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Unanswered Questions After High Court Strikes Down Prometheus

By **Gary Connell**
SHERIDAN ROSS

THE RECENT unanimous Supreme Court ruling in Mayo Collaborative Services v. Prometheus Laboratories Inc. invalidated U.S. Patent Nos. 6,355,623 and 6,680,302, finding that the claimed inventions covered laws of nature. While the ruling provides some guidance on the issue of what makes an invention eligible for patent protection, the Prometheus decision left many unanswered questions.

Section 101 of the Patent Act defines what types of inventions can be patented — process, machine, manufacture, or composition of matter — and has been interpreted to exclude "laws of nature, natural phenomena and natural ideas." These items are excluded because they are thought to be basic tools of innovation, the monopolization of which would impede rather than promote technological progress.

The Prometheus patents covered methods to optimize the therapeutic effectiveness of certain drugs for gastrointestinal disorders by administering the drug to a patient and determining the level of a metabolite of the drug in the patient. If the metabolite is less or more than a specified amount, then there is a need to increase or decrease the amount of the drug in subsequent administration.

The patent system has an inherent tension between acting as an incentive to spur innovation by granting valuable exclusive rights to inventors and restricting access to or raising the cost to access inventions. The Prometheus decision assumed that the grant of exclusive rights for a patent was a necessary evil to be tolerated for the benefit of incentivizing invention. The court did not recognize that the grant of exclusive rights may be a necessary condition to accumulate the investment needed to bring certain inventions in the life sciences to public benefit. However, the court did recognize that broadly excluding laws of nature from patent protection could eviscerate patent law, but it noted that to

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transform an unpatentable law of nature into a patentable *application* of a law of nature, the patent must amount to something "significantly more" than a patent on the law of nature itself. The court posed the question as whether "the patent claims add *enough* to their statements …to allow the [claimed] processes they describe to qualify as patent-eligible processes that apply natural laws." The court did not, however, provide concrete guidance for determining whether an invention has that "significantly more" something needed to make an invention patent eligible.

The Prometheus patent claims were quite specific about the amount of the metabolite 6-thioguanine that indicated a need to increase or decrease dosage. However, the court found the step of determining the amount of 6-thioguanine to be a conventional step because the patent acknowledged that scientists already knew that the amount of 6-thioguanine correlated with the effectiveness of drug dosage, just not the specific amounts that were identified and claimed by the Prometheus inventors.

The court concluded the Prometheus patents improperly covered laws of nature and suggested that the question of whether an invention is considered to be a law of nature depends on the degree to which other steps in the process are "conventional" or "unconventional." The Prometheus claims were characterized by the court as merely informing a relevant audience about certain laws of nature with additional steps that were well understood, routine and conventional, and that were already engaged in by the scientific community. The court left for another day "whether were the steps at issue here less conventional, these features [of restricting access to or raising the cost of using inventions] of the claims would prove sufficient to invalidate them."

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A number of questions remain after this decision. Just days after the Prometheus decision, the court remanded the Association for Molecular Pathology v. Myriad case to the federal circuit for consideration in view of Prometheus. The Myriad case addresses the patent eligibility of other types of subject matter in the life sciences area. The federal circuit will likely struggle to apply the Prometheus decision to the facts of the Myriad case.

One of the many unanswered questions the lower court will need to specifically address in rendering a decision in Myriad is what is a "law of nature?" In Prometheus, the court did not address whether the relationship between thiopurine metabolites and drug effectiveness is a natural law, but assumed it to be so, despite the drug being a synthetic compound and the amount of metabolite produced by a certain dose being variable between individuals. This type of subject matter is very different from the example of $E=mc^2$ used by the court as a prototypical law of nature. The court specifically declined to adopt a minimalist test that *any* step beyond a law of nature was sufficient to make an invention patent-eligible. Rather, the court formulated the fundamental patent eligibility analysis as being to what degree any steps other than the law of nature are *conventional*. What that actually means is left unanswered and will need to be defined by courts interpreting the Prometheus decision.

Finally, the patent eligibility analysis of the court also brought in a host of policy issues by suggesting that a higher degree of unconventionality could offset what the court viewed as the necessary evil of granting exclusive patent rights.

If given broad application, Prometheus has the potential to significantly restrict the ability to patent many inventions in the life sciences, such as diagnostic methods and applications of personalized medicine. These inventions are vital to the life sciences industry, and the Prometheus decision runs the risk of creating disincentives for investment in an industry heavily reliant on patents to justify the enormous cost of regulatory requirements and long development times. •

— Gary Connell is a shareholder with Sheridan Ross P.C., the oldest intellectual property law firm in the Rocky Mountain region.