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U.S. Court Again Upholds Myriad Isolated DNA Claims

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On August 16, 2012, just four weeks after it heard **oral arguments**, the U.S. Court of Appeals for the Federal Circuit issued its second decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.* (the ACLU "gene patenting"/BRCAI case). Once again, all judges on the three-judge panel agree that the diagnostic method claims based on "comparing" or "analyzing" DNA sequences are not patent-eligible and that the drug screening method claim is patent-eligible. The majority holds that all of the "isolated DNA" claims are patent-eligible, including those encompassing genomic DNA. Judge Bryson once again dissented with regard to the genomic DNA claims, but agreed with the majority that the cDNA claims satisfy 35 USC § 101.

Background

This case stems from Myriad's appeal of the March 29, 2010 summary judgment decision of the U.S. District Court for the Southern District of New York that invalidated the challenged claims in seven Myriad patents as patent-ineligible under 35 USC § 101. The Federal Circuit issued its first decision in this case on July 29, 2011, and the ACLU sought review by the U.S. Supreme Court. After the Supreme Court issued its decision in ***Mayo v. Prometheus***, it granted certiorari in *Myriad*, vacated the July 29, 2011 decision, and remanded the case to the Federal Circuit for reconsideration in view of *Mayo*. The Federal Circuit accepted supplemental briefing on remand, and heard **oral arguments** on July 20, 2012.

The Decision On Remand

The same three-judge panel heard the case on remand, and the judges reached essentially the same results on the interpretation of 35 USC § 101. Once again, Judge Lourie wrote the opinion for the court, Judge Moore concurred in the result, and Judge Bryson concurred in part and dissented in part.

Isolated DNA Composition Claims Are Patent-Eligible

On the merits, the majority holds that Myriad's composition claims directed to "isolated" DNA molecules are directed to subject matter that can be patented under 35 USC §101. Judge Lourie summarizes the majority decision as follows:

> The isolated DNA molecules before us are not found in nature. They are obtained in the laboratory and are man-made, the product of human ingenuity. While they are prepared from

> products of nature, so is every other composition of matter. All new chemical or biological molecules, whether made by synthesis or decomposition, are made from natural materials.

Citing the Supreme Court's decisions in *Chakrabarty* and *Funk Brothers* as setting forth a "markedly different test" for distinguishing patent-eligible compositions from patent-ineligible products of nature, Judge Lourie explains that isolated DNA molecules satisfy this test because they "have a distinctive chemical structure and identity . . . from those found in nature." Although Judge Lourie makes clear that the court's decision holds that "all of the claimed isolated DNAs" satisfy § 101, he emphasizes that the claimed cDNA molecules "are especially distinctive" because they "lack[] the non-coding introns present in naturally occurring chromosomal DNA," and so "are even more the result of human intervention into nature and are hence patent-eligible subject matter."

Judge Bryson concurs with this aspect of the majority decision as it relates to the cDNA claims only.

Diagnostic "Analyzing" Claims Are Not Patent-Eligible

The court characterizes Myriad's diagnostic method claims as consisting of "analyzing and comparing certain DNA sequences." The court finds those claims to be "indistinguishable from the claims the Supreme Court found invalid under § 101 in *Mayo*," and finds that they are "only directed to the abstract mental process of comparing two nucleotide sequences." Thus, the court again holds those claims to be not patent-eligible.

All judges joined in this part of the decision.

Drug Screening Claims Are Patent-Eligible

The court characterizes the drug screening method claim as being directed to a method that comprises the steps of:

1. growing host cells transformed with an altered BRCA1 gene in the presence or absence of a potential cancer therapeutic,
2. determining the growth rate of the host cells with or without the potential therapeutic and
3. comparing the growth rate of the host cells

The court notes that the method uses transformed host cells, which are not naturally occurring, but which "are derived by altering a cell to include a foreign gene, resulting in a man-made, transformed cell with enhanced function and utility." This fact ensures that this claim satisfies § 101:

> [O]nce one has determined that a claimed composition of matter is patent-eligible subject matter, applying various known types of procedures to it is not merely applying conventional steps to a law of nature. The transformed, man-made nature of the underlying subject matter in claim 20 makes the claim patent-eligible. The fact that the claim also includes the steps of determining the cells' growth rates and comparing growth rates does not change the fact that the claim is based on a man-made, non-naturally occurring transformed cell—patent-eligible subject matter.

All judges joined in this part of the decision.

Judge Moore's Concurrence-In-Part

Judge Moore characterizes the cDNA claims as presenting "the easiest analysis," because they "have a distinctive character and use, with markedly different chemical characteristics from either the naturally occurring RNA or any continuous DNA sequence found on the chromosome." With regard to other isolated DNA claims, she again states:

> If I were deciding this case on a blank canvas, I might conclude that an isolated DNA sequence that includes most or all of a gene is not patentable subject matter.

Nevertheless, she joins the majority decision because "Congress has, for centuries, authorized an expansive scope of patentable subject matter," and the USPTO "has allowed patents on isolated DNA sequences for decades."

Judge Bryson's Concurrence-In-Part and Dissent-In-Part

Judge Bryson explains in his opinion why he believes that the isolated DNA claims (other than the cDNA claims) are not directed to patent-eligible subject matter. Judge Bryson invokes the Supreme Court's analysis in Mayo:

> Just as a patent involving a law of nature must have an "inventive concept" that does "significantly more than simply describe . . . natural relations," Mayo, 132 S. Ct. at 1294, 1297, a patent involving a product of nature should have an inventive concept that involves more than merely incidental changes to the naturally occurring product. In cases such as this one, in which the applicant claims a composition of matter that is nearly identical to a product of nature, it is appropriate to ask whether the applicant has done "enough" to distinguish his alleged invention from the similar product of nature. Has the applicant made an "inventive" contribution to the product of nature? Does the claimed composition involve more than "well-understood, routine, conventional" elements? Here, the answer to those questions is no.

Looking Ahead

It is expected that at least the ACLU/plaintiffs will petition for certiorari at the Supreme Court. While the outcome of this Federal Circuit decision is not surprising, many will be relieved that the court maintained the status quo as we move one step closer to final resolution of the issues by the U.S. Supreme Court.

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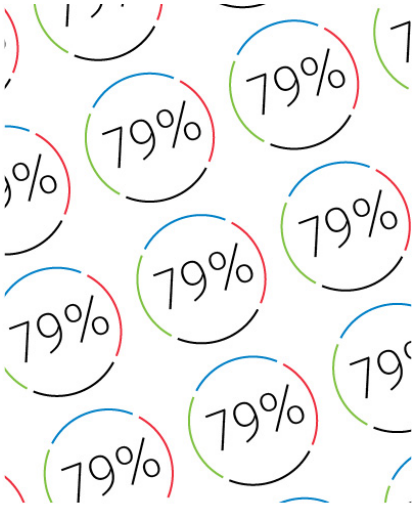

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