Client Alert

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After *Myriad* Oral Argument, Supreme Court Set to Decide Patentability of Isolated Human DNA Molecules

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Today, the Supreme Court of the United States heard oral argument in *Association for Molecular Pathology v. Myriad Genetics, Inc.* (No. 12-398) to decide the question, "Are human genes patentable?" The Court's decision in *Myriad* could have broad implications for biotechnology companies. Morrison & Foerster was present at the argument. Although one must be cautious about reading tea leaves from oral argument, a majority of Justices at the argument seemed skeptical that isolated human genes are patentable subject matter.

BACKGROUND

Myriad Genetics, Inc. is the patentee of several U.S. patents with claims directed to the human genes BRCA1 and BRCA2. The presence of mutations in these genes is highly correlated with the risk of developing breast or ovarian cancer. A coalition of groups and individuals brought a declaratory-judgment action over the patentability of the BRCA1 and BRCA2 claims.

A divided Federal Circuit panel held that claims covering isolated DNA sequences are patentable subject matter under 35 U.S.C. § 101. In March 2012, the Supreme Court sent the case back to the Federal Circuit for that court to reconsider its decision in light of the Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). In *Mayo*, the Supreme Court reaffirmed the principle that laws of nature are not patentable. On remand, the Federal Circuit wholly reaffirmed its prior ruling.

The challengers petitioned the Supreme Court for review. The Supreme Court granted certiorari to decide one question: "Are human genes patentable."

THE BRIEFS BEFORE THE SUPREME COURT

The plaintiffs assert that Myriad "did not invent any genes or variants or cause their significance" and that Myriad's patents "cover the BRCA genes of every person in the United States, even genes that Myriad has never seen." Because human genes and genetic variants of those genes are "products of nature," they are not eligible for patenting. The fact that the BRCA genes have been isolated from the human body makes no difference because under that rationale, "a kidney 'isolated' from the body would be patentable, gold 'isolated' from a stream would be patentable, and leaves 'isolated' from trees would be patentable." The challengers' position is supported, in whole or in part, by 24 amicus briefs, including briefs by the American Medical Association, AARP, and the American Intellectual Property Association.

Myriad contends that the claimed isolated DNA molecules "fall on the inventive side of the line" drawn by Section 101 and Supreme Court precedent. According to Myriad, "[o]nly by human intervention have the claimed molecules come about." "Where others failed, Myriad identified the BRCA genes, and then, using information it

had collected and discerned from studying the genes, characterized, defined, and isolated these particular molecules. The creation of new molecules never before available to the public is invention." Myriad's position is supported by 26 amicus briefs, including briefs by the American Bar Association, the Biotechnology Industry Organization (BIO), the Pharmaceutical Research and Manufacturers of America (PhRMA), and a number of pharmaceutical companies.

The Solicitor General filed an amicus brief on behalf of the United States, nominally supporting neither party, but which, in practical terms, is seen as supporting the challengers. In a departure from the position of the Patent Office, the Solicitor General argues that "isolated but otherwise unmodified DNA is not patent-eligible." According to the Solicitor General, the "public's ability to study and use native DNA would be unduly compromised if changes caused by the extraction of naturally-occurring substances from their native environments were sufficient to trigger patent-eligibility." The Solicitor General departs from the challengers when it comes to "complementary DNA" (cDNA) molecules, which the government describes as "synthetic molecules built by scientists to include, in a single contiguous DNA segment, only the exons of a naturally occurring gene, without the introns and regulatory regions that are normally interspersed with exon sequences in genomic DNA."

ORAL ARGUMENT

The Justices' questioning at oral argument suggests that a majority of Justices seem inclined to agree with the challengers' argument that isolated human genes are not patent-eligible. As to cDNA, however, several Justices suggested that it is the product of human invention and would be eligible for patenting under Section 101, although it may or may not be patentable under other doctrines such as obviousness.

The Challengers' Argument

Counsel for the challengers began his argument by asserting that Myriad invented "nothing." The decisions as to what the genes contained were "made by nature," not by Myriad. Myriad merely "unlocked the secrets" of the genes; it did not invent them.

A number of Justices asked the challengers to clarify exactly what they contend is and is not patentable. Justice Sotomayor asked why the test for the presence of the BRCA genes had not been patented. Justice Scalia asked why the method of isolating the genes was not patented. Justice Kennedy asked whether the challengers were asserting that the process of "tagging" the isolated DNA was not patentable. Counsel answered that the method was patented but had been freely licensed for years, and he clarified that the challengers were not asserting that the process of tagging the DNA could not be patented.

Justice Alito was one of the only Justices to ask questions at oral argument suggesting outright agreement with Myriad that isolated genes can be patented. Justice Alito asked how the isolated DNA was different from a plant in the Amazon that is discovered to have therapeutic properties but which requires a chemical to be extracted and concentrated. Counsel agreed that the process of concentrating the substance might make it patentable. Justice Alito suggested that that was no different from isolating the gene because both the isolated gene and the concentrated plant substance have a different "function" and are in a new "form."

