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Federal Circuit Reaffirms Patentability of Isolated DNA Molecules in View of Supreme Court's Mayo v. Prometheus *Decision*

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INTRODUCTION

On August 16, 2012, the U.S. Court of Appeals for the Federal Circuit decided *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, No. 2010-1406, on remand from the Supreme Court to consider the impact of *Mayo Collaborative Services v. Prometheus, Inc.*, 566 U.S. ___, 132 S. Ct. 1289 (2012). As explained below, the Federal Circuit's ruling largely aligns with the same panel's previously vacated July 29, 2011 decision.

On the threshold issue of jurisdiction, the Court reaffirmed the district court's decision to exercise declaratory judgment jurisdiction because at least one Plaintiff had an intention to actually and immediately engage in allegedly infringing activities.

On the merits, the Court once again held— albeit in a fractured analysis —that Myriad's composition claims directed to "isolated" DNA molecules, whether limited to cDNAs or not, are 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 conclusion that Myriad's claimed method of screening potential cancer therapeutics is not patent-eligible subject matter because that method involves the creation of "transformed" host cells. 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 similar claims were held to be unpatentable in *Mayo*.

BACKGROUND

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 BRCA genes and 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 sequence to identify the presence of cancer-predisposing mutations; and (3) a method claim to "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 these 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). Before reaching the § 101 issue, the district court held that Article III standing existed under the Supreme Court's "all the circumstances" test, *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007), because the Plaintiffs, who included several doctors and scientists, were ready and able to perform clinical BRCA testing, but prevented from doing so. *Id*. at 390-91.

With respect to the § 101 issues, the district court held that the composition claims were drawn to nonpatentable "products of nature," noting that isolated DNA molecules are not "markedly different" from native DNA molecules. *Id*. at 222, 232. With respect to the method claims, the district court, pre-*Bilski*, held them all patent-ineligible under the now-overruled machine-or-transformation test because the claims covered mental processes independent of any physical transformations. *Id*. at 233-37.

In its initial July 29, 2011 decision on appeal, the Federal Circuit affirmed the district court's standing holding because one Plaintiff, a doctor, had stated his intention to "actually and immediately engage in allegedly infringing BRCA-related activities." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 653 F.3d 1329, 1344-47 (Fed. Cir. 2011). On the § 101 issues, the Federal Circuit reversed with respect to the composition claims, reasoning that isolated DNA are free-standing portions of native DNA molecules that are "not the same molecules as DNA as it exists in the body." *Id*. at 1351-52. With respect to the method claims directed to merely "analyzing" and "comparing" two DNA molecules, the Federal Circuit affirmed that they were not patentable because they claimed only abstract mental processes without any transformative step. *Id*. at 1355-56. By contrast, the Court found the method claim for "screening" potential cancer therapeutics via changes in cell growth rate to be patent eligible because it includes a "growing" transformative step. *Id*. at 1357-58.

After the Federal Circuit's initial decision, the Supreme Court issued its decision in *Mayo*, affirming that diagnostic methods that essentially claim natural laws are not eligible for patent protection. Following its decision, the Supreme Court granted certiorari in the *Myriad* case and vacated and remanded the Federal Circuit's decision for further consideration in light of *Mayo*.

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

The Court also 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 28 n.7.

"ISOLATED" DNA MOLECULES CONTINUE TO BE STATUTORY PATENTABLE SUBJECT MATTER

At the outset, the Court noted that, "[w]hile *Mayo* and earlier decisions concerning method claim patentability provide valuable insights and illuminate broad, foundational principles," they "do[] not control the question of patent-eligibility of" claims to isolated DNA molecules. *Id.* at 38, 42. As it did in its initial decision, the Court applied a framework based upon two Supreme Court decisions, *Chakrabarty* and *Funk Brothers*. *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, reasoning that "the Supreme Court has drawn a line between compositions that . . . have similar characteristics as in nature, and compositions that human intervention has given 'markedly different,' or 'distinctive,' characteristics." *Id*. at 44 (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 45. The Court stated that *BRCA1* and *BRCA2* in their isolated states are "different molecules from DNA that exists in the body" in that they involve "***human intervention*** to cleave or synthesize a discrete portion of a native chromosomal DNA, ***imparting on that isolated DNA a distinctive chemical identity as compared to native DNA***." *Id*. at 45 (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 48. In fact, the Court found the informational content of DNA molecules to be "irrelevant." *Id*. Therefore, the Court repeated its 2011 holding that "isolated" DNA molecules are drawn to patentable subject matter because such claims "cover molecules that are markedly different—have a distinctive chemical structure and identity—from those found in nature." *Id*. at 44.

The Court explained 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 53-55. The Court further noted the "settled expectation of the inventing and investing communities" and stated that, should DNA inventions be excluded from the broad scope of § 101, it must come from Congress, not the courts. *Id*. at 54.

