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Federal Circuit Decision in *Myriad Genetics* Confirms that Isolated Human DNA Molecules are Patentable

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INTRODUCTION

On July 29, 2011, the Federal Circuit issued its opinion in *Assoc. for Molecular Pathology et al. v. U.S. Patent and Trademark Office et al. (Myriad Genetics)*. The three-judge panel reversed the district court's denial of summary judgment and found that claims covering isolated DNA sequences are patentable subject matter under 35 U.S.C. § 101. The court held that because the isolated DNA molecules are chemically cleaved from native DNA, they have "markedly different" characteristics and therefore do not fall within the "products of nature" exception to § 101. In addition, the court ruled all but one of Myriad's method claims invalid, because they claim abstract mental processes involving merely "comparing" or "analyzing" gene sequences without any transformative step as required by *Prometheus*. Interestingly, the decision served as a rejection of arguments made by the government that genes should no longer be considered patentable subject matter—arguments that represented a clear departure from PTO practice over the last 30 years.

MYRIAD BACKGROUND

On May 12, 2009, a coalition of groups and individuals brought a declaratory judgment action against the U.S. Patent Office, Myriad Genetics, Inc. and the University of Utah Research Foundation over several U.S. patents with claims directed to the human genes BRCA1 and BRCA2. By some estimates 5-10% of women who develop breast cancer are likely to have a mutation in their BRCA1 or BRCA2 genes, and it has been estimated that women with one of these mutations can have an approximately 40-85% lifetime risk of developing breast cancer. These inherited mutations can also be an indicator of an increased risk of ovarian cancer. Genetic tests are available to determine if a person carries one of these mutations.

The district court issued an order on November 1, 2009, holding the association of plaintiffs could proceed with their action for declaratory judgment. On April 2, 2010, the court issued another order holding that each of the disputed claims encompassed non-patent-eligible subject matter under 35 U.S.C. § 101. The final judgment was entered on April 19, 2010, Myriad filed its appeal on June 16, 2010, and the Federal Circuit issued its opinion on July 29, 2011. Judge Lourie wrote the opinion for the majority, with Judge Moore writing a separate concurrence-in-part, and Judge Bryson concurring-in-part and dissenting-in-part.

JURISDICTION

Before turning to the merits, the court held that only one of the plaintiffs—Dr. Ostrer, a researcher at New York University—had standing to bring a declaratory judgment action. Dr. Ostrer stated unequivocally that he would immediately resume BRCA1/2 testing in the event of invalidation, and that he was ready, willing and able to perform that testing. The court found that Dr. Ostrer had therefore alleged a "controversy of sufficient reality and immediacy" to grant him standing to bring a declaratory judgment action under *Medimmune, Inc. v. Genentech, Inc.* 549 U.S. 118, 127 (2007).

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Notably, Dr. Ostrer announced in early July that he would be leaving his position at NYU for the Department of Genetics at the Albert Einstein Medical Center in the Bronx, effective August 2011. Because the plaintiffs have the burden to establish declaratory judgment jurisdiction, and this requirement continues from the time the complaint is filed through the appeals process, questions remain as to whether Dr. Ostrer will continue to have standing. Myriad raised this issue in a letter to the court on July 27, and Dr. Ostrer responded with a letter on July 29—the same day the opinion was announced—assuring the court that Einstein Genetics did in fact have the capability and motivation to begin immediate BRCA1/2 testing should the patents be invalidated. Myriad is likely to raise this issue either in a petition for rehearing en banc by the Federal Circuit, or in an immediate appeal to the Supreme Court.

COMPOSITION CLAIMS

Turning to the patentability of isolated DNA sequences, the Federal Circuit held that the claims to the BRCA1 and BRCA2 genes “are drawn to patentable subject matter because the claims cover molecules that are markedly different—have a distinctive chemical identity and nature—from molecules that exist in nature.” The court explained that, because the covalent bonds that connect the claimed DNA sequence must be “chemically cleaved” in order to isolate it, that act of human intervention “imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA.”

