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Supreme Court Applies Willful Blindness Doctrine to Induced Infringement

By Benjamin R. Askew

Most Supreme Court observers would be surprised to find that a Supreme Court decision in a patent case could have an impact on criminal law. But when the United States Supreme Court recently interpreted 35 U.S.C. §271(b) – a patent statute – for the first time, the Court applied the willful blindness doctrine to induced infringement and issued an opinion that many commentators – and Justice Anthony M. Kennedy – believe may have significant consequences in criminal law.

The case is Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060 (2011), and the 8-1 opinion was authored by Justice Samuel A. Alito. The Court held that induced infringement under §271(b) has the same knowledge requirement as contributory infringement under §271(c). In other words, one accused of inducing infringement must know that the third party conduct it is inducing constitutes infringement. This was an expected result, because the Court previously held that contributory infringement had a knowledge requirement. As the Court stated, "[i]t would thus be strange to hold that knowledge of the relevant patent is needed under §271(c) but not under §271(b)."

The controversial aspect of the Court's decision is that "willful blindness" may suffice to meet the knowledge element for induced infringement. The willful blindness doctrine is well-established in criminal law. As described by the majority, "courts applying the doctrine of willful blindness hold that defendants cannot escape the reach of these [criminal] statutes [that require knowledge] by deliberately shielding themselves from clear evidence of critical facts that are strongly suggested by the circumstances."

In This Issue

In Global-Tech, the defendant's subsidiary (Pentalpha) in Hong Kong, was tasked with designing a deep fryer meeting certain specifications. Pentalpha reverse-engineered and copied the plaintiff SEB's deep fryer in Hong Kong, which was identical to the patented U.S. model but did not have US patent markings. Pentalpha then sold the deep fryers to various companies that sold to end-users under their respective trademarks. The district court upheld the jury's finding of induced infringement – despite a lack of direct evidence that Pentalpha knew of SEB's patent – because there was adequate evidence showing that "Pentalpha deliberately disregarded a known risk that SEB had a protective patent."

The Federal Circuit affirmed, and Pentalpha appealed. The Supreme Court agreed with Pentalpha that "deliberate indifference" is not the appropriate standard under §271(b), but nevertheless affirmed the Federal Circuit because the evidence was sufficient to find knowledge under the willful blindness doctrine. To meet the willful blindness test: (1) "the defendant must subjectively believe that there is a high probability that a fact exists," and (2) "the defendant must take deliberate actions to avoid learning of that fact."

The lone dissenter, Justice Kennedy, agreed that "271(b) must be read in tandem with 271(c), and therefore that to induce infringement a defendant must know 'the induced acts constitute patent infringement.'" The dissent criticized the Court for holding that willful blindness suffices to meet 271(b)'s knowledge requirement. Justice Kennedy stated that "[t]he Court appears to endorse the willful blindness doctrine here for all federal criminal cases involving knowledge…" and "i[t] does so in a civil case…." Time will tell how this opinion impacts criminal law, but for purposes of patent law, the knowledge element of induced infringement can be met by a showing of willful blindness.

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Benjamin practices in the firm's intellectual property area. Ben has extensive experience in numerous areas of litigation, including patent and copyright litigation, complex commercial litigation, and unfair competition law. He represents a wide range of clients in various industry sectors and litigates cases in federal and state courts and in arbitration. Ben has also practiced within the firm's business litigation practice area.

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A Cure for the "Plague on the Patent System" May be Near

By Fredericka B. Jura

Defendants accused of patent infringement often file "inequitable conduct" counterclaims, whereby a defendant alleges that the patent-in-suit is unenforceable because of something the patentee did – or failed to do – while procuring the patent from the U.S. Patent and Trademark Office (PTO). Most often, the accused conduct is failing to provide the PTO with information relevant to the patent application. Proving inequitable conduct requires both intent and materiality: the patentee's intent to deceive the PTO and materiality of the information withheld from the PTO. Inequitable conduct counterclaims have become so commonplace that the Federal Circuit claimed they plague "not only the courts but also the entire patent system." (*Therasense, Inc. v. Becton, Dickinson and Co.,* No. 2008-1511, --- F.3d ----, 2011 WL 2028255 at *8 [Fed. Cir. May 25, 2011]). An estimated 80 percent of patent infringement cases include allegations of inequitable conduct (*Id*).

