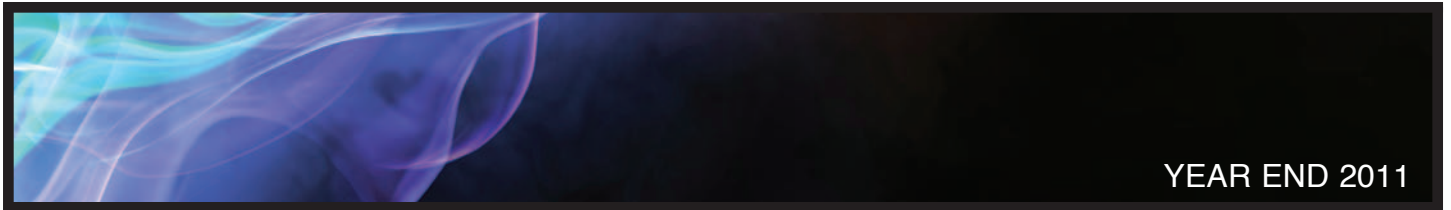




IDEAS ON INTELLECTUAL PROPERTY LAW



YEAR END 2011

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Cantor Colburn LLP

Intellectual Property Attorneys

Turning a blind eye backfires

Supreme Court addresses induced patent infringement

You've probably heard the old saying, "Ignorance of the law is no excuse." In the patent world, its slightly wordier corollary might be, "Willful blindness to induced patent infringement is no defense." The U.S. Supreme Court addressed this matter loud and clear earlier this year in its opinion in *Global-Tech Appliances, Inc. v. SEB S.A.*

Getting burned

SEB invented an innovative deep fryer, obtained a patent for its design and began selling it in the United States. Sunbeam subsequently asked Pentalpha Enterprises, a company wholly owned by Global-Tech Appliances, to supply it with deep fryers.

Pentalpha bought an SEB fryer that was made for sale in a foreign market and, therefore, didn't have U.S. patent markings. It copied all of the fryer's features except those that were cosmetic and retained an attorney to conduct a right-to-use study. Pentalpha didn't inform the attorney that it had directly copied SEB's design, and the attorney issued an opinion letter stating that the deep fryer didn't infringe any patents he'd found.

The company then began selling its fryers to Sunbeam, which resold them in the United States under its own trademark at a price that undercut SEB's price.

Boiling mad

SEB sued Sunbeam for patent infringement. Although Sunbeam notified Pentalpha of the lawsuit, Pentalpha went on to sell its fryers to other companies for resale in the United States.

After settling with Sunbeam, SEB turned its sights on Pentalpha, alleging that it actively induced Sunbeam and other companies to sell Pentalpha fryers in violation of SEB's patent rights. A jury found for SEB on the induced infringement theory, and the district court entered a judgment for SEB.

On appeal, the U.S. Court of Appeals for the Federal Circuit affirmed. It found that induced infringement under Section 271(b) of the Patent Act requires a showing that the alleged infringer knew or should have known that its actions would induce actual infringement.



The court further held that deliberate disregard of a known risk of infringement was a form of actual knowledge that satisfied the requirement. Pentalpha appealed again to the Supreme Court.

Starting the blaze

Sec. 271(b) provides that "whoever actively induces infringement of a patent shall be liable as an infringer." The Supreme Court found this provision ambiguous as to the intent necessary to establish liability.

For instance, the provision could require only that the inducer lead another to engage in conduct that happens to amount to infringement. Or it could mean that the inducer must persuade another to engage in conduct that the inducer knows infringes.

To resolve the ambiguity, the Court looked to the history of induced infringement. It noted that induced infringement wasn't considered a separate theory of indirect liability before Sec. 271 was enacted. Rather, it was considered evidence of contributory

America Invents Act brings big changes to patent law

Patent owners got some big news this fall. On Sept. 16, 2011, President Obama signed into law the Leahy-Smith America Invents Act of 2011 — more commonly known as the America Invents Act (AIA). It brings the broadest set of patent law changes in almost 60 years.

