The Legal Intelligencer

Patent Law and Uneasy Compromises at the U.S. Supreme Court

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Stephen A. Miller and Diana Lin

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At oral argument in *Association for Molecular Pathology v. Myriad Genetics*, the U.S. Supreme Court recently grappled with the question of whether human genes are patentable. Justice Stephen Breyer seemed to capture the justices' sentiment in the lively argument session: "The patent law is filled with uneasy compromises." The compromises that the justices choose will affect the future work of the U.S. Patent and Trademark Office (PTO) and shape the path of genetic research in the future.

Background

Myriad Genetics Inc. obtained patents for the two human genes that correspond to the increased risk of breast and ovarian cancers, dubbed BRCA1 and BRCA2. Myriad argued that, by isolating BRCA1 and BRCA2, it created something patentable and separate from the gene as it appeared when it was still attached to the DNA sequence in the human body. Researchers, physicians, geneticists, breast cancer organizations and other health care providers vehemently opposed the patentability of BRCA1 and BRCA2, arguing that the patents issued for these two genes covered "products and laws of nature." In challenging the patents in the U.S. District Court for the Southern District of New York, the plaintiffs alleged that the effect of the patents for the genes would be to "pre-empt scientific inquiry and medical care to the detriment of patients' health and scientific advancement," a pre-emption that presented a constitutional violation.

The district court agreed with the plaintiffs. The judge issued a comprehensive opinion granting summary judgment to the plaintiffs on the basis that Myriad did nothing to alter the "essential characteristic" of the genes.

A divided panel of the U.S. Court of Appeals for the Federal Circuit reversed. Each member of the panel issued a separate opinion regarding the patentability of genes. Judge Alan Lourie focused on the breaking of a covalent bond holding BRCA1 and BRCA2 in place in the larger genetic chain as creating a structurally different, and thus, new and patentable product. Judge Kimberly Moore upheld the patentability of BRCA1 and BRCA2 on the "historical background" of the PTO's practice of granting gene patents and the scientific industry's reliance on that practice. The lone dissenter, Judge William Bryson, determined that the simple isolation of BRCA1 and BRCA2 was not enough to render the genes patentable. There was no new "use" of the isolated genes, as they had to function in isolation in the same manner as they functioned in the body.

The U.S. Supreme Court granted a writ of certiorari in an attempt to bring clarity to this area of patent law.

Oral Argument

The Supreme Court eagerly explored the uneasy compromises inherent in patent law at oral argument. The justices were particularly interested in whether the isolated BRCA1 and BRCA2 genes could be patentable as a new composition of matter or as a new function of matter. Toward that end, the justices sought to compare the isolation of human genes to other examples. Justice Samuel Alito, for instance, queried plaintiffs' counsel regarding the discovery of a chemical in the leaves of an Amazonian plant that would cure breast cancer — was the chemical patentable? Had the leaf been transformed into something new or transformed, and therefore eligible for a patent?

One of the stickiest points for the plaintiffs occurred when Justice Elena Kagan asked about the incentive for companies to continue to isolate certain mutated genes if they knew they could not receive patent protection for the isolated genes. The plaintiffs' counsel, after several attempts to dodge the question, weakly offered that scientists would continue to perform this research out of "curiosity" or "because they want a Nobel Prize." Disappointed, Kagan pointed out that perhaps other patent possibilities existed to incentivize research in this process, but she did not know what they were. The plaintiffs' counsel was unable to provide her with any examples but stated that the company that isolated the gene would receive "enormous recognition," whereupon Justice Antonin Scalia dryly noted, "Well, that's lovely."

Scientific questions also arose regarding the distinctions between isolated DNA and cDNA, which is DNA synthesized from a messenger RNA template and contains only the expressed genes of an organism. Was it possible, the justices wondered, to obtain a patent for the cDNA, which is created in a laboratory using natural processes, while not patenting isolated DNA?

U.S. Solicitor General Donald B. Verrilli Jr. declined to engage in the ultimate discussion of whether the patents at issue were sustainable but strongly suggested that a patent on cDNA would allow the perhaps-unpatentable isolated DNA to remain available for other scientists and researchers to use. The solicitor general also highlighted that, while a company like Myriad may not be able to obtain a patent on the DNA itself, the company could certainly get a patent on the uses of the DNA. Patenting the uses of the DNA versus the DNA itself "doesn't tie up all other potential uses of the substance and that's the key."

Much of the questioning of Myriad's counsel centered on whether the isolated gene could exist naturally in the human body as fragmented cDNA, as explained in an amicus brief. Myriad's counsel introduced the analogy of a baseball bat, explaining that it does not exist until it is "isolated" from a tree, but it is still considered the product of human invention and thus eligible for a patent. Alito, in attempting to understand whether the isolated DNA existed naturally within the human body and was thus ineligible for a patent, wondered if it would be possible for a tree branch to fall off a tree, into the ocean, and wash up on shore as a baseball bat. Myriad's counsel admitted that Alito's bat analogy had merit but that the patent law was "all about pushing the frontiers" rather than wondering if something somewhere might exist to prevent a patent.

The justices pushed Myriad's counsel on this point. Was it possible, for instance, for the first person to discover a chromosome to receive a patent for the discovery? What about the liver? Kagan and Breyer were particularly "bothered" by the idea that patents would be available for "anything from inside the body that you can snip out and isolate." Myriad's counsel dodged the question and instead pressed the court to view the patents as economic instruments that provided benefits resulting from human ingenuity. He hammered the point that the PTO had already declared genes patentable and that its view had not dampened the "explosion" in biotechnological research.

Future of patent law

Patent law represents an attempt to strike the right balance among competing interests in order to encourage innovation. In *Myriad Genetics*, those big-picture issues are front and center, as reflected by Breyer's wistful observation from oral argument. The justices will attempt to further refine those uneasy compromises — here, perhaps hedging toward a decision that offers patent protection for particular genetic

sequences while rejecting patent protection for wholesale isolation of a gene. •

Stephen A. Miller *practices in the commercial litigation group at Cozen O'Connor's Philadelphia office. Prior to joining Cozen O'Connor, he clerked for Justice Antonin Scalia on the U.S. Supreme Court and served as a federal prosecutor for nine years in the Southern District of New York and the Eastern District of Pennsylvania.*

Diana Lin *also practices in the firm's commercial litigation group in Philadelphia. She is a cum laude graduate of Yale University and a magna cum laude graduate of Temple University's Beasley School of Law, where she was a Beasley Scholar.*
