Justices Consider Patent Process For Personalized Medicine Industry

BY MICHAEL SHUSTER

In the past decade, personalized medicine has emerged as one of the most promising areas of medical research. It holds great potential for improving patient outcomes and reducing human suffering as well as driving down health care costs.

But innovation needs to be nurtured. In the U.S., the primary mechanism to incentivize innovation is the patent process. The Constitution states that Congress shall have the power to "promote the progress of science and useful arts by securing for limited times to authors and investors the exclusive right to their respective writings and discoveries."

However, concerns have surfaced that the system is out of balance and impeding rather than advancing technological progress. Where there is no protection of rights, there is very little incentive to innovate, often described as the tragedy of the commons. But it is also true that innovation suffers where there are numerous rights holders – a phenomenon coined by Michael Heller as the tragedy of the anti-commons.

Section 101 of Title 35 U.S.C governs the scope of what is patentable. The U.S. Supreme Court has interpreted the code to establish a threshold of patentability that excludes abstract ideas, products of nature and laws of nature. In the past five years, the Court has had an unprecedented focus on where that threshold lies reflecting a broader policy struggle.

A clear understanding of the limits of the "law of nature" doctrine as well as analysis of method claims for "preemption" as a way of deciding whether a claim is so broad as to effectively remove from the public domain all uses of a law of nature, would be a welcome development for the nascent personalized medicine industry.

So far, the Supreme Court has ruled narrowly. In *LabCorp. v. Metabolite* (2006), the Court took and then dismissed the question of whether "assay and correlate" style claims are unpatentable because they claim a law of a law of nature. *LapCorp.* concerned claims directed to a method that uses the natural correlation in mammals between levels of the amino acid homocysteine and vitamin B levels so that homocysteine measures (that are easier to determine than measures of vitamin B) are used as a proxy for determining whether an individual is B vitamin deficient. The Court initially agreed to review the case but then dismissed it because the Section 101 issue had not been raised below. Justice Stephen G. Breyer wrote a blistering dissent evidencing a strong view that such "assay and correlate" claims should not be within Section 101's scope. However, that viewpoint now has moderated based on the transcript of the Dec. 7, 2011 oral argument in *Prometheus v. Mayo* in which Justice Breyer now characterizes the *LabCorp.*-style claims as directed to a patent-eligible application of a law of nature, and not to the law of nature itself.

More recently, in *Biliski v. Kappos* (2010), the Supreme Court rejected the "machine or transformation" test as the only way for determining the patent-eligibility for business method claims. It refers to Section 101 as a "dynamic provision designed to encompass new and unforeseen inventions," suggesting it anticipates new innovations will require additional clarification.

A year later in *Classen Immunotherapeutics v. Biogen Idec* (2011), the Federal Circuit distinguished between claims that it characterized as claiming a law of nature – choosing a immunization schedule – as unpatentable, and those directed to the application of that law – choosing an immunization schedule and then administering the vaccine based on that schedule – as patentable.

And in *Association for Molecular Pathology v. USPTO* (2011), the Federal Circuit held that isolated nucleic acid molecules were not products of nature and therefore patent eligible. However it also ruled that claims to detecting germ line alterations in BRCA1 genes are not eligible for patent protection because it could be accomplished by "mere inspection alone," and so it "directed to the abstract mental process of comparing two nucleotide sequences."

In the pending *Prometheus v. Mayo* case, many claims are at issue, but all were limited to the administration of a specific drug for a specific disease and for determining the specific metabolite level at which the dose should be adjusted.

The fundamental question is, are any of these claims so broad as to be a basic "law of nature" and ineligible for patent protection? Or are they considered to be applications of a law of nature?

In oral arguments last December, the justices appear to recognize that useful discovery is often characterized by a significant investment that might merit protection. As Justice Breyer put it, "whether it's true in this case or not, discovering natural laws is often a very expensive process."

Justice Antonin Scalia's comments appear to recognize that claims in the *Prometheus* case are directed to the use of the "law of nature" and not to the law of nature itself. "But doesn't – doesn't any – any medical patent rely on natural processes? I mean, even if you invent a new drug, what that new drug does – is natural. It affects the – the human physiognomy in a certain natural way."

Likewise, Justice Breyer seems to indicate that the phrases in the claim "administer the drug, determine the level, are the application of the law nature that they found."

The justices appear to recognize that limits within the claim prevent it from "pre-empting" all use of the law of nature. As Justice Sonia Sotomayor put it, "But the point is, there's still a limit to their range. You are claiming at one point they said it was limitless, but we disagree with that."

And so, the *Prometheus* decision is unlikely to create any major change in patentable subject matter law. With luck, it will clarify the question of how to draw the line between laws of nature and their application.

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