Are patents on genetic testing really a thing of the past?

Victoria Argyle and Tim Stirrup

Baldwins Intellectual Property, PO Box 5999, Wellesley St, Auckland

(email: *victoria.argyle@baldwins.com* or *tim.stirrup@baldwins.com*)

On 13 June 2013, the United States Supreme Court issued its landmark decision on the practice of gene patenting in *Association for Molecular Pathology* et al. *v Myriad Genetics, Inc.* et al. ("*AMP v Myriad*").[1] The Court found that an isolated DNA sequence is not patentable. The decision has been hailed by some as a thrilling victory for patients. This, however, may overstate the significance of the decision.

Background

In the late 1980s, several groups were involved in the search for a genetic basis for breast and ovarian cancer. In 1990 a team of scientists from the University of California announced the precise location and sequence of the BRCA1 and BRCA2 (BRCA1/2) genes, mutations of which are associated with increased risk for breast and ovarian cancer. In 1994, another group of scientists from the University of Utah founded Myriad Genetics. Myriad, together with others, filed the first patent applications relating to the BRCA1 and BRCA2 genes in 1994 and 1995, respectively. Then, in 1996, Myriad launched their BRACAnalysis® product, which detects the mutations in BRCA1/2 genes responsible for putting women at high risk for breast and ovarian cancer. Since then, Myriad have obtained 24 granted United States patents relating to the BRCA1/2 genes, providing them with exclusive rights to the provision of BRCA1/2 diagnostic testing.

The Arguments

The BRCA1/2 genes represent only two of several hundred isolated DNA sequences for which patent protection has been granted in the United States. This practice of issuing so called "gene patents" has generated a great deal of controversy, as they provide their owners or licensees with exclusive rights to the DNA sequences concerned. Consequently, the Association for Molecular Pathology ("AMP") has actively lobbied against the existence of, and exclusive licensing of, such patents.

In *AMP v Myriad*, AMP and others challenged nine composition claims in three of Myriad's 24 patents on BRCA1/2, these claims relating to isolated DNA sequences (or genes) and complementary DNA (cDNA) sequences. Before the case reached the Supreme Court, other claims relating to methods of using the BRCA1/2 genes were also challenged. These claims were not considered by the Supreme Court.

AMP and others argued that the coverage provided by Myriad's patents restricted research and therefore limited scientific progress. They also argued that Myriad's monopoly made it impossible for a patient to obtain a second opinion on their diagnosis, and kept the cost of BRCA1/2 testing high by preventing competition. As well as these 'moral' arguments, AMP pointed out that United States patent law excludes products of nature from patentability. They argued that isolated DNA is insufficiently different from DNA found in the body to be patentable. Myriad argued that isolated genes and their diagnostic tests were patentable on the basis that an isolated DNA sequence is no different from any other chemical compound. They also argued that an isolated DNA sequence itself is patentable, since isolation of the DNA sequence renders it different in character from that present in the human body.

Decision

The Supreme Court held that an isolated DNA sequence is not sufficiently different from the un-isolated product of nature and is therefore not patentable. Complementary DNA (cDNA), on the other hand, which differs mainly in respect of the lack of the non-coding introns, is patentable because it is not naturally occurring. Justice Thomas did provide one caveat to this; a very short strand of cDNA which is indistinguishable from natural DNA is also not patentable.

The Impact of the Myriad Decision

For many, the Supreme Court's decision represented the end of Myriad's monopoly on the BRCA1/2 genes and heralded the ability for patients to access alternate tests or to get a comprehensive second opinion about their results. Furthermore, given that a significant number of isolated genes have been patented in the United States, the decision represents a major shift in patent law. However, it is important to recognise what the decision does not do. Many of Myriad's unchallenged claims relate to methods which apply knowledge about BRCA1/2 genes. As indicated above, the patentability of these claims were not considered by the Court. Nor did the Court have to consider the patentability of DNA in which the order of naturally occurring nucleotides has been artificially altered.

Consequently, there is an increasingly widespread belief that the decision will not have a dramatic impact on the life sciences industry, especially given the expense and technology required to develop competing tests. Indeed, following the decision Myriad was quick to point out that they still had "more than 500 valid and enforceable claims in 24 patents conferring strong patent protection for its BRACAnalysis® test".[2]

Within hours of the Supreme Court issuing its decision, United States companies Ambry Genetics and Gene by Gene Limited separately announced their intention to begin offering fast, accurate and affordable genetic testing for the BRCA1/2 mutations to the public. Myriad and its partners promptly alleged that these competing tests infringe claims in ten different patents, including some claims challenged in the original lawsuit (but critically, not the claims that the Court rejected).

In its complaints against Ambry Genetics and Gene by Gene Limited, Myriad alleges that their patent claims covering various methods for detecting or screening BRCA1/2 mutations, synthetic primers, probes and arrays are infringed. Myriad are seeking monetary damages and have requested an injunction to prevent Ambry and Gene by Gene 'free-riding' off what Myriad say is the hundreds of millions of dollars invested in developing the science and market for clinical diagnostic testing for hereditary cancers.

On 15 August 2013, Gene by Gene Limited announced that it is teaming with Ambry Genetics to fight Myriad's infringement lawsuit on the basis that Myriad's patent claims are invalid and that Myriad is abusing its monopoly by enforcing the patents.

This latest round of litigation will test Myriad's assertions following the Supreme Court decision that they have other valid patent claims protecting their market position.

Conclusion

The Supreme Court decision in *AMP v Myriad* is narrow in that it only excludes isolated DNA gene sequences from patentability. The decision indicates that application of the knowledge about gene function, for example, for genetic predisposition testing, is still patentable. Therefore, it cannot yet be said that controlled access to genetic testing is a thing of the past. Myriad continues to hold enforceable patent rights which may continue to prevent competitors entering into the market of BRCA1/2 gene testing, at least until Myriad's patent rights expire. Given the latest lawsuits filed by Myriad, litigation in this area is likely to continue for some time to come.

If you have any queries regarding intellectual property related matters (including patents, trademarks, copyright or licensing), please contact:

tim.stirrup@baldwins.com or *victoria.argyle@baldwins.com* Patent Proze, Baldwins Intellectual Property, PO Box 5999, Wellesley Street, Auckland

Bibliography

1. *Assn. for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398 (U.S. June 13, 2013). Source: http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf, viewed 20 August 2013.
2. Statement issued by Myriad Genetics on 13 June 2013. Source: http://investor.myriad.com/releases.cfm, viewed 20 August 2013, statement entitled "Supreme Court Upholds Myriad's cDNA Patent Claims".

Victoria Argyle and Tim Stirrup of Baldwins Intellectual Property in Auckland specialise in chemistry and biotechnology patents. Victoria obtained her PhD in supramolecular chemistry from the University of Otago in 2009. She is currently working towards registration as a patent attorney. Tim obtained his PhD in molecular biology from the University of Southhampton in the UK in 2007. He qualified as a registered New Zealand and Australian patent attorney in 2011.