

IT'S (NOT) ONLY NATURAL

Five tips in the wake of *Mayo v. Prometheus* and the “law of nature.”

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MANY SAY THAT PERSONALIZED medicine is the wave of the future. And biotechnology is without doubt on the cutting edge of medicine. In recent years, biotech drugs have shown increased efficacy—and sometimes the power to cure—for patients with specific biochemical profiles. Physicians have also started optimizing drug dosages for individual patient metabolisms, improving outcomes while minimizing side effects. Diagnostic testing, which many companies have tried to patent for certain diseases, is the first, critical step in this process.

But the challenge for biotech companies has been to obtain broad patent coverage without claiming a “law of nature,” which is impermissible.

In a highly anticipated decision, the U.S. Supreme Court has now addressed this issue in *Mayo v. Prometheus*. The court’s 9-to-0 opinion invalidating Prometheus Laboratories Inc.’s patent claims is sparking impassioned commentary in the biotech industry. Many are ques-

tioning the value of existing diagnostic patent portfolios and even whether to invest in creating new ones. Yet the decision is not as dire as it first appears. Patent applicants can take practical steps to avoid the problems outlined by the Supreme Court. And the Patent and Trademark Office, for now, has indicated that its patentability assessment methods have not changed.

Prometheus began this case in 2004 by asserting two patents against Mayo Collaborative Services Inc. in California federal district court. The patents claimed an example of personalized medicine that involved administering a particular drug to a patient, determining the level of the drug’s metabolite in the patient, and recognizing whether the amount of drug administered might be too high or low based on the metabolite level. Because each patient metabolizes drugs differently, the idea was to provide an optimal dose to improve the drug’s efficacy in each patient treated for certain gastrointestinal disorders.

Some of the arguments in Mayo’s Supreme Court brief are echoed in the court’s opinion. Mayo began by arguing that if Prometheus’s patents were found valid, the company would monopolize the field of blood testing for the drug metabo-

lites at issue. Mayo also asserted that the patent claims covered anything a doctor might do with knowledge of the correlation above as it related to any type of autoimmune disease. In particular, Mayo argued that the claims simply combined a natural phenomenon with well-known, widely used data-gathering steps and that a physician would inevitably perform those steps in treating a patient, thus preventing practitioners from further investigating and refining the metabolite ranges in the patent claims.

The Supreme Court focused its analysis on whether the claimed subject matter was patent-eligible under 35 U.S.C. section 101. In the decision below, the U.S. Court of Appeals for the Federal Circuit had applied a “machine-or-transformation” test in considering this issue and upholding the claims. The Federal Circuit concluded that the act of measuring metabolite levels was sufficiently transformative so as not to be a mere recognition of a natural correlation.

The Supreme Court disagreed with this analysis and stated that even if such a test were satisfied, it could not justify the claiming of a natural law or phenomenon. The Supreme Court also addressed those portions of the claims that were not per se natural phenom-

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ena. It opined that those steps were simply “well understood, routine, conventional activity previously engaged in by scientists who work in the field.” The court added that such steps are not sufficient to transform a law of nature—defined as a completely natural process that exists “in principle apart from any human action”—into a patent-eligible claim, and that the claims merely instructed physicians to apply a natural law.

The Supreme Court further commented on two other patent law concepts: novelty and obviousness under 35 U.S.C. sections 102 and 103. It recognized that patent eligibility sometimes overlaps with these concepts, but it left unanswered when it is appropriate to address them. (The *Prometheus* decision itself only analyzes subject matter eligibility under section 101.) According to the Supreme Court, considering novelty and nonobviousness in this case “would [have made] the ‘law of nature’ exception to section 101 patentability a dead letter,” and be inconsistent with the court’s precedent.

MANY IN THE INDUSTRY BELIEVE THAT the Supreme Court’s decision is a game changer. What do you do when applying for new patents? How do you assess old ones? Those with large diagnostic portfolios have much to consider, including their in-licensed or out-licensed patents. The good news is that the sky, in fact, is not falling.

One day after the Supreme Court decided *Prometheus*, the patent office issued a memo to its examiners instructing them to continue examining patent claims for patentable subject matter using the office’s existing guidance (based on *Bilski v. Kappos*, a 2010 Supreme Court case

that also involved the issue of patentable subject matter). Generally, that guidance instructs examiners to use the “machine-or-transformation” test as an investigative tool, but not as the only test to be used for analyzing patent-eligible subject matter.

The patent office memo informs examiners that a patent-eligible claim may not be directed to a monopoly on a law of nature, natural phenomenon, or abstract idea. Instead, such a claim requires other elements or a combination of elements that transform it into something significantly more than a law of nature, natural phenomenon, or abstract idea.

HERE ARE A FEW PRACTICAL TIPS TO consider in light of *Prometheus* and the PTO’s follow-up memo:

- Strong, patent-eligible claims should include active steps requiring more than mental activity, and include more than a suggestion that a person take an applicable natural law or phenomenon into account. (This was the Supreme Court’s assessment of the “wherein” clauses in the *Prometheus* claims.)

- For claims of issued patents where additional coverage may be desired, patent owners and those with portfolio licenses should consider filing continuation applications if there is a pending application in the patent family, an appropriate priority date, and support in the specification for detailed claim amendments.

- For other claims where no pending applications in the patent family are pending, supplemental examination may be considered. The America Invents Act, signed into law in September 2011, creates a supplemental examination procedure that allows patent subject matter eligibility to be considered. This procedure must be initiated by the patent owner.

- For pending applications, consider adding claim steps that go beyond “conventional or obvious” “[pre]solution activity,” which the Supreme Court suggested is not enough by itself to arrive at a patent-eligible application of a natural phenomenon.

- Devote particular attention to including detailed dependent claims linked to a broader, but still viable, base claim. In other words, if you’re going to claim broadly, make sure you also claim narrowly, even if you have to pay a modest additional fee to the patent office for the extra claims.

Prometheus has generated a great deal of controversy, but the holding can be addressed by applying the practical IP management techniques outlined above. Diagnostic patents, like other patents, must claim more than a natural correlation, phenomenon, or law recognized in a particular context. Such patents can still be procured and are of continuing value to industry and investors alike.

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