METHODS OF "COMPARING" AND "ANALYZING" SEQUENCES ARE NOT STATUTORY PATENTABLE SUBJECT MATTER

Turning to Myriad's challenged method claims, the Court "renew[ed its] conclusion" that the method claims directed to "comparing" and "analyzing" sequences fall outside the scope of § 101 because they "claim only abstract mental processes." *Id*. at 56. The Court reasoned that, because the claims fail to specify any action prior to the step of "comparing" or "analyzing" two sequences, they recite only the step of comparing two different sequences. *Id.* at 58.

Unlike its analysis of the claims directed to isolated DNA molecules, the Court found these particular claims to be "indistinguishable" from those found to be unpatentable in the Supreme Court's *Mayo* decision. *Id*. Indeed, the Court noted that the method claims at issue "do not even include a *Mayo*-like step of 'determining' the sequence of BRCA genes by, *e.g.*, isolating the genes from a blood sample and sequencing them, or any other putatively transformative step." *Id.* at 59. As such, the Court found that these claims failed to claim a patent-eligible method under § 101.

METHODS OF SCREENING POTENTIAL CANCER THERAPEUTICS ARE STATUTORY PATENTABLE SUBJECT MATTER

In contrast, the Court—consistent with its previous decision—found the remaining sole method claim for screening potential cancer therapeutics via changes in cell growth rate to be patent-eligible. That claim required 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 60. The Court concluded that these steps include "more than the abstract mental step of looking at two numbers and 'comparing' two host cells' growth rates." *Id*. In particular, the Court found that the "'transformed' host cells[,] like the patent-eligible cells in *Chakrabarty*, are not naturally occurring." *Id*.

The Court also reasoned that this claim "does . . . more" than the claims found to be unpatentable in *Mayo*. Specifically, the claim "applies certain steps to transformed cells that, as has been pointed out above, are a product of man, not of nature." *Id.* at 60-61. In other words, "once 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." *Id.* at 61. Accordingly, this claim was held to constitute 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 (summarized above), 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. For the reasons explained above, 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.[1] The Court, however, diverged with respect to isolated DNA molecules consisting of naturally occurring sequences.

The concurrence, like the majority, found *Chakrabarty* and *Funk Brothers* to be "clearly more analogous" than *Mayo*. *Myriad*, slip op*., concurrence-in-part* at 7. 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. *Id.* at 4.

In its opinion, 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.* at 10. Thus, the concurrence concluded that the short isolated DNA molecules are patent-eligible subject matter. *Id.* at 12.

The concurrence stated that long isolated DNA molecules, such as genes and gene fragments, "present a more difficult case." *Id.* at 12. In particular, the concurrence concluded that large isolated DNA molecules "do[] not clearly have a new utility," but rather appear to serve the same function as natural DNA in encoding proteins. *Id*. at 13. 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*. Ultimately, however, the concurrence concluded that long isolated DNA molecules are patent-eligible subject matter primarily because of: (1) substantial historical precedent recognizing the expansive scope of patentable subject matter; (2) the PTO's long standing policy of allowing patents on isolated DNA sequences; and (3) the settled expectations of the biotechnology industry. *Id.* at 13-17. The concurrence determined that holding otherwise would constitute a "fundamental alteration in the scope of patentable subject matter" that would "'risk destroying the legitimate expectations of inventors in their property.'" *Id*. at 16 (citation omitted). The concurrence also noted the broad scope of § 101 and determined that it was Congress that should decide whether any changes in scope are necessary. *Id.* at 19-20.

In contrast, the dissent found that isolated DNA sequences were patent-ineligible subject matter. The dissent reasoned 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. In the dissent's view, simply plucking the leaf, or plucking the isolated DNA sequence, neither makes it a man-made invention nor imparts "'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 "[t]he 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.*

Moreover, although acknowledging that the Supreme Court's *Mayo* decision "does not decide this case," the dissent found the analysis in that case to be "nevertheless instructive." *Id.* at 14. Specifically, the dissent focused on *Mayo*'s requirement that claims "add 'enough' to the natural laws" to be considered patentable. Applying that test to the present case, the dissent reasoned that, because the claimed isolated DNA molecules are "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." *Id.* at 15. The dissent answered this question in the negative, concluding that "[t]he nucleotide sequences of the claimed molecules are the same as the nucleotide sequences found in naturally occurring human genes." *Id* at 16.

The dissent also 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 18-19.

CONCLUSION

The Federal Circuit's second *Myriad* decision holds, once again, that 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, particularly in light of the Supreme Court's *Mayo* decision.

The Court's most recent decision in the evolving area of patent-eligible subject matter continues to construe § 101 relatively broadly. Given the importance of this legal issue to the biotechnology community and the divided nature of the decision, it would not be surprising to see this case subjected to an *en banc* rehearing or even another grant of certiorari by the Supreme Court.

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[1] 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 16-19.