

Federal Circuit's Myriad Decision Reaffirms Patentability of Isolated DNA Sequences

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Summary of Opinion

On July 29, 2011, The U.S. Court of Appeals for the Federal Circuit decided [*Ass'n for Molecular Pathology v. Myriad Genetics, Inc. See No. 2010-1406*](#) (Fed. Cir. July 29, 2011). The case was an appeal from a district court summary judgment decision holding that all claims of patents held by Myriad Genetics, Inc. ("Myriad"), including claims directed to isolated DNA molecules, were invalid under 35 U.S.C. § 101 as patent-ineligible subject matter.

On the threshold issue of jurisdiction, the Federal Circuit affirmed district court's decision to exercise declaratory judgment jurisdiction, albeit on narrower grounds, by concluding that at least one Plaintiff had standing to challenge the validity of Myriad's patents because that Plaintiff had an actual and imminent plan to engage in potentially infringing activities.

On the merits, the Court held that Myriad's patent composition claims directed to "isolated" DNA molecules, whether limited to cDNAs or not, are directed to patent-eligible subject matter under 35 U.S.C. § 101. Thus, the Court reversed the district court's grant of summary judgment of invalidity under § 101. The Court also reversed the district court's decision that Myriad's method claims directed to screening potential cancer therapeutics is directed to patent-ineligible subject matter, holding that the claims were patent eligible because they contained "transformative steps." The Court, however, affirmed the district court's decision that Myriad's method claims directed to "comparing" and "analyzing" DNA sequences are patent ineligible because they include no transformative steps and instead cover only abstract, mental steps.

The Court's decision regarding claims directed to "isolated" DNA molecules followed Supreme Court precedent in construing § 101 language broadly. See 35 U.S.C. § 101; *Myriad*, slip op. at 36 (citation omitted) ("In choosing such expansive terms . . . modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."). Notably, in deciding the patentability of Myriad's method claims, the Court employed the "machine-or-transformation" test as a means by which to determine statutory subject matter under § 101 in light of *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). See also *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1350 (Fed. Cir. 2010).

Background of Proceedings

Plaintiffs sought a declaration that fifteen claims from seven patents assigned to Myriad are drawn to patent-ineligible subject matter under 35 U.S.C. § 101. Three categories of claims were considered:

(1) composition claims directed to “isolated” human genes *BRCA1* and *BRCA2* (collectively “*BRCA*”) and certain mutations in those genes that correlate with a predisposition to breast and ovarian cancers; (2) method claims directed to “analyzing” or “comparing” a patient’s *BRCA* sequence with the normal, or wild-type, sequence to identify the presence of cancer-predisposing mutations; and (3) a method claim directed to a method of screening potential cancer therapeutics by growing cells, detecting the rate of growth, and comparing rates of cell growth in the presence or absence of a potential cancer therapeutic.

On March 29, 2010, Judge Robert W. Sweet of the United States District Court for the Southern District of New York issued a summary judgment opinion invalidating all of the composition of matter claims directed to *BRCA1* and *BRCA2*, as well as all of the method claims, under 35 U.S.C. § 101. See *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

As to the threshold question of jurisdiction, the district court held that Plaintiffs, including several doctors and scientists seeking to perform clinical *BRCA* testing and patients unable to gain access to affordable *BRCA* testing, had established Article III standing under the “all the circumstances” test. Thus, they were able to bring a declaratory judgment suit challenging the validity of Myriad’s patents. *Id.* at 390-91.

On the merits, the district court held that the challenged composition claims were drawn to non-patentable subject matter because the isolated DNA molecules fall within the judicially created “products of nature” exception to § 101. The district court held that isolated DNA molecules are not “markedly different” from native DNA molecules. *Id.* at 222, 232. The court focused on the fact that DNAs are the “physical embodiment of information,” and that this information is preserved in the isolated DNA molecules and is essential to their utility as molecular tools. *Id.* at 222-32.

With respect to the method claims, the district court held them all patent-ineligible under the machine-or-transformation test.¹ *Id.* at 233. The court held that the “analyzing” and “comparing” claims covered mental processes independent of any physical transformations. *Id.* at 233-35. Likewise, the court held that the one method claim “comparing” the growth rate of cells claimed a basic scientific principle without a necessary transformative step. *Id.* at 237.