Several Justices, including Justices Scalia, Kennedy, and Kagan, asked whether there would be sufficient incentives for biotechnology companies to perform the type of work that Myriad performed if the genes are not patentable.

Justice Sotomayor stated that the isolated gene itself "has no value," but rather it is "the use you put the isolation to" that has value.

As to cDNA, the Justices were far less receptive to the challengers' argument. Justice Sotomayor stated that cDNA is "not a product of nature; it's a product of human invention." Justice Breyer stated that there is "no such thing in nature" as cDNA and that cDNA has properties that are not true of the isolated DNA. Justice Kennedy suggested that cDNA has features that regular DNA does not. Counsel repeatedly tried to assert that cDNA is found in nature, but he appeared to make little headway.

The Solicitor General's Argument

Solicitor General Donald Verrilli himself argued as amicus on behalf of the United States, reflecting the importance of this case. The Solicitor General's middle-ground position—that isolated genes are not patentable but that cDNA is—appeared to be carrying the day with several of the Justices.

The Chief Justice queried whether patentability under Section 101 was the proper way to consider these issues, suggesting that the doctrine of obviousness was the better course. He stated that taking a small part of something bigger is obvious, and thus it would be obvious to take an isolated gene from an entire chromosome. "I don't understand how a small part of something bigger isn't obvious," remarked the Chief Justice. Nevertheless, the Solicitor General urged the Court to focus on patentability under Section 101 as it did in *Mayo*.

Justice Alito pointed out that the government has changed its position and that there are conflicting opinions within the Executive Branch. The Solicitor General acknowledged as much.

Justice Kagan brought up Justice Alito's hypothetical about the Amazonian plant. The Solicitor General contended that the use of the substance in the plant would be patentable but that the substance itself would not.

Myriad's Argument

Counsel for Myriad withstood a barrage of questioning about the patentability of merely isolated human genes, which several Justices stated are "found in nature."

Justice Sotomayor, for example, likened the case to a new recipe for improved chocolate-chip cookies, stating that the cookie might be patentable because the inventor has done something new with the ingredients but that the basic ingredients themselves—salt, flour, eggs, and butter—could not be patented.

Myriad's counsel argued that there was human invention in the decision where to begin the gene and where to end the gene—i.e., where to snip the gene from the rest of the chromosome. He likened isolating the gene to a baseball bat that has been isolated from the rest of a tree, stating that a baseball bat is found in nature but the decision where to start and end it is decided by humans. Justices Scalia and Breyer resisted the analogy, stating that this DNA is found in the human body. The Chief Justice also stated that the baseball-bat analogy is "quite different" because that is not just snipping. "Here," he stated, "what's involved is snipping. You've got the thing there and you snip—snip off the top and you snip off the bottom and there you've got it."

Justice Kennedy remarked that isolated DNA is not useful until "tags" are added to it. He thus suggested that DNA that is isolated but not tagged is not different from how it exists in the body.

Justice Breyer stated that "the patent law is filled with uneasy compromises." Returning to the hypothetical about

the plant in the Amazon, Justice Breyer stated that the historically recognized compromise is that processes to extract the substance from the plant are patentable, that newly discovered uses of the substance are patentable, but that the substance itself is not. This "hornbook patent law," he suggested, keeps substances themselves free of patent restrictions but encourages innovation to develop new uses for those substances.

Myriad's counsel urged the Court to defer to the views of the Patent Office, which "sits at the intersection of law and science." He pointed out that the Patent Office did not join the Solicitor General's brief and has adopted the position that isolated genes are patentable. Justice Ginsburg responded that the federal government has disavowed the Patent Office's position, and that "the strength of the presumption would be diluted" as a result. Justice Kagan referred to the Patent Office as "very patent happy."

Justice Kagan asked whether the "first person who found a chromosome and isolated it" from the body could have patented chromosomes. She also asked whether "the first person who found a liver" could patent the liver. Myriad's counsel answered that these would be patentable under Section 101 but might not be under other provisions, such as 35 U.S.C. § 103. Justice Breyer responded that "that's the problem" because it would mean "[a]nything from inside the body that you snip out and isolate" could satisfy Section 101. Justice Sotomayor added that "if you cut off a piece of the liver or a piece of the kidney," that does not make it patentable, suggesting that the same should be true of a piece of a chromosome.

In the most explicit signs that the Court might accept the Solicitor General's view, Justice Kennedy asked Myriad's counsel whether, if the Court were to agree with the government, it would "give the industry sufficient protection for innovation and research." And in the challengers' rebuttal, Justice Sotomayor asked whether there would be "some value to us striking down isolated DNA and upholding the cDNA."

Myriad had argued in its brief that the Federal Circuit erred in concluding that any of the challengers has standing. At oral argument, none of the Justices asked any questions about Myriad's standing argument, suggesting that standing likely will not be a basis for the Court's decision in this case.

CONCLUSION

One should not read too much into the Justices' questions at oral argument because the Court does sometimes rule differently from how observers expect it to rule based on questioning. Many Justices today, however, did seem to be searching for a middle ground in which isolated human genes could not be patented but synthetic cDNA is patent-eligible under Section 101. A decision is expected by the end of June 2013.

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