To motivate innovators to drive the economy forward, the AIA streamlines the patent application process and opens a more direct route to resolving patent infringement disputes. The law's centerpiece is its transitioning of U.S. patent law from a first-to-invent patenting system to the first-inventor-to-file system used in many other countries.

It's important to note that the AIA's provisions will phase in gradually over the 18 months following its date of enactment. So the law's true impact won't be known for some time. We'll cover the new law and its impact in more depth in future issues.

infringement. The enactment separated contributory infringement into two categories:

1. Induced infringement in Sec. 271(b), and
2. Sale of a component of a patented invention in Sec. 271(c).

The Supreme Court pointed out that it had previously concluded that a violator of Sec. 271(c) must know that the combination for which its component was specially designed was both patented and infringed. It determined that this conclusion — “now a fixture in the law” — compelled the same knowledge requirement for Sec. 271(b) in light of the two provisions' common origin.

Turning up the heat

The Court, however, rejected the notion that deliberate indifference to a known risk that a patent exists satisfies the knowledge requirement. But it did allow that “willful blindness” would suffice. The Supreme

Court reasoned that the concept of willful blindness is well established in the criminal context and saw no reason why it shouldn't apply in civil lawsuits for induced patent infringement.



So how is willful blindness shown? According to the Court, the doctrine has two requirements. The defendant must:

1. Subjectively believe there's a high probability that a patent exists, and
2. Take deliberate steps to avoid knowing that fact.

The two requirements, it said, give willful blindness an appropriately limited scope that surpasses mere recklessness or negligence.

As the Supreme Court put it, “Under this formulation, a willfully blind defendant is one who takes deliberate actions to avoid confirming a high probability of wrongdoing and who can almost be said to have actually known the critical facts.”

Turning to the case at hand, the Court had no trouble holding that a jury could find from the evidence that Pentalfa met the two requirements for willful blindness.

Fanning the flames

The *Global-Tech Appliances* ruling greatly clarifies the standards for induced infringement. Unfortunately for patent holders, it also raises the burden of proof from that laid out by the Federal Circuit. ○

Please note: The recently passed America Invents Act may have implications on similar cases involving patent infringement, as it has changed the standard for patent re-examination. Ask your intellectual property law attorney for details.

It's all in the genes ... or is it?

Patentability of "isolated" DNA molecule affirmed

If you felt a particularly strong gust of wind this past summer, it might have been the collective sigh of relief released by the biotech industry after the U.S. Court of Appeals for the Federal Circuit released a highly anticipated decision.

In *Association for Molecular Pathology v. U.S. Patent and Trademark Office and Myriad Genetics Inc.*, a three-judge panel held that an "isolated" DNA molecule is patentable — at least in part. In doing so, the panel shot down a controversial district court ruling that could have invalidated all patents for such molecules.

Origins of the lawsuit

Myriad Genetics held seven patents related to a test for mutations in BRCA genes that are associated with

a predisposition to breast and ovarian cancers. In 1998, Myriad began sending cease-and-desist letters to various providers of clinical BRCA testing services.

Eventually, a broad consortium of plaintiffs — including testing services, researchers, medical organizations and patients — sought a declaratory judgment that 15 claims in Myriad's patents were invalid because they covered subject matter ineligible for patents.

The challenged claims related to isolated gene sequences and diagnostic methods of identifying mutations in these sequences. Specifically, they comprised three composition claims and 12 method claims — one covering a screening method and 11 covering methods of "analyzing" a patient's BRCA sequence or "comparing" it with the normal sequence to identify the presence of cancer-predisposing mutations.

The district court agreed with the plaintiffs and invalidated all of the claims, sending a shock wave through the biotech community, which has long understood that such claims *were* patentable.

Composition claims

On appeal, the Federal Circuit found that the composition and screening method claims were patentable, but the analyzing and comparing claims were not.

