March 22, 2012

The U.S. Supreme Court, in a unanimous decision authored by Justice Breyer, clarified the scope of patentable subject matter by holding that a diagnostic method for optimizing drug dose is not patentable because the underlying steps of the patent claims did not sufficiently "transform" this newly discovered law of nature. *Mayo Collaborative Servs., DBA Mayo Med. Labs., et al. v. Prometheus Labs., Inc.,* 566 U.S. __ (2012). The Court's decision relies heavily on Supreme Court precedent and balances the scales of what is and is not patentable subject matter. This decision will place further value on thoughtful patent application and claim drafting to satisfy the Supreme Court's shifting standard for patent eligibility. Particularly for inventions that employ mental correlations or computational steps, it will be important to describe the invention in terms of novel and non-obvious physical activity.

Historical perspectives and claims at issue

This case began in 2004 when Prometheus sued Mayo for patent infringement. Prometheus is the exclusive licensee of two patents directed to methods of determining optimal dosing of thiopurine drugs to treat autoimmune diseases. The drugs—a 6-mercaptopurine ("6-MP") and a prodrug azathiopurine that converts to 6-MP in the body—have been used for many years despite concerns over toxicity in some patients. The claims at issue comprise an "administering step," a "determining step," and "wherein" clauses. Exemplary Claim 1 of one of the patents recites:

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 $8x10^8$ 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 $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

The district court granted Mayo's motion for summary judgment of invalidity under 35 U.S.C. § 101 holding that the claims are directed to correlations of thiopurine metabolism, which are natural phenomenon and not patent eligible. (*Prometheus Labs., Inc. v. Mayo Collaborative Servs.,* No. 04-CV-1200, 2008 WL 878910, (S.D. Cal. Mar. 28, 2008)) Prometheus appealed to the United States Court of Appeals for the Federal Circuit. The Federal Circuit reversed the district court's decision, and held that if the so-called "machine or transformation" test is applied, the "administering" and "determining" steps render the claims patent eligible. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.,* 581 F.3d 1336 (Fed. Cir. 2009).

Mayo then petitioned the Supreme Court. Without comment, the Court vacated and remanded the Federal Circuit's decision in light of the Court's *Bilski* decision that clarified the use of the "machine or transformation" test. *Bilski v. Kappos,* 130 S. Ct. 3218 (2010). On remand, the Federal Circuit again found Prometheus' claims patent eligible, holding that in light of *Bilski,* the claims at issue recite specific treatment steps that involve a particular application of natural phenomenon. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.,* 628 F.3d 1347 (Fed. Cir. 2010). The Federal Circuit specifically addressed the transformative nature of the Prometheus claims, declaring that "methods of treatment … are always transformative when one of the defined groups of drugs is administered to the body to ameliorate the effects of an undesired condition."

Mayo again petitioned the Supreme Court, which granted *certiorari* on the following question:

Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of these naturally occurring

correlations, simply because well-known methods used to administer prescription drugs and test blood may involve ‘transformations' of body chemistry.

The Supreme Court's decision: Patent eligibility for newly discovered natural laws requires novel and non-obvious transformation

Generally, patent eligible subject matter is viewed to encompass "anything under the sun that is made by man." *Diamond v. Chakrabarty,* 447 US 303 (1980). The Supreme Court, however, has excepted "laws of nature, natural phenomena, and abstract ideas, [which] are not patentable." In this most recent interpretation of Section 101, the Court again clarified the breadth of the exception, finding that patent claims drawn to laws of nature where the underlying method steps are not sufficient to "transform" the laws of nature, through novel and non-obvious activity, do not equate to patentable subject matter.

The Court's opinion focused primarily on the "administering," "determining," and "wherein" steps of Prometheus' claim. According to the Court, such "claimed processes are not patentable unless they have additional features that provide practical assurance that the processes are genuine applications of [natural] laws." In essence, the patentees' additional steps must "transform" the natural law in order to be patent eligible. And in this case, the Court determined that Prometheus' claim failed to transform the natural law of drug metabolism into patentable subject matter.

Specifically, with respect to the "administering step," the Court held that this step "simply identifies a group of people who will be interested in the correlations" and that "[d]octors had been using these drugs for this purpose long before these patents existed." Accordingly, applying an "administering" label to an existing process fails to transform the natural law.

Turning to the "determining step," the Court declared that this step "tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use." According to the Court, methods for determining metabolite levels are well known in the art, and this step merely "tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field." Again, the Court disagreed that adding a "determining" step transforms the natural law.

