



## PATENT LAW 2009: The Year in Review

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In 2009, the Court of Appeals for the Federal Circuit (CAFC) decided several cases that will affect the field of patent and trademark law. In addition, there have been developments in a handful of important cases that await review before the CAFC and the U.S. Supreme Court. Finally, there have been a number of noteworthy developments in the United States Patent and Trademark Office (USPTO), including the appointment of a new Director and the proposal and implementation of several new procedures and programs. A brief discussion of some of these cases and developments is presented below.

### STATUTORY SUBJECT MATTER

An *en banc* CAFC narrowed the scope of patentable processes in the 2008 case of *In re Bilski*. This past year, the Supreme Court granted a petition to review the case and heard oral arguments, and the much-anticipated decision is expected in the spring of 2010.

The CAFC had a couple of opportunities to apply *Bilski's* "machine-or-transformation" test in 2009. In *In re Ferguson*, the court held that certain claims directed to a method of bringing a product to market were not tied to a particular machine or apparatus, and did not transform a particular article into a different state or thing, and therefore were not directed to patent-eligible subject matter. In contrast, in an important decision for pharmaceutical patents, a unanimous panel held that claims directed to methods for calibrating the proper dosage of a drug for treating autoimmune diseases were patentable in *Prometheus Labs v. Mayo*. Specifically, the court found that the required administration of a drug "transforms an article into a different state or thing" and that the *in vivo* transformation was an "integral" part of the calibration method.

### CLAIM AND CONTINUATION LIMITATION RULES RESCINDED

In 2007, the USPTO attempted to implement new rules which would have limited the number of claims in an application, limited continuing applications, and imposed other burdensome requirements on applicants. In 2008, the Eastern District of Virginia granted GlaxoSmithKline's motion for summary judgment, permanently enjoining the USPTO's proposed rules. The USPTO appealed to the CAFC.

This past year, a divided CAFC panel affirmed-in-part and reversed-in-part; however, the CAFC later

vacated the divided panel decision and agreed to hear the matter *en banc*. The USPTO rescinded the proposed regulations in October, putting an end to the uncertainty and signaling a victory for the applicant community.

### VENUE

In late 2008, the CAFC seemingly made it easier to transfer venue away from plaintiff-friendly courts, including the Eastern District of Texas and its "rocket docket." The court stressed in *In re TS Tech* that the district court had given far too much weight to the plaintiff's choice of venue and did not properly consider the potential inconvenience to witnesses and the location of evidence.

In 2009, the CAFC had several chances to address venue following *TS Tech*. The court determined that venue was proper in *In re Volkswagen*, in large part because other lawsuits involving the same patents were pending in the Eastern District of Texas. On the other hand, in *In re Genentech*, the CAFC directed the district court to transfer venue from the Eastern District of Texas to the Northern District of California due to, among other things, inconvenience to witnesses and access to evidence. Similarly, in *In re Hoffmann-La Roche*, the CAFC ordered the district court to transfer venue from the Eastern District of Texas to the Eastern District of North Carolina in part because the accused drug was developed and tested in North Carolina and because documents and witnesses could be found there.

### WRITTEN DESCRIPTION

A CAFC panel held that claims directed to a method for treating disease were invalid for inadequate written description in *Ariad v. Eli Lilly*. The CAFC then ordered an *en banc* rehearing to address its jurisprudence on the written description requirement. The court is set to determine whether 35 U.S.C. § 112, paragraph 1 contains a written description requirement separate from the enablement requirement and, if so, the proper scope and purpose of the written description requirement. This important decision is expected in 2010.

### METHOD CLAIMS AND INFRINGEMENT LIABILITY

35 U.S.C. § 271(b) provides a statutory prohibition against supplying components of a patented invention for offshore assembly. In *Cardiac Pacemaker v. St. Jude*, the CAFC, sitting *en banc*, held that the statute

only applies to product claims, and does not apply to method and process claims. The court reasoned that method steps do not have any physical components amenable to export, and therefore concluded that "because one cannot supply the step of a method, Section 271(b) cannot apply to method or process patents."

