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Unanimous U.S. Supreme Court Finds Personalized Medicine Claims Are Not Patentable

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On March 20, 2012, the U.S. Supreme Court issued a unanimous decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, holding that Prometheus' claims directed to methods of optimizing the dose of specific drugs used in the treatment of specific conditions are invalid under 35 USC § 101 because they impermissibly claim laws of nature. While such method claims are not patent-eligible in many countries, the Supreme Court decision is significant in the context of U.S. patents, where diagnostic and therapeutic methods are generally patentable. Indeed, the Supreme Court's decision in Prometheus invalidated claims that the Federal Circuit had upheld twice.

In reaching its decision, the Supreme Court made clear that the Federal Circuit's "machine-or-transformation" test for assessing patent-eligibility may not be useful when the "transformation" flows from "entirely natural processes." Rather, the Supreme Court indicated that, in order to satisfy 35 USC § 101, method claims that are based on a law of nature must recite an additional element that is not "routine" or "conventional" in the art.

The Claims at Issue

The Supreme Court focused on claim 1 as being representative of the claims at issue:

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 . . . and
- (b) determining a level of 6-thioguanine in the subject . . .

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.

The Supreme Court Decision

Justice Breyer wrote the unanimous opinion for the Supreme Court, which starts by quoting the language of 35 USC § 101, and noting that "[t]he Court has long held that this provision contains an important implicit exception:

“[L]aws of nature, natural phenomena, and abstract ideas” are not patentable.

The Supreme Court phrased the issue in terms of what is required “to transform an *unpatentable law of nature* into a *patent-eligible application* of such a law.” The Court cited earlier precedent (such as *Flook* and *Bilski*) as holding that

a process that focuses upon the use of a natural law also contain *other elements* or a combination of elements, sometimes referred to as an ‘inventive concept,’ sufficient to ensure that the patent in practice amounts to *significantly more* than a patent upon the natural law itself.

The Court characterized Prometheus’ claims as “set[ting] forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm.” The Court thus considered whether “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.” The Court decided that the recited “administering,” “determining” and “wherein” steps are *not* sufficient to “transform the nature of the claim” into one that is patent-eligible.

The Court considered the “administering” step as “simply refer[ring] to the relevant audience,” which was a “preexisting audience,” because doctors already knew to use thiopurine drugs to treat the recited conditions. The Court suggested that even a new “audience” might not have saved the claims, noting that the “prohibition against patenting abstract ideas “cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.””

The Court found the “wherein” clauses to do little more than “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 Court gave more consideration to the “determining” step, but found it not to bring the claims under § 101 because “methods for determining metabolite levels were well known in the art.” The Court cited the principle that “[p]urely ‘conventional or obvious’ ‘[pre]-solution activity’ is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.”

Finally, the Court considered the claims as a whole, but found that looking at “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.”

Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.

Summarizing the holding, the Court stated:

To put the matter more succinctly, 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.

Confounding Patent-Eligibility and Prior Art

The Supreme Court decision already is being harshly criticized for confounding the patent-eligibility requirements of § 101 with the novelty and non-obviousness requirements of §§ 102 and 103. Indeed, the Court acknowledged in its decision that “in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and ... the § 102 novelty inquiry might sometimes overlap.” While the “conventional” nature of the method steps recited in *Prometheus* did not appear to be in dispute, this issue could be more difficult to resolve in other cases. For example, a claim may be challenged under § 101 because the method steps are “conventional” and also challenged under § 102 for the same reason. The question then will be whether overcoming the prior art issue would be sufficient to overcome the patent-eligibility issue. The Supreme Court suggests that it might not be that simple when it leaves open the possibility that even claims that recite non-conventional steps could fail to satisfy § 101 if the claims wholly preempt a law of nature.

Patenting Personalized Medicine

While the Supreme Court decision informs us of the importance of reciting “additional features” to take personalized medicine claims beyond a law of nature, it does not provide much concrete guidance on how to “add enough” so that the claims “qualify as patent-eligible processes that *apply* natural laws.” Clearly, the Court will not give much weight to any “conventional” steps that are recited in the claims, even if they are concrete or physically transformative. Additionally, the Court seems to say that if a law of nature itself has a limited application, any claims based on such a law of nature must be even more narrow, so as not to preclude others from exploiting or innovating around the law of nature.

Patent holders in the personalized medicine space should consider seeking the advice of U.S. patent counsel, to determine whether this decision may be relevant to the validity of their U.S. patents. Even if the granted claims appear to be similar to *Prometheus*’ claims, it may be possible to strengthen or uphold the validity of the patent through the reissue process. A similar approach can be taken in pending applications, such as by amending or adding claims to more directly focus on specific applications of any underlying laws of nature.

Personalized medicine is an important field at the frontier of innovative healthcare. Although this Supreme Court decision may cast a shadow of uncertainty over certain patent claims, it is important to keep in mind that the Supreme Court did not announce a general rule that undermines the validity of all personalized medicine patents, but rather indicated that the validity of such claims must be assessed on a fact-specific, case-by-case basis.

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