26 STAN. L. & POL'Y REV. ONLINE 16
November 2, 2014

GENE PATENTING AFTER THE U.S. SUPREME COURT DECISION—DOES *MYRIAD* MATTER?

Robin Feldman*

INTRODUCTION

The Supreme Court decision in the *Myriad*[1] gene patenting case was heralded by many as a major event.[2] After 30 years of patenting history, the Justices unanimously declared that isolated gene sequences are ineligible for patenting.[3] Despite the chorus of joy emanating from many corners, however, the question facing the biotechnology industry, and thus, ultimately, doctors and patients is whether the Supreme Court decision actually matters? This essay seeks to provide an answer, which depends not only on what was rejected by the Court, but also what survived.

The essay first provides basic context on the doctrine of patentable subject matter and other recent Supreme Court cases in this arena. The second part describes the invention covered by the patent in the *Myriad* and explains what was decided in the Supreme Court decision. The third part describes the potential impact of *Myriad* on the biotechnology industry, focusing on what was *not* decided in the Supreme Court's pronouncements. Finally, the last section examines the Supreme Court's whisper in a footnote of the *Myriad* decision and suggests that although key patents claims survived *Myriad,* many of these may ultimately fail under obviousness doctrines.

---

* Harry & Lillian Hastings Professor of Law, and Director of the Institute for Innovation Law, University of California Hastings College of the Law. I am deeply indebted to Glenn Cohen for his gracious comments on prior drafts and to Alana Canfield Mannage for invaluable research assistance.

1. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. __, 133 S. Ct. 2107 (2013).

2. Lawrence O. Gostin, *Who Owns Human Genes? Is DNA Patentable?* J. AM. MED. ASS'N., Aug. 28, 2013, at 791-92.

3. *See generally Myriad*, 133 S. Ct. 2107.

I. PATENTABLE SUBJECT MATTER

Myriad concerned whether isolated gene sequences constitute the type of subject matter that may be eligible for a patent. The Constitution grants Congress the power to grant patents in order to "promote the progress of . . . the useful arts,"[4] and § 101 of the Patent Act provides for patents in new and useful processes, machines, manufactures, or compositions, as well as improvements on those.[5] Early in the nation's patent law history, the Supreme Court identified certain types of inventions that are not subject to protection under § 101 of the Patent Act. These include abstract ideas, laws of nature, and natural phenomena.[6] The Court has noted that these areas provide "the basic tools of scientific and technological work,"[7] and are the "building blocks of human ingenuity."[8] Thus, the Court found that granting patents on things that fall within these subject matter areas would threaten to preempt use of such building blocks throughout entire fields of endeavor.[9]

It is important to note that *Myriad* is only one paragraph of a long conversation between the Supreme Court and the Federal Circuit—the centralized federal appeals court charged with deciding patent cases—about what is patentable and what the proper legal tests should be. *Myriad* was the third in a quartet of cases on the topic, and it is always possible that more could follow. The first case related to business method patents—ways of going about doing something, such as one-click shopping. In that case, *Bilski*, the Supreme Court rejected the Federal Circuit's analysis of the question.[10] In one particularly stunning section of the opinion, the Supreme Court noted that, "Nothing in today's opinion should be read as endorsing interpretations of § 101 that the Court of Appeals for the Federal Circuit has used in the past."[11]

In other words, the Justices suggested they disagreed with everything the Federal Circuit had ever said about patentable subject matter in the Circuit's 30-year history.[12] The *Bilski* decision was not a model of clarity,[13] however, and the Supreme Court would have more to say as the line of cases unfolded.

---

4. U.S. CONST. art. 1, § 8.

5. 35 U.S.C. § 101 (2012).

6. *See* Alice Corp. Pty. v. CLS Bank Int'l., 134 S. Ct. 2347, 2354 (2014) (citing O'Reilly v. Morse, 15 How. 62, 112-20 (1854); Le Roy v. Tatham, 14 How. 156, 174-75 (1853)).

7. *Id.* (quoting Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. __, 133 S. Ct. 2107, 2116 (2013)).

