).

The decision has worried some commentators but it should not worry biotechnology companies that are truly innovative and which are seeking patent protection for biotechnological inventions, that is, inventions which make use of isolated biological materials in new, inventive and useful ways. New therapies, diagnostic methods, even cures, will still be able to be patented. This decision merely reinforces the basic premise of patent law that you cannot patent something other than an invention. And a gene, even if it is isolated, is not an invention.



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## OPINION

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# Services and gene patenting: GTG

**G**enetic Technologies has always operated within the existing legal and patent framework.\* Should the rules change, the company will operate within the new rules.

In order to offer the BRCA tests we secured the legally issued Australian Myriad patent – and pay a substantial fee for the right to offer these tests. Some government funded laboratories and research organizations illegally do not pay, are providing quasi commercial pathology services and enjoying larger profit margins.

Should this patent protection be removed in Australia, Genetic Technologies would benefit financially as it would no longer stand out as the entity in Australia paying royalties for tests such as BRCA.

Despite the American district court decision at the end of March, we anticipate a lengthy appeal process that will probably reach the American Supreme Court. This decision should in no way be regarded as final.

However the intellectual benefits of patent protection serve a greater good in the longer term.

While we are watching the BRCA genes case, the issue is much greater than this. Take the example of the HER2 gene. Discovery of this gene was the catalyst for development of the widely used breast cancer treatment Herceptin. Without patent protection this life prolonging drug may never

have been developed.

Genetic Technologies is a small, efficient biotechnology company employing 80 highly qualified Australian scientists, customer service and business people. This company is regarded as Australia's foremost private genetics lab. Its priority is to provide the world's best gene testing and cancer testing for Australians.

By providing a private BRCA testing service, we are able to determine the risk profile for women in as little as two weeks.

Before Genetic Technologies provided this test in Australia the public institutions providing this service typically took many months, sometimes years, to provide results to women vulnerable to breast cancer.

Patent protection massively contributes and is necessary for new drug development and better diagnostics. Why would effort and resources be devoted to discovery in Australia if the patent incentive were to be removed. Australia would be out of step with the rest of the world and its successful history of medical research would have a final chapter.

*\*Genetic Technologies was an early pioneer in recognising important new applications for 'non-coding' DNA. The Company has since been granted patents in 24 countries around the world, securing intellectual property rights for particular uses of non-coding DNA in genetic analysis and gene mapping across all genes in all multicellular species.*