

# **DEVELOPMENTS IN PATENT LAW 2009**

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## I. PATENTABILITY, VALIDITY, AND PROCUREMENT

### A. Statutory Subject Matter

*In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), *cert granted*, *Bilski v. Kappos*, 129 S.Ct. 2735 (June 1, 2009). The U.S. Supreme Court granted certiorari in this important case involving the patentability of business methods. The case originated in the U.S. Patent and Trademark Office (PTO), which rejected Bilski's patent application. The patent claimed a method of reducing consumption risk by engaging in a series of transactions between a commodity provider and market participants in a way that balanced risk. The PTO rejected the patent application on the basis that it was not a "process" as that term is understood in patent law.

The Federal Circuit affirmed the PTO in an en banc decision, concluding that under controlling U.S. Supreme Court precedent, in order to be patentable a process must either be tied to a machine or it must transform something. Because Bilski's claims met neither prong of this "machine-or-transformation" test, it was deemed to be unpatentable. In his dissenting opinion, Judge Mayer would have gone farther, imposing a "technological arts" requirement for patentability. Two other judges filed dissenting opinions.

The Bilski case represents a rare opportunity for the Supreme Court to weigh in on the outer limits of patentable subject matter, an issue it has not addressed for nearly 30 years. In 2006, three Supreme Court Justices filed an opinion dissenting from the dismissal of certiorari in another patent case, *Laboratory Corp. of America v. Metabolite*. Justice Breyer, writing for the three dissenters, clearly rebuked the Federal Circuit's *State Street Bank* line of cases, which had seemingly endorsed patentability for inventions that produced a "useful, concrete, and tangible result." Justice Breyer noted that such a liberal test for patentability "would cover instances where this Court has held to the contrary." The Federal Circuit's Chief Judge Michel, writing for the *Bilski* majority, acknowledged the rebuke and clarified that the "useful, concrete and tangible result" language was not the test for patentability.

Bilski's petition for certiorari focused on two themes: First, Bilski argued that the Federal Circuit was once again applying rigid tests in patent cases that allegedly conflicted with Supreme Court precedent. Second, Bilski argued that the Federal Circuit incorrectly limited process patents to industrial manufacturing methods, ignoring the realities of innovation in the modern information age. According to Bilski, the boundaries of patentable subject matter should extend to anything under the sun made by man, with the recognized exceptions of laws of nature, natural phenomena, and abstract ideas. In its responsive brief, the PTO played down any purported conflict with Supreme Court precedent.

Since the U.S. Supreme Court granted Bilski's certiorari petition, more than 40 amicus briefs have been filed, most of them filed in support of neither party. Heavily represented among the amicus filers are companies in the software, pharmaceutical, and medical diagnosis fields. In advocating reversal of the Federal Circuit's "machine or transformation" test, some amicus parties have urged a broader "usefulness" test, while others have urged the Supreme Court to focus on whether an invention provides a "technological contribution."

Yet others have suggested that the test should distinguish between applied inventions that would be patentable and abstract inventions that would not. Few amicus filers have urged outright affirmance of the Federal Circuit's decision.

The courtroom at the U.S. Supreme Court on November 9, 2009 was overflowing with patent attorneys, many having waited in line for more than three hours to get in. Following the oral argument, one thing seems certain – Mr. Bilski is not likely to get a patent on his method of hedging consumption risk. The afternoon argument, which began promptly at 1:00 pm, evoked numerous questions from the Court. None of the Justices seemed sympathetic to Bilski's case. Several of the Justices pressed Bilski's counsel to explain why a method of conducting business is the type of invention that was intended to be covered under the patent laws. The Justices struggled, however, with whether the Federal Circuit's "machine or transformation" test was the appropriate test for process patents, and prodded both sides to propose alternatives.

Justice Scalia asked why the "useful arts" mentioned in the U.S. Constitution didn't indicate an intention to limit inventions to manufacturing arts involving workers. Justice Ginsberg asked why, in view of Europe's prohibition on patenting business methods, the United States should not adopt a similar rule. Justice Breyer asked whether the framers of the Constitution would have intended to force competitors to search for and avoid patents covering methods of doing business, and asked whether he could have patented his method of teaching antitrust law. (Bilski's response: Yes, if it was new and not obvious). Justice Sotomayor seemed concerned that the "machine or transformation" test was too rigid and might foreclose patenting future areas of technology.

Chief Justice Roberts pressed Bilski's counsel several times to explain why his three-step method involving "initiating transactions" among various parties was not merely an unpatentable abstract idea, and debated with Bilski's counsel whether any of the steps involved physical steps. At one point, Chief Justice Roberts challenged Bilski's counsel to explain why picking up the phone and calling somebody to sell a commodity involved anything "physical." Justice Scalia asked why, if the framers of the Constitution intended to cover business methods, hadn't inventors patented methods of training horses back in the early days of the country.

Bilski's attorney argued that the test for patentability should focus on whether there was a practical application of a useful result, a test that was met by Bilski's claims. He also argued that by enacting Section 273 of the patent statute, which provides a defense for infringement of "business method" patents, Congress clearly intended for business method inventions to be covered under the patent laws. The Justices seemed concerned that Bilski's proposed test was overly broad.

Several of the Justices asked whether the State Street Bank case – thought by some to have given rise to "business method" patents after it was decided in 1998 – would have reached the same outcome today under the Federal Circuit's "machine or transformation" test. Malcolm Stewart, arguing on behalf of the PTO, said that it would, given that State Street Bank involved only a claim to a machine, not any process claims, so the "machine or

transformation” test would not be applicable. Some of the Justices seemed puzzled by this distinction, and pressed Stewart to explain why the test would not apply. It is unclear whether their concerns were adequately addressed.

Justice Alito asked whether the Supreme Court should have agreed to hear the case at all, given that it could have been decided on the narrower grounds that *Bilski* was claiming an abstract idea. Mr. Stewart, arguing on behalf of the PTO, responded that the PTO wanted to win on the primary ground advanced – the “machine or transformation” test. He also defended that test as leaving some flexibility for future decisions. Deciding the case on the alternate ground would leave a hole in the law, he said, creating uncertainty for the PTO and patent applicants. The Supreme Court has not issued a decision on this issue for nearly 30 years.

In the end, the Supreme Court may adopt a variant of the Federal Circuit’s “machine or transformation” test that leaves open the possibility for patenting future forms of technology that would not satisfy the current Federal Circuit test. Or, as suggested by some of the Justices, it is possible the Court might affirm the decision on the alternative ground that *Bilski*’s process claims are a mere “abstract idea” and, therefore, precluded under existing Supreme Court precedent. What seems unlikely is that *Bilski* will end up with a patent on his method of hedging consumption risk.

The *Bilski* “machine or transformation” test has presented some difficulties for the PTO, which has been left to apply it in pending patent applications without much guidance from the Federal Circuit. The rejection rate for computer-related inventions, for example, has increased substantially, especially for method claims that recite little or no machine structure. In one case, for example, the PTO’s Board of Appeals concluded that a method reciting a “monitoring device” failed the *Bilski* test because “monitoring device” was not a specific machine. In other cases, the PTO’s Board of Appeals has struggled to determine what type of “transformation” would make a claim patentable. Patent attorneys have been left wondering how to claim various types of software and diagnostic processes in a way that would pass the *Bilski* test.

*Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009). The Federal Circuit overturned a lower court decision that had invalidated a patent on a method of treating certain autoimmune diseases as not constituting patentable subject matter. Prometheus is the exclusive licensee of two patents that claim methods for calibrating the proper dosage of certain drugs used to treat autoimmune diseases. Upon administration to a patient, the drugs are broken down by the body into various metabolites. The patents involve measuring these metabolites in order to optimize the therapeutic efficacy of the drugs while minimizing toxic side effects. The patent claims generally include two method steps: First, a step of administering a drug to a subject; and second, determining levels of the drug’s metabolites in the subject’s body. The measured metabolite levels are then compared to pre-determined levels that indicate a need to increase or decrease the level of the drug to be administered for treatment.

Mayo (including the famed Mayo Clinic) initially purchased and used Prometheus’s patented

test, but in 2004 announced that it intended to use its own test instead. Prometheus sued Mayo for patent infringement, and the district court ruled on summary judgment that Mayo literally infringed the patents. On a cross-motion for summary judgment, however, the court concluded that the claims were invalid because they recited non-statutory subject matter. According to the district court, the claims were not statutory because they merely recited “data gathering” steps and a mental step of warning of an adjustment in dosage. The district court also concluded that the steps were not statutory because they merely recited natural phenomena, as the inventors did not “invent” the claimed correlation. Finally, the district court determined that because the claims covered the correlations themselves, they “wholly pre-empted” the correlations and thus did not qualify as a patentable process.

On appeal, the Federal Circuit reversed. Beginning with its recent decision in *In re Bilski*, which was decided after the district court had invalidated the patents, the Federal Circuit stated that a process (method) claim is statutory if either (1) it is tied to a particular machine or apparatus; or (2) it transforms a particular article into a different state or thing. Moreover, the use of a specific machine or transformation must impose meaningful limits on the scope of the claim, and the involvement of the machine or transformation must not merely be insignificant extra-solution activity – it must be central to the purpose of the claimed process. For example, a mere data-gathering step would not normally qualify as a significant claim activity.

The Federal Circuit concluded that the claims met the transformation prong of *Bilski* because they transform an article into a different state or thing and that transformation is “central to the purpose of the claimed process.” According to the Federal Circuit, the transformation “is of the human body following administration of a drug and the various chemical and physical changes of the drug’s metabolites that enable their concentrations to be determined.”

The Federal Circuit rejected the district court’s conclusion that the claimed steps were merely “data gathering” steps, given that the purpose of the invention was to treat the human body, a point that was made clear both in the patent specification and the claims. The appeals court also rejected the district court’s reliance on the 2006 dissenting opinion by three Justices in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, on the basis that it “is not controlling law and also involved different claims from the ones at issue here.” According to the Federal Circuit, “when administering a drug such as AZA or 6-MP, the human body necessarily undergoes a transformation.” The transformation is not the result of a natural process, but is instead the result of the non-natural administration of a drug to a subject. Even claims that did not include the “administering” step were found to be patentable, because the “determining” step was also found to be transformative and central to the claimed methods. According to the Federal Circuit, determining the levels of the drug in a subject necessarily involves a transformation, because those levels cannot be determined by mere inspection but instead require some form of manipulation or modification of substances. The Federal Circuit also rejected the district court’s conclusion that the claims “wholly preempted” the use of correlations between metabolite levels and efficacy or toxicity.

The decision will undoubtedly have an immediate impact on patent applicants seeking to

claim methods of treatment that involve administration of a drug that is transformed in the body. Pharmaceutical companies and universities involved in medical research, for example, can be expected to have patent applications approved by the PTO and patents upheld in litigation. The decision may also have implications for other areas of technology, such as business methods and computer software, given that the Federal Circuit has indicated that it will give a fairly broad reading of the “transformation” prong of *Bilski*. In view of the U.S. Supreme Court’s recent decision to grant certiorari in the *Bilski* case itself, however, patent applicants and owners may have to await the Supreme Court’s decision – expected in 2010 – to make any final decisions.

*In re Comiskey*, 554 F.3d 967 (Fed. Cir. 2009) (revised opinion). The Federal Circuit denied a petition to rehear its original decision in this case (issued in 2007), which held that a claim directed to a method and system for conducting mandatory arbitration did not constitute patentable subject matter because it merely recited “mental steps.” It did, however, issue a revised opinion. In the revised opinion, the Federal Circuit reaffirmed its “mental steps” rejection of the method claims, but remanded the system claims to the PTO to determine whether they were patentable in view of the fact that they arguably recited the use of a machine.

#### **B. Written Description Requirement**

*Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 560 F.3d 1366 (Fed. Cir. 2009), *rehearing granted*, 2009 WL 2573004 (August 21, 2009). The Federal Circuit held that a method claim was invalid because it failed to comply with the written description requirement. In accordance with prevailing case law, the Federal Circuit held that the written description requirement is separate and distinct from the enablement requirement. However, on August 21, 2009, the Federal Circuit granted a petition for rehearing in the case, vacating the decision and directing the parties to brief the question whether 35 U.S.C. § 112, first paragraph, contains a written description requirement separate from an enablement requirement. A decision is expected in early 2010.

#### **C. Invalidating Public Use Bar to Patentability**

*Clock Spring, L.P. v. Wrapmaster, Inc.*, 560 F.3d 1317 (Fed. Cir. 2009). A patent claiming a method for repairing a pipe was held to be invalid because it was publicly used more than one year before a patent application was filed. The Federal Circuit rejected Clock Spring’s argument that the public use was experimental because there was no evidence that any control was exercised over the testing and there was no documentation showing that the purported testing was intended to test durability as alleged by Clock Spring.

**D. Obviousness (Post-KSR)**

*The Procter & Gamble Company v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989 (Fed. Cir. 2009). The validity of Procter & Gamble's patent covering the drug Actonel, an osteoporosis treatment, was upheld against a charge of obviousness. The Federal Circuit affirmed the district court's conclusion that in the unpredictable chemical arts, it would not have been "predictable" to modify a prior art compound to arrive at the claimed invention. Furthermore, there was insufficient evidence that a person of ordinary skill in the art would have a reasonable expectation of success in modifying the prior compound. Finally, evidence of commercial success and long-felt unmet needs buttressed the district court's conclusion.

*In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009). The Federal Circuit affirmed a decision from the PTO's Board of Patent Appeals and Interferences that a claim to an isolated nucleic acid molecule was unpatentably obvious. First, the Federal Circuit rejected Kubin's argument that two prior art references did not provide any guidance regarding how to prepare a cell culture that would serve as a useful starting source, in view of Kubin's own patent specification, which mentioned one of the references as evidence of conventional methods of isolating and encoding a sequence. More importantly, the Federal Circuit repudiated its 1995 decision *In re Deuel*, which held that it was improper to apply an "obvious to try" rationale in concluding that a claim would have been obvious. In this case, the prior art taught the protein of interest, a motivation to isolate the gene coding for that protein, and illustrative instructions to use a monoclonal antibody specific to the protein for cloning the gene. Therefore, the claimed invention was "the product not of innovation but of ordinary skill and common sense." The Federal Circuit also rejected the argument that the "obvious to try" rationale should not apply to the "unpredictable art" of biotechnology.

*Perfect Web Technologies, Inc. v. Infousa, Inc.*, \_\_\_ F.3d \_\_\_, 2009 WL 4281939 (Fed. Cir. December 2, 2009). A patent covering a method of managing bulk e-mail distribution was held on summary judgment to be obvious. The Federal Circuit affirmed, concluding that "common sense" could be relied upon to show that repeating previously-known steps until a threshold value was met would have been obvious. It was not necessary to rely on expert testimony to establish the obviousness of modifying the prior art.

**E. Definiteness (35 U.S.C. § 112, Second Paragraph)**

*Blackboard, Inc. v. Desire2Learn Inc.*, 574 F.3d 1371 (Fed. Cir. 2009). In yet another case invalidating patent claims containing means-plus-function clauses, the Federal Circuit affirmed a district court's conclusion that 35 claims of Blackboard's on-line education system were invalid because they failed to comply with the definiteness requirement of 35 U.S.C. § 112, second paragraph. The claims recited a server computer including a "means for assigning a level of access" to data files. Although the patent specification described an access control manager (ACM) that creates an access control list, the district court concluded that this was inadequate because it failed to describe how the levels themselves are assigned to the data files in the first place. The Federal Circuit affirmed, concluding that "the ACM is essentially a black box that performs a recited function. But how it does so is left

undisclosed.” This decision provides yet another cautionary tale about claiming software functions using means-plus-function claim language.

**F. Ability of Patent Applicant to Introduce New Evidence in § 145 Action**

*Hyatt v. Doll*, 576 F.3d 1246 (Fed. Cir. 2009). A patent applicant whose application was rejected by the PTO sued the PTO Director under 35 U.S.C. § 145, which permits applicants to introduce new evidence in support of patentability. The D.C. District Court refused to permit the applicant in this case to submit a declaration because he had previously refused to submit it to the PTO in response to a request by the PTO. Judge Moore dissented, arguing that Hyatt should have been entitled to enter any new evidence, regardless of whether it had been withheld before the PTO.

**G. Reexamination of Patent Based on Previously-Considered Prior Art**

*In re Swanson*, 540 F.3d 1368 (Fed. Cir. 2008). In this appeal of a reexamination decision from the PTO, the Federal Circuit affirmed the unpatentability of claims based on the same prior art that had been raised in the initial examination of the patent and also raised in prior litigation involving the patent owner. Despite the fact that the same prior art had been previously considered both in initial examination and in previous litigation, the Federal Circuit concluded that a “substantial new question” of patentability was still presented by that prior art. The reexamination statute only addressed prior art previously considered by the PTO, not a court in litigation. And the 2002 amendment to the reexamination statute explicitly permitted reliance on the same prior art previously considered, as long as the precise issue raised in the initial examination was not re-presented in the reexamination proceeding. In this case, the prior art reference at issue was relied upon as a secondary reference for the limited purpose of teaching one aspect of the claim. In the reexamination request, in contrast, the reference was relied upon as a primary reference to anticipate the claim, which presented a “substantial new question” of patentability.

**H. Obviousness-Type Double Patenting**

*In re Fallaux*, 564 F.3d 1313 (Fed. Cir. 2009). In this appeal from the PTO, the Federal Circuit upheld an obviousness-type double patenting rejection. Despite the fact that the term of patents is now (since 1995) measured from the filing date of the earliest priority application, thus preventing an improper patent term extension in most cases where continuing applications are filed, the double patenting doctrine is still needed to prevent harassment by multiple patent assignees. In this case, because the parent and child patent applications were owned by different entities, a terminal disclaimer could not be filed to overcome the rejection.

**I. What Constitutes “Publication” For Purposes of Statutory Bar**

*In re Lister*, 583 F.3d 1307 (Fed. Cir. 2009). The patent statute, 35 U.S.C. § 102(b), bars a patent if the claimed invention was described in a “printed publication” more than one year before the filing date of the patent. In this case, Lister filed a copyright registration in 1994

for his method of playing golf. In 1996, more than one year later, he filed a patent application. The PTO rejected his application on the basis that his earlier copyright registration constituted a “printed publication” more than one year before the filing date. The Federal Circuit agreed that because copyright registrations can be inspected in person at the Copyright Office (but not copied or accessed through a database), his earlier manuscript could constitute a “printed publication” within the meaning of the statute. However, because the Copyright Office’s online database at the time did not permit anyone to search for copyright registrations by keyword of the text or title (it only permitted searching by author name and first word of the title), it was not sufficiently accessible to those interested in searching for it. (Note: the database now does permit keyword searching, making this a potential new source of prior art for those trying to invalidate patents).

## II. INTERPRETATION OF PATENTS

### A. Claim Construction

*Welker Bearing Co. v. PHD, Inc.*, 550 F.3d 1090 (Fed. Cir. 2008). A claim reciting a “mechanism for moving said finger” was interpreted to be a means-plus-function limitation under 35 U.S.C. § 112, sixth paragraph, and thus limited to the corresponding structures disclosed in the patent. Under this more narrow interpretation, the claim was held to be not infringed. According to the Federal Circuit, “the unadorned term ‘mechanism’ is simply a nonce word or a verbal construct that is not recognized as the name of structure and is simply a substitute for the term ‘means for.’”

*Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371 (Fed. Cir. 2009). A patent claim reciting a refrigerator shelf frame including “a relatively resilient end edge portion which temporarily deflects and subsequently rebounds to snap-secure” another piece was interpreted to require only that the frame be resilient at the time of assembly, when it was warm, and not necessarily after a refrigerator containing the shelf was shipped or used. Based on this interpretation, shelves assembled in Mexico that were later shipped to the United States were held to infringe, even though the frames were no longer “relatively resilient.” The court interpreted the clause to be a structural limitation, not a process limitation.

*Abbott Laboratories v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009). In this case, the Federal Circuit resolved a conflict in its case law precedent concerning the interpretation of so-called “product-by-process” claims, which are drafted in such a way that they cover a product but do so by reciting the process used to produce the product. Such claims are sometimes used to claim products whose structure is difficult to identify and claim. In 1991, the Federal Circuit held in *Scripps Clinic* that a product-by-process claim is not limited to a product prepared by the process set forth in the claims. In 1992, the Federal Circuit reached the opposite conclusion in *Atlantic Thermoplastic*, concluding that product-by-process claims are limited to products actually produced using the process recited in the claims. Resolving the conflict en banc, the Federal Circuit adhered to the *Atlantic Thermoplastic* holding, concluding that no infringement of a product-by-process claim can be found unless the accused product is actually produced by the process recited in the claims. In this case, a

claimed product “obtainable by” various steps in the claim was held to be not infringed. Three judges dissented, arguing that certain inventions whose structure is not fully known or readily described can only be claimed using the product-by-process format.

## **B. Contributory Infringement**

*Ricoh Co. Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325 (Fed. Cir. 2008). Ricoh sued Quanta for infringing patents relating to optical disc drives for computers. The district court held on summary judgment that Quanta’s sale of disc drives that were capable of performing the patented method did not create liability for contributory infringement, because such disc drives could also operate in a non-infringing manner, and thus qualified as a “substantial noninfringing use” exception per 35 U.S.C. § 271(c). The Federal Circuit noted that this case presented an important and previously unresolved question – the scope of liability under section 271(c). Ricoh provided evidence that Quanta’s disc drives included software and hardware modules that had no substantial noninfringing use other than to perform the patented methods. The Federal Circuit vacated and remanded the district court’s summary judgment ruling, concluding that “it is entirely appropriate *to presume* that one who sells a product containing a component that has no substantial noninfringing use in that product does so with the intent that the component will be used to infringe.” (emphasis added). The Federal Circuit reasoned that one should not be able to escape liability for contributory infringement merely by including an infringing component in a larger product that only sometimes operates using the infringing component. *Id.* at 1337-38. Judge Gajarsa dissented, arguing that Quanta did not sell “components” adapted to perform the patented method, but instead only sold optical disc drives, and that the majority’s holding would subject every seller in the chain of commerce to such liability.

## **C. Induced Infringement**

*Ricoh Co. Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325 (Fed. Cir. 2008). To be liable for induced infringement, there is no requirement that the accused inducer communicate in some fashion with the direct infringer. In this case, the district court granted summary judgment to Quanta Computer of no induced infringement because of lack of sufficient intent. Ricoh offered evidence of Quanta’s product specification sheets; evidence that Quanta fine-tuned software arguably used for infringing purposes, and Quanta’s instructions on its website. Nevertheless, the district court granted summary judgment of no inducement because there was no evidence that any of these “affirmative acts” were communicated to the alleged direct infringer. The Federal Circuit vacated and remanded, concluding that under the Supreme Court’s decision in *Grokster*, there was no requirement that the accused inducer communicate the nature of its actions to the alleged direct infringers. *Id.* at 1342. The Federal Circuit also stated that specific intent to infringe may be inferred from circumstantial evidence where a defendant has both knowledge of the patent and specific intent to cause the acts constituting infringement. *Id.* at 1342. In this case, Ricoh offered evidence that Quanta’s design separated the infringing from non-infringing functions, which might be relevant to whether Quanta had a specific intent to encourage infringement by another.

#### **D. Direct Infringement**

*Ricoh Co. Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325 (Fed. Cir. 2008). One who sells or offers to sell software containing instructions that perform a patented method does not directly infringe the patent under 35 U.S.C. § 271(a). In other words, selling a device that performs the patented method is not an infringement of the method claim. (It might be possible, however, for the patent owner to establish contributory or induced infringement).

*Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 576 F.3d 1348 (Fed. Cir. 2009). The Federal Circuit held en banc that 35 U.S.C. § 271(f), which generally permits a patent owner to establish infringement where a person exports components of a patented invention intending that they be combined outside the U.S. in a manner that would infringe a U.S. patent, does not apply to method claims. The court overruled its 2006 decision in *Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co.*, 425 F.3d 1366 (2006), which held to the contrary. In this case, the Federal Circuit held that St. Jude Medical could not be held liable for infringing a method claim by exporting implantable cardioverter defibrillators (ICDs) that could perform the patented method. This case may also have implications for computer software, where software is exported and may be used to perform steps of a patented method.

#### **E. Doctrine of Equivalents – “Ensnarement” Defense Not Jury Issue**

*Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009). The doctrine of equivalents permits a patent owner to prove that, even though an accused device does not literally fall within the scope of the patent claims, infringement can be found if the differences between the accused device and the patent claims are “insubstantial.” The accused infringer can then interpose an “ensnarement” defense – essentially proving that the broader effective scope of the claims would “ensnare” prior art and thus render them invalid. At issue in this case was whether the district court was entitled to decide the accused infringer’s ensnarement defense as a matter of law, or whether it was an issue for the jury to decide. The Federal Circuit concluded that ensnarement is a purely legal issue for the court to decide as a limitation on the doctrine of equivalents.

### **III. ENFORCEMENT OF PATENTS**

#### **A. Venue**

*In re TS Tech USA Corp*, 551 F.3d 1315 (Fed. Cir. 2008). In recent years, many plaintiffs in patent infringement lawsuits have filed suit in the U.S. District Court for the Eastern District of Texas. That jurisdiction has developed a reputation as being “plaintiff friendly,” with juries in recent years awarding eye-popping damage awards against accused infringers. Judges in that district have rarely granted motions to transfer suits to other jurisdictions. In this case, Lear Corp. sued TS Tech for patent infringement in the Eastern District of Texas for patents relating to vehicle headrest assemblies. TS Tech moved to transfer the case to the Southern District of Ohio, but the district court denied the motion. TS Tech filed a petition for a writ of mandamus with the Federal Circuit, seeking to force a transfer. The Federal

Circuit granted the petition.

Applying Fifth Circuit law (the circuit in which the district court sits), the Federal Circuit noted that a motion to transfer should be granted when the transferee venue is “clearly more convenient” than the venue chosen by the plaintiff. The test involves both public and private factors for determining whether a forum is more convenient. Private factors include the relative ease of access to sources of proof; the availability of compulsory process to secure attendance of witnesses; the cost of attendance for witnesses; and other problems that make a trial easy, expeditious and inexpensive. The public factors include relative court congestion; local interest in having localized interests decided at home; familiarity of the forum with the law governing the case; and the avoidance of unnecessary problems of conflicts of laws.

Applying the factors to this case, the Federal Circuit concluded that TS Tech’s extensive contacts with the Southern District of Ohio (where it was incorporated and had its principal place of business) indisputably made it a forum where the case could have been brought. The Federal Circuit first held that the district court gave too much weight to the plaintiff’s choice of venue, treating it as a separate “factor” in the test. Second, the Federal Circuit held that the district court ignored the Fifth Circuit’s *Volkswagen* test, which states that when a distance between the existing venue and a proposed venue is more than 100 miles, the inconvenience to the witnesses increases in relationship to the additional distance to be traveled. Because all of the identified key witnesses were located in Ohio, Michigan and Canada, the district court erred in completely disregarding the 100-mile rule. Third, the district court erred by ignoring the location of the physical evidence, which was located in Ohio, Michigan, and Canada, by concluding that many of the documents were stored electronically and thus the relative access to the evidence did not favor transfer. Finally, the district court erred by ignoring the public interest factors, given that there was no connection between the parties and the jurisdiction other than the sales of vehicles containing accused products in the jurisdiction. Given that the vehicles were sold throughout the United States, there was no “localized” connection to the Eastern District of Texas favoring venue in that jurisdiction.

Note: it appears that in response to this decision and others, some patent infringement plaintiffs have begun simultaneously suing multiple defendants in the Eastern District of Texas, in an effort to avoid having another single jurisdiction qualify as clearly more convenient.

*In re Genentech, Inc.*, 566 F.3d 1338 (Fed. Cir. 2009). Following its *TS Tech* decision, the Federal Circuit ordered a district court to transfer a patent infringement lawsuit from Texas to California. Genentech filed a motion in the district court to transfer the lawsuit to California, where it was based and where most of the witnesses and documents were located. The district court denied the motion. In granting Genentech’s petition, the Federal Circuit concluded that Genentech was not required to show that “key witnesses” resided in California, nor was it required to show the significance of their proposed testimony. The Federal Circuit also rejected the district court’s conclusion that Texas was more convenient than California for witnesses traveling from Europe.

*In re Volkswagen of America, Inc.*, 566 F.3d 1349 (Fed. Cir. 2009). In this companion case issued on the same day as *In re Genentech* (above), the Federal Circuit denied Volkswagen's petition to order the lawsuit transferred from Texas to Michigan. Plaintiff MHL sued numerous automobile companies for patent infringement in the Eastern District of Texas. Unlike *Genentech*, this case involved numerous parties having the same infringement issue being decided. The Federal Circuit agreed with the district court's conclusion that "judicial economy is served by having the same district court try the cases involving the same patents." (Note: This case serves as a model for patent infringement plaintiffs seeking to retain venue in the plaintiff-friendly Eastern District of Texas).

*In re Hoffmann-La Roche Inc.*, \_\_\_ F.3d \_\_\_, 2009 WL 4281965 (Fed. Cir. Dec. 2, 2009). The Federal Circuit granted Hoffmann-La Roche's petition for a writ of mandamus, ordering that the case be "promptly transferred" from the Eastern District of Texas to the Eastern District of North Carolina. Novartis, which is headquartered in California, sued Hoffmann-La Roche for patent infringement in the U.S. District Court for the Eastern District of Texas. Hoffmann-La Roche moved to transfer, arguing that the suit should be brought in the Eastern District of North Carolina, where most of the documentary evidence was located. The district court denied the motion, relying in part on the fact that, just prior to the litigation, Novartis had transferred 75,000 pages of documents in electronic format to its attorney's office in the Eastern District of Texas. In granting the petition for mandamus, the Federal Circuit referred to Novartis's transfer of documents into Texas as "a fiction which appears to have been created to manipulate the propriety of venue."

## **B. Damages**

*Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009). Depuy Spine obtained a jury verdict of \$149 million for Medtronic's infringement of a patent relating to a surgical screw. The damage award was based on Depuy's lost profits due to the infringement. Medtronic argued on appeal that there was no evidence that demand for the patented product – one of the four requirements to show lost profits – was driven by a particular "top-loading feature" of the screw that distinguished the patented screw from the prior art. The Federal Circuit rejected this argument, holding that only demand for the patented product as a whole, not demand for individual features of the patented product that distinguish it from the prior art, is needed to prove lost profits under the four-factor *Panduit* lost profits analysis. The Federal Circuit did, however, reverse an additional jury award of \$77 million in allegedly lost "pull-through" sales for unrelated and unpatented products, concluding that "there is no basis for extending [lost profits] to include damages for [unpatented] items that are neither competitive with nor function with the patented invention." It rejected Depuy's argument that a business relationship created by the patented product would have led to further sales of unpatented products.

*Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301 (Fed. Cir. 2009). Lucent sued Gateway and others for infringing patents relating to a “date-picker” tool used in Microsoft’s Outlook software. Microsoft intervened in the case. A jury awarded \$357 million for Microsoft’s infringement, based on Lucent’s theory of 8% royalty applied to sales revenue for the accused products. On appeal, the Federal Circuit upheld the infringement and validity rulings, but vacated the damages award as not sufficiently supported by the evidence. The Federal Circuit concluded that in arriving at a lump-sum reasonable royalty, the jury improperly relied solely on a few irrelevant lump-sum software licenses entered into by other companies. The Federal Circuit also concluded that the infringing “date-picker” feature of Outlook was such a small part of the overall product that it could not support a \$357 million damage award.

### C. **Injunctions (Post-eBay)**

*Acumed LLC v. Stryker Corp.*, 551 F.3d 1323 (Fed. Cir. 2008). Acumed sued Stryker for infringement of a patent covering an orthopedic nail used to treat bone fractures. After a jury found infringement, the district court in 2006 entered a permanent injunction, applying the “general rule” in patent cases that an injunction will issue once infringement and validity have been adjudged. While Stryker’s first appeal at the Federal Circuit was pending, the U.S. Supreme Court rendered its decision in *eBay Inc. v. MercExchange*, which held that the traditional four-factor test for permanent injunctions must be applied in patent cases. The Federal Circuit in the first appeal thus vacated the injunction and remanded the case to the district court to reevaluate the injunction under *eBay*. Following remand, the district court again entered a permanent injunction, and Stryker again appealed.

On the second appeal, the Federal Circuit affirmed the grant of the permanent injunction, concluding that the district court properly applied the four-factor *eBay* injunction standard. Those factors are (1) irreparable injury to the plaintiff; (2) inadequacy of monetary damages to compensate for the injury; (3) balance of hardships favors the plaintiff; and (4) public interest would not be harmed by an injunction. As to the first factor, the Federal Circuit rejected Stryker’s argument that Acumed’s prior licenses of its patent to others demonstrated that there was no irreparable injury and that damages would be adequate to compensate for the infringement. Because the district court had discretion to consider whether no adequate remedy at law existed for Stryker’s future infringement, the district court did not err in considering the first factor. According to the Federal Circuit, “a plaintiff’s past willingness to license its patent is not sufficient per se to establish lack of irreparable harm if a new infringer were licensed.” Adding a new competitor to the market might create irreparable harm that the prior licenses did not.

As to the balance of the hardships, the Federal Circuit agreed with the district court that the balance favored Acumed and rejected Stryker’s attempt to include hardship effects on Stryker’s customers and patients. It also upheld the district court’s reliance on a non-infringing alternative design that Stryker could have (but did not) sell.

Finally, as to the public interest, the Federal Circuit found no fault with the district court's conclusion that there was no public health issue created by keeping the allegedly superior Stryker design off the market, given that the evidence was equivocal on that point.

#### **D. Inequitable Conduct**

*Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009). In this important case, the Federal Circuit held that in order to plead inequitable conduct in a patent case, the proponent must plead with particularity “the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” Although knowledge and intent may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) know of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.

In this case, the district court did not abuse its discretion in refusing to permit the defendant to amend its complaint to add inequitable conduct assertions against the patent owner. First, the proposed amendment failed to identify the specific individual who allegedly knew of the material information and deliberately withheld it from the PTO. Second, it failed to identify the patent claims the withheld material was relevant to. Third, it merely stated that the withheld information was “material” but did not explain the alleged significance of the information with reference to any patent claims. Finally, there were no specific allegations regarding scienter – the pleading merely stated that the patent owner “was aware” of the information, but did not state that any particular person had knowledge of specific information material to patentability. “A reference may be many pages long, and its various teachings may be relevant to different applications for different reasons. Thus, one cannot assume that an individual who generally knew that a reference existed, also knew of the specific material *information* contained in that reference.” Deceptive intent was pleaded “on information and belief,” but the Federal Circuit held that the facts pleaded did not plausibly suggest any “deliberate decision to withhold a known material reference” or to make a knowingly false misrepresentation, one of which is necessary to infer deceptive intent.

This case may make it more difficult for defendants to raise inequitable conduct allegations in patent cases, especially since evidence of intent is difficult to obtain.

#### **E. Scope of Patent Licenses**

*Corebrace LLC v. Star Seismic LLC*, 566 F.3d 1069 (Fed. Cir. 2009). A patent license that granted to the licensee the right to “make, use, and sell” the patented invention also necessarily included the right to have the patented invention made by a third party. According to the Federal Circuit, “The right to ‘make, use, and sell’ a product inherently includes the right to have it made by a third party, absent a clear indication of intent to the contrary.”

**F. Waiver of Patent Rights Due to Failure to Submit to Standards Org.**

*Qualcomm Inc. v. Broadcom Corp.*, 548 F.3d 1004 (Fed. Cir. 2008). The Joint Video Team (JVT) was created as a joint venture between two standard-setting organizations (SSOs) to develop an industry standard for video compression technology. The standard adopted by the JVT was later named the H.264 video compression standard. Qualcomm was a member of the American National Standards Institute (ANSI), which was a member of the JVT. Qualcomm sued Broadcom for infringement of two patents that allegedly covered products conforming to the H.264 standard. Qualcomm had insisted up until the last few days of trial that it had not participated in the JVT during development of the H.264 standard. At the last minute, a Qualcomm witness produced numerous emails indicating that it had in fact participated in the process. A jury concluded, among other things, that Qualcomm had waived its right to enforce the patents because it did not submit the patents to the organization. Qualcomm appealed.

On appeal, the Federal Circuit first noted that although the written JVT policies provided no express requirement to disclose patents unless a member submitted a technical proposal, the policy stated that the goal of the JVT was to develop a royalty-free “baseline” and that members were “encouraged to disclose as soon as possible” patents associated with any standardization proposal. The written materials also stated that information should be provided on a “best effort basis.” Additionally, evidence showed that members’ understanding of the written policies showed that there was a duty to disclose patents that might cover the standard. The Federal Circuit therefore concluded that Qualcomm had an obligation to disclose its patents to the JVT.

Following its earlier decision in *Rambus v. Inc. v. Infineon Technologies*, the Federal Circuit agreed with the district court that the scope of Qualcomm’s duty of disclosure extended to any patent that “reasonably might be necessary” to practice the standard. The test is an objective – not subjective – one, in that it does not depend on a member’s state of mind. In other words, would a reasonable competitor expect to practice the H.264 standard without needing a license under the patent? After concluding that Qualcomm indisputably did not disclose its patents to the JVT and evidence at trial showing that Qualcomm itself believed that its patents were necessary to practice the standard, the Federal Circuit affirmed, but ruled that implied waiver, rather than express waiver, was the appropriate legal remedy, and it modified the scope of the waiver to extend only to any products that practice the H.264 standard, rather than the broader scope of enforceability granted by the district court.

**G. Personal Jurisdiction**

*Autogenomics, Inc. v. Oxford Gene Technology Ltd.*, 566 F.3d 1012 (Fed. Cir. 2009). In this declaratory judgment action brought against a British patent holder, the Federal Circuit held that activities of the patent holder relevant to establishing specific personal jurisdiction in a particular forum must “relate in some material way to the enforcement or the defense of the patent,” and not merely relate to the patentees’ own commercialization efforts in the jurisdiction. In this case, Oxford’s attendance at conferences in California and sales of products in California were irrelevant to establishing specific personal jurisdiction.

Moreover, Oxford's joint venture agreement with another California company did not relate to the patent at issue, and an alleged non-exclusive license to yet another California company did not relate to the validity and enforceability of the patent. E-mails from Oxford to Autogenomics concerning a possible license agreement were also deemed insufficient to establish personal jurisdiction for purposes of a declaratory judgment action.

#### **H. Patent Misuse as a Defense to Infringement**

*Princo Corp. v. International Trade Commission*, 563 F.3d 1301 (Fed. Cir. 2009), *vacated and rehearing granted*, 583 F.3d 1380 (Fed. Cir. 2009). U.S Philips Corp., which owns certain patents covering compact discs, brought an action in the ITC to block imports of Princo's CDs. The ITC found that Princo's CDs infringed six Philips patents and rejected Princo's patent misuse defense. On appeal, Princo argued that Philips misused its patents by offering only a "package" license for patents including those not necessary (not "essential") to manufacture CDs that complied with an industry standard. The Federal Circuit concluded that "perfect certainty is not required to avoid a charge of misuse through unlawful tying" – it is not patent misuse if an objective manufacturer, faced with the patent, might reasonably believe that a license is necessary to manufacture CDs in compliance with the industry standard. The Federal Circuit remanded, however, for further proceedings as to Princo's argument that Philips and Sony agreed to prevent licensing the patent to develop CDs that might compete with the industry standard.

#### **I. Patent Exhaustion**

*Transcore, LP v. Electronic Transaction Consultants Corp.*, 563 F.3d 1271 (Fed. Cir. 2009). Following the U.S. Supreme Court's 2008 decision in *Quanta Computer, Inc. v. LG electronics, Inc.*, which held that certain patents were "exhausted" by the licensed sale of parts, the Federal Circuit in this case held that Transcore's patent infringement claims were barred because of a prior settlement agreement between Transcore and the supplier of devices installed by the defendant in this case. Transcore makes automated toll collection systems such as E-ZPass, and owns several patents covering the technology. After Transcore sued a competitor (Mark IV Industries) for patent infringement, Transcore settled the litigation in exchange for a \$4.5 million payment. In the settlement agreement, Transcore agreed not to sue Mark IV for future infringement of certain of its patents. After Electronic Transaction Consultants Corp (ETCC) installed Mark IV devices, Transcore sued ETCC for patent infringement, but the district court ruled that the patent rights were exhausted by the settlement. The Federal Circuit rejected Transcore's argument that sales made by Mark IV under a covenant not to sue were not "authorized" sales under *Quanta*.

#### **J. Patent Marking Not Required If Only Method Claims Asserted**

*Crown Packaging Technology, Inc. v. Rexam Beverage Can Co.*, 559 F.3d 1308 (Fed. Cir. 2009). The Federal Circuit concluded that when a patent owner asserts only method claims in a patent (as opposed to apparatus claims), there is no requirement to mark the patent number on devices made under the patent.

**K. Ownership of Patents**

*Sky Technologies LLC v. SAP AG*, 576 F.3d 1374 (Fed. Cir. 2009). Patent ownership was properly transferred by operation of state foreclosure law, giving the plaintiff clear title to the patent in suit. Thus, no separate assignment of the patent was required to vest patent ownership in the plaintiff.

**L. Declaratory Judgment Jurisdiction**

*Hewlett-Packard Co. v. Acceleron LLC*, \_\_\_ F.3d \_\_\_, 2009 WL 4432580 (Fed. Cir. December 4, 2009). Acceleron sent a letter to HP “calling attention” to its patent and offering to enter into discussions over the patent, which it said “related to” HP’s Blade Servers. HP responded, asking Acceleron if it had any further information but declining to agree not to bring a declaratory judgment action against Acceleron. Acceleron sent a second letter, giving HP two weeks to respond and stating that “If I do not receive [a signed agreement] by then, I will understand that you are not interested in discussing this patent, and you do not have anything to say about the merits of this patent, or its relevance to your Blade Server products.” Shortly thereafter, HP filed a declaratory judgment action in Delaware, seeking a declaratory judgment that HP did not infringe. Acceleron moved to dismiss for lack of subject matter jurisdiction, which the court granted. The Federal Circuit reversed. It began by noting that declaratory judgment jurisdiction exists where “a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license.” The appeals court rejected Acceleron’s argument that it had never asserted its rights under the patent, and concluded that jurisdiction existed. The court noted that Acceleron was solely a licensing entity, and without enforcement it received no benefits from its patents. The court explained that Acceleron took the affirmative step of contacting HP, making an implied assertion of its rights under the patent against HP’s Blade Server product, and HP disagreed.

**IV. OTHER**

**A. Patent Attorneys Testifying as Experts**

*Sundance, Inc. v. Demonte Fabricating Ltd*, 550 F.3d 1356 (Fed. Cir. 2008). Sundance sued Demonte for infringing a patent relating to a cover system for a truck trailer. A jury concluded that claim 1 was infringed but that it was invalid as obvious. The judge granted Sundance’s motion for judgment as a matter of law, concluding that the patent was not obvious and setting aside the jury’s invalidity verdict. The Federal Circuit reversed, concluding that the patent claim was invalid as obvious. Before reaching that conclusion, however, the Federal Circuit held that the district court erred by permitting Demonte’s patent attorney to testify regarding issues of infringement and validity. The court pointed out that factual issues concerning infringement and validity are to be determined from the perspective of a person of ordinary skill in the art, and Demonte’s patent attorney was not qualified as a technical expert in the particular field of the patent. “Admitting testimony from a person . . . with no skill in the pertinent art, serves only to cause mischief and confuse

the factfinder. Unless a patent lawyer is also a qualified technical expert, his testimony on these kinds of technical issues is improper and thus inadmissible.” The Federal Circuit concluded that “it is an abuse of discretion to permit a witness to testify as an expert on the issues of noninfringement or invalidity unless that witness is qualified as an expert in the pertinent art.” *Id.* at 1363. The Federal Circuit then reinstated the jury’s invalidity verdict, concluding that there was no dispute that all the claimed features were found in the prior art.

**B. Limits on Continuation Applications and Number of Claims**

*Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009), *vacated and rehearing granted*, 2009 WL 1916498 (July 6, 2009). In this closely-watched case, the Federal Circuit issued a split decision partially upholding the authority of the U.S. Patent and Trademark Office (PTO) to impose strict new limits on patent applicants. The court struck down the PTO’s proposed rule limiting the number of continuing patent applications that an applicant may file, but -- in a surprise to many patent attorneys -- upheld the right of the PTO to limit the number of claims in each patent application to no more than five independent claims and 25 total claims, and to limit the number of requests for continued examination (RCEs) that an applicant may file. One of the three panel members filed a dissenting opinion, arguing that all of the regulations were invalid. The lawsuit was originally filed by GlaxoSmithKline, which obtained an injunction in 2008 against the PTO’s enactment of the proposed new regulations.

At issue on appeal was the PTO’s statutory authority to issue regulations that are “substantive” in nature – as opposed to merely “procedural” regulations. The court generally agreed with the plaintiffs that the PTO does not have authority to enact “substantive” regulations. After struggling with the distinction between “substantive” and “procedural,” the panel majority nevertheless concluded that the proposed regulations were merely “procedural” in nature because they imposed new duties on applicants but did not completely foreclose applicants from filing more than the specified number of continuation applications or patent claims.

For example, the court pointed out that if an applicant desired to file more than the specified number of patent applications or patent claims, it could do so by following the procedures set forth by the PTO. As many practitioners are aware, the detailed procedures are quite onerous and may weaken the scope of a patent in later litigation. Despite the fact that the PTO had published comments suggesting that requests to exceed the limit would rarely be granted, the court concluded that the PTO was not bound by those comments, and that applicants would be entitled to judicial review of such denials. The court also rejected Glaxo’s position that the detailed patentability statements and analysis that must be submitted in an Examination Support Document (ESD) – the mechanism by which the claim limits could be exceeded – might subject patent applicants to charges of inequitable conduct.

Although it concluded that the PTO’s limits on continuing applications were procedural in nature, the court nevertheless held that such limits were contrary to the U.S. patent statute and therefore invalid. Because Section 120 of the patent statute provides that later-filed patent applications claiming priority to an earlier application “shall have the same effect” as

the earlier-filed application, the court found that an arbitrary limit on the number of continuation applications was not permitted by the statute.

The panel majority reached a different conclusion concerning the PTO's limits on the number of Request for Continued Examination (RCEs). Because RCEs are governed by a different section of the patent statute that contained different language, and because the different section specifically mentions the authority of the PTO to enact regulations governing re-examination of applications under the RCE provisions, the court concluded that the PTO's proposed regulations were not contrary to the statute.

The Federal Circuit also upheld the authority of the PTO to limit the number of claims in a patent application unless an ESD is filed. Drawing an analogy to an earlier case in which the Federal Circuit had upheld the right of the PTO to require additional information from applicants, the court concluded that requiring an ESD in certain circumstances did not improperly shift the burden of proving patentability onto applicants.

The Federal Circuit remanded the case to the district court for further review, and pointed out that nothing in its ruling prevented the district court from considering whether the new regulations had other defects, such as being impermissibly retroactive or being arbitrary and capricious. However, on July 6, 2009, the Federal Circuit granted Tafas's petition for rehearing en banc and vacated the original panel decision. The PTO has now rescinded the rules.