

An Overview of Recent U.S. Supreme Court Jurisprudence in Patent Law

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Summary

Patent law jurisprudence is continually being developed through litigation over activities that allegedly infringe a patent holder's rights. The losing party in these cases may appeal the district court's decision to the U.S. Court of Appeals for the Federal Circuit, a specialized tribunal established by Congress that has exclusive appellate jurisdiction in patent cases. Parties dissatisfied with the Federal Circuit's rulings may petition the U.S. Supreme Court to review the appellate court's decision. However, the Supreme Court is not required to entertain the appeal; it has discretion to decide whether to grant certiorari to review the case. While the Supreme Court has left the Federal Circuit's opinions undisturbed in the vast majority of patent cases since the creation of the specialized patent court in 1982, the Court has shown, over the past several terms, an increased willingness to hear cases that raise patent law issues. The Supreme Court Justices' apparent newfound interest in patent cases perhaps stems from a recognition of the growing importance of intellectual property to the nation's information-based economy, as well as a desire to correct perceived errors in lower courts' interpretation and application of patent law.

This report provides a brief summary of the Supreme Court's patent law jurisprudence in the following nine cases that have been decided since 2005: *Merck KGaA v. Integra Lifesciences I, Unitherm Food Systems v. Swift-Eckrich, Illinois Tool Works v. Independent Ink, eBay v. MercExchange, Laboratory Corporation of America Holdings v. Metabolite Labs., MedImmune v. Genentech, KSR International Co. v. Teleflex Inc., Microsoft v. AT&T*, *Quanta Computer, Inc. v. LG Electronics, Inc.,* and *Bilski v. Kappos.*

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Introduction

While Congress may consider legislation to amend the U.S. patent system to address perceived deficiencies,[1] the U.S. Supreme Court also plays a significant role in clarifying vague or ambiguous language in the Patent Act that is often at the heart of disputes between parties involved in patent infringement suits. In the latter half of this decade, the Supreme Court has granted certiorari in nine patent cases, perhaps in recognition of the increasing importance of intellectual property to technological innovation, as well as in order to correct errors in lower courts' interpretation and application of patent law.[2] What follows is a general overview of the facts and outcomes of these recent cases, presented in chronological order starting from the October Term 2004.

October Term 2004

Merck KGaA v. Integra Lifesciences I

It is normally an infringement of a patent holder's rights for anyone, without prior authorization, to use, make, offer to sell, or sell any patented invention within the United States.[3] However, there are exceptions to this general rule; for example, a statutory exception codified at 35 U.S.C. § 271(e)(1) provides: "It shall not be an act of [patent] infringement to ... use ... or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of information" under the Federal Food, Drug, and Cosmetic Act.[4] This is a "safe harbor" provision that immunizes parties from liability for their otherwise infringing acts.

The factual history of *Merck KGaA v. Integra Lifesciences I* is as follows.[5] Integra Lifesciences I, Ltd. ("Integra") is an American pharmaceutical company that owns patents related to compounds known as RGD peptides. Merck KGaA ("Merck") is a German pharmaceutical corporation that was interested in developing a drug to control angiogenesis, a process that plays a critical role in the spread of many diseases, including cancerous tumor growth, diabetic retinopathy, and rheumatoid arthritis.[6] Merck conducted experiments using the RGD peptides to determine their efficacy in inhibiting angiogenesis. Integra sued Merck, seeking monetary damages for Merck's

[1] Bills have been introduced in the 111th Congress that would substantially reform several provisions of the Patent Act, including H.R. 1260, S. 515, and S. 610. For more information on legislative efforts to amend the patent law, *see* CRS Report R40481, *Patent Reform in the 111th Congress: Innovation Issues*, by Wendy H. Schacht and John R. Thomas.

[2] By Supreme Court custom, a petition for a writ of certiorari is granted when four of the nine Supreme Court justices vote to review a decision of a lower appellate court. Since 1982, patent cases have reached the Court from the U.S. Court of Appeals for the Federal Circuit, a specialized tribunal that has exclusive jurisdiction to hear appeals from all district court judgments in civil actions arising under federal patent law. 28 U.S.C. §1295. The purpose for the latter court's creation twenty-five years ago by Congress was to promote predictability and uniformity in the patent law. For more information on the Federal Circuit, *see* CRS Report RL31703, *Patent Law and Innovation: The Creation, Operation and a Twenty-Year Assessment of the U.S. Court of Appeals for the Federal Circuit*, by John R. Thomas.

[3] 35 U.S.C. § 271(a).

[4] 35 U.S.C. § 271(e)(1).

[5] For a more detailed discussion of the *Merck* case, *see* CRS Report RL33114, *Safe Harbor for Preclinical Use of Patented Inventions in Drug Research and Development:* Merck KGaA v. Integra Lifesciences I, Ltd., by Brian T. Yeh.

[6] Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 863 (Fed. Cir. 2003).

alleged infringement of its patented compounds. In defense, Merck asserted, in part, that its actions involving the RGD peptides came within the statutory safe harbor discussed above.

At trial, the U.S. District Court for the Southern District of California instructed the jury that, for Merck to prevail on the "safe harbor" defense, it must prove by a preponderance of the evidence that it was objectively reasonable for the company to believe that "there was a decent prospect" that the experiments "would contribute, relatively directly," to the generation of information likely to be relevant to the drug approval regulatory process.[7] The jury found Merck liable for infringing Integra's patents because Merck had failed to show that § 271(e)(1) protected its research activities.

In June 2003, a divided panel of the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") affirmed the district court's determination as to Merck's liability. The panel majority narrowly construed the safe harbor provision as exempting from infringement liability only *clinical* research activities[8] that contribute "relatively directly" to information submitted to the Food and Drug Administration (FDA) for consideration in the drug approval process.[9] Merck appealed the Federal Circuit's decision to the U.S. Supreme Court.

The question presented to the Supreme Court was "whether uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the Food and Drug Administration (FDA), are exempted from infringement by 35 U.S.C. § 271(e)(1)."[10] In vacating the Federal Circuit's interpretation of the safe harbor provision, the Supreme Court unanimously ruled that the exemption applies to all uses of patented inventions that are "reasonably related" to the process of developing *any* information for FDA submission, including *preclinical* use of patented inventions in the drug research and development process.[11] The Court explained that, under certain conditions, the safe harbor provision is even "sufficiently broad" to protect the use of patented compounds in experiments that are not ultimately submitted to the FDA or drug experiments that are not ultimately the subject of an FDA submission.[12]

[7] Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 200 (2005).

[8] Drug development may be divided into three general stages: basic research, preclinical research, and clinical studies. Basic research involves the testing of thousands of compounds to discover any biological activity relevant to understanding the cause of a disease; the preclinical stage involves more focused research on a smaller group of chemical compounds in the hopes of finding the best candidate for clinical development; and clinical studies are the testing of the drug on human subjects in preparation for FDA approval. James N. Czaban & Nishita Doshi, *Supreme Court Applies Broad Interpretation of Bolar Amendment to Protect Innovative Drug Research From Claims of Patent Infringement,* 70 PAT., TRADEMARK, & COPYRIGHT J. (BNA) 1726 (June 24, 2005).

[9] *Integra,* 331 F.3d at 867.

[10] *Merck*, 545 U.S. at 195.

[11] *Id* at 202.

[12] *Id.* at 206.

October Term 2005

Unitherm Food Systems v. Swift-Eckrich

One of the statutory bars to patentability of an invention is "novelty."[13] For an invention to be considered "novel," it must not be wholly "anticipated" by the so-called "prior art," or public domain materials such as publications and other patents.

In early 2000, the food company ConAgra informed companies that sold equipment and/or processes for browning precooked meats that such browning processes may infringe its patent on "A Method for Browning Precooked Whole Muscle Meat Products," and offered those companies the opportunity to license its patent. A competitor, Unitherm, sued ConAgra for a declaratory judgment that the patent was invalid and unenforceable, and that ConAgra had violated federal antitrust laws by attempting to enforce a patent that was obtained by committing fraud on the U.S. Patent and Trademark Office.[14]

The U.S. District Court for the Western District of Oklahoma ruled that ConAgra's patent was invalid[15] because of evidence that Unitherm's president had invented the process described in that patent six years before ConAgra had filed its patent application. The court then allowed the antitrust claim to proceed to trial. Before the case was submitted to the jury, ConAgra filed a motion with the court for a judgment as a matter of law, on the grounds that no reasonable jury would have a legally sufficient evidentiary basis to support a verdict in favor of Unitherm on the antitrust issue.[16] The District Court denied the motion, and the jury returned a verdict for Unitherm. ConAgra, however, failed to renew its request for judgment as a matter of law by filing another motion after the verdict, a procedural requirement under Federal Rules of Procedure 50(b), nor did it request a new trial under Federal Rules of Procedure 59.

