Commentary

The aftermath of Bilski

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In *Bilski* v. *Kappos*,[1] the Supreme Court attempted to clarify what constitutes patentable subject matter. In so doing, the Court determined that the Federal Circuit's 'machine-or-transformation' test is not the exclusive test for patent eligibility. The machine-or-transformation test states that a claimed process is patent-eligible if it is tied to a particular machine or transforms a particular article into a different state or thing.[2] Rather than relying on this single test, the Supreme Court stated that there is a long-line of precedent that provides guidance on the issue of patent eligibility. The *Bilski* decision affirms the Court's long-held view that Section 101 of the Patent Statute should be read broadly.[3] For example, the Court has held that laws of nature, abstract ideas and physical phenomena are not patent eligible.[4] However, anything that is manipulated by the 'hand of man' is eligible for consideration.[5] Thus, while *Bilski* leaves some ambiguity in terms of what qualifies for patent protection, it is clear that the Court has once again rejected a bright-line test offered by the Federal Circuit.

What guidance does *Bilski* provide on the important issue of patent eligibility? First, it is clear that if a claim passes the machine-or-transformation test, it is surely patent-eligible. The Supreme Court did not reject the machine-or-transformation test, but stated that it is a 'useful and important clue' for determining whether a claim should be let in the door for examination.[6] However, claims that fail the machine-or-transformation test may still be eligible if they don't fall into one of the prohibited categories. When a claim does fail the machine-or-transformation test, one must look to the Supreme Court's lengthy precedent for guidance.[7] Second, it is clear that the Supreme Court continues to disagree with the Federal Circuit's desire to create bright-line tests. For example the *Bilski* decision is in line with the Court's view of the Federal Circuit's bright-line test for obviousness in *KSR* v. *Teleflex*.[8] For Section 101, it is clear that the Court was taking an expansive view of patent eligibility and that view does not fit neatly into a single, all-purpose test.

The legacy of *Bilski* will be played out initially in two important Federal Circuit cases that were recently remanded by the Supreme Court for consideration in light of that decision. Those cases are *Mayo Collaborative Services* v. *Prometheus Laboratories* and *Classen Immunotherapies, Inc.* v. *Biogen IDEC*.

In *Prometheus*, the patentee obtained two patents on methods for calibrating the dose of certain drugs for treating gastrointestinal disorders. The patented methods involve administering the drug and then measuring levels of a metabolite in order to optimize therapeutic efficacy. On appeal, the Federal Circuit, applying the machine-or-transformation test, determined that the *Prometheus* claims were indeed patentable subject matter. According to the Federal Circuit, the steps of administering a drug and determining the level of its metabolite is a 'transformation' because of chemical changes that occur in the patient upon administration of the drug.

Classen obtained four patents on methods of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disease. The methods involved immunizing a treatment group and comparing the incidence of chronic immune-mediated disorders in the treatment group relative to a control group. On appeal, the Federal Circuit held

that the *Classen* claims were not patent eligible subject matter because the claims were not 'tied to a particular machine or apparatus' and did not 'transform a particular article into a different state or thing'.

The Federal Circuit's decisions in both *Classen* and *Prometheus* were based on the presumption that the 'machine-or-transformation' test was the sole test for determining patent-eligible subject matter. Presumably, the Supreme Court sent both cases back to the Federal Circuit for reconsideration in view of the Court's *Bilski* decision. Since the Federal Circuit found that the *Prometheus* claims were statutory subject matter under the machine-or-transformation test, the presumption is that the decision in that case will not change based upon the Supreme Court's *Bilski* ruling. However, since the claims were found ineligible for patent protection in *Classen*, the Federal Circuit's reconsideration of that case may shed light on how that court interprets the Supreme Court's mandate in *Bilski*.

NOTES

1. *Bilski* v. *Kappos*, --- S.Ct. ----, 2010 WL 2555192 (U.S., 2010).
2. *In re Bilski,* 545 F.3d 943, 954 (CAFC, 2008).
3. *Bilski*, 2010 WL 2555192 at 6.
4. *Id., citing Diamond* v. *Chakrabarty,* 447 U.S. 303, 309 (U.S., 1980).
5. *Diamond* v. *Chakrabarty,* 447 U.S. 303, 308 and FN6 (U.S., 1980).
6. *Bilski*, 2010 WL 2555192 at 8.
7. *Bilski*, 2010 WL 2555192 at 11, *referencing Diamond* v. *Diehr,* 450 U.S. 175 (U.S. 1981); *Parker* v. *Flook,* 437 U.S. 584 (U.S. 1978); and *Gottschalk* v. *Benson,* 409 U.S. 63 (U.S. 1972).
8. *KSR Intern. Co.* v. *Teleflex Inc.*, 550 U.S. 398 (U.S., 2007).

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