Therasense may change all that. In a divided en banc decision (meaning the full court participated and some judges dissented), the Federal Circuit adopted a more stringent standard for proving inequitable conduct. *Therasense* addressed both the intent and materiality requirements and confirmed that courts must consider each requirement independently. (*Therasense*, 2011 WL 2028255 at *9-10).

With respect to intent, the Court held that a defendant must prove by clear and convincing evidence that the patentee knew of the information it withheld from the PTO, knew that it was material and made a deliberate decision to withhold it (*Therasense*, 2011 WL 2028255 at *9). A finding of negligence is not sufficient to show intent (*Id*). While a court may infer intent from circumstantial evidence, the specific intent to deceive must be "the single most reasonable inference able to be drawn from the evidence," (*Id*. at *10). "When there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found," (*Id*).

With respect to materiality, the Court created a "but-for" standard: Information is material if the PTO would not have allowed a claim to issue had it been aware of the undisclosed information (*Id*. at *11). In making this patentability determination, the Court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction (*Id*). As an exception, the "but for" standard need not be proven in cases involving affirmative egregious misconduct (*Id*. at *12).

Even when materiality and intent are proven, the Federal Circuit stated that a patent should only be rendered unenforceable due to inequitable conduct "… where the patentee's misconduct resulted in the unfair benefit of receiving an unwarranted claim," (*Id*).

Post *Therasense*, defendants will likely think twice before filing an inequitable conduct counterclaim. If and when a defendant asserts inequitable conduct, the allegation should be supported by evidence that meets the high standards set forth in *Therasense*. The *Therasense* decision will likely increase the ability of plaintiffs to resolve claims of inequitable conduct early on through motions to dismiss and motions for summary judgment.

As noted above, the Federal Circuit was divided on its *Therasense* decision. Chief Judge Randall Rader authored the majority opinion, joined by Judges Pauline Newman, Alan Lourie, Richard

Linn, Kimberly Moore and Jimmie Reyna. Judge Kathleen O'Malley concurred, and Judge William Bryson dissented, joined by Judges Arthur Gajarsa, Timothy Dyk and Sharon Prost. Stay tuned on whether the Supreme Court will weigh in on the issue.

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Fredericka is a licensed patent attorney, practicing in Thompson Coburn LLP's Intellectual Property group, focusing on patent and trademark litigation. Her patent litigation experience includes performing patent infringement analyses and representing clients in patent infringement suits across the country. She also represents clients before the Trademark Trial and Appeal Board. In this capacity, she has drafted summary judgment motions and trial briefs, as well as managed the various technical aspects of trial preparation before the Board. Ericka has experience drafting settlement agreements involving both patent and trademark rights.

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Boston Scientific Corp. v. Johnson & Johnson: The Federal Circuit Finds Broad Molecular Claims in an Unpredictable Application Fail the Written Description Test

By Joseph B. Franklin, Ph.D.

In *Boston Scientific Corp. v. Johnson & Johnson* (*"BSC"*), WL 2184283/LEXIS 11465 (2011), the Federal Circuit invalidated claims to a broadly defined genus of molecules because the behavior of those molecules in the invention, a drug-delivery device, was unpredictable. The court found that these patents failed the written description requirement because they did not sufficiently indicate which molecular species, among the broad genus, performed the claimed function. The BSC decision informs practitioners that merely because a molecular genus is well-defined in the literature, a further description—in the context of a particular application—is necessary.