ConAgra appealed to the Federal Circuit, asserting that there was insufficient evidence to sustain the jury's verdict. The Federal Circuit determined that ConAgra's failure to file a postverdict motion did not preclude the company on appeal from raising the challenge to the sufficiency of the evidence on the antitrust claim.[17] The appellate court then proceeded to review the evidence and after concluding it was insufficient, vacated the jury's judgment in favor of Unitherm and remanded the case for a new trial.[18]

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[13] *See* 35 U.S.C. § 102 ("A person shall be entitled to a patent unless—(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.")

[14] Unitherm Food Sys. v. Swift-Eckrich, Inc., 546 U.S. 394, 396-98 (2006). Such a "Walker Process" claim stems from the Supreme Court's 1965 decision in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.,* 382 U.S. 172 (1965), which permitted an antitrust claim for monopolization or attempted monopolization based on enforcement of a patent procured by fraud.

[15] Interpreting the construction and validity of patent claims is a matter of law reserved exclusively for the court; it is not an issue for a jury to decide. Markman v. Westview Instruments, 517 U.S. 370 (1996).

[16] FED. R. CIV. P. 50(a).

[17] Unitherm Food Sys. v. Swift-Eckrich, Inc., 375 F.3d 1341, 1365 n.7 (2004).

[18] *Id.* at 1362-65.

In a 7-2 decision, the U.S. Supreme Court held that the Federal Circuit was precluded from reviewing the case, and reversed its judgment. The Court explained that a party's failure to file a postverdict motion challenging the sufficiency of the evidence under Rule 50(b) renders an "appellate court without power to direct the District Court to enter judgment contrary to the one it had permitted to stand."[19] Strict compliance with this postverdict motion rule is necessary, according to the Court, because "[d]etermination of whether a new trial should be granted or a judgment entered under Rule 50(b) calls for the judgment in the first instance of the judge who saw and heard the witnesses and has the feel of the case which no appellate printed transcript can impart."[20] Because ConAgra did not file such a motion in the district court, it is not entitled to pursue a new trial on appeal, the Court ruled.[21]

Illinois Tool Works v. Independent Ink

This case involved the practice of Trident (a subsidiary of Illinois Tool Works) of selling its patented printing systems (consisting of patented ink jet printheads and patented ink containers) to manufacturers of printers only on the condition that those manufacturers (and their customers) agree to purchase their ink exclusively from Trident, although such ink itself is unpatented.[22] Independent Ink, a competitor manufacturer of ink that could be used in those printheads, sued Trident, alleging that Trident's practice was an illegal tying arrangement and monopolization in violation of federal antitrust laws.[23] Traditionally, for tying to constitute an antitrust violation, the plaintiff must affirmatively establish that the defendant has market power (i.e., control over the market in which his product competes). Independent Ink asserted that Trident "necessarily ha[d] market power in the market for the tying product [printheads] as a matter of law" solely by virtue of its patent on the printhead system. The U.S. District Court for the Central District of California rejected that claim and found that there had been no affirmative evidence of the relevant market nor of Trident's position in it.[24] Thus, the court granted summary judgment in favor of Trident.

In January 2005, the Federal Circuit reversed the district court's decision, holding that "a rebuttable presumption of market power arises from the possession of a patent over a tying product."[25] In so ruling, the appellate court emphasized that it had a "duty ... to follow the precedents of the Supreme Court until the Court itself chooses to expressly overrule them."[26] The Supreme Court has held for more than 60 years that where a patented product was the "tying" product, there was a presumption that the existence of a patent monopoly creates sufficient market power to support an antitrust violation.[27] Congress, however, rejected this presumption for

[19] *Unitherm Food Sys.,* 546 U.S. at 401 (citation omitted).

[20] *Id.* (citation omitted).

[21] *Id.* at 403.

[22] For a more detailed discussion of the *Illinois Tool Works* decision, *see* CRS Report RS22421, *Antitrust Effect of Patent on Tying Product:* Illinois Tool Works Inc. v. Independent Ink, Inc., by Janice E. Rubin.

[23] Conditioning the purchase of a product ("tying product") on the simultaneous purchase of some other product ("tied product") is considered unlawful under the antitrust laws. Also, an agreement not to purchase any future requirements for the tied product from any source other than the original vendor is considered an unlawful tie. *See* 15 U.S.C. § 1; Systemcare, Inc. v. Wang Laboratories Corp., 117 F.3d 1137, 1142-3 (10th Cir. 1997).

[24] Independent Ink, Inc. v. Trident, Inc. 210 F. Supp.2d 1155, 1163-1168 (C.D. Cal. 2002).

[25] Independent Ink, Inc. v. Ill. Tool Works Inc., 396 F.3d 1342, 1344 (Fed. Cir. 2005).

[26] *Id.* at 1351.

[27] International Salt Co. v. United States, 332 U.S. 392 (1947); United States v. Loew's, Inc., 371 U.S. 38 (1962).

purposes of establishing the patent misuse defense[28] when it amended the Patent Act in 1988.[29] Yet neither Congress nor the Supreme Court had decided whether the presumption remained in antitrust jurisprudence when the tying product is patented.

In March 2006, the Supreme Court vacated the Federal Circuit's judgment without dissent,[30] holding that "the mere fact that a tying product is patented does not support such a presumption."[31] The Court explained that its reevaluation of its precedents establishing the per se rule was prudent in light of Congress's narrowing of the patent misuse defense, as well as the "vast majority of academic literature" that had extensively criticized the "patent equals market power" presumption.[32] Thus, the Court in this case eliminated the presumption in antitrust law and stated that "in *all* cases involving a tying arrangement, *the plaintiff must prove* that the defendant has market power in the tying product."[33]

eBay v. MercExchange[34]

A patent holder has the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States, or importing the protected invention into the United States.[35] Whoever performs any one of these five acts during the term of the invention's patent, without the patent holder's authorization, is liable for infringement.[36] To prevent the violation of any right secured by a patent, the Patent Act provides that a federal court "may grant injunctions in accordance with the principles of equity."[37]

eBay operates a website that allows sellers to list products for sale and buyers to purchase those goods either through an auction system or at a fixed price. MercExchange alleged that eBay's "Buy It Now" functionality on its website, which permits users to buy items at fixed prices rather than bid for them, comes within the claims of its patent,[38] and filed a patent infringement lawsuit against eBay in September 2001. Although the jury returned a verdict finding that eBay had willfully infringed MercExchange's patent, the U.S. District Court for the Eastern District of

[28] The doctrine of patent misuse is an affirmative defense to patent infringement, that "requires that the alleged infringer show that the patentee has impermissibly broadened the physical or temporal scope of the patent grant with anticompetitive effect." Windsurfing Int'l v. AMF, Inc., 782 F.2d 995, 1001-02 (Fed. Cir. 1996) (internal quotations and citation omitted).

[29] 35 U.S.C. § 271(d)(5) now requires that, in order for a patentee to be found guilty of patent misuse on account of a "tie," a specific finding that "in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned."

[30] The case was decided 8-0; Justice Samuel Alito did not participate in the consideration or decision of the case because he was not a member of the Court when the case was argued.

[31] Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28, 31 (2006).

[32] *Id.* at 43-44.

[33] *Id.* at 46 (emphasis added).

[34] For a more detailed explanation and analysis of the *eBay* case, *see* CRS Report RL33429, *Availability of Injunctive Relief in Patent Cases:* eBay, Inc. v. MercExchange, L.L.C., by Brian T. Yeh.

[35] 35 U.S.C. § 154(a)(1). However, there is no statutory requirement that a patentee make, use, or sell its invention. Rite-Hite Corp. v. Kelley Co., Inc., 56 F.3d 1538, 1547 (Fed. Cir. 1995).

[36] 35 U.S.C. § 271(a).

[37] 35 U.S.C. § 283.

[38] MercExchange's patent "pertains to a system for selling goods through an 'electronic network of consignment stores.'" MercExchange, L.L.C. v. eBay, Inc., 401 F.3d 1323, 1327 (Fed. Cir. 2005).