The composition claims covered BRCA1 and BRCA2, isolated human genes that are free-standing portions of a naturally occurring DNA molecule that has been severed or synthesized to consist of just a fraction of the molecule. The plaintiffs argued that such isolated genes aren't patentable because they're products of nature.

But the court found that, though BRCA1 and BRCA2 can be found in a naturally occurring DNA molecule, they're "markedly different" from native DNA



molecules and, in their isolated state, aren't the same molecules as DNA molecules as they exist in the body. Human intervention in severing or synthesizing a portion of a native DNA molecule gives the isolated DNA a distinctive chemical identity, meaning isolated DNA molecules are patentable.

The challenged claims related to isolated gene sequences and diagnostic methods of identifying mutations in these sequences.

The Federal Circuit panel noted that its decision was consistent with the long-standing practice of the U.S. Patent and Trademark Office (PTO), which granted the first gene patents in the early 1980s. And, since then, Congress hasn't indicated that the PTO's position is incorrect.

Method claims

Applying the "machine-or-transformation" test for the patentability of method claims, the court found that the method for screening potential cancer therapeutics via changes in cell growth rates included transformative steps (that is, growing the cells and determining their growth rate) that were central to the method's purpose. Therefore, the method was patentable.

The claims for analyzing or comparing two gene sequences to identify mutations, on the other hand, weren't patentable subject matter because they failed the Supreme Court test from *Bilski v. Kappos*, as the claims were abstract concepts that included only mental processes.

Future review

The majority opinion was accompanied by a concurring opinion by one panel member, as well as an opinion by another panel member who partly concurred and partly dissented. The panel members' different approaches, and the many different types of isolated DNA, make it likely that courts will revisit these issues in the future. ○

Please note: The recently passed America Invents Act may have implications on similar cases involving genetic testing in the future. Ask your intellectual property law attorney for details.

Standard raised for "inequitable conduct" defense

In response to more than a decade of increasing criticism, the U.S. Court of Appeals for the Federal Circuit has raised the standard for inequitable conduct in the en banc decision *Therasense, Inc. v. Becton, Dickinson and Co.* By doing so, it's reduced the chances that infringers will be able to successfully argue that patents should be rendered unenforceable because of purportedly wrongful conduct during patent prosecution.

Sin of omission

The case involved a patent for disposable blood glucose test strips. During patent prosecution, Therasense responded to challenges by the U.S. Patent and Trademark Office (PTO) regarding an earlier patent by claiming that, unlike the new patent, the earlier patent required the tested blood to contain protective membranes. The company, however, didn't disclose a brief filed with the European Patent

Office (EPO) that stated that protective membranes were optional in the earlier invention.

In 2004, a competitor sued Therasense to obtain a declaratory judgment that its product didn't infringe Therasense's new patent. The district court found the patent unenforceable for inequitable conduct because of a failure to disclose to the PTO the arguments made to the EPO.

A system plagued

The Federal Circuit in this case criticized the expansion and overuse of the inequitable conduct defense, describing it as plaguing not only the courts, but also the patent system. The court noted that the defense originated from three Supreme Court cases involving egregious misconduct such as perjury and the manufacture of false evidence intended to deceive both the PTO and the courts. To prevent such egregious misconduct, the Court adopted a potent equitable remedy: unenforceability of the *entire* patent.

As the Federal Circuit observed in *Therasense*, the plague of inequitable conduct has occurred because the original defense has evolved over time to now sometimes encompass the mere nondisclosure of information to the PTO through "gross negligence." This has prompted applicants to drown the PTO with



inconsequential information and has fed the use of the defense as a common tactic to protract litigation.

Bar, raised

In its decision, the Federal Circuit tightened the reins on the inequitable conduct defense: Gross negligence will no longer satisfy the intent requirement. The accused infringer must prove that the applicant knew of the reference, realized that it was material and made a deliberate decision to withhold it.

