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Mayo v. Prometheus: A Year Later

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ABSTRACT: Last year's U.S. Supreme Court decision in *Mayo v. Prometheus* regarding the patent eligibility of diagnostic method claims will probably have the most profound lasting effect of any recent court decision on the biopharmaceutical industry. The Mayo decision changed the evaluation of patent eligibility of a method claim under 35 U.S.C. § 101. The new evaluation is a more difficult standard to clear and needs to be considered prior to filing a patent application.

The recent "Myriad case" has generated the most publicity of any patent case before the U.S. Supreme Court in the last ten years, maybe more. The U.S. Supreme Court ruled that isolated genes are not patent eligible but reaffirmed that non-naturally occurring DNA such as cDNA and man-made variants are patent eligible.[1] Because of the continued patent eligibility of non-naturally occurring DNA, last year's U.S. Supreme Court decision in *Mayo v. Prometheus*[2] regarding the patent eligibility of method claims will probably have the more profound lasting effect upon the biopharmaceutical industry than the Myriad case. In *Mayo*, the issue was whether methods for determining an effective amount of a drug being administered to a patient were patent eligible under 35 U.S.C. § 101. Most of the § 101 cases (e.g., *In re Bilski*,[3] *Myriad*, etc.) before the U.S. Supreme Court have simply determined whether a particular type of subject matter is patent eligible. In contrast, the *Mayo* decision fundamentally changed how a method claim is analyzed under § 101.

■ THE LAW

Section 101 of the Patent Act defines what subject matter is eligible for a patent.

> *Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.*

The Court has long recognized exceptions to this section. "[L]aws of nature, natural phenomena, and abstract ideas are not patentable."[4] These exceptions frame what is not patent eligible, although some would argue that these exceptions are not necessary.[5] Patent eligibility was thus summarized by the Court's statement that "anything under the sun that is made by man"[6] is patent eligible. Thus, § 101 was a "coarse filter"[7] that provided a broad scope of patent eligibility where sections 102 (novelty), 103 (obviousness), and 112 (written description and enablement) determine whether a claim is patentable.

■ PRE-*MAYO* ANALYSIS

The backbone of diagnostics is the recognition of a relationship between a biomarker, a level of a chemical, etc., and a disease state, efficacy, etc. For years, the recognition of A correlated with B was patentable. A step of simply correlating two factors is now deemed a mental step.[8] Thus, steps of administering and/or determining were added to claims to demonstrate a transformation and/or manipulation of a sample. When viewing a method claim as a whole, these transformations and manipulations demonstrated a method that was a physical application of a natural relationship and was thus patent eligible.

Many diagnostic/testing methods can be characterized as applications of laws of nature. For example, an assay to determine a disease state is the application of knowing the indication of a disease state and being able to test for that indication. Thereby, an assay transforms a material (a patient sample) or subject from one state to a second state. For example, administration of a vaccine transforms a patient from a susceptible state to an immune protected state. An assay also could have manipulated a substance (e.g., blood) to effect a change in the substance in furtherance of the method. These sorts of transformations and manipulations were active steps and not exceptions to patent eligibility.

In *Mayo*, the claims at issue involved a diagnostic method that provided information regarding treatment efficacy. Since humans metabolize drugs differently, the claimed method personalized the therapeutic efficacy of a particular treatment. In summary, the methods (1) administered a thiopurine drug to a patient with a specific gastrointestinal disorder, (2) determined the level of the metabolite in the patient, and (3) indicated whether the metabolite was above or below particular thresholds meaning the amount of drug was toxic or ineffective, respectively. Twice, the Federal Circuit found this claim to be patent eligible. Administering a drug to a patient transformed the patient from one state to another. Likewise, the determining step indicated that a sample was manipulated in such a way that was not natural. When analyzing the claim as a whole, the Federal Circuit did not find that the method was a law of nature, natural phenomena, or an abstract idea. As such, the Federal Circuit found the methods to be patent eligible.[9]

■ THE SUPREME COURT'S *MAYO* ANALYSIS

The Supreme Court reversed the Federal Circuit's decision by finding the method patent ineligible. The decision characterized the method as simply setting forth laws of nature. The Court then provided a new blueprint for analyzing method claims to determine patent eligibility.

