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Supreme Court Remands *Myriad* for Reconsideration in Light of *Mayo*

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Advisory

Following close on the heels of last week's controversial decision in *Mayo Collaborative Services v. Prometheus Laboratories*, the United States Supreme Court sent another hotly contested biotech case back down for further consideration by a lower federal court. In *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court granted certiorari to the parties in the *Myriad* case, vacated the decision of the Court of Appeals for the Federal Circuit, and then promptly remanded the case to the Federal Circuit for reconsideration in accordance with the Supreme Court's March 20th decision in the *Mayo* case, which held that a diagnostic method claim that simply recites a law of nature is unpatentable subject matter under 35 U.S.C. §101.

The patents being challenged in the *Myriad* case also contain diagnostic method claims. These claims, which recite "comparing" or "analyzing" BRCA1 and BRCA2 gene sequences, had been deemed ineligible for patent protection by the Federal Circuit. This conclusion is unlikely to change upon remand.

However, the *Myriad* case raises several other issues. Also at issue in *Myriad* are method claims for screening of therapeutics and composition of matter claims for isolated DNA. Prior to the remand, the Federal Circuit had found these claims to be patentable subject matter, holding that the claimed screening methods were also patentable because they include the transformative step of "growing cells" and that *isolated* DNA is patentable subject matter since it is chemically distinct from native DNA. The Federal Circuit's reconsideration of and application of the *Mayo* decision to the screening method claims and to the composition of matter claims will be worth watching.

The Federal Circuit will have to review the method claims for screening of therapeutics to determine whether the step of "growing cells" in the presence of a potential cancer therapeutic is still transformative in light of the *Mayo* decision. The question will be whether the step "transformed the process into an inventive application of the [law of nature]."

How the Federal Circuit applies the *Mayo* case to Myriad's claims on isolated gene sequences will also be of great interest to the biotechnology community. One consideration from the *Mayo* decision that will likely be important to the analysis of isolated gene claims is whether the term "isolated" is a "feature[] that provide[s] practical assurance that the process is more than a drafting effort." The Federal Circuit's earlier detailed discussion that these "isolated DNA molecules do not exist as in nature" and must be "chemically cleaved" from their natural environment, and thus are "distinct chemical entit[ies]," may indicate one basis by which the Federal Circuit can distinguish these claims from *Mayo*. A second, countervailing, consideration from *Mayo* may be whether the "isolation" of DNA should be considered a "well-understood, routine, conventional activity previously engaged in by scientists who work in the field." While this argument was unpersuasively made before the Federal Circuit in 2011, it may now garner more support.

The Federal Circuit's treatment of the *Myriad* claims on remand may provide better guidance on how to ensure that biotechnology patent claims survive future patentability challenges. Both *Mayo* and *Myriad* will undoubtedly have long-term ramifications in the pharmaceutical and biotechnology industries. Any potentially affected or interested parties should continue to follow the developments in this area, but it seems this may be just the beginning of a much longer conversation.

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