The Federal Circuit in this case criticized the expansion and overuse of the inequitable conduct defense.

To establish materiality, the court adopted a "but-for" standard — in other words, proving materiality now requires proof that the patent wouldn't have issued *but for* the misconduct. The court also created an exception for affirmative egregious misconduct. When the patentee has engaged in such misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material regardless of whether the but-for standard is met.

It should be noted that the Federal Circuit also eliminated the "sliding scale" of proof for inequitable conduct, whereby patents could be unenforceable if the record showed *strong* evidence of *either* intent *or* materiality — even if there wasn't evidence of both. The court specifically instructed that district courts shouldn't use a sliding scale.

Petition filed

A "petition of cert" to move *Therasense* to the Supreme Court has been filed but, as of this writing, the Court has yet to pick it up. So both plaintiffs and defendants will have to stay tuned for whether this case is the final word on the doctrine of inequitable conduct. ○

Please note: The recently passed America Invents Act may have implications on similar cases involving patent infringement, as it has changed the standard for patent re-examination. Ask your intellectual property law attorney for details.

When trademark and patent injunction standards collide

In a recent trademark dispute, *Voice of the Arab World, Inc. v. MDTV Medical News Now*, preliminary injunction standards for trademark cases collided with those for patent cases. The decision by the U.S. Court of Appeals for the First Circuit holds an important lesson for those seeking injunctions.

Broadcasters bicker

The case involved a dispute over the mark “MDTV” between two broadcasters of health care information. Voice of the Arab World (VOAW) sought a declaratory judgment that it had a right to use and register the mark and hadn’t infringed Medical News Now’s (MNN’s) mark. MNN filed a trademark infringement counterclaim and requested a preliminary injunction prohibiting VOAW from using the mark.

The district court granted the injunction, relying on the First Circuit’s rule that a trademark plaintiff who demonstrates a likelihood of success on its claim creates a presumption of irreparable harm justifying an injunction.

Not just for patents

VOAW appealed, arguing that the presumption of irreparable harm was inconsistent with a 2006 decision by the U.S. Supreme Court. In that case, *eBay Inc. v. MercExchange, L.L.C.*, the Court rejected the presumption of irreparable harm for permanent injunctions in *patent* cases, finding instead that the traditional four-factor test for equitable relief applied.

Although *eBay* dealt with a permanent injunction, the Supreme Court noted in a 1987 case, *Amoco Production Company v. Village of Gambell*, that the “standard for a preliminary injunction is essentially

the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success.”

Under the four-factor test, the party seeking the preliminary injunction must show:

1. It’s likely to succeed on the merits,
2. It’s likely to suffer irreparable harm without the injunction,
3. The balance of equities tips in its favor, and
4. An injunction is in the public interest.



In *Voice of the Arab World*, the First Circuit held that this test also applies to *nonpatent* cases. It didn’t, however, address whether its previous rule regarding the presumption of irreparable harm in trademark cases was inconsistent with *eBay*, citing MNN’s excessive delay in seeking an injunction as the reason the presumption didn’t apply. The court found that the presumption has previously been held inapplicable in cases involving such delays, making it unnecessary to decide whether the presumption survived *eBay*.

Thus, the First Circuit reversed the district court’s grant of the preliminary injunction and remanded the case to that court to apply the four-factor test.

Patently obvious

As this case shows, it’s generally a mistake to delay seeking an injunction. Whether you’re a trademark holder or a patent holder, even if you can satisfy the test you could still lose out. ○



Cantor Colburn LLP

Intellectual Property Attorneys

20 Church Street
22nd Floor
Hartford, CT 06103

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Hartford, CT 860.286.2929 | Washington, D.C. 703.236.4500 | Atlanta, GA 404.607.9991 | Houston, TX 713.266.1130 | Detroit, MI 248.524.2300

Managing Partners: Michael A. Cantor and Philmore H. Colburn II