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Diagnostic method patents in jeopardy

Mayo v. Prometheus: A looming 'disaster' for tech transfer?

Researchers and tech transfer leaders were shaken by the recent *Mayo v. Prometheus* decision handed down by the U.S. Supreme Court, which suggests that any research development based on a law of nature is not patentable. If the decision is interpreted broadly, an untold number of promising research projects could have no prospects for commercialization.

But is the situation that dire? Some experts, like **Mark J. Nuell**, PhD, a partner with the law firm of Birch Stewart Kolash Birch in San Diego, CA, say the decision could have a devastating impact on what is increasingly seen as a promising avenue of research.

"It's a disaster as far as I can tell for the biotechnology industry as a whole," he says. "It's going to push development of diagnostics back to the universities and privately funded research institutes that don't care if they sell a new product or not. They're just interested in finding new knowledge. People operating for a profit won't be able protect what they're doing without falling prey to copycats."

The decision effectively raises the bar for any patent claim derived from a natural law, Nuell says. The Court has made clear that simply adding a known technology to the natural law is not enough to make the process patentable, he says. "If you're going to write a diagnostic claim now, you're into a realm where you need some sort of a new reagent for affecting that test," he says. "Saying that you achieve the end result through polymerase chain reaction won't pass muster. You're going to have to show that you're using some kind of new, super reagent in the polymerase reaction or something like that. Diagnostic claims will have to rely on a new reagent or a wholly new methodology in order to become patent-eligible subject matter."

Commercialization efforts at research institutions will shift more to the incremental improvements in diagnostics, reagents, and analytic methods, Nuell predicts. Those could be patentable in their own right, he notes.

Court says process not unique

The unanimous Supreme Court decision held that the personalized medicine dosing process invented by Prometheus is not eligible for patent protection because the process is effectively an unpatentable law of nature. The Prometheus invention identifies "relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove [either] ineffective or cause harm. Claim 1, for example, states that if the levels of 6-TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per 8×10^8 red blood cells, then the administered dose is likely to produce toxic side effects," as summarized in the court decision.

In addition to claiming the boundaries between over- and under-dosage of thiopurine based upon measuring 6-TG in the blood, some of the Prometheus claims include additional limitations such as administering thiopurine to a patient and determining the blood level of 6-TG.

The Supreme Court determined that the correlation between 6-TG blood levels and over/under thiopurine dosage is an unpatentable law of nature. What Prometheus was trying to patent is merely a natural process -- a consequence of the ways in which thiopurine compounds are metabolized by the body, the Court said.

Furthermore, the court concluded that the manner in which Prometheus applied this natural process was nothing new. "Because methods for

making such determinations were well known in the art, this step simply tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists in the field,” the opinion states. “Such activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.”

The conclusion states that a newly discovered law of nature is itself unpatentable and the application of that newly discovered law is also normally unpatentable if the application merely relies upon elements already known through prior art. But the Court did leave some wiggle room, stating that “an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.” To reach that level, the application must be “significant,” not “too broadly preempt” use of the natural law, and include other elements that constitute an “inventive concept” that is significant and separate from the natural law itself. (The full text of the Supreme Court decision is available at <http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf>.)

Implications for software patents

The decision could be applied beyond medical patents, notes **Fred DuFresne**, an inventor and entrepreneur in software, intellectual property and technical medicine in Roanoke, VA, who holds more than a dozen patents around the world. Software patents also could be affected, he says.

“Software-centered patents should be issued for technologies involved in the creation of other

software and the operation of the system,” he says. “This is different than patent claims that apply existing software technologies as part of a process. In that case, the other steps in the process, method or system must support patentability.”

Severe limits on diagnostic patents

The decision has been hailed as a win for advocacy groups that want to see medications and medical advances made available to a wider patient population and at a lower price, but Nuell says he does not see *Mayo v. Prometheus* as good news for patients -- or anyone else for that matter.

“Instead of having these products available at a higher price, now what I’m afraid will happen is that none of them will get developed at all,” Nuell says. “The state of diagnosis will be impaired. People took a short view of things, and I don’t think this will be good for anyone in the long run.”