In 2010, the Federal Circuit held, *en banc*, that section 112 of the patent statute requires a written description of the invention that is distinct from the enablement requirement (See *Ariad Pharms., Inc. v. Eli Lilly & Co.,* 598 F.3d 1336 [2010]). Written description and enablement are statutory siblings, born of the text of 35 U.S.C. § 112: "The specification shall contain a *written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable* any person skilled in the art…to make and use" the invention (emphasis added). Though the written description requirement applies to any field of invention, it pres-

ents a special challenge to the validity of certain chemical and biotechnology claims. The Federal Circuit's holding in *BSC* is the most recent in a line of cases invalidating claims that have, according to the court, shared a common shortfall: staking out a wider genus of molecules than is adequately described.

Writing for the majority in *Ariad*, Circuit Judge Alan D. Lourie explained why the written description requirement, though generally applicable, has particular significance in chemical and biotechnology cases. Many claims, and particularly those claiming mechanical inventions, may meet the written description requirement on their own. However, when a patent claims a genus of potential molecules, it must demonstrate to a skilled artisan (via the written description) that the inventor had sufficient possession of component species to allow a claim to the entire genus. *Ariad* offers two scenarios in which molecular inventions may be particularly prone to failing the written description requirement.

In the first scenario, the disclosure may *enable* the synthesis of a broader set of molecules than the inventor has sufficiently described. This enablement is distinct from written description, and it is the *written description requirement* that acts to limit the scope of the claims to those molecules that the inventor possessed. In this sense, "possession" means that the written description "reasonably conveys" to a skilled artisan, that the inventor had possession on the filing date. (See *Ariad*, 598 F.3d at 1351). The requisite descriptiveness varies according to the level of knowledge in a particular field, and a valid claim may not necessarily describe every possible permutation of a generic invention. (See *Capon v. Eshhar*, 418 F.3d 1349, 1359 [2005]).

There is a second scenario in which biological patents, in particular, pose a written-description problem: When a patent claims a genus of molecules by function (for example, an inventor might claim those species "that catalyze the reaction A→ B"). In such a case, *Ariad* explains, the description is inadequate when skilled practitioners would not be able to identify which species, among a broadly defined genus, actually perform the claimed function.

In BSC, the court indicated that the claims at stake fell roughly into this second category—where a broad genus, limited by function, is described inadequately. The patents (three filed in 1997 and a fourth in 2001) described vascular stents that the inventors coated with a gradually eluting drug to reduce the re-narrowing, or restenosis, of treated blood vessels. The 1997 patents claimed stents with either rapamycin or "macrocyclic lactone analog[s]" of rapamycin as the therapeutic agent. The 2001 patent claimed rapamycin or its "macrocyclic triene analog[s]" as the therapeutic agent.

The invalidity inquiry focused on the broadness of the claimed genera of rapamycin analogs, since the only structural restriction on these genera was the presence of a particular chemical functional group, or moiety. (The rapamycin molecule contains one lactone moiety and one triene moiety.) The Federal Circuit adopted the trial court's construction of the generic claim terms, defining them broadly to encompass rapamycin itself and molecules "with structural similarity to rapamycin." The court observed that "the universe of potential compounds that are structurally similar to rapamycin and classifiable as macrocyclic lactones is potentially limitless."

The patentee (Cordis) argued that these molecular genera were nevertheless sufficiently narrow in this particular case. Cordis attempted to establish, with expert testimony, that the structure-function relationship of rapamycin was well-known at the time of filing—enough so that a skilled artisan would have been able to distinguish between functional and non-functional analogs of rapamycin.

The court rejected Cordis' arguments, holding that the claimed genera were described too broadly. The court revived an old analogy stating that patents, and chemical patents in particular, must provide "blaze marks" to guide a skilled practitioner in selecting useful species from the forest of a broadly defined genus. Minor changes in the structure of the rapamycin molecule, the court found, "may have significant and unpredictable effects on functionality."

