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June 17, 2013

Patent Eligibility Considerations Following the Supreme Court's *Myriad* Ruling

On June 13, 2013, the Supreme Court issued its long-awaited decision in *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, U.S., No. 12–398 (*Myriad*). In a unanimous opinion, the Court held that a naturally occurring DNA segment is a product of nature and therefore not patent-eligible, reversing, in part, the prior holding of the Federal Circuit (*Association for Molecular Pathology v. PTO*, 689 F.3d 1303 (Fed. Cir. 2012)). Additionally, the Court affirmed the Federal Circuit's finding that laboratory-created cDNA, which is not present in nature, is indeed patentable subject matter. In distinguishing patent-eligible subject matter from the natural phenomena it can be based on, the Supreme Court offered the biotechnology industry, and the patent community generally, some guidance about the susceptibility of patent claims to challenges under Section 101 of the Patent Act (35 U.S.C. §101) but failed to clarify its prior jurisprudence on the bounds of Section 101.

Technical and Procedural Background

Myriad Genetics, Inc. (Myriad) made a major breakthrough in the cancer screening industry when it identified the precise location and nucleotide sequences of the BRCA1 and BRCA2 genes. Mutation of these genes has been linked to hereditary breast and ovarian cancer. Using this discovery, Myriad designed medical screening tests to detect such mutations and obtained a number of related patents, three of which were before the Supreme Court.

Myriad's patent claims at issue relate to two types of DNA products. The first is isolated portions of the DNA code for the BRCA1 and BRCA2 genes. Other than the minor chemical changes that occur during the process of isolation of the claimed DNA sequences (as a result of severing the covalent bonds holding together the naturally occurring DNA), the claimed DNA code is identical to DNA in its natural state.

The second set of DNA products claimed in Myriad's patents are cDNA sequences. cDNA is a synthetic DNA molecule, which is made in a laboratory by allowing nucleotides to bind to an isolated mRNA molecule. The resulting cDNA contains certain parts of the code of the underlying DNA but is a different molecule and cannot be found in nature.

When deciding a declaratory judgment action seeking to invalidate Myriad's patents, the district court found Myriad's patent claims to isolated DNA and cDNA invalid in light of the Supreme Court's prior line of cases on patentable subject matter under Section 101. The Federal Circuit initially reversed the district court, but after a remand from the Supreme Court in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 556 U.S. __ (2012), the Federal Circuit affirmed in part and reversed in part, finding that both isolated DNA and cDNA are patent eligible under Section 101. The three judges on the panel each offered distinct rationales for their positions on isolated DNA. Judge Lourie found isolated DNA patentable because of the chemical alteration that takes place when severing the chemical bonds that hold together the DNA molecule. Judge Moore agreed that isolated DNA is patentable but relied instead on the Patent and Trade Office's (PTO) established practice of granting gene patents

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and the attendant reliance interests of patent owners. Judge Bryson dissented from the panel's finding on isolated DNA and concluded that isolated DNA is not patent-eligible, finding neither the chemical change nor the PTO policy dispositive. All three judges agreed that patent claims on cDNA meet the patent eligibility requirements of Section 101.

The Supreme Court's Decision

In its *Myriad* decision, the Supreme Court drew a sharp line between what it determined to be a "product of nature" ineligible for patent protection and the wide range of related inventions that may be entitled to patent protection. In doing so, the Court provided some limited direction to the patent community on how to draft patent claims that may involve eligibility issues, while failing to provide any meaningful guidance on the underlying inquiry of what is patent-eligible subject matter.

Isolated DNA Is Not Patent-Eligible …

In ruling that Myriad's DNA code claims were ineligible for patent protection, the Supreme Court made clear that policy considerations cannot trump its long-standing interpretation of Section 101, which excludes products of nature and abstract ideas from patentability. To be sure, there were persuasive policy reasons for affirming the Federal Circuit's determination of patent eligibility. Of perhaps the greatest significance, and the policy rationale most heavily relied on by Myriad, was the immense resources devoted to identifying and then sequencing the BRCA1 and BRCA2 genes. Nevertheless, the Supreme Court found that, "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry." Though Myriad urged a recognition of its extensive effort in the Court's patent eligibility analysis, the Court maintained that "extensive effort alone is insufficient to satisfy the demands of §101."

The other significant policy rationale considered by the Court was deference to the PTO's past practice of awarding gene patents — a rationale that Judge Moore of the Federal Circuit found persuasive. Myriad's BRCA1 and BRCA2 gene patents are only a few of the thousands of gene patents that the PTO has granted. The Supreme Court considered a prior instance of deference to PTO practice in the field of plant breed patents and indicated that such deference requires (or, at least, would be satisfied by) an endorsement of the views of the PTO by Congress in subsequent legislation. While Judge Moore found such endorsement in a reference to "patents on claims directed to or encompassing a human organism" in Congress's Consolidated Appropriations Act of 2004, the Supreme Court dismissed the cited language for failing to reference genes or DNA explicitly, further driving home the point that the Court will not be swayed by policy considerations when it comes to patent eligibility.