Myriad appealed the district court’s decision on all grounds.

Declaratory Judgment Jurisdiction

In affirming the district court’s finding of standing, the Federal Circuit applied *MedImmune’s* “all the circumstances” test to a declaratory judgment action. See *Myriad*, slip op. at 25; see also *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 S.Ct. 764 (2007). The Court applied a three-part framework (standing, ripeness, mootness) for determining whether a constitutional minimum of standing was met in this case. See *Myriad*, slip op. at 25. The Court concluded that one Plaintiff—a doctor who stated his intention to “actually and immediately engage in allegedly infringing *BRCA*-related activities”—had established standing to maintain a declaratory judgment suit. *Id.* at 27-28. In contrast, the Court held that two other doctors who only stated that they would “consider” resuming *BRCA* testing do not have standing, holding that “some day intentions” are insufficient to support an “actual or imminent” injury for purposes of standing. *Id.* at 30-31.

The Court declined to consider jurisdiction with respect to the patients, but noted that it “fail[s] to see how the inability to afford a patented invention could establish an invasion of a legally protected interest for purposes of standing.” *Id.* at 27.

Accordingly, the Court affirmed declaratory judgment jurisdiction on narrower grounds than the district court. *Id.* at 35.

“Isolated” DNA Molecules Are Statutory Patentable Subject Matter

The Court applied a framework based on two Supreme Court’s decisions, *Chakrabarty* and *Funk Brothers*, in deciding the patent eligibility of isolated DNA molecules. See *Diamond v. Chakrabarty*, 447 U.S. 303, 100 S.Ct. 2204 (1980); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 68 S.Ct. 440 (1948). The Court contrasted the two decisions: in *Chakrabarty*, the man-made bacteria qualified as patentable subject matter because it was a non-naturally occurring manufacture or composition of matter; whereas in *Funk Brothers*, the bacteria was a mixture of naturally occurring inoculants and thus unpatentable. *Chakrabarty*, 447 U.S. at 309-10; *Funk Bros. Seed Co.*, 333 U.S. at 132. The Court focused on the distinction between a product of nature and a human-made invention in its § 101 analysis. It stated that “the Supreme Court has drawn a line between compositions that, even if combined or altered in a manner not found in nature, have similar characteristics as in nature, and compositions that human intervention has given ‘markedly different,’ or ‘distinctive,’ characteristics.” *Id.* at 41 (citation omitted).

Applying this framework to the isolated DNA molecule claims, the Court found that isolated DNA is a free standing portion of the native DNA molecule that has been cleaved to “consist of just a fraction of a naturally occurring DNA molecule.” *Id.* at 42. The Court stated that *BRCA1* and *BRCA2* in their isolated states are “not the same molecules as DNA that exists in the body; **human intervention** in cleaving or synthesizing a portion of a native chromosomal DNA **imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA.**” *Id.* at 42 (emphasis added).

Significantly, the Court disagreed with Plaintiffs’ argument that the native and isolated DNA molecules are the same because they retain the same nucleotide sequence. Instead, the Court pointed out that “it is the distinctive nature of isolated DNA molecules as isolated compositions of matter that determines their patent eligibility rather than their physiological use or benefit.” *Id.* at 44. In fact, the Court stated that the informational content of DNA molecules is “irrelevant.” *Id.* at 45. Therefore, the Court held that “isolated” DNA molecules are drawn to patentable subject matter because such claims “cover molecules that are markedly different—have a distinctive chemical identity and nature—from molecules that exist in nature.” *Id.* at 41.

The Court articulated that its decision comports with the long-standing practice of the PTO, which has allowed patents directed to DNA molecules for almost three decades. *Id.* at 47-48. The Court further noted the “settled expectation of the inventing community” and stated that, should DNA inventions be excluded from the broad scope of § 101, it must come from Congress, not the courts. *Id.* at 45.

Methods of “Comparing” And “Analyzing” Sequences Are Not Statutory Patentable Subject Matter

Turning to Myriad’s challenged method claims, the Court concluded that the method claims directed “comparing” and “analyzing” sequences fall outside the scope of § 101 because they claim only abstract mental processes and fail to satisfy the machine-transformation test. *Id.* at 49-50. Noting that the Supreme Court’s *Bilski* decision rejected the “machine-or-transformation” test as the

exclusive test for determining patent eligibility of processes, the Court nevertheless used it as an “important clue” in deciding patentability. *Id.* at 49 citing *Bilski*, 130 S. Ct. at 3227.