Virginia refused to issue an injunction against the Internet auctioneer, after determining that (1) monetary damages would be an adequate remedy at law, (2) MercExchange would not be irreparably harmed in the absence of an injunction, (3) the balance of hardships fell slightly in eBay's favor, and (4) the public interest would not necessarily be furthered in this case, because MercExchange "does not practice its patents"[39] and "exists merely to license its patented technology to others."[40]

On appeal, the Federal Circuit unanimously affirmed the jury's verdict on the finding of infringement.[41] However, the appellate court ruled that MercExchange was entitled to an injunction to prevent further infringement by eBay, finding inadequate the district court's reasons for refusing to issue an injunction.[42] According to the Federal Circuit, "Because the right to exclude recognized in a patent is but the essence of the concept of property, the general rule is that a permanent injunction will issue once infringement and validity have been adjudged."[43]

In May 2006, the Supreme Court unanimously vacated the Federal Circuit's judgment and remanded the case to the district court for further proceedings consistent with the Court's opinion in this case.[44] Although the Court noted that "we take no position on whether permanent injunctive relief should or should not issue in this particular case,"[45] the Court clarified that the traditional principles of equity that govern issuance of injunctive relief "apply with equal force to disputes arising under the Patent Act,"[46] thus dispelling any notion that patent disputes are subject to different standards than those applicable to cases arising under other areas of law.

The Court explained that neither of the lower courts had "fairly" applied the traditional equitable principles in determining whether injunctive relief should issue in this case. The district court had erred by improperly suggesting that injunctive relief was categorically unavailable in cases where patent holders only license their patents rather than commercialize the invention themselves. On the other hand, the Federal Circuit was incorrect in pronouncing a rule, unique to patent cases, that strongly favored injunctions when infringement has been adjudged.

Two concurring opinions, written by Chief Justice John Roberts, Jr., and Justice Anthony Kennedy, were filed in *eBay v. MercExchange* and reveal an apparent disagreement among the justices. Chief Justice Roberts' concurring opinion, joined by Justices Antonin Scalia and Ruth Bader Ginsburg, predicted that injunctive relief will likely continue to be the usual remedy for patent infringement, consistent with the "long tradition of equity practice."[47] A district court's equitable discretion in granting or denying an injunction in patent cases, therefore, is not unfettered, in the view of these three Justices.

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[39] MercExchange, L.L.C. v. eBay, Inc, 275 F. Supp. 2d 695, 714-15 (E.D. Va. 2003).

[40] *Id.* at 712.

[41] MercExchange, L.L.C. v. eBay, Inc., 401 F.3d 1323, 1329 (Fed. Cir. 2005).

[42] *Id.* at 1339.

[43] *Id.* at 1338 (citation and internal quotations omitted).

[44] eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).

[45] *Id.* at 394

[46] *Id.* at 391. Justice Clarence Thomas, the author of the Court's opinion, noted that this observation finds express statutory support in the Patent Act, which states that district courts "may" issue injunctions "in accordance with the principles of equity." 35 U.S.C. § 283.

[47] *eBay,* 547 U.S. at 395 (Roberts, C.J., concurring).

While agreeing with Chief Justice Robert's concurrence that "history may be instructive" in applying the four-factor test when the circumstances of a patent case are similar to those of earlier cases, Justice Kennedy's concurring opinion, joined by Justices John Paul Stevens, David Souter, and Stephen Breyer, suggested that historical practice might not necessarily be helpful for courts to follow when dealing with some patent infringement suits in the current business environment: "[T]rial courts should bear in mind that in many instances the nature of the patent being enforced and the economic function of the patent holder present considerations quite unlike earlier cases."[48] Justice Kennedy acknowledged the emergence of patent holding companies and their impact on patent litigation today:

> An industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees.... For these firms, an injunction, and the potentially serious sanctions arising from its violation, can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent.... When the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest.[49]

Laboratory Corporation of America Holdings v. Metabolite Labs

According to the Patent Act, one who "invents or discovers any new and useful process, machine, manufacture, or any composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."[50] Thus, an invention may be patented if it falls within one of these statutory classes of subject matter: processes, machines, manufactures, and compositions of matter. The Supreme Court has articulated limits for patentability, previously stating that "laws of nature, natural phenomena, and abstract ideas" may not be patented.[51] The Court has elaborated on this restriction in several cases:

> [A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of ... nature, free to all men and reserved exclusively to none."[52]

The patent at issue in *Laboratory Corporation v. Metabolite Labs* involves a way of detecting a deficiency in two B vitamins, cobalamin and folate, in the human body. Low levels of these vitamins can cause serious illnesses in humans.[53] Metabolite Laboratories holds a license to a patent that claims a medical diagnostic method for detecting cobalamin or folate deficiency. This patented method requires two separate steps: first, measuring a body fluid for elevated levels of a

[48] *Id.* at 396 (Kennedy, J., concurring).

[49] *Id.* at 396-97.

[50] 35 U.S.C. § 101.

[51] Diamond v. Diehr, 450 U.S. 175, 185 (1981).

[52] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)).

[53] Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1358 (Fed. Cir. 2004).

particular amino acid (homocysteine), and second, noticing that an elevated level of this amino acid correlates with a deficiency in the two vitamins.[54]

Metabolite filed a patent infringement lawsuit against Laboratory Corporation (LabCorp), a clinical reference laboratory that performs tests to help health care providers in diagnosing and treating their patients. The lawsuit asserted that LabCorp committed infringement on the patented method when it induced doctors to infringe by performing homocysteine tests and making the correlation. In November 2001, a jury found that the patent was valid and deemed LabCorp guilty for willful patent infringement. The U.S. District Court for the District of Colorado entered an injunction against LabCorp from performing any homocysteine tests.

In June 2004, the Federal Circuit affirmed the district court's decision. The appellate court explained that infringement of the patent at issue occurs when a physician determines there is a cobalamin or folate deficiency by "correlating" a particular test result (of elevated levels of homocysteine) with B vitamin deficiencies.[55] This is the "direct" infringement of the patent,[56] for which LabCorp was held liable for inducing.[57] The Federal Circuit cited evidence in the record that LabCorp was liable for such infringement because its educational publications and informational materials distributed to medical doctors stated that elevated total homocysteine correlates to vitamin deficiencies.[58]

The question presented on which the Supreme Court granted certiorari in this case was: "Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to 'correlat[e]' test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result."[59]

In its petitions submitted to the Supreme Court on this question, LabCorp urged reversal of the Federal Circuit's judgment. LabCorp argued that upholding the patent claim in this case would amount to allowing a patent on a scientific principle or scientific fact, in violation of patent jurisprudence that prohibits patenting laws of nature, natural phenomena, and abstract ideas.[60]

In reply, Metabolite's briefs argued that the Supreme Court should dismiss the case on procedural grounds. Metabolite noted that the issue of whether the diagnostic method met subject matter patentability requirements should not be considered by the Court, because the matter was never properly raised or addressed in LabCorp's arguments before the district court or Federal Circuit.[61]

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[54] *Id.* at 1358-59.

[55] *Id.* at 1363-64.

[56] *Id.* at 1364 ("The record shows that physicians order assays and correlate the results of those assays, thereby directly infringing.").

[57] Inducement of patent infringement is punishable under 35 U.S.C. § 271(b)("Whoever actively induces infringement of a patent shall be liable as an infringer.").

[58] *LabCorp*, 370 F.3d at 1365.

[59] Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2004), *cert. granted,* 546 U.S. 975 (October 31, 2005) (No. 04-607).

[60] Brief for Petitioner at 17, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124 (2006) (No. 04-607).

[61] Brief for Respondent at 19-26, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124 (2006) (No. 04-607).

Therefore, Metabolite reasoned, the Court should dismiss the writ of certiorari or affirm the Federal Circuit's decision.

In a per curiam decision[62] issued on June 22, 2006, the Court dismissed the case, stating only that the writ of certiorari was improvidently granted.[63] The effect of the dismissal is that the Federal Circuit's judgment affirming infringement liability and the patent's validity is left undisturbed.

Three justices dissented to the dismissal of the writ. Justice Stephen Breyer, writing for himself and Justices John Paul Stevens and David Souter, argued that the question is not unusually difficult to decide, the parties have fully briefed the question, and that the Court has the authority to decide it. Furthermore, he opined that "those who engage in medical research, who practice medicine, and who as patients depend upon proper health care, might well benefit from this Court's authoritative answer."[64] Justice Breyer explained that he would have held the patent invalid because "[t]here can be little doubt that the correlation between homocysteine and vitamin deficiency ... is a 'natural phenomenon'" that is not patentable.[65]

In addition, Justice Breyer offered insight into his views regarding the legal correctness of the Federal Circuit's *State Street Bank* decision in 1998, which had held that a process is patentable if it produces a "useful, concrete, and tangible result."[66] (This controversial Federal Circuit decision has paved the way for inventors to obtain patents on "methods" or techniques of doing business; for example, the patent in the *eBay* case discussed above is a so-called "business method" patent.) Justice Breyer criticized the *State Street Bank* ruling, asserting that "[T]his Court has never made such a statement and, if taken literally, the statement would cover instances where this Court has held the contrary."[67]

October Term 2006

MedImmune v. Genentech[68]

Under Article III of the U.S. Constitution, the jurisdiction of federal courts is limited to actual, ongoing cases and controversies.[69] The Declaratory Judgment Act, codified at 28 U.S.C. § 2201,

[62] Chief Justice John G. Roberts Jr. did not take part in consideration or decision of the case.

