

'Machine or transformation test' put to the test itself

The process of assessing risk in commodities trading can seem a world away from the development of medical diagnostics. But the legal case known as *Bilski v. Kappos* is set to affect both.

In April 1997, Bernard Bilski and Rand Warsaw applied for a patent on a three-step method—composed of transactions between sellers and consumers—that brokers can use in hedging the risk of trading in commodities, such as coal for a power plant. An examiner in the US Patent and Trademark Office rejected the patent on the basis of Section 101 of the country's Patent Act, which determines what is eligible to be patented. The examiner denied this patent because “the invention is not implemented on a specific apparatus and merely manipulates [an] abstract idea and solves a purely mathematical problem without any limitation to a practical application,” as described in the appeal that Bilski and Rand filed with the Board of Patent Appeals and Interferences. In March 2006, that appeal was heard, and the board upheld the examiner's rejection.

Bilski and Warsaw continued to pursue their patent with the US Court of Appeals for the Federal Circuit, which provided an opinion last year. To be eligible for patenting, the court ruled, a claim must be tied to a machine or must transform something, which is now known as the ‘machine or transformation’ test. The machine-related eligibility comes from the wording of Section 101. For

the transformation side, the court cited several Supreme Court rulings, including *Gottschalk v. Benson* from 1972, which states, “transformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular machines.” Whether the machine-or-transformation test stands or falls now lies with the Supreme Court, which was scheduled to publish a decision as *Nature Medicine* went to press.

Although it remains to be seen, what might be rejected for patenting on the basis of this test, many in the biotechnology and pharmaceutical industries worry that this ruling blocks the patent eligibility of key elements of today's medical industry, such as biomarkers.

Bilski v. Kappos “is extremely important, because it is revisiting what is patent-eligible subject matter,” explains Anne Schneiderman, a patent attorney based in Ithaca, New York, who works with clients in biotechnology, medical devices and pharmaceuticals. Schneiderman takes issue with the machine-or-transformation standard for patent-eligible subject matter. She notes, “it is an extremely backward-looking test. It jeopardizes the whole point of the patent system, which is to reward innovation and not to try to anticipate what might be an invention in the future.”

Many groups filed amicus briefs calling on the US Supreme Court to overturn the *Bilski* decision. The Washington, DC-based Biotechnology Industry Organization (BIO), for one, wants to see patent eligibility remain broad. In August, BIO—along with the Advanced Medical Technology Association, the Wisconsin Alumni Research Foundation and the Regents of the University of California—filed a brief that claims that the machine-or-transformation test “casts doubt on the protection of certain inventions and particularly inventions defined by method claims in the biotechnology arts...” In particular, this brief notes that this test could jeopardize the ability to patent biomarkers.

As Hans Sauer, BIO's associate general counsel for intellectual property, explains, “we told the court that they are addressing a business case and to be careful to not impact industries that they do not want to affect.”

If patent eligibility gets too narrow, BIO worries about its smaller-company members that want to patent intellectual property at a very early stage of technology development. Simply identifying a biomarker, for example, is not inherently related to a machine or transformation. “At that stage, you don't



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know if the patent will protect anything, but if the technology turns out to require lots of investment with bigger biotechs or pharma, that will hugely depend on existing IP,” Sauer explains.

The American Medical Association, in contrast, filed an amicus brief with the opposite position in conjunction with several other institutions, including the Mayo Clinic. The groups take a cautionary stance on the interpretation of Section 101. “If construed too broadly, Section 101 blocks the spread of medical knowledge, creates unfair monopolies, harms patients and drives up the cost of healthcare,” the brief, filed 2 October 2009, states.

One case has already put the machine-or-transformation test to work. In *Prometheus v. Mayo* (see page 1243), Prometheus Laboratories battled the Mayo Clinic over drug dosing tests that measure metabolites produced after administering thiopurines, which are used to treat some autoimmune diseases. The US Court of Appeals for the Federal Circuit applied the machine-or-transformation test and concluded on 16 September 2009 that, for example, a drug's effect on the human body creates a patent-eligible transformation.

Despite the ruling in *Prometheus v. Mayo*, some experts still anticipate potential problems with the machine-or-transformation test. The test assumes that someone filing a patent application knows exactly how the technology will be used, but if something is really innovative, even futuristic, it might be hard to say how it could eventually be tied to a machine or make a transformation.

“I hope that *Bilski* prevails and that the machine-or-transformation test does not continue,” says Schneiderman. “If you can't protect something that is really on the cutting edge, it will have a chilling impact on pursuing innovation in areas that relate to breakthrough technology.”

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Brian Kelly, director of technology transfer at Cornell University notes that, in the case of auctioning off phase 3 clinical trials, “there is still significant expense incurred up to that point” in phases 1 and 2. As for the international prize, questions as to how exactly the prize would be paid for, and whether it would truly cover the costs incurred from drug development—have yet to be answered.

Ownership rights do compound health disparities between the haves and have-nots, adds Kelly, but blaming patents for problems in developing countries is too limited a view of the issue. “You can't look at this in isolation,” says Kelly “it's not simply a health-care problem—it's a socioeconomic one. ‘Big pharma’ isn't going to solve it.”

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