The Supreme Court Speaks on Diagnostic Patents—
Mayo v. Prometheus and Myriad

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The Supreme Court issued two long-awaited decisions that are likely to have broad-reaching effects on diagnostic method patents, as well as personalized medicine patents. On March 20, 2012, the Supreme Court unanimously reversed the Federal Circuit in Mayo Collaborative Services v. Prometheus Laboratories, Inc., holding that Prometheus’ claim, which had been twice upheld by the Federal Circuit, was an unpatentable law of nature. Shortly thereafter, the Court granted certiorari in the hotly-contested biotech case of Association for Molecular Pathology v. Myriad Genetics, vacated the Federal Circuit’s opinion, and remanded the case to the Federal Circuit for further consideration in accordance with the Mayo decision.

At issue in Mayo was whether the correlation between blood levels and optimal dosages of a drug was a patentable process or an unpatentable law of nature. The method claim at issue recited three elements: (1) administering a drug, (2) determining the level of the drug metabolite, and (3) a “wherein” clause that generally notes a metabolite level for dose adjustment. Justice Breyer wrote that despite the recited method steps, “the patent claims [did not] add enough to their statements of the [natural] correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws[.]” Since all of the steps “must be taken in order to apply the laws in question,” the Court found that the claims did not confine their scope to particular applications of those laws, and indicated that a patent on such a method would “tie up” too much of the future use of these laws of nature. Thus, the Court held the claim to be an unpatentable law of nature. Notably, the Court did not decide whether including steps that were “less conventional” than those recited in Mayo would make similar claims patentable, but the discussion of the Diehr and Flook precedents emphasized the importance of specificity.

The claims challenged in the Myriad case are also directed to diagnostic methods. The claims, which recite “comparing” or “analyzing” BRCA1 and BRCA2 gene sequences, had been deemed ineligible for patent protection by the Federal Circuit. It is unlikely that this conclusion will be changed upon remand.

However, the Myriad case raises several other issues. Also at issue in Myriad are method claims for screening of therapeutics, as well as composition of matter claims for isolated DNA. Prior to remand, the Federal Circuit had determined that these claims represented patentable subject matter. The Federal Circuit reasoned that the claimed screening methods were patentable because they included 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 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 ruling to the claims in Myriad directed to isolated gene sequences will also be of great interest to the biotechnology community. One consideration from the Mayo decision that will likely be important 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 reasoning 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 entity[]s,” 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.” This argument did not persuade the Federal Circuit in 2011, but it may now garner more support. The Federal Circuit’s treatment of the Myriad claims on remand is likely to provide better guidance on how to ensure that biotechnology patent claims survive future patentability challenges.

Applied broadly, the Court’s decisions are likely to affect many pending and issued diagnostic method and personalized medicine patent claims, as well as strategies for protecting innovations in these areas. As an initial step, patent applicants, owners, and licensees should review and evaluate their patents and applications to see how the Court’s decisions might affect their claims. As the specificity of each claim will undoubtedly vary, all claims may not be affected in the same way, so evaluation should be done on a claim-by-claim basis with the assistance of counsel. The owners of issued patents with questionable claims may want to consider narrowing reissues. Going forward, diagnostic method claims will need to be written paying closer attention to the specificity and transformative nature of the method steps. In terms of an offensive strategy, companies may also want to review and evaluate competitor diagnostic patent claims and revisit prior freedom to operate analyses in view of this decision.

Both Mayo and Myriad are likely to 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, as it seems this may be just the beginning of a much longer conversation.

This advisory was prepared by Nutter’s Intellectual Property practice. For more information, please contact your Nutter attorney at 617-439-2000.

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