

PATENT WATCH



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Australian court upholds Myriad's gene patent

An Australian appeals court has ruled that isolated DNA molecules are eligible for patenting. The case, between Myriad Genetics and gene patent opponent Yvonne D'Arcy, was closely watched, as an analogous dispute in the United States overturned established patent law when it ruled that isolated DNA was not eligible for patenting (*Nature Biotech.* **32**, 403–404; 2014).

“The decision means that it is business as usual with respect to patenting of genetic technologies in Australia,” says Mark Summerfield, Special Counsel with specialist intellectual property firm Watermark, Melbourne, Victoria, Australia. “It confirms the position of the Australian Patent Office, which has been granting claims directed to isolated genetic materials since the early 1990s.” The case centred on a patent (AU 686004) that claimed an isolated nucleic acid encoding a mutant BRCA1 polypeptide, which is associated with increased risk of breast and/or ovarian cancer. The opponent of the patent asserted that the isolated BRCA1 DNA was exactly the same as the naturally occurring DNA, since it encodes the same polypeptide, and so should not be eligible for patenting.

Under Australian patent law, patent eligibility depends upon whether the invention consists of an artificially created state of affairs (that is, whether it would not

exist without human intervention) that has economic significance. That the naturally occurring BRCA1 DNA and the isolated DNA contain the same genetic information had no bearing on this test of patent eligibility. (By contrast, the US Supreme Court noted this similarity in its test for patent eligibility.) Rather, the court said that the determination of patent eligibility should focus on the differences in structure and function of the isolated DNA that were imposed by human intervention (that is, through the isolation of the DNA).

Following on from this, the court held that the isolated DNA described in Myriad's patent was different to the naturally occurring DNA; its removal from the cellular environment means the isolated DNA cannot, for example, have introns removed, or be transcribed or translated, distinguishing the isolated DNA

as artificial. The isolation of the nucleic acid also led to a result — the treatment of breast and ovarian cancers — that is economically useful.

To be patented though, an isolated DNA sequence still needs to pass the usual requirements of inventiveness (that is, non-obviousness) and usefulness.

Myriad's patent has never been enforced in Australia, so the outcome of this court case will not impact BRCA1 testing. But the decision is reassuring for the drug discovery community. “The court's consistent approach to patent eligibility, which carefully avoided any special treatment for genetic technologies, enables biotechnology companies to proceed with confidence in protecting their innovations in Australia,” says Summerfield.

However, this may not be the final word on the case, as an application to appeal the decision has been lodged with the Australian High Court.

D'Arcy versus Myriad Genetics: <http://www.austlii.edu.au/au/cases/cth/FCAFC/2014/115.html>

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