WSGR ALERT

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U.S. SUPREME COURT IN *BILSKI V. KAPPOS* PAVES THE WAY FOR BROADER SCOPE OF PATENT-ELIGIBLE PROCESS CLAIMS

On June 28, 2010, the U.S. Supreme Court issued a decision in *Bilski v. Kappos,* No. 08-964, slip op. (U.S. June 28, 2010) rejecting the rigid "machine-or-transformation" test for patent-eligible subject matter proffered by the U.S. Court of Appeals for the Federal Circuit as an unduly restrictive interpretation of the Patent Act. *Bilski* follows the Court's decision in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), which similarly rejected the Federal Circuit's rigid "teaching-suggestion-motivation" test for obviousness.

While the *Bilski* decision is most directly applicable to business-method-type claims, pharmaceutical and biotechnology companies likely will see its application to claims directed to, for example, diagnostic, dose titration, or characterization methods.

Background

35 U.S.C. § 101 provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

Bilski and Warsaw filed a patent application that contained claims directed to processes for hedging risk in the field of commodities trading. The U.S. Patent and Trademark Office (USPTO) rejected the claims under 35 U.S.C. § 101 as patent-ineligible subject matter because the claimed processes did not recite a specific apparatus or involve a physical transformation. The U.S. Court of Appeals for the Federal Circuit upheld the rejection of the claims, validating the so-called "machine-or-transformation" test applied by the USPTO. [*In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (*en banc*).] The Federal Circuit articulated the machine-or-transformation test as follows:

> A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. (*Id.* at 954.)

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Upon *certiorari* to the Federal Circuit, the U.S. Supreme Court focused on the language of § 101 and found that the USPTO's and the Federal Circuit's narrow reading of the term "process" to absolutely exclude all processes that are not tied to a particular machine or apparatus, or that do not transform a particular article into a different state or thing, imposes "limitations that are inconsistent with the text and the statute's purpose and design." (*Bilski*, slip op. at 6.) Rather, the Court held that the term "process" should be interpreted in accordance with its ordinary, contemporary, and common meaning. (*Id.* at 7.)

The Court went on to state that the machine-or-transformation test is but one of many "useful and important clue[s]" for determining whether particular types of claimed processes are patent eligible under § 101. (*Id.* at 8.) The Court declined to set forth what other tests may be used to determine patent eligibility under § 101, and left it to the USPTO and the lower courts to establish standards consistent with the broad interpretation of "process" espoused by the Court.

Ultimately, however, the Court upheld the rejection of Bilski's and Warsaw's claims on the ground that they were directed to "an abstract idea" that falls outside the scope of the "process" set forth in § 101. (*Id.* at 13.)

Looking Forward

In view of the Court's invitation to the USPTO and the lower courts to establish appropriate standards for determining patent eligibility under § 101 that are not inconsistent with the ordinary meaning of "process," the USPTO issued a memo on June 28, 2010. The memo instructed the examiners to continue to reject claims if the claims do not meet the machine-or-transformation test "unless there is a clear indication that the method is not directed to an abstract idea." It therefore appears that the USPTO currently is reading the Court's *Bilski* decision very narrowly.

Further, the day after *Bilski* was decided, the Court vacated and remanded two cases to the Federal Circuit for further proceedings consistent with its *Bilski* decision. The first, *Classen Immunotherapies, Inc. v. Biogen Idec, et al.*, Case No. 2006-1634, -1639 (Fed. Cir. 2008), dealt with claims directed to processes for determining an immunization schedule, and the second, *Prometheus Labs., Inc. v. Mayo Collaborative Services, et al.*, Case No. 2008-1403 (Fed. Cir. 2008), dealt with claims directed to processes for optimizing therapeutic efficiency of a drug.

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The disposition of these cases will be instructive as to the interpretation of the *Bilski* decision, especially in the biotechnology arena, and may affect the USPTO's position.

Wilson Sonsini Goodrich & Rosati's patents and innovation strategies practice is actively monitoring the status of the *Classen* and *Prometheus* cases, and the guidance issued by the USPTO. If you have any questions or would like additional information, please feel free to contact Vern Norviel, Jeffrey Guise, Matthew Langer, Peter Eng, Peter Munson, Michael Hostetler, Karen Wong, or Esther Kepplinger.

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