8. *Id.* (quoting Mayo Collaborative Serv. v. Prometheus Labs., Inc., 566 US. __, 132 S. Ct. 1289, 1301 (2012)).

9. *Id.* at 2354-55.

10. Bilski v. Kappos, 561 U.S. 593, 612 (2010).

11. *Id.*

12. *See generally* Robin Feldman, *Coming of Age for the Federal Circuit,* 18 GREEN BAG (forthcoming 2014) (*available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id =2496763*)

The second case, more directly relevant to gene patenting, was *Mayo v. Prometheus*.[14] *Mayo* was a personalized medicine case about using the drug thiopurine to treat autoimmune diseases; specifically, different patients metabolize the drug differently and the patent holder determined correlations between metabolite levels and dosage levels so that physicians could pinpoint whether a particular patient's dose was too low such that it was likely to be effective or too high such that it risked harmful side effects. The Supreme Court found the diagnostic method unpatentable and again rejected the Federal Circuit's analysis.[15] The third was *Myriad*, which is discussed below. The final decision in the quartet was handed down this summer by the Supreme Court in the case of *Alice v. CLS Bank*.[16] In *Alice,* the Supreme Court considered a software patent on computerized escrow accounts. Focusing on pre-emption and analyzing the "inventive content," the Court ruled that one should ask whether steps added to an abstract idea were merely well-known and routine. Thus, this entire series of cases—including *Myriad*—must be understood in the context of the Supreme Court's deep and relentless skepticism about what the Federal Circuit has been deciding regarding patentable subject matter and the reasons the Federal Circuit has articulated for those decisions.

II. THE INVENTION IN *MYRIAD*

Myriad involved inventions related to gene mutations associated with certain forms of breast and ovarian cancer. The mutations are loosely referred to as the BRCA1 and BRCA2 mutations. Myriad, the patent holder, claimed an isolated piece of DNA with the nucleotide sequence of interest. The patent holder did not claim the sequence in its form in the human body. That, of course, would have been unpatentable as a product of nature. Rather, the patent holder claimed the relevant DNA sequences in a form outside the human body, isolated from the remainder of the cellular components.[17] *Myriad* also claimed cDNA. cDNA is essentially the mirror image of the DNA sequence, with the noncoding regions spliced out.

---

13. There were three separate opinions authored by the Justices, with Justice Kennedy delivering the opinion of the Court as to all but two sections for which Justice Scalia declined to join. For additional discussion of the *Bilski* decision and lack of clarity, see *id.;* Robin Feldman, *A Conversation on Judicial Decision-Making*, 5 HASTINGS SCI. & TECH. L.J. 1, 19-21 (2013).

14. Mayo Collaborative Serv. v. Prometheus Labs, Inc., 566 US. __, 132 S. Ct. 1289 (2012).

15. *Id*. at 1305.

16. Alice Corp. Pty. Ltd. v. CLS Bank Int'l., 134 S. Ct. 2347 (2014).

17. *Myriad*, 133 S. Ct. at 2111.

The Supreme Court ruled that DNA sequences are not patentable.[18] From the Court's perspective, isolated DNA sequences are the same as that which is found in nature and thus are unpatentable.[19] Myriad did not create nor did it alter the sequence. Thus, the company could not claim to have created "a new composition of matter." The Court swept aside what it considered a number of technical issues and looked at the problem in very simple terms: this is not new—therefore, it is not patentable.

In contrast to rejecting patenting of gene sequences, the Court ruled that cDNA is, at least in theory, patentable. Specifically, it survives the requirement of being the kind of thing that can be patented—"patentable subject matter," in patent law lingo—although it may not survive other requirements of the patent system. cDNA survives as patentable subject matter in the Justice's opinion because it is *not* what is found in nature, at least not ordinarily.

III. THE IMPACT OF *MYRIAD:* WHAT WAS NOT DECIDED

Although the case appeared revolutionary in scope, the practical impact is less clear. If patent holders can block access to much of what we care about in the lab, then denial of patenting for DNA may be a pyrrhic victory for those who would celebrate. In fact, this appears to be the case. Many of the activities in the lab today involve cDNA, rather than pure DNA sequences. Bacteria—which are the workhorses of the modern lab and provide the backbone for the process of recombinant DNA—need cDNA to operate, rather than the raw sequences.

