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U.S. Supreme Court Raises the Patent-Eligibility Bar for Diagnostic Methods

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In a unanimous decision, the United States Supreme Court addressed the issue of patent eligibility of diagnostic method claims (*Mayo v. Prometheus*)[1]. This decision could have a significant impact on the fields of personalized medicine and medical diagnostics since the claims at issue, directed to a blood-testing method for optimizing a particular therapy, were invalidated because they did not define patent-eligible subject matter. This decision reverses the Court of Appeals for the Federal Circuit's holding that the claims were patentable because they included substantial physical limitations.

In *Mayo v. Prometheus*, the claims recite methods physicians may use to determine if a patient's dose of a drug used in the treatment of autoimmune diseases is too low or too high. The main claim of the patent essentially recites a two-step method including an "administering" step in which a drug is administered and a "determining step" in which levels of a metabolite of the drug are measured. The claim concludes with "wherein" clauses which indicate a need to increase or decrease the amount of drug to be subsequently administered to the patient[2].

According to the Supreme Court, such claims encompass non-patentable "laws of nature, natural phenomena, and abstract ideas". In particular, the Court dissected the claims and found that the "administering" step simply refers to the relevant audience (doctors), the determining step involves methods for determining metabolite levels well known in the art and "the "wherein" clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient. The Supreme Court also found that the claims failed to constitute patentable subject matter, even when considered as a whole: "the claims inform a relevant audience about certain laws of nature; 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. For these reasons we believe that the steps are *not sufficient* to transform unpatentable natural correlations into patentable applications of those regularities" [emphasis added].

The Court explained 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 must limit its reach to a particular application of the law. Further, the Court stated, "[i]f a law of nature in not patentable, then neither is a process reciting a law of nature, unless that process has *additional features* that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself" [emphasis added].

Comment : The Supreme Court did not completely shut the door on all claims involving laws of nature, but its decision certainly creates uncertainty for diagnostic method patent claims and for the personalized medicine industry. With the use of a relative terminology such as "nothing significant", "not sufficient" or "enough", the Court's decision is vague on what is now required for patent-eligibility of claims in this field. The Court did not want to decide whether the invalidated claims might be patent eligible if their steps were less conventional, but the opinion suggests that inclusion of novel and inventive additional features might have transformed the invalidated claims in a patentable application of the natural law. However, the Court confirmed that claims to novel compositions or methods of treatment will still be eligible to patent protection.

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[1] *Mayo Collaborative Services* v. *Prometeus Labs., Inc*, No. 10-1150 (U.S. Supreme Court March 20, 2012) (PDF)

[2] Claim 1 of Prometeus U.S. Patent No. 6,355,623 : "A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject."