



PATENT LAW 2011: The Year in Review

By Stephen J. Petroski

In 2011, the Leahy-Smith America Invents Act (AIA) was enacted, representing the most significant reform of U.S. patent law since 1952. Also, 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. A brief discussion of some of these cases and developments is presented below.

PATENT REFORM

The highly-anticipated AIA was signed into law on September 16, 2011. The AIA brought some immediate changes to patent law, such as new virtual marking provisions and the elimination of the best mode defense for proceedings commenced after enactment of the AIA.

Additional provisions will take effect on September 16, 2012. For example, there will be substantial changes to post-grant procedures and patent owners will be able to request supplemental examination such that the USPTO may consider, reconsider or correct information believed to be relevant to a granted patent.

On September 16, 2013, the U.S. will move from the current first-to-invent system to a "modified" first-to-file system in an effort to harmonize with the patent laws of other jurisdictions. Also, a new 35 U.S.C. §102 will significantly change what will be considered prior art.

A more complete summary of the AIA is available [here](#).

INEQUITABLE CONDUCT

One of the objectives of supplemental examination introduced by the AIA is to allow patentees to "cleanse" themselves of possible inequitable conduct, which has been increasingly raised as a defense to patent infringement over the years. However, the CAFC's 2011 *en banc* decision in *Therasense v. Becton Dickinson* brought a sweeping change to the law of inequitable conduct, making it much harder to prove the defense.

Proving inequitable conduct requires a showing that the patentee misrepresented or withheld material information from the USPTO and did so with the intent to deceive. The *Therasense* court announced a new, heightened "but-for" materiality rule – prior art is "but-for" material if the USPTO would not have allowed a claim had it been aware of the undisclosed prior art.

Regarding intent, there must be a "specific intent to deceive." The court stressed that specific intent and materiality must be established separately by clear and convincing evidence; thus, courts should not use a "sliding scale" where a weak showing of intent may be found sufficient based on a strong showing of materiality.

The *Therasense* court left open the possibility that inequitable conduct may be found when a patentee has engaged in "affirmative acts of egregious misconduct," such as the filing of an unmistakably false affidavit. However, the exception does not apply to mere nondisclosure of prior art, so claims of inequitable conduct based on such omissions still require proof of but-for materiality.

Following *Therasense*, a handful of CAFC panel decisions highlighted the heightened requirements to prove inequitable conduct. In *Cordis v. Boston Scientific*, the court recognized that *Therasense* does not allow for specific intent to deceive to be inferred from the evidence if multiple reasonable inferences can be made. Thus, the inventor's good faith explanation for not disclosing a reference was enough to rebut the defendant's threshold showing of intent to deceive. In *Powell v. Home Depot*, the patentee had filed a Petition to Make Special on grounds that he was obligated to manufacture and supply devices to Home Depot embodying the claims sought. After negotiations with Home Depot fell through, the patentee failed to update and actively encouraged the USPTO to decide the petition. The CAFC panel held this did not rise to the level of an "affirmative act of egregious misconduct."

STANDARD OF PROOF FOR INVALIDITY

Courts have long required "clear and convincing" evidence of a patent's invalidity. This is partly in deference to the USPTO, which examined the patent and found it valid; however, some have argued that a lower evidentiary threshold should apply to prior art that was not considered by the USPTO. In *Microsoft v. i4i*, a unanimous Supreme Court held that the "clear and convincing" evidentiary threshold applies to all prior art, including newly-discovered prior art that was not considered by the USPTO during the examination process. The Court did state that the jury could be instructed that the evidence was not considered by the USPTO.

INDUCED INFRINGEMENT

Induced infringement under 35 U.S.C. §271(b) requires knowledge that induced acts constitute patent infringement. In an 8-1 decision, the Supreme Court held in *Global-Tech v. SEB* that the knowledge element can be met by a showing of "willful blindness" to possible evidence that the accused device may infringe a patent. In *Global-Tech*, the evidence showed that the accused company had engaged a patent attorney to conduct a right-to-use study but did not tell the attorney that it had copied the patentee's product. The Court concluded that the company exhibited "willful blindness" because it subjectively believed that the copied product was patented and intentionally failed to inform the patent attorney of this fact.

JOINT INFRINGEMENT OF METHOD CLAIMS

In *McKesson v. Epic Systems*, a fractured CAFC panel followed its earlier decision in *Akamai v. Limelight Networks*, holding that a method claim is jointly infringed only if there is an agency relationship between multiple parties who perform the method steps of the claim, or if one party is contractually obligated to the other party to perform the method steps. In *McKesson*, the health care provider had completed several steps of the asserted method claim and had allegedly induced separate parties (users) to complete the remaining steps. The court held that there was no joint infringement because the users were not acting under the "control and direction" of the health care provider. The court concluded the patent not infringed because: 1) no party could be considered a direct infringer of the patent; and 2) as there was no underlying direct infringement, there could be no induced infringement.

The CAFC vacated the *Akamai* and *McKesson* opinions and heard *en banc* arguments in each case. The *en banc* decision is expected in 2012 and should provide guidance on several questions, such as what "control and direction" actually means and, more generally, whether a patentee can prevail on a direct infringement claim where not all elements are performed by one actor.

STATUTORY SUBJECT MATTER

The Supreme Court in 2010 addressed patentable subject matter under 35 U.S.C. §101 in *Bilski v. Kappos*. The Court resolved *Bilski* by resorting to the principle, established by its earlier decisions, that abstract ideas, laws of nature and physical phenomena are not patentable.

The Supreme Court is tackling patentable subject matter again in *Mayo v. Prometheus*, with a decision expected in 2012. The appeal will address whether a

method involving administering a drug and determining a metabolite level is "transformative" and an "application of naturally occurring correlations" rather than an unpatentable "law of nature."

CAFC panels attempted to apply *Bilski* in a number of 2011 cases. For example, in *Association for Molecular Pathology v. USPTO*, the court held that composition of matter claims directed to isolated DNA sequences recited patent-eligible subject matter because the isolated DNA has a distinctive chemical identity from the native DNA found in the body. However, the court held that method claims directed to "analyzing" or "comparing" the gene sequences are not patent-eligible because they claimed only abstract mental processes. Several parties have sought review by the Supreme Court. If *certiorari* is granted, the Court will likely address an important question: are human genes patentable?

In *Classen v. Biogen IDEC*, a fractured CAFC panel held that methods for immunizing infants for infectious diseases, which include the step of "immunizing" subjects using a lower-risk immunization schedule, are directed to patent-eligible subject matter. The court held that the presence of one or more mental steps such as "comparing" and "identifying" was not of itself fatal to eligibility because the claims included a "specific, tangible application." On the other hand, the court found that a method of determining whether an immunization schedule affects a certain disorder was not patent-eligible because it did not require the information to be used for immunization purposes.

In *CyberSource v. Retail Decisions*, the court held that a method for verifying the validity of a credit card transaction over the internet was not patent-eligible since it only claimed computations that could be "performed entirely in the human mind." The court further held that claims drafted in *Beauregard* form were not patent-eligible because the different form "was nothing more than a computer readable medium containing program instructions for executing" the method claim. Tying the method claim to software, and the storage device for the software, did not render it patentable just by placing the invention in a different category.

Finally, in *Ultramercial v. Hulu*, method claims directed to distributing copyrighted materials by allowing free access to the materials in exchange for watching an advertisement were held to recite patentable subject matter. Specifically, the court found that the methods claim a "practical application" of the idea that "advertising can serve as currency" and that "the invention involves an extensive computer interface."