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Mayo v. Prometheus

The Supreme Court deals a blow to some biotech patents

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By Matt Gibson

In a unanimous decision, the U.S. Supreme Court ruled that a patent directed to adjusting a drug dosing regimen based on metabolite levels measured in the patient is not eligible for patent protection under 35 U.S.C. § 101 because it amounts to patenting a law of nature.

Prometheus Laboratories, Inc. is the exclusive licensee of the patents at issue, which protected a method for determining the proper dose of thiopurine drugs to administer to an ulcerative colitis patient by measuring the levels of a particular thiopurine metabolite. Mayo Clinic and Mayo Collaborative Services began using and selling its own test which, although slightly different, was still found at the district court level to infringe Prometheus's patents. In defense, Mayo asserted that the patents were invalid for being directed to unpatentable subject matter. The district court agreed with Mayo and found that the patents claimed a law of nature and were therefore ineligible for patent protection. On appeal, the U.S. Court of Appeals for the Federal Circuit reversed and found that the patent involved a transformation (drug being converted to metabolite) and that the scope of protection was narrowly defined to a particular area such that it did not preempt all use of the natural process. The Supreme Court disagreed.

Section 101 of the Patent Act defines patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." The Supreme Court has long held that this provision has an implicit exception — namely, that laws of nature, natural phenomena, and abstract ideas are not themselves eligible for patent protection. However, the Supreme Court has also long held that *application of a law of nature* to a process may be eligible for patent protection where it results in significantly more than a patent on the natural law itself.

The Supreme Court in *Mayo v. Prometheus* concluded that the claims at issue amounted to no more than a patent on a law of nature itself. The patent at issue included claims that essentially called for three steps:

1. Administering a dose of thiopurine drug to a patient;
2. Measuring a thiopurine metabolite level in the patient; and
3. Decreasing the dose if the metabolite level is above a specified high level or increasing the dose if the metabolite level is below a specified low level

Although the patent was based on the new and useful discovery of the correlation between metabolite levels and indications of toxicity and efficacy, the Supreme Court held that the mere discovery of this correlation and the application of it using routine, conventional activity was not enough to transform the

law of nature into patentable subject matter. The court further explained that the steps of the method added nothing of significance beyond the natural law itself.

This Supreme Court decision has had immediate impact in the biotechnology arena. Most notably, a few days after the *Prometheus* decision was handed down, the Supreme Court vacated the Federal Circuit's ruling in the highly publicized Myriad Genetics "Gene Patent" case (*Assoc. of Molecular Pathology et al. v. US Patent and Trademark Office*) and remanded back to the Federal Circuit for consideration in view of *Prometheus*. Additionally, in just a matter of weeks since *Prometheus*, at least one district court has invalidated a similar patent based on the Supreme Court's decision.

What is the practical effect of this decision? First and foremost, it may affect the enforceability of some biotech patent portfolios, especially those geared towards diagnostic methods and personalized medicine. Similarly, existing or potential license agreements based on patents of this nature could be impacted by this decision. Finally, healthcare providers and testing facilities may want to reconsider offering tests they otherwise avoided due to high royalties or threat of litigation. However, it should be understood that this decision does not automatically invalidate all patents directed to diagnostic methods and personalized medicine. Patents and patent applications related to diagnostic tests/personalized medicine methods as well as licenses involving such patents, and tests covered by such patents should be considered in view of *Prometheus*. That being said, the reach of *Prometheus* is likely not limited to these types of patents and may prove to change the way courts and the Patent Office looks at many types of method/process patents, including business method patents.

LINKS

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