



PATENT LAW 2010: The Year in Review

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In 2010, the U.S. Supreme Court and the Court of Appeals for the Federal Circuit (CAFC) decided several cases that will affect the field of patent law. In addition, there have been developments in a handful of important cases that await review before the Supreme Court and the CAFC. Finally, there have been a number of noteworthy developments in the United States Patent and Trademark Office (USPTO), including an increase in patent issuances as well as the extension or expansion of programs designed to accelerate examination. A brief discussion of some of these cases and developments is presented below.

STATUTORY SUBJECT MATTER

The CAFC in 2008 narrowed the scope of patentable processes under 35 U.S.C. §101 by holding that a claimed process is not patent eligible unless (1) it is tied to a particular machine or apparatus or (2) it transforms a particular article into a different state or thing. On appeal, the Supreme Court in *Bilski v. Kappos* rejected the CAFC's so-called "machine-or-transformation" test as the exclusive test for patentable processes. The Court noted that the test provides an "investigative tool" for determining patentability of certain processes, but emphasized that past precedent had established only three exceptions to statutory subject matter: abstract ideas, laws of nature, and physical phenomena. Some believe that the decision introduced even more uncertainty as to the scope of patent eligible processes; in particular, the decision did not offer much guidance as to the meaning of "abstract ideas."

The CAFC had two opportunities to apply the Supreme Court's *Bilski* decision in late 2010. In the first case, *RCT v. Microsoft*, a CAFC panel recognized that the *Bilski* decision had established a "coarse eligibility filter" with the intention of instructing courts "to not define 'abstract' beyond the recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter." The panel held that claims directed to methods for half-toning gray scale images are patent eligible in

large part because "the invention presents functional and palpable applications in the field of computer technology," and that "inventions with specific applications or improvements to technologies in the marketplace are not likely to be so abstract" that they run afoul of 35 U.S.C. §101. The decision is considered a victory for computer software and related fields insofar as they are related to "computer technology," although it remains to be seen how the decision will impact non-computer technologies. At the very least, the decision serves as a useful initial guidepost for the level of abstractness needed to support a 35 U.S.C. §101 rejection.

In the CAFC's second post-*Bilski* decision, *Prometheus v. Mayo*, a CAFC panel held that claims directed to methods for calibrating the proper dosage of a drug for treating autoimmune diseases are patentable. The court rejected the argument that the claims are simply directed to natural phenomena. Instead, the panel applied the machine-or-transformation test and concluded that the claims recite a transformation as a result of the physical administration of a drug to a subject, and that such a process cannot be considered a natural phenomenon. Importantly, the court stated that methods of treatment "are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition." This decision is an important one for the pharmaceutical and biotechnology industries since claims that recite administration of a drug or biological agent would appear to be patent eligible on that basis alone.

WRITTEN DESCRIPTION

An *en banc* CAFC considered aspects of the written description requirement found in 35 U.S.C. §112. In *Ariad v. Lilly*, the court confirmed that the written description requirement is separate and distinct from the enablement requirement. The CAFC also held that the purpose of the written description requirement is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of

art as described in the specification. The majority opinion largely follows precedent developed since the CAFC decided *Regents of the University of California v. Lilly* in 1997.

OBVIOUSNESS

In September, the USPTO issued examination guidelines highlighting case law developments on obviousness under 35 U.S.C. §103 since the 2007 Supreme Court decision in *KSR v. Teleflex*. These guidelines are intended to be used by Examiners in conjunction with the Manual of Patent Examining Procedure when applying the law of obviousness. The guidelines also provide some direction for practitioners on countering obviousness assertions. For example, the guidelines state that "it is true that practitioners have been required to shift the emphasis of their nonobviousness arguments to a certain degree. However, familiar lines of argument still apply, including teaching away from the claimed invention by the prior art, lack of a reasonable expectation of success, and unexpected results. Indeed, they may have even taken on added importance in view of the recognition in *KSR* of a variety of possible rationales."

STANDARD OF PROOF FOR INVALIDITY

The CAFC and other courts have long required "clear and convincing" evidence of a patent's invalidity. This is partly in deference to the USPTO, which examined the application and deemed it appropriate to grant a patent. In *Microsoft v. i4i*, a CAFC panel refused to lower this evidentiary threshold as it applies to newly-discovered prior art that was not considered by the USPTO during the examination process.

The Supreme Court granted a petition to review the case and a decision is expected in 2011. Applicants and practitioners alike may be inclined to search for and disclose more art for consideration by the examiner during prosecution of the application if the Supreme Court lowers the evidentiary standard.

INEQUITABLE CONDUCT

Inequitable conduct requires a finding of both materiality and intent to deceive. In recent years, different CAFC panels have been applying

materiality-intent balancing frameworks that are inconsistent with one another. For example, various panel decisions have been in tension as to how much, if at all, a finding of materiality affects the required finding of deceptive intent.

This past year, the CAFC granted a request for an *en banc* rehearing on the issue of inequitable conduct in *Abbott v. Therasense*. A decision is expected in 2011. This decision will hopefully address several unanswered questions related to inequitable conduct including: the proper standard for materiality, whether the materiality-intent balancing framework should be modified or replaced, and under what circumstances, if any, is it proper to infer intent from materiality.

DEVELOPMENTS AT THE USPTO

David Kappos pledged to reduce application backlog and pendency when he was introduced as new Director of the USPTO in 2009. There are tangible signs of improvement; the USPTO issued an all-time high of 219,614 utility patents in 2010, up 31 percent from 2009 and the most significant annual increase on record. Also, the patent application backlog was reduced by about 30,000 applications between December 2009 and December 2010, according to USPTO data. Unfortunately, the total backlog has remained relatively steady at a staggering 1.2 million applications.

To help address the problem, the USPTO plans to hire more examiners in 2011, including at the first ever USPTO satellite office in Detroit. In addition, various pilot programs designed to accelerate examination were expanded or extended in 2010. For example, the USPTO expanded the eligibility for the Green Technology Pilot Program to include applications filed on or after December 8, 2009. Further, the USPTO announced a six-month extension of the First Action Interview Pilot Program; any request to enter the program must now be filed on or before April 1, 2011. Finally, Patent Prosecution Highway Programs between the USPTO and foreign patent offices continue to thrive as existing agreements have been extended and agreements with additional patent offices have been established.