



PATENT LAW 2008: The Year in Review

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In 2008, the Board of Patent Appeals and Interferences (BPAI), the Court of Appeals for the Federal Circuit (CAFC) and the U.S. Supreme Court decided several cases that will affect the field of patent law. In addition, there have been developments in a handful of important cases which await review before the higher courts. Finally, new rules proposed by the U.S. Patent and Trademark Office (USPTO) governing the prosecution of patent applications have been delayed. A brief discussion of some of these cases and developments is presented below.

STATUTORY SUBJECT MATTER

The CAFC in *In re Bilski* narrowed the scope of patentable processes, including business methods. Prior CAFC decisions, including *State Street Bank* in 1998, had ruled a process patentable if it produced a “useful, concrete and tangible result.” The court in *Bilski* held this test insufficient to determine patentability and replaced it with a “machine-or-transformation” test outlined in prior Supreme Court cases. Under the machine-or-transformation test, a process is patentable only if: (1) it is tied to a particular machine or apparatus; or (2) it transforms a particular article into a different state or thing. In its decision, the CAFC assured that business methods would still be patentable if they satisfied the machine-or-transformation test. The decision is vague as to how the test is to be applied and this will likely be clarified in future decisions. Nevertheless, *Bilski* calls into question the validity of many already issued business method patents and further raises the bar for pending method applications.

PATENT EXHAUSTION

The patent exhaustion doctrine generally holds that the first authorized sale of a patented item exhausts the patentee’s rights to that item. In *Quanta v. LG Electronics*, a unanimous Supreme Court reversed the CAFC and held that that authorized sales of products that do not fully practice the invention can still trigger exhaustion when the products include essential features of the patent and the “reasonable and intended use” of the product is to practice the patent. The Court also made clear that the patent exhaustion doctrine applies to method patents as well as product patents.

DECLARATORY JUDGMENT

The CAFC continued to interpret the 2007 Supreme Court *MedImmune* decision, which generally made

patent owners more vulnerable to declaratory judgment actions by supplanting the CAFC’s “reasonable apprehension of suit” test with an “all the circumstances” test. For example, in *Caraco Pharmaceutical v. Forest Labs*, the CAFC held that a generic drug applicant could bring a declaratory judgment action to challenge a brand company’s patent even after the brand company granted a covenant not to sue. On the other hand, in *Prasco Laboratories v. Medicis Pharmaceutical*, the CAFC held that a patent holder’s marking of its products and enforcement of unrelated patents against different products is not sufficient to establish a requisite case or controversy.

DESIGN PATENTS

The CAFC substantially changed the test for infringement of a design patent. In *Egyptian Goddess v. Swisa*, the court rejected the previously used “point of novelty” and related “non-trivial advance” tests. Instead, relying heavily on an 1871 Supreme Court decision, the CAFC held that the “ordinary observer” test is the sole test for infringement. The CAFC noted that other tests had moved away from the precedent set by the Supreme Court more than one century ago. The CAFC held that the proper test for infringement asks how an ordinary observer with knowledge of the prior art designs would view the differences between the claimed and accused designs.

Egyptian Goddess also clarified two other points of law: (1) the accused infringer has the burden of bringing forward prior art to prove noninfringement; and (2) claim construction in design patent cases is largely unnecessary because the fact finder can use the patent’s figures to illustrate what is claimed.

OBVIOUSNESS

In 2008, the CAFC had several opportunities to address obviousness following *KSR v. Teleflex*, the 2007 case in which the Supreme Court rejected the CAFC’s rigid application of the “teaching-suggestion-motivation” (TSM) test for obviousness. In some recent CAFC cases, the predictability of the art in question has become an important factor in determining obviousness.

These cases indicate *KSR* may have more of an impact on the electrical and mechanical arts. For example, in *Asyst Technologies v. Emtrak*, the CAFC affirmed the lower court’s judgment that a communications structure was obvious. The CAFC

adopted language from the *KSR* opinion in stating that the invention was obvious despite the use of a multiplexer instead of a bus because “[i]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” Similarly, in *Lexion Medical v. Northgate Technologies*, the CAFC affirmed the district court’s judgment of obviousness in finding that the invention at issue simply modified the prior art via a simple and minor improvement: adding a recharge part that allows for the replenishment of water for extended use during laparoscopic surgeries.

On the other hand, a handful of cases suggest that *KSR* has had less of an impact on the chemical and pharmaceutical arts. For example, in *Eisai v. Dr. Reddy’s*, the CAFC held that because of the general unpredictability of the chemical arts, the infringer needed to establish some reason for the patent holder to modify lansoprazole by removing a fluorine substituent. However, the infringer was unable to show—even through expert witnesses—any reason why a skilled artisan would have made this modification. Likewise, the CAFC affirmed the district court’s judgment of nonobviousness in *Ortho-McNeil Pharmaceutical v. Mylan Labs*. The invention, the anticonvulsant TOPAMAX® (topiramate), was discovered while the inventor was researching diabetes. The CAFC held that it was not obvious to discover the anticonvulsant in part because the inventor would have had to select “among several unpredictable alternatives.”

INDEFINITENESS

The BPAI issued a rare *en banc* precedential decision in *Ex Parte Miyazaki*, announcing that the USPTO will use a lower standard of review than the federal courts for finding claims indefinite. Because of the statutory presumption of patent validity, the CAFC has previously held that post-issuance claims “do not compel absolute clarity” and only claims “not amenable to construction” or “insolubly ambiguous” are indefinite.

The BPAI spelled out the lower standard as follows: “if a claim is amenable to two or more plausible claim constructions, the USPTO is justified in requiring the applicant to more precisely define the metes and bounds of the claimed invention by holding the claim unpatentable . . . as indefinite.”

INEQUITABLE CONDUCT

In *Star Scientific v. RJ Reynolds* and *Praxair v. ATMI*, two CAFC panels presented different tests as to

whether an applicant “intended to deceive” in withholding a material reference. In *Star Scientific*, the CAFC stated that the intent to deceive can only be found if it is the “single most reasonable inference” from the evidence. The court made clear that “materiality does not presume intent.” In *Praxair*, the CAFC indicated that an inference of intent is generally appropriate when: (1) highly material information is withheld; (2) the applicant knew of the information and knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding. The two tests appear to be in tension if, for example, the applicant was negligently unaware of the materiality, with the *Praxair* test more likely to produce a finding of intent to deceive. It is hoped that the CAFC will clarify this issue soon.

PATENT REFORM

Legislation containing sweeping patent reform measures was introduced in the U.S. Senate (S. 1145) in 2007, but did not reach the floor in 2008.

In December, the Federal Trade Commission (FTC) held a public hearing to explore the evolving market for intellectual property. The FTC will likely publish a new report on the state of patent law in the U.S. Commentators have suggested that the report will serve as the basis for any patent reform measures in 2010.

NEW USPTO RULES

In April, the Eastern District of Virginia granted GlaxoSmithKline’s motion for summary judgment, permanently enjoining the USPTO’s proposed claim and continuation rules. To recap, the rules would have limited the number of claims that could be presented in an application and the number of applications that could be prosecuted for “patentably indistinct” inventions. Additionally, the rules would have required applicants to notify the USPTO of related applications, and would have placed significant new restrictions on the filing of continuing applications. The USPTO appealed to the CAFC and a decision is expected in 2009.

Also, new rules for *ex parte* appeals in the USPTO were scheduled to go into effect in December. The rules would have increased the complexity and cost of appeals due to new procedural and substantive requirements for appeal briefs. Implementation of the rules was delayed for review by the Office of Management and Budget (OMB). The OMB has not completed its review as of this writing.