The court concluded that the unpredictable nature of the drug-eluting stents required more written disclosure than Cordis' patents provided. Even though the structure-function relationship for some rapamycin species had been disclosed at the time of filing, the court found that researchers continued to have difficulty identifying those rapamycin analogs that would function *in the drug-eluting stents*. For instance, though rapamycin analogs had been disclosed previously, the court found these prior disclosures insufficient because drug-eluting stents were still at the experimental stage, even in 2001. Therefore, the patents did not convey "that the inventor had possession of the claimed sub-genus" of rapamycin analogs capable of functioning in drug-eluting stents.

Unfortunately for the patentees, language in the patents themselves contradicted arguments that rapamycin analogs were well understood at the time of invention. The court noted several statements from the 1997 patents, among them declarations that "the precise mechanism of rapamycin *is still under active investigation*." (emphasis added by the court). Not only did the 2001 patent fail to disclose any species within the claimed sub-genus, it admitted that "[t]he molecular events that are responsible for the actions of rapamycin…are still being elucidated."

Further, in rebutting a separate non-obviousness challenge, Cordis presented the remarkably inconsistent argument that the stent field was actually quite immature at the time of filing—that "proposed solutions" to restenosis "were anything but predictable." Cordis' dissonant positions on the predictability of the stent field underscore the potentially competitive relationship between the requirements of non-obviousness and adequate written description.

Overall, BSC demonstrates that the written description requirement limits the ability to claim a relatively well characterized genus of molecules when the behavior of those molecules within the context of an invention, such as a drug-delivery device, is unpredictable. How molecular structure determines function *in the claimed application* must be described within the patent, if it is not sufficiently established at the time of filing.

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Joseph is a 2011 Summer Associate with Thompson Coburn and a law student at Washington University School of Law. He received his Bachelor of Science in Biology from Duke University in 2004 and his PhD in Cell Biology from Yale University in 2010. Joseph's work experience includes working for the Department of Cell Biology at Yale University conducting Ph.D. research.

Supreme Court Decision in *Stanford University v. Roche Molecular Sys., Inc.* Looms Over Inventor/ Employee Relationships

By Jonathan G. Musch

In copyright law, an employer's ownership of employee creations made during the course of their employment is well-defined and clear (under the work made for hire doctrine). This is not the case in patent law, where rights to an employee's invention do not automatically vest with an employer. The recent United States Supreme Court decision *Stanford University v. Roche Molecular Systems, Inc.* does little to prevent such ownership collisions, and portends a future that will necessitate vigilance by employers who seek to control patent rights in the inventions of their employees *(Board of Trustees of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., . Co. v. Convertible Top Replacement Co.,* 131 S.Ct. 2188 (June 6, 2011). Given the stances taken by the Justices in this case, a future case may overturn the Federal Circuit's *FilmTec Corp. v. Allied Signa* decision (929 F.2d 1568 [Fed. Cir. 1991]. The *FilmTec* case permits present assignments of future inventions, enabling employers to obtain one broad, catch-all assignment upon hiring that can affect the transfer of the patent rights upsetting at least two decades of employee assignment practice. This article reviews the current state of the law concerning assignment practice, analyzes the impact of future rulings from the Supreme Court on this issue, and suggests some simple procedures that can be adopted now to minimize problems in the future.

The nature of patents can complicate ownership of rights in the inventions. Only natural persons can be named inventors on a patent. These inventors possess the rights to their inventions in the first instance and ownership can only be transferred by contract or operation of statute. This can complicate the ownership picture concerning an employee's invention, particularly in the case of universities, where interests of universities, the employee researchers, public funding, and private sponsorship or collaborations collide. A properly-worded "present assignment of a future invention" under the *FilmTec* decision can sidestep this potentially troublesome issue. Under *FilmTec*, an employee can completely assign his rights in an invention before that invention is made, avoiding ownership disputes. As explained by the *FilmTec* decision: "Once a [present assignment of a future invention] is made and an application for patent is filed, … title to the rights accruing thereunder would be in the assignee . . . no further act would be required," (Id. at 1572-73).

The *Stanford University v. Roche Molecular Systems* case involved the intersection of a university conducting federally-funded research (Stanford), a private biomedical research company (Cetus, later Roche Molecular Systems), and a Stanford research fellow who conducted research for a time at the research company (Dr. Holodniy). Dr. Holodniy joined Stanford and signed an employee Copyright and Patent Agreement, which stated that he "agree[d] to assign" to Stanford his "right, title and interest in" inventions resulting from his employment at the University. Shortly thereafter, Dr. Holodniy commenced work on a method to quantify HIV levels in blood samples, a method that incorporated certain techniques developed by Cetus. As a condition of visiting Cetus and using its technology, Dr. Holodniy signed a Visitors Confidentiality Agreement that specified that Dr. Holodniy "will assign and do[es] hereby assign" to Cetus his "right, title and interest in each of the ideas, inventions, and improvements made "as a consequence of [his] access" to Cetus. Dr. Holodniy and others then developed an HIV blood test, a test commercialized by Roche. Stanford

University sued Roche for patent infringement and Roche argued that Stanford lacked standing because the Cetus Agreement gave Roche rights in Dr. Holodniy's invention. The Federal Circuit, relying on *FilmTec*, held that the Cetus Agreement was a present assignment of a future invention, which effectively assigned all of Dr. Holodniy's rights to the invention to Cetus. The Federal Circuit found that the Stanford Agreement, signed first in time by Dr. Holodniy, was merely a promise to assign in the future.

Stanford University petitioned the Supreme Court on the limited issue of whether the Bayh-Dole Act (The Bayh-Dole Act (35 U.S.C. § 202) relates to the federal government's rights in inventions arising out of federally-funded research projects) automatically enabled federal contractors (here Stanford) to obtain rights in federally-funded inventions, but not on whether the Federal Circuit's finding concerning the chain of title was proper. The majority opinion affirmed the Federal Circuit and confirmed the idea that rights to an invention belong to the inventor and that any transfer of ownership by statute must be unambiguous. Here, the Bayh-Dole provision permitting federally-funded contractors to "retain title" to inventions did not unambiguously alter the ownership in patented inventions. Based on the issue presented, the majority's conclusion is unsurprising. The dissent (Justices Breyer and Ginsburg) reached beyond the issue presented to express their views on the Federal Circuit's *FilmTec* rule. The dissent contends that prior to *FilmTec*, neither forward-looking assignment would have effected a transfer of rights, meaning that a subsequent assignment to Stanford by Dr. Holodniy as part of the patent application would have been dispositive of ownership. The dissent argues that the "slight linguistic differences in the contractual language, [between the Cetus and Stanford agreements] seems to make too much of too little" and questions "why …we should prefer the Federal Circuit's *FilmTec* rule to the rule, of apparently much longer vintage, that would treat both agreements" the same. These statements reflect the position of two justices, but comments made by the majority and concurrence suggest that they are explicitly deferring review of that issue in this opinion. This indicates that, given the right case, the Supreme Court may strike down the *FilmTec* rule and return to the dissent's rule of "much longer vintage," thus requiring post-invention assignments to secure rights.

Employers should conduct pre-hire and exit interviews/investigations to avoid surprise inventorship disputes, institute protocols to obtain assignments from employee inventors as soon as practicable upon disclosure of the invention to the employer, and investigate any joint ventures with third parties.

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Jonathan's practice focuses on several aspects of intellectual property litigation, including patent, copyright, trademark, trade dress, and unfair competition law. In this role, he has both prosecuted and defended patent, trademark, trade dress, and copyright infringement actions in federal court. Jonathan's practice has also included litigating several state court actions. He has managed cases of all sizes and represented clients ranging from small businesses to very large corporations.

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