

## Supreme Court Issues Groundbreaking Decision Limiting the Types of Methods that are Eligible for Patenting

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Today, the U.S. Supreme Court handed down a unanimous decision holding that method claims for applying a law of nature using merely conventional steps are not eligible for patent protection. While the Court's reasoning in this decision has a dramatic impact on the patentability of various innovations in the life sciences, its scope extends far beyond that field. The ramifications of the decision will be significant for fields such as software engineering, information science, chemistry and electrical engineering.

In *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 10-1150, 566 U.S. \_\_\_\_ (March 20, 2012) the Court once again reversed the Federal Circuit on a fundamental issue of patent law. The Court stated that the "Machine or Transformation" test for patentability, which the Court endorsed as a useful, though not exclusive, test for the patentability of method claims less than two years ago in the *Bilski* case, does not trump the prerequisite requirement that "laws of nature, natural phenomena and abstract ideas" cannot be patented.

The Court's ruling puts to rest a developing rift within the Federal Circuit regarding how and when patent-eligibility should be considered by courts. One line of recent Federal Circuit decisions, led by the opinions of Chief Judge Rader, cautioned that courts ought not venture into the "swamp" of patentability analysis if other provisions of the patent law can determine the outcome of a case. Another line of opinions held that patentability analysis is the gateway that courts must use to determine validity of a contested patent. In its holding today, the Court rejected the notion that a patentability determination under other provisions of the patent laws could displace a threshold analysis of patentable subject matter under 35 U.S.C. § 101.

Further, the Court's ruling appears to revive the previously discredited practice of dissecting a claim into its parts, in this instance to determine whether the claim does more than simply recite a law of nature and then set forth conventional steps for applying that law. In recent years, claim analysis had shifted away from such dissection to analysis of the claim as a whole, since many inventions result from innovative combinations of known elements.

At issue in *Mayo* was a method of determining whether a given dose of a particular drug is too high, resulting in toxicity, or too low, rendering it ineffective. The method at issue involves measuring the level of certain metabolites in a patient's blood.

The Court determined that the claimed method simply recited a law of nature and a series of steps that "involve well-understood, routine, conventional activity previously engaged in by researchers in the field." The Court held that upholding such claims "would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries."

The Court stated, without analysis, that the relationships between the metabolite concentrations and the likelihood that a drug dosage would be ineffective or cause harm were "laws of nature." The Court found that the claims did not do significantly more than simply describe these natural (*i.e.*, biological) relationships. "To put the matter more precisely, do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent eligible processes that *apply* natural laws?" (italics in original).

The Court answered that question with a resounding "no" by looking at each of the additional claimed steps, which were an "administering" step, a "determining" step and a "wherein" step. The Court found those steps insufficient "to transform the nature of the claim." The Court also stated, "[T]o consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately."

Explaining the situation in another manner, the Court stated that, "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...."

The Court supported its reasoning with its own precedents as well as others, for instance a 19<sup>th</sup> century English case for improving the manner in which air was introduced to a

furnace. The Court in *Mayo* found it important that such a patent was upheld where it included not only a law of nature, but also “several unconventional steps.”

The reference to constituent process steps as conventional or non-conventional means that in determining whether an invention is drawn to subject matter that is statutory (*i.e.*, patent-eligible), the U.S. Patent and Trademark Office or a court must consider not only the subject matter itself, but the state of the art in that field. While some lower courts after *Bilski* had been determining subject matter eligibility with scant, if any, reference to the specific language of the claims, this decision calls on them to analyze not only the claim language itself but the prior art as well, even before determining whether that prior art makes the claim unpatentable due to lack of novelty or to obviousness. This approach risks blurring the analysis of patent eligibility with the analysis of novelty and non-obviousness.

In finding the claims unpatentable, the Court repeatedly used comparative and conclusory phrases such as “*overly broad*,” “*improperly tying up the future use of laws of nature*” and “*forecloses more future invention than the underlying discovery could reasonably justify*” (italics added). The Court aptly observes that, “Courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature.” Undoubtedly, future commentators will wonder how such institutions can be expected to make the italicized comparisons, given such limitations.

Regardless, the Court explicitly instructs in *Mayo* that such institutions make these determinations as part of a subject-matter eligibility analysis, rather than by relying on the other sections of the patent law that may be easier to apply, lest the “law of nature” exception to patent-eligibility become a “dead letter.”

For companies and researchers in the life sciences, the impact of this decision cannot be underestimated. Claims directed to simple correlations between a conventional assay result and a biological outcome (such as those at issue in *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006)) are now almost certainly invalid for being drawn to unpatentable subject matter because they preempt a law of nature, under the *Mayo* Court’s analysis. Less clear is the fate of claims that rely on a larger number of biological inputs and the use of complex algorithms to generate useful information about biological outcomes such as those covering multi-analyte index assays.

For other industries as well, this decision has a clear impact. For instance, the question about whether patent-eligibility is merely a “coarse filter” that should be avoided when possible is now settled—the patent eligibility analysis must be undertaken. The Court’s approach of dissecting method claims to determine which portions state laws of nature and which portions recite conventional steps is in sharp contrast with how the USPTO and courts have been analyzing claims in recent years. If such holding is extended to include the other branches of the “implicit exception” to patentability that the Court references (*i.e.*, natural phenomena and abstract ideas), then a very wide swath of science and technology areas are implicated. Given that lower courts are currently struggling with how best to circumscribe all three of these judicially created exception areas, it will be a number of years before there is settled law that will provide guidance for the types of methods that remain patentable.

The continued viability of the Machine-or-Transformation test, itself only a few years old, is now in doubt, given that the Court has now held it neither necessary (*Bilski*) nor sufficient (*Mayo*) to determine that an invention is patent-eligible.

The *Mayo* decision further highlights a neglected area in the law regarding patentability. The Constitution secures “for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” The section on patentability in the patent statute at issue in *Mayo* (§ 101) begins, “Whoever invents or discovers any new and useful process....” The Court’s opinion repeatedly references discoveries as examples of subject matter that is not eligible for patenting. If the toxicity level of a particular drug is not a “discovery” in the classic sense of the term, then it will be very difficult to know what kinds of “discoveries” may be patentable.

Given that Congress has just concluded significant patent reform with passage of the America Invents Act in September 2011, it is unlikely that Congress will be able to address any concerns that may arise from this decision in the near future. Likewise, as the *Mayo* decision is a unanimous decision of the Court, it is highly unlikely that the Court itself will move significantly from what it has pronounced today. As such, this decision is likely to do precisely what the Court thought it was avoiding — “creating significantly greater legal uncertainty” — by making patent-eligibility a primary consideration.

We will continue to address issues that are sure to arise from this decision in the coming months and years.

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