

Patents

Supreme Court Remand of *Myriad* Case Leaves Gene Patent Eligibility in Question

A week after its unanimous decision rejecting method claim patent eligibility, the U.S. Supreme Court on March 26 remanded to the U.S. Court of Appeals for the Federal Circuit a case testing whether patent claims on isolated DNA are patent-eligible subject matter (*Association for Molecular Pathology v. Myriad Genetics Inc.*, U.S., No. 11-725, remanded 3/26/12).

The high court granted the petition for writ of certiorari filed by the American Civil Liberties Union and the Public Patent Foundation on behalf of the Association for Molecular Pathology and other plaintiffs arguing that composition of matter claims of the patents on the BRCA1 and BRCA2 genes, which are associated with breast cancer, are ineligible for patenting under 35 U.S.C. § 101.

But the court simultaneously vacated the CAFC opinion that was generally favorable to the claims (5 LSLR 803, 8/12/11) and remanded the case for reconsideration in light of its decision in *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, No. 10-1150 (U.S., 3/20/12).

The court in *Mayo* held that method steps claimed by Prometheus Laboratories that involve measuring the level of certain metabolites in the blood of patients taking thiopurine drugs for autoimmune diseases encompass well-known activities and cannot transform a law of nature into a patent-eligible application of such a law (6 LSLR 284, 3/23/12; *see related item in this section*).

Attorneys and other experts contacted by BNA were divided on the effect the *Mayo* decision will have on what the CAFC will decide on remand in *Myriad*, named after patent-holder and co-defendant Myriad Genetics Inc. Some attorneys suggested that the CAFC will not change its original holding that isolated DNA and cDNA are patent-eligible, while others said that the CAFC will find the themes in the Supreme Court's *Mayo* decision very relevant in its reconsideration of *Myriad*.

Myriad's Attorney Discounts *Mayo's* Effect. The Supreme Court ruled in *Mayo* that "to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the

law of nature while adding the words 'apply it.' " It concluded that the steps of the method claims at issue in *Mayo* failed to "add enough" to the "inventive concept" of the asserted patents—the correlations between metabolite levels and effectiveness of a drug.

While the court provided no standards for determining when steps provide "enough," it indicated that the inventive concept must be embedded in the application rather than in the law of nature. The court said in *Mayo* that, as to the asserted claims, "any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately."

The plaintiffs/petitioners in *Myriad* found the Supreme Court's remand to signal that the CAFC will now find that *Myriad's* isolated DNA sequences are unpatentable.

The ACLU issued a press release immediately after the high court's order was announced. "In light of recent rulings from the court that mere laws of nature cannot be patented, we hope that the lower court will come to the correct conclusion this time around," said Chris Hansen, staff attorney with the ACLU Speech, Privacy and Technology Project. "It's inconceivable that a company can own a patent on something as naturally occurring as DNA."

However, *Myriad's* counsel Gregory A. Castanias of Jones Day, Washington, discounted the effect of the *Mayo* decision. "Method claims like those that were at issue in *Mayo* are often drafted in broad and abstract fashion, while our claims are drawn to specific compositions of matter," he told BNA March 26.

Second, "there is a long-standing history" of granting claims like those owned by *Myriad*, he said, citing the Patent and Trademark Office's 2001 Utility Examination Guidelines. "Isolation of the DNA molecules results in a human-made invention," he said. "Tens of thousands of patent claims are reliant on that interpretation."

"*Myriad's* claims are something fundamentally different than what was at issue in *Mayo*," Castanias said, predicting little or no impact of the decision on his case. "The composition of matter [claimed in *Myriad's* patents] never before existed. The public now has it available and can take advantage of it."

However, Jonathan Loeb in a Dechert LLP blog noted that Judge Allen Lourie's CAFC opinion in *Myriad* held that isolated DNA sequences are patentable because

“BRCA1 and BRCA2 in their isolated state are not the same molecules as DNA as it 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.” According to Loeb, “This ‘distinctive chemical identity’ test seems a slender reed now that the Supreme Court rejected the Federal Circuit’s holding in *Mayo* that the human interventions of ‘administering’ a drug and ‘determining’ its levels in the body conferred patentability to Prometheus’s claims.”

Effect of Myriad’s Isolated DNA Claims on Remand.

Howard W. Bremer of the Wisconsin Alumni Research Foundation told BNA that Myriad’s claimed methods of “comparing” or “analyzing” DNA sequences, which were unanimously held invalid as patent-ineligible by the CAFC, “are likely still dead in view of the *Mayo* decision.” However, he said, the method for screening potential cancer therapeutics that the CAFC upheld might still be upheld as patent-eligible because the Supreme Court’s reasoning in the *Mayo* decision is distinguishable for reasons given in Judge Pauline Newman’s opinion in the remand of *Classen Immunotherapies Inc. v. Biogen IDEC*, Fed. Cir., Nos. 2006-1634, 2006-1649, 9/12/11.

The most discussed issue concerning the *Myriad* remand is the extent to which *Mayo* can be applied to the composition of matter claims—on isolated DNA—challenged in *Myriad*.

“I think, honestly, not very much,” Gerald J. Flattmann Jr. of Paul Hastings, New York, said. “The *Mayo* court is really looking at whether a law of nature can be incorporated into a patent claim in a novel and nonobvious way,” he explained, “whereas the Federal Circuit decided *Myriad* on a different ground, because they were not products of nature but rather human-made products, not existing previously in a natural state.”