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Specifically, the method was characterized as describing "relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of thiopurine drug will prove ineffective or cause harm." To the Court, the inventive concept was a law of nature since there is nothing man made in how the body interacts with a compound. After finding the inventive concept patent ineligible, the Court analyzed whether the rest of the claim added "significantly more than simply describe these natural relations."

In the Court's analysis, the "administering step simply refers to the intended audience, namely doctors who treat patients with certain diseases..." Thus, the administering step no longer transformed a subject but rather identified an audience. The decision distinguished this step from administering a new drug, compound, molecule, etc., to treat a condition since the use of thiopurine drugs to treat these diseases had already been in practice. The Court found that administering a known drug for a known condition did not add "significantly more" to qualify the natural relationship as patent eligible. In a bit of irony, the Court acknowledged that it requires human intervention (i.e., administration of the drug) for this "natural law" to even occur.

Regarding the determining step, the Court found that methods for determining levels of drug metabolites in the blood were well-known ("purely conventional or obvious"). In this patent, no new methods of determining metabolite levels were disclosed. For the first time, the Court introduced the concepts of novelty and obviousness into the analysis of patent eligibility.[10] Novelty and nonobviousness are standards under § 102 and § 103 for claims to be patentable. Whether a composition or method, or parts thereof, was new and nonobviousness had always been separate determinations. These concepts had not bled into § 101 analysis previously. The Court found that the use of conventional methods did not impart patent eligibility to a natural law.

Although the Court said it viewed the claim as a whole, the analysis does not support the Court's assertion. In this new analysis, the first determination is whether the inventive concept of a method claim is a law of nature (i.e., a natural relationship). If so, then the next determination is whether the rest of the claim adds "significantly more" to the natural principle. Conventional and obvious processes do not add "significantly more." This is the current analysis to determine patent eligibility of a method claim.

POST-*MAYO*

The *Mayo* decision was issued more than a year ago. This decision has made it very difficult for biopharmaceutical diagnostic patent claiming that does not have a novel aspect to the testing method. New diagnostics are often the product of a new understanding of a particular biological relationship that is not necessarily dependent on new test methods. Under *Mayo*, this relationship without anything further is a natural law and not patentable. There has been no magic elixir to claim around the hardships this decision provides for claiming diagnostic methods.

However, there are ways to combat the issues resulting from this decision (e.g., "a *Mayo* rejection") in new applications.[11] (1) Avoid making the "law of nature" the central part of the claim (e.g., just the recognition of a drug level correlated with efficacy); (2) avoid using solely general "determining"-type steps; (3) emphasize anything out of the ordinary; and (4) attempt to characterize a relationship as not being a natural law.

Additionally, diagnostics are becoming more commonly a combination of traditional life sciences (e.g., pharmaceutical and biotechnology) and computing. Thus, patenting this combination (e.g., a computing function to determine a correlation based on detected levels) may also avoid the issues associated with the *Mayo* analysis. In the post-*Mayo* environment, claiming biopharmaceutical diagnostic methods will require more specificity as to the assay.

SUMMARY

The new patent eligibility analysis provided in *Mayo* has narrowed the breadth of eligibility. Although diagnostic methods have been limited, they have not been precluded.

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Notes

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REFERENCES

(1) *Assoc. Molecular Pathol. v. Myriad Genetics Inc.*, U.S. (2013).

(2) *Mayo Collaborative Servs. v. Prometheus Lab., Inc.*, 132 S. Ct. 1289 (2012).

(3) *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

(4) *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

(5) Patent claims to laws of nature and natural phenomena would be anticipated, and abstract ideas do not meet the utility requirement under § 101.

(6) *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

(7) *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 868 (Fed. Cir. 2010).

(8) *Bilski. supra*.

(9) This is distinguishable from the claim being patentable. The claim may still not have been patentable. Many commentators believed that the claim would have been found obvious under 35 U.S.C. § 103 if litigated on this issue.

(10) Sherkow, J. S. And How: Mayo v. Prometheus and the Method of Invention. *Yale L. J.* **2012**, *122*, 351−358.

(11) Existing applications and patents should have already been evaluated. If they have not been evaluated, they should be and options discussed.