[63] Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124 (2006).

[64] *Id.* at 126 (Breyer, J., dissenting).

[65] *Id.* at 135.

[66] State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998)). For more information about this decision, *see* CRS Report RL30572, *Patents on Methods of Doing Business*, by John R. Thomas.

[67] *LabCorp,* 548 U.S. at 136 (Breyer, J., dissenting).

[68] For a more detailed explanation and analysis of the *MedImmune* case, *see* CRS Report RL34156, *A Nonrepudiating Patent Licensee's Right To Seek Declaratory Judgment of Invalidity or Noninfringement of the Licensed Patent:* MedImmune v. Genentech, by Brian T. Yeh.

[69] U.S. CONST. art. III, § 2, cl. 1 ("The Judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority;—to all Cases affecting Ambassadors, other public Ministers and Consuls;—to all Cases of admiralty and maritime Jurisdiction; to Controversies to which the United States shall be a Party;—to Controversies between two or more States; between a State and Citizens of another State; between Citizens of different States,—between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.").

authorizes a federal court to issue a judgment declaring the legal rights of any interested party seeking such declaration, "whether or not further relief is or could be sought," in a "case of actual controversy within its jurisdiction." The Supreme Court has held that an action for declaratory relief qualifies as a "case or controversy" under Article III;[70] furthermore, it has explained: "[T]he question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."[71]

The question that the Supreme Court faced in *MedImmune v. Genentech* is whether a patent licensee must terminate or breach its license agreement before it can bring suit to obtain a declaratory judgment that the underlying patent is invalid, unenforceable, or not infringed.[72]

MedImmune, Inc. is a pharmaceutical company that manufactures a drug, Synagis, used to prevent respiratory tract disease in infants and young children. A year before the U.S. Food and Drug Administration approved Synagis for marketing to consumers, MedImmune had entered into a patent license agreement with the biotechnology company Genentech in 1997, concerning an existing Genentech patent relating to the production of "chimeric antibodies" (the Cabilly I patent) and also a then-pending patent application for "the coexpression of immunoglobulin chains in recombinant host cells."[73] MedImmune agreed to pay royalties on sales of any "licensed products" that it may make or sell which would infringe the claims of either of the patents, if not for the license agreement.[74]

In December 2001, Genentech was awarded a patent on the "coexpression" application that was the subject of the licensing agreement ("Cabilly II patent"). Genentech sent MedImmune a letter, asserting that the Synagis drug came within the scope of the new Cabilly II patent, and that therefore it was a "licensed product" for which royalties are owed under the 1997 license agreement. MedImmune, however, believed the Cabilly II patent invalid and unenforceable or, alternatively, that Synagis did not infringe the patent's claims. Despite this assessment, MedImmune paid the royalties "under protest," because it considered Genentech's letter a threat to sue for patent infringement if it failed to comply with the demands therein.[75]

MedImmune initiated a declaratory judgment action against Genentech, seeking a declaration that the patent was invalid. Genentech filed a defense motion pursuant to Federal Rules of Civil Procedure 12(b)(1), asserting that the federal courts lacked Article III jurisdiction over the claim because no "actual controversy" existed between the parties. The U.S. District Court for the Central District of California granted the motion, dismissing the case for lack of subject matter jurisdiction.[76] The district court explained that it was obliged to dismiss the case[77] due to the controlling precedent of the Federal Circuit's *Gen-Probe Inc. v. Vysis, Inc.* decision in 2004, which had held that "a patent licensee in good standing cannot establish an Article III case or

[70] Nashville, Chattanooga & St. Louis Railway Co. v. Wallace, 288 U.S. 249 (1933); Aetna Life Ins. Co. v. Haworth, 300 U.S. 227 (1937).

[71] Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273 (1941).

[72] MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 120 (2007).

[73] *Id.* at 121.

[74] *Id.*

[75] *Id.* at 122.

[76] MedImmune, Inc. v. Genentech, Inc., 2004 U.S. Dist. LEXIS 28680, at *13 (C.D. Cal. 2004).

[77] Dismissal of an action is required if a court lacks subject matter jurisdiction. Ex parte McCardle, 74 U.S. 506 (1869).

controversy with regard to validity, enforceability, or scope of the patent because the license agreement 'obliterates any reasonable apprehension' that the licensee will be sued for infringement."[78] Because MedImmune continued to pay royalties under the license agreement, it was a licensee in good standing and was not under threat or in reasonable apprehension of suit, the court reasoned.[79]

On appeal, the Federal Circuit affirmed the district court's judgment, relying on its earlier *Gen-Probe* decision in determining that there was a lack of a justiciable controversy.[80]

In an 8-1 decision, the Supreme Court reversed the Federal Circuit's judgment and remanded the case to the district court. The Court held that a patent licensee is not required to repudiate its license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed.[81] However, the Court "express[ed] no opinion" on whether such a nonrepudiating licensee is relieved of its contract obligations during the suit challenging the patent's validity.[82]

Writing for the majority, Justice Antonin Scalia first explained that the Article III "case or controversy" requirement would have been satisfied if MedImmune had refused to make royalty payments.[83] At issue here, however, was whether a case or controversy still existed when MedImmune's compliance with the license terms eliminated the immediate threat of injury from a patent infringement lawsuit. Justice Scalia offered a comparison to a situation where the government threatens legal action, in which there is no requirement that "a plaintiff [] expose himself to liability before bringing suit to challenge the basis for the threat—for example, the constitutionality of a law threatened to be enforced."[84] In such a case, courts have not found Article III jurisdiction to be lacking despite the fact that the plaintiff's own action (or inaction) in failing to violate the law eliminates the imminent threat of prosecution.[85] Although a *private* party rather than the government threatened the enforcement action in *MedImmune*, this distinction does not make a significant legal difference that would eliminate jurisdiction, Justice Scalia argued.[86] Thus, the Federal Circuit erred when it upheld the district court's dismissal of the case for lack of jurisdiction.

In lone dissent, Justice Clarence Thomas maintained that a patent licensee in good standing must breach its license prior to challenging the validity of the underlying patent. He stated: "[T]he declaratory judgment procedure cannot be used to obtain advanced rulings on matters that would be addressed in a future case of actual controversy."[87] In his view, MedImmune's suit was an attempt to seek a ruling on hypothetical or conjectural matters, and thus federal courts lacked Article III jurisdiction over its claims.

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[78] *MedImmune,* 549 U.S. at 122 (quoting Gen-Probe, Inc. v. Vysis, Inc., 359 F.3d 1376, 1381 (Fed. Cir. 2004)).

[79] *MedImmune*, 2004 U.S. Dist. LEXIS 28680, at *13-14.

[80] MedImmune, Inc. v. Genentech, Inc., 427 F.3d 958, 963 (Fed. Cir. 2005).

[81] *MedImmune*, 549 U.S. at 137.

[82] *Id.* at 124. This comment leaves open the question of whether the nonrepudiating patent licensee may be able to recover those royalties if the patent is finally held invalid.

[83] *Id.* at 128.

[84] *Id.* at 128-29.

[85] *Id.* at 129.

[86] *Id.* at 130.

[87] *Id.* at 137 (Thomas, J., dissenting).

KSR International Co. v. Teleflex Inc.[88]

Section 103(a) of the Patent Act provides one of the statutory bars for patentability of inventions, such that a patent claim is invalid if "the differences between the subject matter sought to be patented and the prior art[89] are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[90] In other words, for the subject matter of an alleged invention or discovery to be patentable, it must be "nonobvious" at the time of its creation. The nonobviousness requirement is met if the subject matter claimed in a patent application is beyond the ordinary abilities of a person of ordinary skill in the art in the appropriate field.[91]

In the landmark 1966 case *Graham v. John Deere Co. of Kansas City,* the Supreme Court established an analytic framework for courts to determine "nonobviousness." The so-called *Graham* test describes several factors that must be assessed:

> While the ultimate question of patent validity is one of law ... the § 103 condition, which is but one of three conditions, each of which must be satisfied, lends itself to several basic factual inquiries. Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.[92]

While a single prior art reference could form the basis of a finding of nonobviousness, multiple prior art references are often involved in the analysis. In such a situation, the Federal Circuit had developed an approach in which an invention would be considered obvious only if there was an explicit or implicit "teaching, suggestion, or motivation" that would lead a person of ordinary skill to combine multiple prior art references to produce an invention.[93] Such a "teaching, suggestion, or motivation" ("TSM") could have come from either (1) the references themselves, (2) knowledge of those skilled in the art, or (3) the nature of a problem to be solved, leading inventors to look to references relating to possible solutions to that problem.[94] Because § 103 of the Patent Act requires that an invention's obviousness be determined from the standpoint of a

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[88] For a more detailed explanation and analysis of the *KSR* case, *see* CRS Report RS22669, *The Obviousness Standard in Patent Law:* KSR International Co. v. Teleflex Inc., by Brian T. Yeh.

