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LEGAL ALERT

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Supreme Court Decision Raises Questions of the Validity of Many Bioscience Patents: Did the Invention "Add Enough?"

by Chuck Hauff, Bill Mulholland and Jeremy Kapteyn

On Tuesday, March 20, 2012, the U.S. Supreme Court issued its decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc*. 566 U.S. ____ (2012). In a unanimous decision, the Supreme Court sided with Mayo and held that method claims involving administering a drug to a patient and determining the effect were not patentable subject matter. The court concluded that the method was directed to a "law of nature" and therefore not patentable. The court reasoned that the Prometheus patent added nothing of significance to the natural correlation between drug dosages and drug metabolite levels and that the patent otherwise had the effect of stifling future innovation in this area. The implications of this case are significant for certain segments of the pharma and biotech industries, particularly those wishing to obtain or enforce patents with certain types of diagnostic claims.

The Technology and Patent Claims

Prometheus Laboratories exclusively licensed two patents claiming the use of thiopurine drugs to treat gastrointestinal and non-gastrointestinal autoimmune diseases, such as Crohn's disease and ulcerative colitis from the Canadian research hospital Hopital-Sainte-Justine. When ingested, the thiopurine drugs are metabolized and produce metabolites in the bloodstream of the patient and the patents claim methods for calibrating the proper dosage of thiopurine drugs.[1]

Thiopurine drugs were known, generally, as was the use of the drugs to treat autoimmune diseases. It was known that the efficacy of the drugs could be determined by measuring the amount of metabolites created. However, non-responsiveness and drug toxicity complicated treatment in some patients and the patents were specifically directed to addressing that problem.

To that end, the patents claim methods that seek to optimize therapeutic efficacy while minimizing toxic side effects. As written, the patented methods include two steps: (a) "administering" a drug that provides the thiopurine drug to a subject; and (b) "determining" the levels of the drug's metabolites created in the subject. The claims are directed to processes that identify correlations between metabolite levels and likely harm or ineffectiveness of the drug with regard to that patient. Specifically, in the Prometheus test, doctors would analyze the levels of certain drug metabolites in a patient's bloodstream to determine whether the proper dose was being administered and could increase or decrease the amount of drug being delivered to increase efficacy and decrease toxic side effects as indicated.

Litigation Summary

Prometheus Laboratories originally sued Mayo Collaborative Services, d/b/a Mayo Medical Laboratories and Mayo Clinic Rochester in the Southern District of California for patent infringement in 2004. The litigation was initiated when Mayo indicated that it was going to stop

purchasing tests from Prometheus and begin selling its own version of the test. The District Court initially found (on cross-motions for summary judgment in 2005) that there was infringement of certain claims, but later determined (on further motions for summary judgment in 2007) that the claims were directed to natural phenomenon rather than patentable subject matter.

Prometheus appealed to the Court of the Appeals for the Federal Circuit and the Federal Circuit concluded that the patent claims did constitute patentable subject matter. *Prometheus Labs, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009). Mayo then filed a petition for writ of certiorari in the Supreme Court. Following that, but prior to the Supreme Court's review of the writ, the Supreme Court issued its decision in *Bilski v. Kappos*, 561 U.S. ___ 130 S.Ct. 328 (2010), and based on that decision, the Supreme Court, without comment, vacated and remanded the Federal Circuit's decision. *Mayo Collaborative Services v. Prometheus Labs, Inc.,* 130 S. Ct. 335 (2010).

On remand, the Federal Circuit again reversed the District Court's grant of summary judgment and upheld the patentability of the claims. *Prometheus Labs, Inc. v. Mayo Collaborative Services,* 628 F. 3d 1347 (Fed. Cir. 2010). In that decision, the Federal Circuit found that the claims "do not wholly preempt all uses of the recited correlations" between metabolite levels and drug efficacy or toxicity. *Id.* at 1355. Rather, the court viewed the claims as comprising specific treatment steps which, in its view, involved a particular application of the natural correlations. *Id.*

The Supreme Court Decision and Implications

In the Supreme Court's opinion, the court noted that the claims set forth laws of nature in the form of a relationship between concentrations of certain metabolites in the blood and the likelihood that a dosage of thiopurine will prove ineffective or have toxic results. *Mayo*, Slip. Op. at 8. The Supreme Court then framed the case by noting "the question

before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add *enough* to their statements of correlations to allow the processes they describe to qualify as patent eligible processes that *apply* natural laws?" *Id.* (Emphasis in original). The court then noted that their answer to that question was "no." *Id.*

The Supreme Court's decision brings into question the validity of similar claims in many patents already issued and likely will have an immediate impact on pending patent applications in the personalized medicine and life sciences areas and litigation relating to those patents.

