



US Supreme Court addresses patent eligibility of isolated DNA and cDNA in *Myriad V*

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Association for Molecular Pathology v Myriad Genetics, Inc, 133 S Ct 2107 (US 2013) ('*Myriad V*'), US Supreme Court, 13 June 2013

Abstract

The US Supreme Court unanimously ruled that Myriad Genetics, Inc's claims to isolated, naturally occurring human DNA sequences are not patent-eligible, but that Myriad's claims to cDNA, which necessarily includes manipulated DNA sequences, are patent-eligible. The court also indicated that claims to methods of generating isolated DNA could be patent-eligible, even though no such claims were at issue. This decision marks the second time the Supreme Court granted *certiorari* in this case, and is yet another in a series of recent decisions by the Supreme Court that identifies the dividing line between patent-eligible and patent-ineligible subject matter.

Legal context

Myriad's patents protecting its discovery and inventions related to the use of the BRCA1 and BRCA2 genes to diagnose breast cancer had, for much of their life, remained unchallenged. Myriad patented isolated versions of these genes, complementary DNA ('cDNA', ie modified versions) of the relevant excerpts of these genes and methods of using these genes to identify genetically predisposed cancer patients and/or evaluate cancer treatments. This ground-breaking discovery has been used to save countless lives, and is the type of innovation that the patent system was created to foster.

However, in the context of this case, a challenge by various medical associations, doctors and patients, represented by the American Civil Liberties Union and the Public Patent Foundation, ignited a debate and resulted in two trips to the US Supreme Court to determine not merely if 'human genes [are] patentable', as the question was phrased to the US Supreme Court in the most recent petition, but when really, if ever, patent protection can be obtained when human genes are involved.

In *Myriad IV* (*Association for Molecular Pathology v US Patent & Trademark Office*, 689 F 3d 1303 (Fed Cir 2012)), the Supreme Court recognized that merely isolating naturally occurring



human genes, without more, is not enough, while fashioning new molecules in the form of cDNA derived from human genes is enough to become patent-eligible. In striking this balance, the Supreme Court reversed 30 years of policy at the US Patent and Trademark Office but nonetheless laid a blueprint for continuing patent protection in this very important area of scientific endeavour.

Facts

This case regards patents owned by Myriad Genetics that involve isolating the BRCA1 and BRCA2 genes from a human body and using the isolated genes to diagnose an increased likelihood of developing breast or ovarian cancer. The patent claims at issue in the current decision cover the exact sequences of the BRCA1 and BRCA2 genes. Another set of Myriad's claims cover corresponding 'cDNA versions' of the same genes.

Complementary DNA is synthetic DNA created in a laboratory. The production of cDNA involves the 'expression' (activation) of a gene, such as BRCA1 or BRCA2, for the purpose of producing a corresponding protein molecule. A derivative molecule, known as messenger RNA ('mRNA'), is then 'transcribed'. mRNA is an intermediate molecule that 'mirrors' the DNA sequence of the transcribed gene. Importantly, mRNA undergoes an 'editing' process in which certain portions of the protein sequence are discarded and the remaining portions joined to form a shortened molecule. The discarded portions are called 'introns' and the remaining portions are called 'exons'. A laboratory technician can reverse this transcription process and synthesize a DNA molecule that 'mirrors' the shortened mRNA molecule. The DNA thus produced is cDNA.

This case began in 2009, when a number of medical associations, doctors and patients challenged the patent eligibility of claims in seven patents held in part by Myriad Genetics, Inc and the University of Utah Research Foundation ('Myriad'). At the trial-court level, all of the claims were held to be patent-ineligible on summary judgment: *Association for Molecular Pathology v US Patent & Trademark Office*, 702 F Supp 2d 181, 220–37 (SDNY 2010) ('Myriad I').

On appeal, in a split decision, the US Court of Appeals for the Federal Circuit ('Federal Circuit') reversed in part, finding all of the isolated DNA composition claims, as well as one method claim directed to screening potential cancer therapies based upon changes in the growth rates of transformed cells, to be patent-eligible: *Association for Molecular Pathology v US Patent & Trademark Office*, 653 F 3d 1329, 1358 (Fed Cir 2011) ('Myriad II'). The Federal Circuit also found one set of method claims directed to identifying cancer-predisposing mutations by analysing or comparing a patient's DNA sequence to a normal sequence to be patent-ineligible.

On petition for *certiorari* for the first time, the US Supreme Court summarily vacated *Myriad II* and remanded the case to the Federal Circuit to be reconsidered in light of its recent



decision in *Mayo Collaborative Services v Prometheus Laboratories, Inc*, 132 S Ct 1289 (US 2012): *Association for Molecular Pathology v Myriad Genetics, Inc*, 132 S Ct 1794 (US 2012) ('*Myriad III*'). In *Mayo*, the Supreme Court invalidated certain blood testing method claims directed towards diagnosing and treating a disease, finding that the subject method claims impermissibly claimed unpatentable laws of nature.