Judge Lourie, writing for the majority, rejected the dissent’s argument that, because the isolated DNA contains the same nucleotide sequence as the native DNA and therefore contains the same “information content,” it has no “markedly different” characteristics from native DNA. Instead, said Judge Lourie, “it is the distinctive nature of DNA molecules as isolated compositions of matter that determines their patent eligibility, rather than their physiological use or benefit.”

Finally, the court pointed out its “finding that isolated DNA molecules are patent-eligible comports with the longstanding practice of the PTO,” which had been issuing DNA molecule patents for over 30 years. Any changes to that practice, the court urged, should come from Congress, not the courts.

JUDGE MOORE’S CONCURRENCE AND JUDGE BRYSON’S DISSENT

In her concurrence, Judge Moore agreed that the claimed isolated DNA sequences are patentable, but disagreed with the majority on how the patentability of such DNA sequences should be determined. Federal Circuit precedent as outlined in *Chakrabarty and Funk Brothers*, Judge Moore explained, requires courts to analyze not only whether an isolated compound has “markedly different characteristics” from nature, but also whether those characteristics impart “a new utility” when compared to nature. Judge Moore pointed out that cDNA can be used as a primer in a diagnostic screening process to detect gene mutations, and that shorter gene sequences can be used as the basis for probes, but that longer strands of isolated DNA cannot be used for either. Therefore, she concluded, the structural and chemical differences in these full-length gene sequences “do not clearly lead to significant new utility as compared to nature.” Ultimately, Judge Moore found that settled expectations within the biotechnology industry, the longstanding PTO practice of granting patents with claims to isolated DNA, and the need for courts to defer to Congress combined to “tip the scales in favor of patentability” of human genes.

In his dissent, Judge Bryson stated that he would not allow isolated gene sequences to be patented simply because they are removed from native DNA. Judge Bryson urged that isolated BRCA1 and 2 are identical to the BRCA genes found in native DNA: “they have the same sequence, they code for the same proteins, and they represent the same units of heredity.” Analogizing to a leaf being snapped from a tree, Judge Bryson concluded that he would not find the mere extraction of BRCA1 and 2 sufficient to render them “markedly different” from native DNA.

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METHOD CLAIMS

Turning to the method claims, all three judges agreed that “all but one of Myriad’s claims are directed to patent-ineligible, abstract mental processes, and fail the machine-or-transformation test.” The court rejected Myriad’s argument that its methods of “comparing” or “analyzing” BRCA sequences satisfy the machine-or-transformation test as outlined in *Prometheus*, because each requires extracting and sequencing a human sample before the sequences can be analyzed. *Prometheus Laboratories v. Mayo Collaborative Services*, 628 F.3d 1347 (Fed. Cir. 2010), *certiorari granted* June 30, 2011, No. 10-1150. The court explained that the claims themselves do not include those steps, nor could the steps of “comparing” and “analyzing” be read to imply that “extracting” or “sequencing” need also be conducted. Thus, the claims did not recite any “transformative step” as required under the Federal Circuit’s reasoning in *Prometheus*. The court concluded that, since the process of comparing and analyzing could be “accomplished by mere inspection alone,” Myriad’s claims failed the machine-or-transformation test, and were instead directed to unpatentable abstract mental processes.

Finally, the court considered Myriad’s one remaining method claim, a method for screening potential cancer therapeutics via changes in cell growth rates. Although the claim was drawn to “comparing” the growth rate of host cells, it also included the steps of “growing” transformed cells in the presence or absence of a potential cancer therapeutic, and “determining” the cells’ growth rates. Because it found these steps to be “inherently transformative,” the court held that the claimed process covered patentable subject matter under § 101.

CONCLUSION

Myriad’s BRCA patents have been weakened somewhat by the invalidation of most of its method claims. But the court’s affirmation of the patentability of human genes represents a significant victory for both Myriad and those segments of the industry that rely upon protection of novel, isolated genes or sequences as part of their business model. With the profound impact this decision will have on the biotechnology industry, it is almost certain that further review will be sought, either before the en banc Federal Circuit or the Supreme Court, or both.

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