Prometheus Patent Quandary

Can you patent a medical observation?

Suppose your doctor measures your body's response to a medication and then contemplates adjusting your medication accordingly. Did your doctor infringe someone's patent?

Maybe.

This spring, the United States Supreme Court is due to issue an opinion in a patent case that has the potential to allow medical observations to be patented. At issue is Prometheus Laboratories' patent for a method of optimizing treatment disorders like Crohn's disease. This case gives the Supreme Court an opportunity to make potentially sweeping pronouncements on the scope of "patentable subject matter," in other words, what types of inventions qualify for patent protection. If Prometheus' patents are upheld, the decision could be followed by a flood of patent applications for activities that take place in the health care field on a daily basis.

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The broadest claim of Prometheus' patents define an invention consisting of three steps: (1) administering a specific drug to a patient, (2) measuring the amount of a particular metabolite in the patient's bloodstream, and (3) considering whether or not to increase subsequent dosages of the drug based on the measurement. The third step is causing controversy.

The concern of many of those opposing Prometheus' patent, such as the American Medical Association and the American Association of Retired Persons, goes beyond the patent in the lawsuit because a broad ruling in Prometheus' favor may encourage patent applications on all kinds of everyday "observations" in the health care field.

Courts have struggled with drawing a well-defined line between patentable methods and processes, and unpatentable abstract ideas. Until recently, the so-called "machine or transformation test" required that a patentable process must either require implementation by a physical machine or transform a physical article from one state to another. Then, in 2010, in the case of *Bilski v Kappos*, the Supreme Court shifted this balance by holding that, while providing "a useful and important clue," the "machine or transformation test" was not the exclusive means of determining patentable subject matter. In other words, there may be methods not tied to a particular machine that do not affect a physical object, but that nonetheless claim something more than an "abstract idea."

Now the Supreme Court will have to decide whether the claims of the Prometheus patent are drawn to one of these methods. The inventors did not claim to have invented the drug that is given to the patient, or a method of measuring the resulting metabolite levels in the patient's bloodstream. Instead, they determined that observing a metabolite level below a certain threshold indicated a need to raise the subsequent dosage of the drug, and a metabolite level above a certain threshold indicated a need to lower the subsequent dosage.

Prometheus sued the Mayo Clinic after learning that Mayo intended to release a testing product that would compete with Prometheus' own product for testing particular metabolite levels. Prometheus argues that Mayo is inducing doctors to infringe the Prometheus patent because doctors who purchase the Mayo product will administer the drug, test the resulting metabolite levels, and then think about whether to adjust the dosage. Importantly, Prometheus claims that the doctors do not have to actually adjust the dosage but that merely considering the correlation between the dosage and the resulting measurement is enough to infringe.

If Prometheus prevails, will doctors begin running to the patent office claiming other inventions based on measurement, observation and consideration? And if "observation" or "consideration" methods are considered patentable, will patients have less access to these methods as a result of claims of infringement? With ever-changing methods and increasing scientific knowledge, the Prometheus case could mean quick and significant changes for the health care industry.

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