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Bilski: the life sciences angle

The *Bilski* case will be closely watched to see whether the Supreme Court will use it to address determination of patent eligibility well beyond business methods

The Supreme Court's decision in *Bilski v Kappos* will address patent eligibility of business methods, a topic of considerable interest to the e-commerce and financial services industries. But it could reach beyond business methods to affect the life sciences: that is, technological methods that affect living organisms, including methods for identifying medical conditions, methods for treating patients and pharmaceutical methods.

The *Bilski* claims are directed to a method of hedging risk in commodities trading. The US Patent and Trademark Office rejected the claims as not being directed to patent-eligible subject matter. The decision was affirmed by a majority of the Federal Circuit sitting *en banc*.

Citing Supreme Court precedent, the Federal Circuit reaffirmed that "fundamental principles" are excluded as patent-eligible subject matter. These include mental processes; abstract concepts and ideas; mathematical relationships; and natural phenomena. The court reiterated, however, that applications of fundamental principles could be patent eligible and noted that Supreme Court precedent draws a distinction between claims that pre-empt the use of fundamental principles versus claims that merely foreclose particular applications of those principles.

The Federal Circuit held that the Supreme Court's machine-or-transformation test is the "definitive test" controlling whether a process is patent eligible. A process is patent eligible if "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing". While recognising the "difficult challenges" the test would create for technologies developed in today's information age, the court felt it was for the Supreme Court to decide whether a new test would be needed to accommodate new technologies.

In September 2009, the Federal Circuit addressed patent eligibility of method claims in the life sciences. In *Prometheus Labs Inc v Mayo Collaborative Servs*, the claimed methods involve calibrating the proper dosage of a treatment drug to be administered to a patient based on measured levels of two metabolites in the body. The methods include administering a drug that breaks down into the metabolites in a body and measuring the levels of one or both metabolites. The measured metabolite levels are then compared to known levels to assess whether adjusting dosage of the treatment drug is necessary.

Using *Bilski*'s machine-or-transformation test, the Federal Circuit found the claims to be patent eligible because they are methods of treatment that involve transformation of the human body. According to the court, the body is transformed following administration of the drug, which then permits the metabolite levels to be measured. Although the drug-to-metabolite transformation occurs from a natural process, the court explained that the transformation is a result of physical administration of the drug "which itself is not a natural process" and therefore does not render the claim ineligible.

The Supreme Court had an opportunity in 2006 to provide guidance to method patents in the life sciences. In *Lab Corp of Am Holdings v Metabolite Labs Inc*, the claimed method detects a patient's vitamin deficiency based on amounts of homocysteine in the body. The method includes just two steps: assaying body fluid for an elevated level of homocysteine; and correlating an elevated level of homocysteine with the vitamin deficiency. The Federal Circuit upheld the claims, but did not specifically address patent-eligibility.

During appeal to the Supreme Court, the justices raised the patent eligibility issue. The court granted *certiorari* and heard oral arguments, but subsequently dismissed *certiorari* as improvidently granted. Justices Breyer, Stevens and Souter dissented. The dissenters reiterated that the Constitution does not include rights for basic scientific principles, and that "sometimes too much patent protection can impede rather than 'promote the Progress of Science and useful Arts'." The dissenters believed that the case was "not at the boundary" of patent eligibility and found the claimed process required "no more than an instruction to read some numbers in light of medical knowledge".

The dissenting comments may foreshadow the court's upcoming *Bilski* decision. An apparently sceptical Supreme Court heard oral arguments for *Bilski* in November. The justices seemed to be concerned with creating the right test for present and future technology. Justice Sotomayor noted that an exclusive test could result in "shoe-horning technologies that might be different". Justice Ginsburg commented, however, that "things that we haven't yet contemplated may be around the corner, and when they happen, we will deal with them". On how to balance the patent system's benefits and drawbacks with respect to patenting information, Justice Breyer replied: "I don't know. And I don't know whether across the board or in this area or that area patent protection will do no harm or more harm than good."

The justices appear to be grappling with issues that go beyond the issues in *Bilski*. Whether the Supreme Court will seize the opportunity to fashion a new patent-eligibility test for all methods or merely provide a narrow ruling confined to *Bilski*'s facts may turn on whether the justices view the issues as matters for the court rather than Congress to address. The court has noted that Congress determines the outer limits of patent eligibility. On several occasions, the court has invited Congress to enter the debate. Perhaps Congress will be more inclined to accept the invitation if the upcoming *Bilski* decision is broad and unpopular.

If the Supreme Court rules narrowly, chances are very high that it will need to revisit the same or very similar issues in cases such as *Prometheus*.

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