Notably absent from its opinion denying the eligibility of Myriad's patent claims was any clear direction from the Supreme Court on what exactly constitutes patent-eligible subject matter under Section 101. We have learned that isolation of DNA from the human genome, and the severing of chemical bonds that accompanies such isolation, is not enough to rise to the level of patent eligible subject matter. But the Supreme Court made clear that its ruling was a limited one, stating, "We merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material." The Court gave no further direction as to the requirements of Section 101. Indeed, the Court may even have left open the door for other types of isolated gene patent claims, pointing out that "Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA." Thus, the *Myriad* decision joins the Supreme Court's *Bilski v. Kappos,* 561 U.S. ___ (2010), and *Mayo v. Prometheus,* 566 U.S. ___ (2012), rulings in declaring patents ineligible under Section 101 but providing no significant guidance to the legal community regarding the limits of patent eligibility.

Such uncertainty regarding the application of Section 101 has caused confusion in the Federal Circuit, as evidenced in its recent *CLS Bank Int'l v. Alice Corp. Pty. Ltd*. (Fed. Cir., May 10, 2013) (en banc) decision. In *CLS Bank*, a divided Federal Circuit attempted to clarify the limits of computer software, splitting 5-5 to affirm the district court holding that several claims relating to methods for reducing risk in financial transactions were not directed to patent eligible subject matter under Section 101. We can expect to see the Federal Circuit continue to grapple with the limits of patent eligibility as appellants test the scope of the *Myriad* decision in the lower courts.

… But Many Other Claims Are Patent-Eligible

Though the Supreme Court foreclosed the possibility of patents that claim only isolated genes, the Court was quick to point out the narrow scope of its ruling and to direct inventors toward what is, or at least might be, patentable.

First, the Court explicitly ruled that the manufactured cDNA at issue in the case is patent-eligible. Though the cDNA is based on the genetic sequence of the original DNA, the Supreme Court determined that "the lab technician unquestionably created something new when cDNA is made." The Court's endorsement of cDNA as patent-eligible subject matter is of great significance in the biotechnology world. The industry is increasingly reliant on cDNA, rather than the underlying natural DNA structures, in genetic testing, and as such, is left with significant room for patent protection broad enough to cover its testing methodologies. (Though the Court did note that it expressed "no opinion whether cDNA satisfies the other statutory requirements of patentability," including Sections 102, 103 and 112 of the Patent Act.) Many current patents on DNA sequences also include claims to the types of synthetic DNA products that the Supreme Court sanctioned as patent-eligible, limiting the impact of the *Myriad* decision on such patents' strength. The Supreme Court also explicitly highlighted the modification of genetic code, making clear that its ruling did not address DNA in which the order of the naturally occurring nucleotides has been altered. Though the Court did not sanction modified code in the same manner it did cDNA, it did invite the biotechnology industry to seek patent protection in this field.

Additionally, the Supreme Court provided notable dicta on "what is *not* implicated by this decision," giving some insight into the types of claims that may withstand Section 101 scrutiny despite their basis in discoveries of natural phenomena or abstract ideas. One such example is that of method claims. The Supreme Court suggested the possibility of a patent on "an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes." Similarly, the Supreme Court pointed to the potential for patenting applications for the knowledge developed in discovering underlying ineligible information, pointing specifically to such claims in the Myriad patents — claims that were unchallenged in the litigation. The Court called attention to Judge Bryson's observation, from his dissent-in-part in the Federal Circuit decision, that a party that is the first to make a significant discovery is "in an excellent position to claim applications of that knowledge." In this dicta, the Court implicitly blessed patent claims addressing breakthroughs regarding products of nature or abstract ideas where the claims somehow manipulate that knowledge through a method or application. Accordingly, patent holders whose patents contain such claims have reason to remain confident in the strength of their patents post-*Myriad* — and those whose patents lack such claims may seek reissue of claims with broad language to direct them narrowly to patent-eligible subject matter.

The Response by the Patent Office

Within hours of the *Myriad* decision, Andrew Hirshfeld, deputy commissioner of the PTO, issued a memorandum to the Patent Examining Corps, providing preliminary guidance on the decision. Hirschfeld directed examiners to "now reject product claims drawn solely to naturally occurring

nucleic acids or fragments thereof, whether isolated or not," and explained that "[c]laims clearly limited to non-naturally-occurring nucleic acids … remain eligible." The memorandum closes with an assurance that the PTO "will issue more comprehensive guidance on patent subject matter eligibility determinations" — something which, although nonbinding on the courts, may be instructive to both patent prosecutors and patent litigators in advising their clients on the bounds of patentability.

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