Also undecided were issues related to the difference between purifying substances as opposed to creating something synthetically. For example, the Justices denied patentability for isolated DNA and approved patentability for cDNA—which they described as synthetically created DNA. They seemed unaware, however, that DNA itself can be constructed synthetically, rather than isolated, and did not indicate how that might viewed. Nor did the Justices clarify whether isolation resulting in a different substance might qualify.

In terms of what Myriad actually decided, the case appears to have had little impact on the biotechnology industry. Raising money is never easy, but companies appear to be adjusting smoothly. Recent US Patent and Trademark Office guidelines[20] certainly are causing heartburn in the antibiotics industry,

18. *Id*. at 2119.

19. *Id*. at 2111.

20. *See* U.S. PATENT AND TRADEMARK OFFICE, GUIDANCE FOR DETERMINING SUBJECT MATTER ELIGIBILITY OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE, NATURAL PHENOMENA, & NATURAL PRODUCTS (March 4, 2014) at 3-5 (using a balancing test to determine whether a claim recites something "significantly different" from a judicial exception to patentability). The long-term impact will depend on how examiners decide whether something is significantly different. It is entirely possible that different units of the USPTO and even different examiners may approach the question differently, creating uncertainties.

but public commentary underway may soften those pronouncements.[21] Most important, venture capitalists in Silicon Valley do not seem particularly wary of the Court's actions.

What the case decided, however, is only part of the story. A single patent can have many separate claims. To fully understand the implications of the decision, one also has to understand the Myriad claims that were *not* part of the Supreme Court decision. Some of these were decided by the Federal Circuit and not appealed by either party. All of them are important. First are the Diagnostic Claims. Specifically, Myriad claimed as part of its patent the method of determining whether a person is predisposed to the relevant form of breast cancer by comparing the person's gene sequence to the sequence in nature that codes for either BRCA1 or BRCA2. The Federal Circuit rejected those claims, and Myriad did not appeal.[22] The company's decision to forgo an appeal of these claims was most likely related to the *Mayo* decision discussed further below, in which the Supreme Court had rejected a somewhat similar set of diagnostic claims. It seems fairly clear under existing law that these kinds of claims are not patentable.

What did survive in the lower court's *Myriad* decision, however, were the research claims. The Federal Circuit upheld those claims, and the parties did not appeal, so the Supreme Court has yet to weigh in.[23] Myriad essentially claimed the method of determining whether a cancer therapeutic is effective. This method is described as growing cells carrying the mutation, both in the presence of and in the absence of the therapeutic agent, and comparing to see if one has a slower growth rate.

To many in the patient-access community, these are troubling claims.[24] The concept of testing a therapeutic against a drug target is well known, and it is not clear that the patent holder has provided anything. Critics of these patents would also argue that the patent holder is trying to control all potential therapeutic approaches without having identified a single one. The implication of upholding these kinds of claims is somewhat uncertain. It is doubtful one will see Myriad knocking on the door of researchers asking for a license or demanding that researchers cease and desist, although either is certainly possible. However, if successful therapeutics are developed, one could imagine Myriad appearing on the doorstep, arguing that developing the therapeutic must have infringed the patent, and demanding a percentage of the take.

---

21. *See* David M. Hoffmeister et al., *USPTO Rules Will Set Back Antibiotic Drug Development,* LAW360, May 23, 2014, *available at* http://www.law360.com/articles/541203/uspto-rules-will-set-back-antibiotic-drug-development (describing problems that the new USPTO rules pose for development of new antibiotics to treat drug-resistant bacteria).

22. *See* Ass'n Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329, 1355; *Myriad*, 133 S. Ct. at 2114.

23. *See Ass'n Molecular Pathology*, 653 F.3d at 1334.

24. *See* Gostin, *supra* note 2, at 792.