[89] "Prior art" is a legal term of art that refers to the materials (usually called "references" in patent law) that comprise the available knowledge regarding the subject matter of the invention sought to be patented, such as other issued patents, publications, and evidence of actual uses or sales of the technology. ROGER SCHECHTER & JOHN THOMAS, PRINCIPLES OF PATENT LAW 4-1 (2d ed. 2004).

[90] 35 U.S.C. § 103(a).

[91] The Federal Circuit has previously set forth a list of factors that are relevant to the inquiry into the level of ordinary skill in the art: "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." Environmental Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 698 (Fed. Cir. 1983).

[92] 383 U.S. 1, 17-18 (1966).

[93] Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F .3d 1568, 1572-73 (Fed. Cir. 1996); Tec Air, Inc. v. Denso Mfg. Mich. Inc., 192 F.3d 1353, 1359-60 (Fed. Cir. 1999).

[94] *Pro-Mold,* 75 F.3d at 1573.

person having ordinary skill in the art "at the time the invention was made," the TSM test was designed, in part, to defend against "the subtle but powerful attraction of a hindsight-based obviousness analysis."[95]

The patents at issue in *KSR International Co. v. Teleflex Inc.* pertain to an adjustable pedal system (APS) for use with automobiles having electronic throttle-controlled engines. Teleflex Inc. holds an exclusive license for the patent on this device that allows a driver to adjust the location of a car's gas and break pedal so that it may reach the driver's foot. KSR International Co. also manufactures an adjustable pedal assembly, and in mid-2000, designed its APS to incorporate an electronic pedal position sensor in order for it to work with electronically controlled engines, which are being increasingly used in automobiles. In 2002, Teleflex filed a patent infringement lawsuit against KSR, asserting that this new design came within the scope of its patent claims. In defense, KSR argued that Teleflex's patents were invalid because they were obvious under § 103(a) of the Patent Act—that someone with ordinary skill in the art of designing pedal systems would have found it obvious to combine an adjustable pedal system with an electronic pedal position sensor for it to work with electronically controlled engines.[96]

The U.S. District Court for the Eastern District of Michigan agreed with KSR that the patent was invalid for obviousness, granting summary judgment in favor of KSR.[97] The court determined that there was "little difference between the teachings of the prior art and claims of the patent-in-suit."[98] Furthermore, the court opined that "it was inevitable" that APS would be combined with an electronic device to work with electronically controlled engines.[99]

Upon Teleflex's appeal, the Federal Circuit vacated the district court's ruling. The appellate court found that the district court had improperly applied the TSM test by not adhering to it more strictly—the district court had reached its obviousness ruling "without making findings as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of [the] invention to make the combination in the manner claimed."[100] In the Federal Circuit's view, unless the "prior art references address the precise problem that the patentee was trying to solve," the problem would not motivate a person of ordinary skill in the art to combine the prior art teachings—here, the placement of an electronic sensor on an adjustable pedal.[101]

The Supreme Court granted certiorari on June 26, 2006, to review the *KSR* case, in which the central question before the Court was whether the Federal Circuit had erred in crafting TSM as the sole test for obviousness under § 103(a) of the Patent Act.[102] On April 30, 2007, the Court unanimously reversed the Federal Circuit's judgment, holding that the TSM test for obviousness was incompatible with § 103 and Supreme Court precedents.[103] Associate Justice Anthony

[95] *In re* Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999).

[96] Teleflex Inc. v. KSR Int'l Co., 298 F. Supp. 2d 581, 585 (E.D. Mich. 2003).

[97] *Id.* at 596.

[98] *Id.* at 592.

[99] *Id.* at 593.

[100] Teleflex, Inc. v. KSR Int'l Co., 119 Fed. Appx. 282, 288 (Fed. Cir. 2005) (internal quotations and citation omitted).

[101] *Id.*

[102] KSR Int'l Co. v. Teleflex, Inc., 119 Fed. Appx. 282 (Fed. Cir. 2005), *cert. granted,* 548 U.S. 902 (June 26, 2006).(No. 04-1350).

[103] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 407 (2007).

Kennedy, delivering the opinion of the Court, explained that the proper framework for a court or patent examiner to employ when determining an invention's obviousness is that set forth in the Court's 1966 opinion, *Graham v. John Deere Co. of Kansas City.* That analytic framework provides "an expansive and flexible approach" to the question of obviousness that the "rigid" and "mandatory" TSM formula does not offer.[104]

Justice Kennedy observed that the *Graham* approach, as further developed in three subsequent Supreme Court cases decided within 10 years of that case,[105] is based on several instructive principles for determining the validity of a patent based on the combination of elements found in the prior art:

- When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one.
- If a person of ordinary skill can implement a predictable variation, it is likely obvious under § 103 and unpatentable.
- If a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.[106]

Justice Kennedy then provided additional guidance for courts in following these principles. To determine whether there was an apparent reason to combine the known elements in the manner claimed by the patent at issue, courts should explicitly engage in an analysis that considers the following elements:

- the interrelated teachings of multiple patents,
- the effects of demands known to the design community or present in the marketplace, and
- the background knowledge possessed by a person having ordinary skill in the art.[107]

The Federal Circuit's TSM test, and its mandatory application, is contrary to *Graham* and its progeny because it limits the obviousness analysis and is too formalistic, Justice Kennedy argued.[108] In addition, he believed that the TSM test hindered the ability of courts and patent examiners to rely upon "common sense."[109]

However, Justice Kennedy allowed that TSM provides "a helpful insight"—that a patent comprised of several elements is not obvious just because each of those elements was,

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[104] *Id.* at 415, 419.

[105] United States v. Adams, 383 U.S. 39 (1966); Anderson's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57 (1969); Sakraida v. Ag Pro, Inc., 425 U.S. 273 (1976).

[106] *KSR,* 550 U.S. at 417.

[107] *Id.* at 418.

[108] *Id.* at 419.

[109] *Id.* at 420-21.

independently, known in the prior art.[110] This "essence" of the TSM test is not necessarily inconsistent with the *Graham* analysis, and thus he predicted that the Federal Circuit has likely applied the TSM test on many occasions in ways that accord with the *Graham* principles. It is the Federal Circuit's rigid application of its TSM rule, however, that the Court deemed was problematic in this case.[111]

Justice Kennedy identified four specific legal errors committed by the Federal Circuit. First, the appellate court had held that courts and patent examiners should look only to the problem the patentee was trying to solve, rather than other problems addressed by the patent's subject matter.[112] Second, the appellate court had assumed that a person of ordinary skill trying to solve a particular problem will be led only to those elements of prior art designed to solve the same problem; however, "common sense teaches ... that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle."[113] The third error of the lower court was its erroneous conclusion that a patent claim cannot be proved obvious by showing that the combination of elements was "obvious to try"; instead, Justice Kennedy noted, "the fact that a combination was obvious to try might show that it was obvious under § 103."[114] The final error was the Federal Circuit's adherence to "rigid preventative rules" to avoid the risk of hindsight bias on the part of courts and patent examiners, because such rules "deny factfinders recourse to common sense."[115]

As to the specific patent claim at issue in this case, the Court adopted the obviousness analysis of the district court and expressly held that the claim "must be found obvious" in light of the prior art.[116]

Microsoft v. AT&T[117]

In 1972, the Supreme Court ruled in *Deepsouth Packing Co. v. Laitram Corp.*[118] that it was not an act of patent infringement to manufacture the components of a patented invention in the United States and then ship them abroad for assembly into an end product. In response to this loophole in the patent law that would have allowed potential infringers to avoid liability, Congress added subsection (f) to § 271 of the Patent Act.[119] This statutory provision now states:

> (1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the

[110] *Id.* at 418.

[111] *Id.* at 419.

[112] *Id.* at 420.

[113] *Id.*

[114] *Id.* at 421.

[115] *Id.*

[116] *Id.* at 422.

[117] For a more detailed explanation and analysis of the *Microsoft* case, *see* CRS Report RS22670, *Exporting Software and the Extraterritorial Reach of U.S. Patent Law:* Microsoft Corp. v. AT&T Corp., by Brian T. Yeh.

[118] 406 U.S. 518 (1972).

[119] Patent Law Amendments Act of 1984, P.L. 98-622, Title I, § 101(a) (1984).

> combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.
>
> (2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

The patent at issue in *Microsoft v. AT&T* concerned AT&T's patent on a speech coder-decoder (a codec). A speech codec is a software program that is capable of converting spoken words into a compact code, or vice versa.[120] AT&T brought suit against Microsoft in 2001, alleging that the speech codec included in Microsoft's Windows operating system infringes its patent.