“Both cases are important Section 101 patent eligibility cases, but I don’t think the Supreme Court’s guidance in *Mayo* is on point,” Flattmann said.

Bremer said that it is unclear what the Supreme Court’s “nonspecific remand” says about the patent-eligibility of isolated DNA sequences, and especially the impact of the *Mayo* decision on such subject matter.

“First, the *Mayo* decision is about methods, while these isolated DNA sequences are a different subject matter, namely chemical molecules. Second, these isolated DNA sequences are definitely not in the ambit of ‘laws of nature,’ but instead chemical molecules that don’t exist in ‘nature,’ and which ‘nature’ cannot make. These chemical molecules are the result of man-controlled extraction/isolation or chemical synthesis techniques. These two differences mean the Supreme Court’s 1980 decision in *Chakrabarty* [*Diamond v. Chakrabarty*, 447 U.S. 303 (1980)], which held that a man-made living organism is patent-eligible, is far more analogous in terms of the claimed subject matter, and thus should control, not the *Mayo* decision.”

Courtenay C. Brinckerhoff of Foley & Lardner in Washington initially agreed. “There are different para-

digms for applying the ‘law of nature’ versus ‘product of nature’ exceptions to 35 U.S.C. § 101, so the court’s specific analysis of the Prometheus method claims [in *Mayo*] may not be directly applicable to the Myriad isolated DNA claims,” she said.

“On the other hand, the principles underlying the exceptions are very similar, so the themes underscored in the *Mayo* decision (e.g., preserving the public right to things occurring in nature) probably are relevant.”

Robert L. Baechtold of Fitzpatrick, Cella, Harper & Scinto, New York, agreed with Brinckerhoff’s reference to the public right, phrasing the question as, “Are you effectively co-opting something that has existed in nature all along?”

And he was more certain of the impact. “The Federal Circuit absolutely has to apply *Mayo*,” he said. “You can’t simply say it’s a composition of matter and that makes a difference.”

Relevance of *Funk Brothers*. Baechtold and Brinckerhoff both cited the potential importance of a 1948 case that has been somewhat controversial but not determinative to date, *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 (1948).

The Supreme Court in *Funk Brothers* held that the aggregation of six species of bacteria into one product is unpatentable where each species has the same effect it always had, no species acquires different use, and combination of species produces no new bacteria, no change in the six species of bacteria, and no expanded range of their utility.

Many in the patent community, and various amicus briefs submitted in the Federal Circuit’s consideration of *Myriad*, argued that *Funk Brothers* was not on point in that “unpatentable” as used by the court meant nonobvious, rather than not patent-eligible. However, those commenting to BNA essentially acknowledged that *Funk Brothers* now matters regardless, given the *Mayo* court’s requirement for nonobvious steps added to a method claim based on a law of nature.

Brinckerhoff operates the PharmaPatents blog and posted an article March 22 titled “My *Myriad* Nightmare,” giving a clear indication of her views on the *Myriad* case and its relationship to *Funk Brothers*. She reminded her readers that the *Funk Brothers* patent was on a “composition comprising a mixture of different nitrogen-fixing strains of bacteria,” but she acknowledged the challenge in distinguishing that case from *Myriad*.

“Isolated DNA is an article of manufacture or a composition of matter—something physical made by man,” Brinckerhoff said in a follow-up e-mail to BNA. “Of course, the same could be said about the combination of bacteria at issue in *Funk Brothers*, which is why *Funk Brothers* is such a difficult case if it is analyzed under 101.”

However, she contended that the CAFC’s prior *Myriad* ruling was true to the underlying principles of the case. “The combination of *Chakrabarty* and *Funk Brothers* appears to indicate that an article of manufac-

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ture or composition of matter must have 'a distinctive name, character and use' from a product of nature and/or be 'markedly different' from a product of nature," she said. "This is exactly how the Federal Circuit analyzed the Myriad isolated DNA claims."

Wishing the Court Provided More Guidance. Flattmann did not mention *Funk Brothers* specifically, but expressed a similar sentiment and, in doing so, brought the question back to the extent to which *Mayo* applies to the *Myriad* litigation. The CAFC "sidestepped" the question of whether Myriad's isolated DNA claims are products of nature, he said, in its ruling that the isolated DNA exhibited markedly different chemical characteristics.

"If the Federal Circuit sticks to that holding, [the challengers'] arguments won't be successful," Flattmann said.

Bremer concluded by saying, "The *Mayo* decision overall, in my opinion, is too philosophical in nature

and gives little or no direction to the lower courts as to what truly is patent-eligible subject matter under 35 U.S.C. § 101 while ignoring the truly operative sections of that statute, particularly sections 102 and 103, to determine if the subject matter presented in a patent application is truly patentable subject matter."

The court has now, "through a plethora of decisions introduced much greater uncertainty into the patent system which has been the backbone of the advances the United States has made over the more than two centuries since its founding and puts the United States into a disadvantageous position in a highly competitive global economy," Bremer said, expressing his wish that the court had provided the CAFC with more guidance by way of *Classen*.

By TONY DUTRA AND JOHN T. AQUINO

The Mayo opinion is at <http://pub.bna.com/ptcj/101150Mar20.pdf>.