From a legal perspective, the court's ruling further highlights the differences between the Supreme Court and Federal Circuit both with respect to what constitutes patentable subject matter and how the issue of whether claims delineate patentable subject matter should be considered. This is the second decision in which the Supreme Court has disagreed with the Federal Circuit (*Bilski* being the first decision). And, perhaps more importantly, the court noted that determination of patentable subject matter is a threshold question, not one that can be taken up after other issues, which may be determinative of the outcome of the case. In this case, for example, the issue of validity was taken up only after the claims had been found to be infringed. Now, under the court's decision in *Prometheus,* the issue of patentable subject matter must be addressed first.

From a practical perspective, not all drug patents are impacted by this decision, but method claims directed to processes including natural laws must apply those laws and "add enough" to the natural laws to delineate patentable subject matter. The court's decision provides little guidance as to how that might be done, but seems to encourage an assessment of the extent to which future innovation may be stifled.

Specifically, the court clearly was concerned with the breadth of the claims and the likelihood that the patent would foreclose more future invention than the underlying discovery could reasonably justify. As it related to Prometheus' patent claims, the court noted "they tie up the doctor's subsequent treatment decision whether that treatment does, or does not, change in light of the imprints he has drawn using the correlations. And they threaten to inhibit the development of more refined treatment recommendations (like that embodied in Mayo's test), that combine Prometheus correlations with later discovered features of metabolites, human physiology or individual patient characteristics." Slip Op. at 18.

The court's analysis of assessing whether the claims improperly tie up future uses of the laws of nature represents an interesting legal construct that will likely be interpreted by lower courts and patent examiners in many different ways. Specifically, while the Court concluded that Prometheus' test methods did not constitute patentable subject matter, they provided very little guidance as to what issues courts should evaluate to determine whether a claim adds sufficient limitations to the use of a natural law so as not to be of such a breadth as to improperly tie up the future use of those laws.

Of note, in this context, the Federal Circuit concluded on not one, but two separate occasions that the claims in question constituted patentable subject matter and, as noted above, in the second instance determining that the patent grant did not go too far. The Supreme Court clearly disagreed.

While the court closes its opinion noting that Congressional action is one way of providing further instruction as to what constitutes patentable subject matter ("we must recognize the role of crafting more finely tailored rules where necessary" Slip Op. at 24), in light of the recent enactment of the American Invents Act in September of 2011 — which reform measures took over a decade to work through Congress — it seems unlikely that immediate

Congressional guidance is likely or, if taken up, that it would provide definitive guidance.

While the impact of the court's decision on the fields of pharmaceuticals and biotechnology remains unclear, it is clear that the issue of whether patent claims encompass patentable subject matter, now clearly a threshold issue in patent enforcement litigation, will depend on the way the lower courts apply this decision in the absence of specific guidance. The effect on pending applications and examination of those applications will rest with the way patent examiners apply this decision. Will they believe the claims “add enough?” Or, will they believe, as the Supreme Court did, that the extension of patent rights too broadly preempts the use of a natural law and unreasonably forecloses further innovation. Leaving decisions of such magnitude to lower courts and patent examiners ensures this topic will be one which will evolve, likely with different outcomes, over the course of the near term.

[1] The thiopurine drugs included 6-mercaptopurine (6-MP) and azathiopurine (AZA), a pro-drug that upon administration to a patient converts to 6-MP. 6-MP is broken down by the body into various 6-MP metabolites, including 6-methyl-mercaptopurine and 6-thioguanine and their nucleotides. [back]

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