Finally, the Court opined that 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." Here, the Court whittled the step down to merely telling "the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decision making." Again, the Court disagreed with Prometheus that this step transformed the natural phenomenon of drug metabolism.

In sum, Prometheus' combination "informs 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." As such, the three additional steps even in combination "are not sufficient to transform unpatentable natural correlations into patentable applications."

The Court found support in its precedent in *Diamond v. Diehr* and *Parker v. Flook.* In *Diehr,* the Court held that "a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use" so long as the steps were not "obvious, already in use, or purely conventional." *Diamond v. Diehr,* 450 US 175 (1981). On the other end of the spectrum, the Court in *Flook* held that "'post-solution activity' that is purely ‘conventional or obvious,'… ‘can[not] transform an unpatentable principle into a patentable process.'" *Parker v. Flook,* 437 US 584 (1978). Analogizing to its precedent, the Court framed Prometheus' claimed process as mere steps that must be taken to apply the laws in question, with the ultimate effect of simply telling doctors to apply the law somehow when treating their patients. In squaring the previous two cases with the present case, the Court summarizes, stating "[t]he claim before us presents a case for patentability that is weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook.*"

Prometheus and the government presented additional arguments that did not convince the Court.

The Federal Circuit in finding patent eligibility had reasoned that "the claimed [Prometheus] processes are therefore patent eligible, since they involve transforming the human body by administering a thiopurine drug and transforming the blood by analyzing it to determine metabolite levels." The Court rejected that reasoning, stating the first transformation step is "irrelevant" as the "'administering' step simply helps to pick out the group of individuals who are likely interested in applying the law of nature," and that the second transformation "could be satisfied without transforming the blood, should science develop a totally different system for determining metabolite levels that did not involve such a transformation." Importantly, the Court stated that the "'machine-or-transformation' test is an *'important and useful clue'* to patentability" but clarifies that the Court has never stated nor indicated that test "trumps the 'law of nature' exclusion."

Prometheus argued that "because the particular laws of nature that its patent claims embody are narrow and specific, the patents should be upheld." The Court declined to draw a line on "whether or not they will interfere significantly with innovation in other fields now or in the future," stating that "even a narrow law of nature (such as the one before us) can inhibit future research."

The Government presented arguments "that virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy § 101's demands." The Court stated that the Government was in essence arguing that "other statutory provisions—those that insist that a claimed process be novel, 35 U. S. C. § 102, that it not be 'obvious in light of prior art,' § 103, and that it be 'full[y], clear[ly], concise[ly], and exact[ly]' described, § 112—can perform this screening function." The Court rejected these arguments, concluding that this stance "would make the 'law of nature' exception to § 101 patentability a dead letter" and would be "not consistent with prior law."

The Court was also unpersuaded by the argument that denying patent coverage here would discourage significantly innovation in the area of diagnostic research. "Patent protection is, after all, a two-edged sword"; "[o]n the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention". Ultimately the Court shifted the burden, recognizing "the role of Congress in crafting more finely tailored rules where necessary" and declined to comment on "whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable."

The Court here interprets "law of nature" broadly to include metabolism of non-naturally provided compounds to which the body would not ordinarily be exposed. Not only does the Court adopt this broad interpretation of section 101, where previous courts had drawn distinct lines between patent eligibility (section 101) and novel/non-obviousness (sections 102 and 103) standards, in this decision, for the first time, the Court significantly blurs these standards.

Looking forward, some take-away messages are (1) a newly discovered law of nature is by itself, as before, unpatentable and (2) applying that newly discovered law is also likely unpatentable if the resulting patent claims merely recite elements that are conventional in the art in connection with a recitation of the newly discovered law. While the Court did not categorically deny patent eligibility to processes that rely on laws of nature, the Court made clear that the "application" must be "significant," not "too broadly preempt" use of the law, and include other elements that constitute an "inventive concept" that is significant and separate from the natural law itself. Moreover, it is notable that the Court stated that the claims at issue were "[u]nlike, say, a typical patent on a new drug or a new way of using an existing drug" and in fact declined to opine regarding whether if "the steps at issue here [were] less conventional, these features of the claims would prove sufficient to invalidate them."

Overall, this decision places further value on thoughtful patent application and claim drafting to satisfy the Supreme Court's shifting standard for patent eligibility. Particularly for inventions that employ mental correlations or computational steps, it will be important to describe the invention in terms of novel and non-obvious physical activity and process steps, such that the claims are interpreted as "transforming" the newly discovered associations and correlations into patentable subject matter.

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