Microsoft filed a motion to exclude evidence of alleged liability arising from foreign sales of Windows, pursuant to § 271(f) of the Patent Act. Microsoft exports overseas a limited number of U.S.-made "golden master disks" containing the software code of its Windows operating system;[121] foreign computer manufacturers may use these disks to replicate the master disk in generating multiple copies of Windows for installation on foreign-assembled computers that are then sold to foreign customers.[122] In considering Microsoft's motion, the U.S. District Court for the Southern District of New York first cited previous Federal Circuit decisions supporting the proposition that software is patentable.[123] Then the court explained that § 271(f) does not limit "components" to only physical machines or tangible structures, but rather could include intangible information or data. Thus, the district court rejected Microsoft's argument that software could not be a "component" of a patented invention under § 271(f).[124] As for the copies made abroad from the golden master disk sent from the United States, the district court held that such copies still came within the scope of § 271(f) in light of the legislative intent of the statute to prohibit the circumvention of infringement through exportation.[125]

Upon Microsoft's appeal, a divided panel of the Federal Circuit affirmed the district court's decision. The appellate court relied on prior Federal Circuit case law that had held that "without question, software code alone qualifies as an invention eligible for patenting, and ... statutory language [does] not limit section 271(f) to patented 'machines' or patented 'physical structures,' such that software [can] very well be a 'component' of a patented invention for the purposes of § 271(f)."[126] The Federal Circuit also ruled that, because "the act of copying is subsumed in the act of 'supplying,'" the exportation of the golden master disks, with the specific intent that they be

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[120] AT&T Corp. v. Microsoft Corp., 2004 U.S. Dist. LEXIS 3340, *1 n.1 (2004); AT&T Corp. v. Microsoft Corp., 2003 U.S. Dist. LEXIS 10716, *2-3 (2003).

[121] Microsoft also sends the Windows code to foreign computer manufacturers via encrypted electronic transmission. AT&T Corp. v. Microsoft Corp., 414 F.3d 1366, 1367 (Fed. Cir. 2005).

[122] *Id.* at 1368.

[123] *AT&T,* 71 U.S.P.Q.2D (BNA) 1118, at *15-17.

[124] *Id.* at *17-24.

[125] *AT&T,* 414 F.3d at 1368; *AT&T,* 71 U.S.P.Q.2D (BNA) 1118, at *25.

[126] *AT&T,* 414 F.3d at 1369, *citing* Eolas Techs. Inc. v. Microsoft Corp., 399 F.3d 1325, 1339 (Fed. Cir. 2005) (internal quotations omitted).

replicated abroad, is an act that comes within the meaning of § 271(f)'s "supplied or caused to be supplied in or from the United States."[127]

In dissent, Federal Circuit Judge Randall R. Rader objected to the majority opinion's view that "supplies" within the meaning of § 271(f) includes the act of foreign "copying." Judge Rader expressed concerns that such an interpretation is, in effect, an impermissible "extraterritorial expansion" of U.S. patent law because it reaches "copying" activity overseas.[128] In his view, AT&T's remedy lies not in U.S. law, but rather the law of the foreign country in which the infringement due to copying occurred.[129]

The Supreme Court accepted Microsoft's petition for a writ of certiorari in October 2006,[130] in order to answer two questions:

> 1. Whether digital software code—an intangible sequence of "1's" and "0's"—may be considered a "component[] of a patented invention" within the meaning of Section 271(f)(1); and, if so,
>
> 2. Whether copies of such a "component[]" made in a foreign country are "supplie[d] ... from the United States."

In a 7-1 decision[131] issued in late April 2007, the Court reversed the Federal Circuit's judgment, holding that Microsoft was *not* liable for patent infringement under § 271(f), as the statute is currently written, when foreign-manufactured computers are loaded with Windows software that has been copied abroad from a master disk or an electronic transmission sent by Microsoft from the United States.[132] In regard to the first question posed in the case, Associate Justice Ruth Bader Ginsburg, writing for the majority, explained that there are two ways to conceptualize software:

> One can speak of software in the abstract: the instructions themselves detached from any medium. (An analogy: The notes of Beethoven's Ninth Symphony.) One can alternatively envision a tangible "copy" of software, the instructions encoded on a medium such as a CD-ROM. (Sheet music for Beethoven's Ninth.)[133]

Abstract software code does not qualify as a component, for purposes of triggering liability under § 271(f), because it is an "idea" lacking physical embodiment and thus it cannot be a "usable, combinable part of a computer."[134] Justice Ginsburg analogized software in the abstract to a detailed set of instructions, similar to that of a blueprint.[135] But information sent abroad that instructs someone on how to build the components of a patented invention does not come within

[127] *AT&T,* 414 F.3d at 1370.

[128] *Id.* at 1372-73 (Rader, J., dissenting). Patent rights are effective only in the United States. Dowagiac Mfg. Co. v. Minnesota Moline Plow Co., 235 U.S. 641, 650 (1915) ("The right conferred by a patent under our law is confined to the United States and its Territories ... and infringement of this right cannot be predicated of acts wholly done in a foreign country.").

[129] *AT&T,* 414 F.3d. at 1373 (Rader, J., dissenting).

[130] Microsoft Corp. v. AT&T Corp., 549 U.S. 991 (2006).

[131] Chief Justice John G. Roberts Jr. recused himself from consideration of and the rendering of a decision in this case.

[132] Microsoft Corp. v. AT&T Corp., 550 U.S. 437, 442 (2007).

[133] *Id.* at 447-78

[134] *Id.* at 451.

[135] *Id.* at 449-50.

the scope of § 271(f); she observed that Congress, in enacting the statutory provision, did not include the export of design tools such as blueprints, schematics, templates, and prototypes.[136] Thus, for the Windows software to be considered a "component" under § 271(f), the software code must be encoded or otherwise expressed in some sort of tangible medium—a computer-readable software "copy" such as a CD-ROM.[137] The Court thus declined to adopt AT&T's characterization of software in the abstract as a combinable component that qualifies for § 271(f) liability.[138]

In reaching its answer to the second question, the Court largely agreed with Judge Rader's dissent from the Federal Circuit's opinion. The copies of Windows used for installation on the foreign computers had been made abroad; those copies were not "supplied" from the United States, even though the master disk from which they were duplicated had been exported, Justice Ginsburg noted. According to her, this distinction is legally relevant for liability purposes under § 271(f); further, such liability is not affected by the ease of copying software.[139]

Furthermore, Justice Ginsburg argued that the traditional presumption against extraterritorial application of U.S. law, particularly in patent law, would help favor the Court construing § 271(f) in a manner that excludes intangible software code and copies of software made abroad.[140] Echoing Judge Rader's advice, Justice Ginsburg observed that "[i]f AT & T desires to prevent copying abroad, its remedy lies in obtaining and enforcing foreign patents."[141]

At the end of the opinion, Justice Ginsburg conceded that the Court's decision effectively creates a "loophole" for software makers to avoid liability under § 271(f).[142] However, she explained that the Court would resist using the "dynamic judicial interpretation" that would be needed to adjust the patent law "to account for the realities of software distribution."[143] The majority opinion expressly invited Congress to consider whether this apparent loophole in favor of software companies, to the extent that it may exist, merits closing.[144]

Associate Justice Samuel Alito, joined by Justices Thomas and Breyer, filed a concurring opinion in which he asserted that a "component" of an infringing physical device under § 271(f) "must be something physical";[145] thus, "[b]ecause no physical object originating in the United States was combined with these computers, there was no violation of § 271(f)."[146] He further observed that "[n]o physical aspect of a Windows CD-ROM—original disk or copy—is ever incorporated into

[136] *Id.* at 453-57.

[137] *Id.* at 449-50.

[138] Indeed, the Court acknowledged that if it were to accept AT&T's position, "it would not matter that the master copies of Windows software dispatched from the United States were not themselves installed abroad as working parts of the foreign computers." *Id.* at 448-49.

[139] *Id.* at 452-53.

[140] *Id.* at 454-55.

[141] *Id.* at 456.

[142] *Id.* at 457.

[143] *Id.* at 457-59 (citation omitted).

[144] *Id.* at 457.

[145] *Id.* at 460 (Alito, J., concurring).

[146] *Id.* at 462.

the computer itself" because the CD-ROM is removed from the computer after the installation process copies the Windows code to the computer's hard drive.[147]

In lone dissent, Associate Justice John Paul Stevens explained that he would affirm the Federal Circuit's majority opinion in the case, because he deemed that judgment to be "more faithful to the intent of the Congress that enacted § 271(f)."[148] In his view, abstract software code, as well as the master disks that Microsoft had exported for copying abroad, should be considered "components" within the meaning of § 271(f). Justice Stevens also objected to the Court's comparison of abstract software to blueprints: "[U]nlike a blueprint that merely instructs a user how to do something, software actually causes infringing conduct to occur. It is more like a roller that causes a player piano to produce sound than sheet music that tells a pianist what to do."[149]

October Term 2007

Quanta Computer, Inc. v. LG Electronics, Inc.