Concern also comes from **Janice A. Vatland**, JD, a shareholder with the law firm of Wolf Greenfield in Boston, MA. *Mayo v. Prometheus* seems to significantly limit what can be patented in the diagnostic field, especially if your claim is centered on what the court might consider a natural law, she says. However, she also says the Prometheus patent was far from airtight, and that stronger attention to claims construction might have resulted in a different ruling.

“The Prometheus claim was written in a way that lends itself to that interpretation by the court. They had a couple steps that were reciting things

Patent office issues guidelines to examiners after Prometheus

The day after the Supreme Court decision in *Prometheus v. Mayo*, the U.S. Patent and Trademark Office issued guidance to its examiners in how to interpret the ruling and apply it to patent applications. The guidance is available online at http://www.uspto.gov/patents/law/exam/mayo_prelim_guidance.pdf. Here is an excerpt from the PTO memo:

“Examiners must continue to ensure that claims, particularly process claims, are not directed to an exception to eligibility such that the claim amounts to a monopoly on the law of nature, natural phenomenon, or abstract idea itself. In addition, to be patent-eligible, a claim that includes an exception should include other elements or combination of elements such that, in practice, the claimed product or process

amounts to significantly more than a law of nature, a natural phenomenon, or an abstract idea with conventional steps specified at a high level of generality appended thereto.

“If a claim is effectively directed to the exception itself (a law of nature, a natural phenomenon, or an abstract idea) and therefore does not meet the eligibility requirements, the examiner should reject the claim under section 101 as being directed to non-statutory subject matter. If a claim is rejected under section 101 on the basis that it is drawn to an exception, the applicant then has the opportunity to explain why the claim is not drawn solely to the exception and point to limitations in the claim that apply the law of nature, natural phenomena or abstract idea.” ►

known in the art, but the real heart of the claim, the real invention, was centered on the correlation," she says. "There weren't any steps that centered on the application, and I think that was the real problem in the Prometheus claim. The Prometheus claims were pretty weak claims and I think that is why they had trouble."

Going forward, claims will have to clearly specify the application of the natural law or correlation, and they will have to avoid relying on active steps that a court could view as insignificant activity, obvious, or already known in the art, Vatland says.

"There are still some questions, because we have to see how the federal courts and the patent office will apply this decision," Vatland says. "I don't think it is the end of diagnostic claims or claims that recite any sort of natural law. There are still some opportunities to get good claims approved."

Vatland urges researchers and commercialization leaders to review projects and claims for adherence with the criteria outlined in *Prometheus v. Mayo*. Discern as early as possible whether a project is likely to meet those patentable subject matter criteria and tailor the research and the claim to that end, she says.

Claims construction options

One strategy might be to shift the focus of such claims away from the actual treatment to the effect of a test or therapy on a cell, tissue, or organ, suggests William K. Merkel, PhD, a partner with the law firm of Marshall Gerstein Borun in Chicago.

"These are different foci for claim drafting.

The effort would be to get away from a claim for treating a body," Merkel explains. "People will understand that if you are treating a body, the laws of nature may apply, but that assumption may not be so quick when you are focused on affecting a cell."

A second approach may be to add more detail, Merkel says. The court seemed to imply that the Prometheus claims were rather broad, he says, in particular because the determining step did not actually cite any techniques for determining the level of metabolite in the blood.

"The narrower the claim, the more detail you put in it, the more likely you are to avoid this eligibility problem," Merkel says. "Given the preliminary guidance, I think we can expect some trouble with a lot of the pending claims and applications. The larger problem is the patents already issued that could be invalidated by *Prometheus v. Mayo*."

Merkel says he has discussed the case with several tech transfer offices, where he hears a great deal of concern about the impact. He cautions tech transfer leaders not to panic -- yet. "I wouldn't go so far as to say the sky is falling," he says. "There is still the chance that other courts will narrowly interpret *Mayo*. But I cannot say that is likely. I understand anyone who is quite upset about the decision in the academic world and tech transfer offices."

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