

BIOBUSINESS BRIEFS

PATENT WATCH

Australia's highest court decides isolated nucleic acids are not patent eligible

In an appeal decision that echoed an analogous 2013 US Supreme Court ruling, the High Court of Australia (the final court of appeal in Australia) has unanimously ruled that claims directed to isolated nucleic acids are not patent eligible. Australia has thus become the second major jurisdiction to limit the ability to protect inventions relating to isolated nucleic acids.

The case between Yvonne D'Arcy and Myriad Genetics Inc. (and others) related to three claims of Australian patent 686004, which incidentally expired in August this year. The subject claims of the appeal were directed to isolated nucleic acids coding for mutant forms of the BRCA1 polypeptide. The decision essentially brings an end to 'gene patents' in Australia.

Previous Federal Court rulings articulated that the process of isolating nucleic acids from the cellular environment led to sufficient differences in the structure and function of the nucleic acids that they could be regarded as an "artificially created state of affairs", which was part of the established test for patent-eligible subject matter. In other words, the previous ruling considered that nucleic acids were chemical compounds, which were sufficiently altered by the process of isolation to qualify as patent eligible. However, the majority in the High Court decided that the substance of the claimed invention did not relate to isolated nucleic acids as a class of chemical compounds; rather, it resided in nucleic acids as a store of genetic information. As a result, the High Court reasoned that the genetic information residing in the claimed nucleic acids was not the product of, nor was it altered by, the process of isolation and therefore the claims were not valid.

Although the decision of the High Court was surprising, in that it overturned two previous rulings in the Australian Federal Court, the reasoning behind the decision of the High Court of Australia distinguishes it from the analogous decision by the US Supreme Court. The decision in the United States held that the mere isolation of naturally occurring chemical compounds (which

includes nucleic acids) did not meet the requirements for patentability. Although the two courts reached the same verdict, the means by which they arrived at that verdict has important implications on how far the decisions extend beyond gene patents. As a result of giving priority to the informational aspect of nucleic acids, it is likely that the decision of the High Court of Australia (in contrast to the decision in the United States), will not extend to non-coding nucleic acids, vectors, probes, regulatory DNA, small interfering RNA (siRNA), other biologics such as antibodies, naturally derived antibiotics or other naturally occurring chemicals. However, the High Court of Australia's decision does appear to extend to nucleic acids such as cDNA; the court considered the claims of the patent would not have been saved if they were directed to BRCA1 cDNA.

This decision has mixed implications for the drug discovery community. On one hand, this decision assists researchers who wish to isolate and study genes that otherwise would have been patented; indeed, this was mentioned at length in the High Court decision (and despite Australia having a research exemption from patent infringement). However, the breadth of patentable subject matter available to the biotech community has been diminished by this ruling, and a considerable number of granted patent claims are now invalid.

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The authors declare no competing interests.

FURTHER INFORMATION

D'Arcy v Myriad Genetics Inc [2015] HCA 35:

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