The Patent Act grants patent holders the exclusive right, during the term of the patent, to exclude others from making, using, offering for sale, or selling their patented invention throughout the United States, or importing the invention into the United States.[150] The patent holder enjoys this limited monopoly as long as he retains ownership of the patented article.[151] However, the judicially created "patent exhaustion" doctrine, also referred to as the "first sale" doctrine, provides that "the initial authorized sale of a patented item terminates all patent rights to that item."[152] In other words, the rights of a patent owner end with the unconditional sale of an article embodying the invention, and the purchaser (or any "downstream purchasers") may use or resell the product without worrying about patent infringement liability.[153] The U.S. Supreme Court first recognized the patent exhaustion doctrine in 1853.[154] Then in a 1942 case, *United States v. Univis Lens Co.*, the Supreme Court extended the patent exhaustion doctrine to unfinished products as well:

> [W]here one has sold an uncompleted article which, because it embodies essential features of his patented invention, is within the protection of his patent, and has destined the article to be finished by the purchaser in conformity to the patent, he has sold his invention so far as it is or may be embodied in that particular article. The reward he has demanded and received is for the article and the invention which it embodies and which his vendee is to practice upon it. He has thus parted with his right to assert the patent monopoly with respect to it and is no longer free to control the price at which it may be sold either in its unfinished or finished form.[155]

[147] *Id.* at 460.

[148] *Id.* at 462 (Stevens, J., dissenting).

[149] *Id.* at 464.

[150] 35 U.S.C. §§ 154(a)(1), 271(a).

[151] United States v. Univis Lens Co., 316 U.S. 241, 250 (1942).

[152] Quanta Computer, Inc. v. LG Elecs., Inc., 128 S. Ct. 2109, 2115 (2008).

[153] Intel Corp. v. ULSI Sys. Technology, 995 F.2d 1566, 1568 (Fed. Cir. 1993).

[154] Bloomer v. McQuewan, 55 U.S. (14 How.) 539 (1853).

[155] 316 U.S. at 250-51.

In *Univis*, the holder of patents relating to multifocal lenses licensed a purchaser to manufacture lens blanks (pieces of glass for use, when ground and polished, as bi- and tri-focal lenses in eyeglasses); these blanks were then sold to wholesalers who ground the blanks into the patented finished lenses,[156] which in turn were sold to prescription retailers for resale to consumers at prices fixed by the patent holder.[157] The lens blanks were also sold to finishing retailers who ground and polished the lenses into finished multifocal lenses and then sold to consumers at prices stipulated by the patent licensor. The United States brought an antitrust suit against the patent holder under the Sherman Act[158] regarding these restrictions on the sale of the finished lenses; in defense, the patent holder argued that its patent monopoly rights shield the price fixing licensing system from the operation of the Sherman Act.[159] The Supreme Court ruled against the patent holder, stating the following:

> [M]erely because the licensee takes the final step in the manufacture of the patented product, by doing work on the blank which he has purchased from the patentee's licensee, it does not follow that the patentee can control the price at which the finished lens is sold.
>
> [E]ach blank ... embodies essential features of the patented device and is without utility until it is ground and polished as the finished lens of the patent.[160]

The three patents at issue in *Quanta Computer, Inc. v. LG Electronics, Inc.* concern the design and operation of certain personal computer technology—specifically, data processing functions carried out by microprocessors, chipsets, and computer memory.[161] The holder of these patents, LG Electronics (LGE), licensed them to Intel Corporation (Intel), via a cross-licensing agreement (License Agreement) that allowed Intel to manufacture and sell microprocessors and chipsets that practice the patented technology.[162] The License Agreement also specifies that no license "is granted by either party hereto ... to any third party for the combination by a third party of Licensed Products of either party with items, components, or the like acquired ... from sources other than a party hereto, or for the use, import, offer for sale or sale of such combination."[163] In a separate agreement (Master Agreement), LGE required Intel to inform Intel's customers that although the Intel products are licensed by LGE and do not infringe LGE patents, the license "does not extend, expressly or by implication, to any product" that the Intel customer makes by combining an Intel product with any non-Intel product.[164]

Intel sold microprocessors and chipsets to Quanta Computer and provided Quanta with the written notice required under the Master Agreement. Despite the warning, Quanta manufactured computer systems that combined the Intel components with non-Intel memory and other computer parts. LGE then brought a patent infringement lawsuit against Quanta. The U.S. District Court for the Northern District of California granted summary judgment of noninfringement of

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[156] The patents "relate[] to the shape, size, composition and disposition of the pieces of glass of different refractive power in the blanks into which they are fused." *Id.* at 247.

[157] *Id.* at 244.

[158] 15 U.S.C. §§ 1, 3, 15.

[159] *Univis,* 316 U.S. at 242, 248.

[160] *Id.* at 249.

[161] *Quanta,* 128 S. Ct. at 2113-14.

[162] *Id.* at 2114.

[163] *Id.*

[164] *Id.*

LGE's patents.[165] The district court observed that the unpatented Intel components must be combined with additional computer parts in order to function and infringe LGE's patents and that, standing alone, they have "no reasonable non-infringing use."[166] Therefore, the court held that under *Univis*, LGE's patent rights were exhausted by the License Agreement. However, the district court issued a subsequent order that limited its ruling, stating that the patent exhaustion doctrine applies only to apparatus claims that describe a physical object (such as a system or device), and *not* to process or method claims that describe how to make or use a product.[167] Thus, the court ruled that although patent exhaustion shields Quanta from liability for infringing LGE's apparatus patents, Quanta may still be held liable for infringing LGE's method patents.[168]

The U.S. Court of Appeals for the Federal Circuit affirmed the district court's holding that method patents cannot be exhausted.[169] However, the appellate court reversed the district court's determination as to the apparatus claims in LGE's patents, finding that the exhaustion doctrine does not apply to a conditional sale or license. Thus, LGE's patents that include apparatus claims were also not exhausted because the License Agreement "expressly disclaims granting a license allowing computer system manufacturers to combine Intel's licensed parts with other non-Intel components."[170]

On June 9, 2008, the Supreme Court unanimously reversed the Federal Circuit's holding that method patents cannot be exhausted; furthermore, the Court held that because the License Agreement "authorizes the sale of components that substantially embody the patents in suit," Intel's sale to Quanta had exhausted LGE's patents.[171] In its brief filed with the Court, LGE had argued that "because method patents are linked not to a tangible article but to a process, they can never be exhausted through a sale."[172] Justice Thomas, the author of the Court's opinion, rejected LGE's reasoning, explaining that

> It is true that a patented method may not be sold in the same way as an article or device, but methods nonetheless may be "embodied" in a product, the sale of which exhausts patent rights. Our precedents do not differentiate transactions involving embodiments of patented methods or processes from those involving patented apparatuses or materials. To the contrary, this Court has repeatedly held that method patents were exhausted by the sale of an item that embodied the method.[173]

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[165] LG Electronics, Inc. v. Asustek Computer, Inc., 65 USPQ 2d 1589 (ND Cal. 2002).

[166] *Id.* at *13, *33.

[167] LG Electronics, Inc. v. Asustek Computer, Inc., 248 F. Supp. 2d 912, 918 (ND Cal. 2003). Patent applications contain one or more claims that define the scope of the subject matter which the applicant regards as his invention. 35 U.S.C. § 112. These claims define the scope of the patentee's rights under the patent. 3-8 DONALD S. CHISUM, CHISUM ON PATENTS § 8.01 (2006). Patent claims may concern physical objects or methods. Many patent applications contain multiple claims that describe the invention in terms of (1) a product or apparatus (e.g., a washing machine), (2) a method of using the product (e.g., a new process for washing clothes), and (3) a method of making that product. ROGER SCHECHTER & JOHN THOMAS, PRINCIPLES OF PATENT LAW 2-2 (2d ed. 2004).

[168] *LG Electronics,* 248 F. Supp. 2d at 918.

[169] LG Electronics, Inc. v. Bizcom Electronics, Inc., 453 F.3d 1364, 1370 (Fed. Cir. 2006).

[170] *Id.*

[171] *Quanta,* 128 S. Ct. at 2113.

[172] *Id.* at 2117.