In its 2012 decision on remand, the same Federal Circuit panel issued another split decision. The Federal Circuit's decision on remand generally mirrored its original decision finding all of the isolated DNA composition claims, as well as one method claim directed to screening potential cancer therapies based upon changes in the growth rates of transformed cells, to be patent-eligible. The panel also found that the Supreme Court's decision regarding method claims in *Mayo* had little impact on the issue of whether Myriad's composition claims were patent-eligible: *Myriad IV*; see generally Charles R Macedo, Michael J Kasdan and David P Goldberg 'Isolated Human Genes and Related Therapeutic Treatment Methods Held Patent-Eligible' (2013) 8 (2) *Journal of Intellectual Property Law & Practice* 96.

The Association for Molecular Pathology once again filed a petition for *certiorari*, which the US Supreme Court granted solely as to the question: '[a]re human genes patentable?' *Association for Molecular Pathology v Myriad Genetics, Inc*, 133 S Ct (US 2012). Thus, only composition claims were the subject of the appeal. The Federal Circuit's ruling on the method claim was left standing.

The US Supreme Court heard arguments in the case on 15 April 2013, and a decision was issued on 13 June 2013.

Analysis

In the current decision (*Myriad V*), after laying out the facts of the case, the US Supreme Court undertook an unexpectedly short analysis of whether Myriad's patents claimed 'naturally occurring phenomena'. Justice Thomas, writing for a unanimous court, reframed the issue presented as follows: It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. Instead, Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13. The question is whether this renders the genes patentable.

In answering this question, the court applied distinctions set forth in two earlier decisions that establish the boundaries of patent-eligible compositions of matter.

In *Diamond v Chakrabarty*, 447 US 303 (1980), 'scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil'. This invention was patent-eligible because it did not claim 'a hitherto unknown natural



phenomenon' but 'a nonnaturally occurring ... composition of matter—a product of human ingenuity "having a distinctive name, character [and] use".' However, in *Funk Brothers Seed Co v Kalo Inoculant Co*, 333 US 127 (1948), the patent applicant mixed different naturally occurring strains of nitrogen-fixing bacteria to create a single inoculant that helped crops improve soil nitrogen levels. This invention 'was not patent eligible because the patent holder did not alter the bacteria in any way'.

From the court's perspective, because 'Myriad did not create anything' but just 'found an important and useful gene', Myriad's invention was less like the patent-eligible invention in *Chakrabarty*, which was a product of human ingenuity, and more like the patent-ineligible invention in *Funk Brothers*, which retained the properties of a naturally occurring phenomenon. The court explained that, even though Myriad isolated DNA from the human genome, 'separating that gene from its surrounding genetic material is not an act of invention' that necessarily creates a non-naturally occurring molecule. This is because Myriad's claims 'understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes', not on 'the specific chemical composition of a particular molecule'.

By way of contrast, the court stated that 'cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments'. This is because 'the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but is distinct from the DNA from which it was derived.' Accordingly the court opined that Myriad's patent claims directed to cDNA were patent-eligible under 35 USC § 101. The court added that an exception might exist where the DNA sequence is so short that there are 'no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.'

In reaching these conclusions, the court pointed out that 'this case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes' and indicated that many of Myriad's unchallenged patent claims 'are limited to such applications' and thus are patent-eligible.

Finally, the court also specifically noted that it did not consider, and has no opinion on, 'the patentability of DNA in which the order of the naturally occurring nucleotides has been altered'.

Justice Scalia issued a separate opinion concurring in the judgment while reserving his opinion on the finer points of molecular biology discussed therein.

Practical significance

While, on the one hand, *Myriad V* overturns decades of patent office practice by holding that composition claims directed merely to isolated, naturally occurring human DNA sequences are not patent-eligible, *Myriad V* also offers guidance on how inventions



related to discoveries of useful DNA sequences can be patent-eligible subject matter. *Myriad V* identifies composition claims to cDNA, which necessarily includes manipulated DNA sequences, as one way to protect such inventions. *Myriad V* also identifies, as another road to patent eligibility, method claims to new applications of knowledge about identified genes.

Thus *Myriad V* seeks to implement the court's policy concerns to preserve a patentee's ability to protect practical applications of discoveries, like the link between BRCA1 and BRCA2 genes to breast cancer, without granting patentees excessively broad protection that precludes the use of important 'handiworks of nature' from further scientific research and other applications. This may be the last round in the *Myriad* litigation but, no doubt, as uncertainty and sharply divided opinions on patent eligibility continue to percolate through the courts, *Myriad V* will not be the final decision of the US Supreme Court on patent eligibility.

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