Oblivious Supreme Court poised to legalize medical patents

By Timothy B. Lee | December 7, 2011

The Supreme Court on Wednesday heard oral arguments in a case that raises a fundamental question: whether a physician can infringe a patent merely by using scientific research to inform her treatment decisions.

Unfortunately, this issue was barely mentioned in Wednesday's arguments. A number of influential organizations had filed briefs warning of the dire consequences of allowing medical patents, but their arguments were largely ignored in the courtroom. Instead, everyone seemed to agree that medical patents were legal in general, and focused on the narrow question of whether the specific patent in the case was overly broad.

This should make the nation's doctors extremely nervous. For two decades, the software industry has struggled with the harmful effects of patents on software. In contrast, doctors have traditionally been free to practice medicine without worrying about whether their treatment decisions run afoul of someone's patent. Now the Supreme Court seems poised to expand patent law into the medical profession, where it's unlikely to work any better than it has in software.

Sorry, that correlation is patented

The case focuses on a patent that covers the concept of adjusting the dosage of a drug, thiopurine, based on the concentration of a particular chemical (called a metabolite) in the patient's blood. The patent does not cover the drug itself—that patent expired years ago—nor does it cover any specific machine or procedure for measuring the metabolite level. Rather, it covers the idea that particular levels of the chemical "indicate a need" to raise or lower the drug dosage.

The patent holder, Prometheus Labs, offers a thiopurine testing product. It sued the Mayo Clinic when the latter announced it would offer its own, competing thiopurine test. But Prometheus claims much more than its specific testing process. It claims a physician administering thiopurine to a patient can infringe its patent merely by being aware of the scientific correlation disclosed in the patent—even if the doctor doesn't act on the patent's recommendations.

This extraordinary claim prompted a broad coalition of public interest groups to write *amicus* briefs urging the Supreme Court to invalidate the patent and others like it. The

American Association of Retired Persons and the American Civil Liberties Union both wrote briefs arguing the patent should be invalidated. The ACLU brief argued that regulating doctors' thoughts runs afoul of the First Amendment. A coalition of three libertarian think tanks filed a brief (which, full disclosure, I played a small part in drafting) warning that legalizing medical patents will cause the same kinds of problems in the medical profession that it has in the software industry.

Also opposing the patent was a broad coalition of medical providers led by the American Medical Association. "If claims to exclusive rights over the body's natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care," the medical organizations' brief argued.

"Conscientious physicians will be unwilling and unable to avoid considering all relevant scientific information when reviewing test results," the doctors wrote. "Thus, as medical knowledge accumulates, patent licenses increasingly will be required for physicians to conduct even well established diagnostic tests."

"Everybody agrees with that"

Unfortunately, the justices seemed oblivious to these arguments. And the man who should have been making them, Mayo counsel Stephen Shapiro, completely ignored them. Instead, he seemed to concede the legality of medical patents in general, and focused on nitpicking the details of Prometheus's patent. Specifically, he noted that the patent covers a broad range of metabolite levels and applies for many different autoimmune diseases, and argued that this made the patent invalid.

Asked by Justice Kennedy if a more specific and complex diagnostic technique involving "two or three different drugs" could be eligible for patent protection, Shapiro said yes. "If it leaves room for others to have their own tests with different numbers and different procedures so that it isn't just one test for the whole country, then yes, if it's specific enough," he said. "The specificity is the key."

Justice Scalia pointed out that making patent-eligibility turn on how complex the diagnostic strategy was, or on how many diseases it claimed to address, was totally unworkable. Shapiro's proposal, he said, was "not a patent rule that we could possibly apply."

Justices Scalia and Breyer showed some skepticism that patents could cover the use of scientific correlations in medical practice. But the other justices expressed no such skepticism. At one point, Justice Kagan offered some advice to Prometheus's lawyer. "What you haven't done is say at a certain number you should use a certain treatment, at another number you should use another treatment," she said. "I guess the first question is why didn't you file a patent like that? Because that clearly would have been patentable. Everybody agrees with that."

Of course "everyone" does not agree with that. In particular, the American Medical Association (and, presumably, many of the nation's doctors) doesn't. Neither does the ACLU, the AARP, or the Cato Institute. Yet if any members of the high court disagreed with Kagan, they didn't speak up.

We've long argued that the Supreme Court should overturn the lower courts' *de facto* legalization of software patents. Instead, the Supreme Court appears poised to take a step in the opposite direction and expand patent law to cover the medical profession. And they seemed oblivious to how dramatic a step that would be.

We really hope the justices will read some of those amicus briefs before they make their ruling.