Finally, there are a number of other claims that were never challenged. These claims, therefore, survive the decision, but the future of similar claims remains quite uncertain unless or until the Federal Circuit and the Supreme Court review them. These and other variations will form the basis of claims drafting that others will use to get around the *Myriad* decision. For example, it is true that one can no longer claim a simple DNA sequence. However, much laboratory activity related to a particular DNA sequence involves a vector, such as bacterial DNA that has been altered in the lab to contain the desired sequence. This vector surely does not exist in nature and thus, a patent claim to such a vector would not directly contravene the *Myriad* decision. The same would be true for a particular type of cell that has been altered in the lab so that it contains the vector. In fact, long before the Supreme Court handed down its decision, patent practitioners were quietly acknowledging that they would be able to draft claims so that rejection of patenting the sequence itself would not matter.

IV. THE SUPREME COURT WHISPER

The practical effect of the Supreme Court's decision in *Myriad* remains unclear. The real question will be whether patent holders can succeed in upholding patents that control much of what one wants to do in the lab, despite the fact that they cannot control the raw sequence itself. From that perspective, the single most important sentence in the Supreme Court's *Myriad* decision is ironically buried in footnote nine. This footnote says simply, "[w]e express no opinion whether cDNA satisfies the other statutory requirements of patentability."[25] In other words, just because cDNA, and other lab creations that differ from nature, are within the realm of things that are considered the proper subject matter of a patent, this does not mean that any particular one will meet the full demands of patentability. The *Myriad* footnote was echoed in the USPTO's cover letter accompanying the recent guidelines, in which examiners were reminded that section 101 is not the sole test for determining patentability.[26]

The footnote language becomes key in light of other recent Supreme Court decisions. As described above, *Myriad* is only one moment in a long conversation between the Supreme Court and the Federal Circuit about patentable subject matter. Of particular importance in the series of cases is *Mayo*, the personalized diagnostics case in which the Supreme Court rejected the patent. In that case, once the Court had decided that the correlation identified was no more

25. *Myriad*, 133 S. Ct. at 2119 n.9.

26. *See* U.S. PATENT AND TRADEMARK OFFICE, *supra* note 20 (with cover letter stating that "[e]xaminers are reminded that section 101 is not the sole tool for determining patentability; where a claim encompasses a judicial exception such as a natural product, sections 102, 103, and 112 will provide additional tools for ensuring that the claim meets the conditions for patentability").

than a law of nature, the Court went on to conclude that everything else being done was just routine, well-understood, conventional activity.

In the same vein, one could conceivably argue that if the sequence is unpatentable, because it is a natural product, everything else that was created—including the cDNA, the vectors, etc.—is simply obvious in light of routine, well-understood, conventional activity. If so, cDNA, vectors, and the like would fail patentability as being obvious to one of ordinary skill in the art. This would require some blending of doctrines that patent law normally separates, but the logic is tantalizing. Will the Federal Circuit, or even the Supreme Court, ultimately agree? It remains to be seen, but *Myriad* and *Mayo* themselves do not squarely answer the issue, an uncertainty that pharma, biotech, and their investors must grapple with.

After the *Myriad* decision, one commentator noted that it must be the end of days when both the *Wall Street Journal* and the ACLU approve of a decision. And indeed, almost everyone seemed to be happy about the *Myriad* decision in some way. The life sciences industry is breathing a sigh of relief because many claims survived. Doctors' and patients' rights groups are happy because more breast cancer tests may now emerge. And those who think the patent system is out of control are happy because, once again, the Supreme Court has slapped down the Federal Circuit and narrowed patents. The only clear losers seem to be the holders of diagnostic patents like those of *Myriad*, but as discussed above, even they can take solace in some of the ways in which they can circumvent the decision.

Despite all of the trumpeting and celebration, however, the impact of the *Myriad* decision is not at all clear, in part because the Court's opinion was heavy on result but very short on broadly applicable reasoning. As a result, any real impact from *Myriad* will depend on how the Patent & Trademark Office and the courts interpret the notion of what should be considered routine, conventional activity. In other words, the legacy of *Myriad* will depend on whether anyone chooses to breathe life into the Supreme Court's whisper in footnote nine, as well as whether the courts find that the circumvention strategies outlined sufficient are too clever by half.