#### **PRODUCT-BY-PROCESS CLAIMS AND INFRINGEMENT LIABILITY**

Two lines of cases produced a nearly two-decade conflict concerning infringement of product-by-process claims. In 1991, a CAFC panel in *Scripps Clinic v. Genentech* defined product-by-process claims as limited solely by the end product. In 1992, a contrary CAFC panel in *Atlantic Thermoplastics v. Faytex* held that infringement of product-by-process claims requires actually using the claimed process steps to make the product. This past year, in *Abbott Labs. v. Sandoz*, an *en banc* CAFC overruled the earlier panel decision and held that process steps in product-by-process claims serve as limitations in determining infringement, and therefore such claims are not infringed by products made by processes other than those claimed. This decision left unanswered the question of the proper standard for examination of product-by-process claims by the USPTO.

#### **INEQUITABLE CONDUCT**

Inequitable conduct requires a finding of both materiality and intent to deceive. A pair of 2008 CAFC panel decisions were in tension as to whether a finding of materiality affects the required finding of intent. In *Star Scientific v. RJ Reynolds*, the CAFC made clear that "materiality does not presume intent." On the other hand, in *Praxair v. ATMI*, a finding of intent was inferred from the high materiality of a withheld prior art reference. In 2009, another CAFC panel relied on *Star Scientific* in a related case: in *AstraZeneca v. Teva*, the court held that a showing of "high degree of materiality" by a party asserting inequitable conduct does not mean that a proportionally lesser showing of intent to deceive is necessary to establish the requisite threshold level of intent, since evidence of mistake, negligence, or even gross negligence is not sufficient to support a finding of inequitable conduct.

The CAFC also heightened the pleading requirement for those making accusations of inequitable conduct in *Exergen v. Wal-Mart Stores*. In particular, the court held that any such pleading requires identification of

specific "who, what, when, where, and how" of material misrepresentation or omission before the USPTO.

#### **TRADEMARKS AND FRAUD**

In a 2003 decision, the Trademark Trial and Appeal Board (TTAB) held that a trademark applicant commits fraud when it "should have known" that a description of goods or services in a trademark registration is false. In the 2009 case of *In re Bose*, the CAFC overruled the TTAB decision and lowered the intent standard for trademark fraud to be consistent with the showing required to establish inequitable conduct in the prosecution of a patent application. The court held that the applicant must file false statements of material fact with the intent to deceive.

#### **DEVELOPMENTS AT THE USPTO**

As new Director of the USPTO, David Kappos indicated that the agency needs to establish a partnership with inventors. To illustrate, the following is an excerpt from an e-mail he sent to examiners: "When a claimed invention meets all patentability requirements, the application should be allowed expeditiously. . . . [B]y engaging with applicants early on, we certainly can get to the point more quickly, and efficiently allow those claims that are entitled to patent protection."

Kappos has pledged to reduce both the application backlog and the pendency of applications. In October, he proposed changes to the examiner count system, which determines the time an examiner has to complete a patent examination and how much credit the examiner is given at each stage of examination. Specifically, the changes would give examiners more time for a first action on the merits and examiner-initiated interviews, with the goal of encouraging examiners to do a high quality first action.

The USPTO also announced that it is expanding its First Action Interview Pilot Program to additional technology areas for a six-month period beginning October 2009. The program entitles an applicant to an interview with the examiner prior to the first action on the merits in a new utility application.

Finally, the USPTO recently announced a pilot program to accelerate the examination of certain "green" technology patent applications. According to a USPTO press release, pending patent applications in certain green technologies are eligible for special status (upon filing of a petition) and given expedited examination, with the goal of reducing the time it takes to patent inventions for these technologies by an average of one year.