The Court held that these claims were abstract mental steps because they claimed a “method for screening a tumor sample” by comparing a first *BRCA* sequence with a second *BRCA* sequence. The Court rejected Myriad’s attempt to read in transformative steps, such as extracting DNA or sequencing DNA, because they were not recited as part of the claims. The Court held that the claims fail to specify any action prior to the step of “comparing” or “analyzing” two sequences, and only recite the step of comparing two different sequences. *Myriad*, slip op. at 50-51. Thus, the Court distinguished these claims from claims that recite an **application** of a formulation or abstract idea. In particular, the Court distinguished the claims from those upheld under § 101 in *Prometheus*, where additional steps were found to be transformative and central to the purpose of the claims. *See id.* at 51-52, *see also Prometheus*, 628 F.3d at 1357. Directed to the abstract mental process of comparing two nucleotide sequences, Myriad’s claims failed to claim a patent-eligible process under § 101.

Methods of Screening Potential Cancer Therapeutics Are Statutory Patentable Subject Matter

In contrast, the Court found the remaining sole method claim for screening potential cancer therapeutics via changes in cell growth rate to be patent eligible because it includes a transformative step. Specifically, the claims comprise the steps of (i) “growing” host cells transformed with *BRCA* in the presence or absence of a cancer therapeutic, (ii) “determining” the growth rate of the host cells, and (iii) “comparing” the growth rate of the host cells. *Id.* at 53. The Court concluded that these steps included “more than the abstract mental step of looking at two numbers and ‘comparing’ two host cells’ growth rates.” *Id.* at 53. In particular, the Court found the step of “growing the cells” to be an “inherently transformative step involving the manipulation of the cells and their growth medium.” *Id.* at 53. The step of “determining” the cells’ growth rate was likewise found to involve physical manipulation of cells and one that is “central to the purpose of the claimed process.” *Id.* Accordingly, this claim was held to be patentable subject matter under § 101.

A Divided Court

The Court’s decision was not unanimous. The Court consisted of a three-judge panel, with Judge Lourie authoring the Court’s opinion, Judge Moore authoring an opinion concurring in part, and Judge Bryson authoring an opinion concurring in part and dissenting in part. As used herein, Judge Lourie’s decision will be referred to as the “majority,” Judge Moore’s opinion as the “concurrence,” and Judge Bryson’s opinion as the “dissent.”

The panel was unanimous with respect to the standing issue and the method claims. The differences in opinion were limited to the claims directed to isolated DNA molecules. For purposes of the Court’s opinions, DNA molecules consist of two different types of molecules: (1) complementary DNA (“cDNA”), *i.e.*, sequences of DNA that do not exist in nature and are synthesized from messenger RNA using complementary base pairing; and (2) isolated DNA molecules that include naturally occurring DNA sequences. The majority held both of these to be patent-eligible subject matter. With respect to cDNA sequences, the panel was in agreement that cDNAs, because they are man-made and do not exist in nature, are patent-eligible subject matter.² The Court, however, diverged with respect to isolated DNA molecules consisting of naturally occurring sequences.

The concurrence, like the majority, analyzed the issue in the context of *Chakrabarty* and *Funk Brothers*. The concurrence, however, emphasized utility as an overriding factor in determining

patentability, *i.e.*, whether isolated DNA molecules have the “potential for significant utility” that is different from that of DNA molecules found in nature. *Myriad*, slip op., *concurrency-in-part* at 7.

The concurrence also emphasized the “chemical considerations” of the patentability of DNA molecules, such as the fact that isolated and natural DNA molecules have different chemical structures and different chemical connections. Therefore, “a fragment of a DNA sequence has different properties than the parent molecule from which it is derived.” *Id.* at 8-9. The concurrence found that isolated DNA molecules “are truncations . . . of the naturally occurring DNA found as part of the chromosome in nature, are not naturally produced without the intervention of man.” *Id.* at 15.

In its opinion, however, the concurrence distinguished between “short” and “long” isolated DNA molecules. Short isolated DNA molecules were described as shorter DNA segments, such as primers and probes. “Long” isolated DNA molecules were described as longer sequences, such as genes and gene fragments. The concurrence concluded that short isolated DNA molecules, such as primers and probes, “have a variety of applications and uses in isolation that are new and distinct as compared to the sequence as it occurs in nature.” *Id.* Thus, the concurrence concluded that the short isolated DNA molecules were an enlargement of the utility found in nature. Therefore, short isolated DNA molecules are patent-eligible subject matter. *Id.* at 16.

The concurrence stated that long isolated DNA molecules, such as genes and gene fragments, were “a much closer case.” *Id.* at 17. In particular, the concurrence concluded that large isolated DNA molecules “do not clearly lead to significant new utility as compared to nature,” but rather appear to serve the same function as natural DNA in encoding proteins. *Id.* at 18. Notably, the concurrence stated that: “[i]f 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.” *Id.* at 18. Ultimately, however, the concurrence concluded that long isolated DNA molecules are patent-eligible subject matter, primarily because of substantial historical precedent recognizing the expansive scope of patentable subject matter, the PTO’s long standing policy of allowing patents on isolated DNA sequences, and the settled expectations of the biotechnology industry. *Id.* at 18-19. The concurrence determined that holding otherwise would be a “fundamental alteration in the scope of patentable subject matter” that would “risk destroying the legitimate expectations of inventors in their property.” *Id.* at 21 (citation omitted). Moreover, the concurrence noted the broad scope of § 101 and determined that it was Congress that should decide whether any changes in scope were necessary.

In contrast, the dissent found that isolated DNA sequences were patent-ineligible subject matter. The dissent found that “isolated genes are not materially different from the native genes” and that “extracting a gene is akin to snapping a leaf from a tree.” See *Myriad*, slip op. *dissenting-in-part* at 6, 10. Simply plucking the leaf, or plucking the isolated DNA sequence, does not make it a man-made invention nor does it impart “markedly different characteristics” from those that occur in nature. *Id.* at 10.

With respect to the potential use of isolated DNA molecules that are different from uses found in nature, the dissent concluded that such uses did not render DNA patent eligible because “the use to which the genetic material can be put . . . is not a new use; it is only a consequence of possession.” *Id.* at 13. Thus, according to the dissent, isolated DNA molecules do not alter the naturally occurring genetic material in a way that satisfies the patentability test of *Chakrabarty*. *Id.*

The dissent criticized the majority’s and concurrence’s reliance on precedent and longstanding PTO policy. In particular, the dissent noted that the government argued in this case that cDNA, but not isolated DNA containing naturally occurring DNA sequences, was patent-eligible subject matter.

Moreover, the dissent concluded that relying on PTO policy in deciding the issue was tantamount to giving the PTO lawmaking power. *Id.* at 17-19. The dissent also expressed concern that continuing to allow the patentability of isolated DNA molecules would hinder scientific progress and may preempt scientific discovery and innovation, such as methods for whole-genome sequencing. *Id.* at 2.

Conclusion

The *Myriad* decision confirms that, in light of *Chakrabarty*, composition claims directed to isolated DNA sequences are patent-eligible subject matter under 35 U.S.C. § 101. In contrast, method claims of analyzing and comparing nucleotide sequences, without more, are not patent-eligible subject matter under § 101. The decision provides guidance regarding the Federal Circuit's reliance on "distinctive" characteristics in determining the patent eligibility of composition claims, the continued use of the machine-or-transformation test after *Bilski*, and how method of treatment claims will be analyzed in light of *Bilski* and *Prometheus*.

Given the importance of this legal issue to the biotechnology community and the divided nature of the decision, it is likely that the patentability of isolated DNA sequences will be the topic of further judicial consideration. It would not be surprising if this decision is reconsidered *en banc* and/or further appealed to the Supreme Court.



If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

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¹ The district court decision was made prior to the Supreme Court's *Bilski* decision.

² The dissent, although agreeing that cDNA is patent-eligible subject matter, concluded that certain of the cDNA claims at issue were invalid because they were overbroad. See *Myriad*, slip op., *dissenting-in-part* at 14-15.