[173] *Id.*

Furthermore, Justice Thomas observed that to preclude exhaustion of method claims "would seriously undermine the exhaustion doctrine. Patentees seeking to avoid patent exhaustion could simply draft their patent claims to describe a method rather than an apparatus."[174]

Justice Thomas also declared that this case is controlled by *Univis:*

> Like the Univis lens blanks, the Intel Products constitute a material part of the patented invention and all but completely practice the patent. Here, as in *Univis*, the incomplete article substantially embodies the patent because the only step necessary to practice the patent is the application of common processes or the addition of standard parts. Everything inventive about each patent is embodied in the Intel Products.... The Intel Products were specifically designed to function only when memory or buses are attached; Quanta was not required to make any creative or inventive decision when it added those parts. Indeed, Quanta had no alternative but to follow Intel's specifications in incorporating the Intel Products into its computers because it did not know their internal structure, which Intel guards as a trade secret. Intel all but practiced the patent itself by designing its products to practice the patents, lacking only the addition of standard parts.[175]

LGE had argued that there was no implied license for Quanta to practice LGE's patents because the License Agreement between LGE and Intel specifically had disclaimed licenses to third parties to combine the licensed product with other components.[176] Justice Thomas, however, dismissed this argument as "irrelevant" because "Quanta asserts its right to practice the patents based not on implied license but on exhaustion. And exhaustion turns only on Intel's own license to sell products practicing the LGE Patents."[177]

Therefore, the dispositive question was whether Intel's sale to Quanta was authorized by the patent holder under the License Agreement (such authorized sale being the trigger for patent exhaustion). Justice Thomas observed that the License Agreement provided Intel with broad authority to "make, use [or] sell" products that substantially practice or embody LGE's patents. Although the Master Agreement required Intel to give notice to its customers that LGE had not authorized those customers to practice its patents, Intel's right to sell the products "was not conditioned on the notice or on Quanta's decision to abide by LGE's directions in that notice."[178] Furthermore, the Master Agreement contained a provision that stated that "a breach of this Agreement shall have no effect on and shall not be grounds for termination of the Patent License."[179] Justice Thomas opined that although patent damages are no longer available to LGE due to patent exhaustion, the Court "express[es] no opinion" on whether LGE may still have other rights to seek damages under contract law, including breach-of-contract claims.[180]

[174] *Id.*

[175] *Id.* at 2120 (citations omitted).

[176] *Id.* at 2122.

[177] *Id.*

[178] *Id.* at 2122.

[179] *Id.* at 2114.

[180] *Id.* at 2122, n.7.

October Term 2009

Bilski v. Kappos

The U.S. Court of Appeals for the Federal Circuit issued two decisions in the 1990s, *In re Alappat*[181] and *State Street Bank & Trust Co. v. Signature Financial Group,*[182] that had expanded the scope of patent-eligible subject matter to include any process that produces a "useful, concrete and tangible result."[183]

The patent application at issue in *Bilski v. Kappos* contained claims that relate to a method of hedging risk in the commodities trading field.[184] The PTO examiner rejected the application on the basis that the claims were not directed to patent-eligible subject matter under § 101 of the Patent Act, a determination that was upheld by the Board of Patent Appeals and Interferences ("Board").[185] The Board held that the transformation of "non-physical financial risks and legal liabilities of the commodity provider, the consumer, and the market participants" is not patentable subject matter.[186] In addition, the Board found that the claimed process did not produce a "useful, concrete and tangible result."

On October 30, 2008, the Federal Circuit issued an opinion in the case, in which it affirmed the Board's decision.[187] More importantly, the appellate court's decision clarified the standards concerning patentability of process claims. In so doing, the Federal Circuit expressly overruled *In re Alappat, State Street Bank & Trust Co. v. Signature Financial Group,* and its other prior decisions that relied on the "useful, concrete and tangible result" test for process patent eligibility.[188] Instead, the Federal Circuit announced a different test that was to exclusively govern the eligibility of process claims for patent protection under § 101 of the Patent Act:

> A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.[189]

In applying the "machine-or-transformation" test to the facts in *Bilski,* the Federal Circuit held that Bilski's process claim failed to satisfy the new legal standard, because the process does not transform any article to a different state or thing, nor does it meet the machine implementation part of the test as well.[190]

On June 1, 2009, the Supreme Court granted certiorari in *Bilski* to consider two questions:

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[181] 33 F.3d 1526 (Fed. Cir. 1994).

[182] 149 F.3d 1368 (Fed. Cir. 1998). For more information about this decision, *see* CRS Report RL30572, *Patents on Methods of Doing Business*, by John R. Thomas.

[183] *Id.* at 1373

[184] *Bilski v. Kappos,* 545 F.3d 945, 949 (Fed. Cir. 2008).

[185] *Id.*

[186] *Id.* at 950.

[187] *Id.* at 943.

[188] *Id.* at 961.

[189] *Id.* at 954.

[190] *Id.* at 963-64.

- Whether the Federal Circuit erred by holding that a "process" must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing ("machine-or-transformation" test), to be eligible for patenting under 35 U.S.C. § 101, despite this Court's precedent declining to limit the broad statutory grant of patent eligibility for "any" new and useful process beyond excluding patents for "laws of nature, physical phenomena, and abstract ideas."
- Whether the Federal Circuit's "machine-or-transformation" test for patent eligibility, which effectively forecloses meaningful patent protection to many business methods, contradicts the clear congressional intent that patents protect "method[s] of doing or conducting business." 35 U.S.C. § 273.

In an opinion written by Justice Kennedy, the Court held that the Federal Circuit was erroneous in declaring that the "machine-or-transformation" test is the *exclusive* test for process patent eligibility under § 101.[191] However, the Court recognized that its precedents have established that the "machine-or-transformation" test is "a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101."[192] Thus, the Court did not invalidate the "machine-or-transformation" test, but rather reversed the Federal Circuit's requirement that the test be the only standard by which processes may be judged for patent eligibility under § 101.

However, the Court did not articulate a different test or adopt new categorical rules for process patent eligibility "that might have wide-ranging and unforeseen impacts,"193 nor did it provide much guidance to the lower courts on this matter. Instead, the Court invited the Federal Circuit to develop additional tests and other limiting criteria regarding what constitutes a patentable process.[194]

The *Bilski* Court also ruled that some business methods may be patentable, because: (1) the Patent Act's definition of "process" does not categorically exclude business methods; and (2) § 273 of the Patent Act contemplates the possibility that some business methods, at least in some circumstances, may be eligible for patenting.[195]

Turning to the particular patent at issue in this case, the Court agreed that Bilski's patent application is not a patentable "process" under § 101. It reached this conclusion without relying upon the "machine-or-transformation" test, but rather its earlier precedents that prohibit the patenting of "laws of nature, physical phenomena, and abstract ideas."[196] Because the Court viewed Bilski's patent claims to be attempts to patent abstract ideas, the claimed processes are ineligible for patent protection under § 101.[197]

In two subparts of the Court's opinion that Justice Scalia did not join, thus representing only a plurality of the Court, Justice Kennedy expressed concern that the "machine-or-transformation"

[191] Bilski v. Kappos, 130 S. Ct. 3218 (2010), at *3226.

[192] *Id.* at *3227.

[193] *Id.* at *3229.

[194] *Id.* at *3231.

[195] *Id.* at *3228.

[196] *Id.* at *3225 (quoting *Chakrabarty,* 447 U.S. at 309).

[197] *Id.* at *3230.

test may negatively impact the Information Age and might "create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals."[198] He also opined that "some business method patents raise special problems in terms of vagueness and suspect validity," but suggested that the Court's precedents on the unpatentability of abstract ideas could serve as a useful limiting principle in considering whether to grant or uphold patents on business methods.[199]

Justice Stevens filed a lengthy concurring opinion, joined by Justices Ginsburg, Breyer, and Sotomayor, in which he agreed with the Court's determinations that the "machine-or-transformation" test was not the sole test for what constitutes a patentable process and that Bilski's patent claim is not a "process" within the meaning of § 101.[200] However, he disagreed with the Court's disposition of the case. He would have rejected the patent application because Bilski's method "describes only a general method of engaging in business transactions—and business methods are not patentable."[201] Therefore, in the view of these four justices, business methods do not qualify as a "process" eligible for patenting under § 101. Justice Stevens reached this conclusion by finding "strong historical evidence" in patent case law and legislative history, that suggested that business methods are not patentable.[202] He also expressed concern that business methods may stifle technological progress (and legitimate business competition and innovation) rather than promote it.[203]

In a brief concurring opinion, joined in part by Justice Scalia, Justice Breyer highlighted the areas of substantial agreement among the members of the Court on several of the fundamental issues of patent law raised by the *Bilski* case. He identified four points that he believed are consistent with the Court's opinion and with Justice Stevens' concurring opinion:

1. While the text of § 101 is broad, it is not without limit.
2. The "machine-or-transformation" test has been repeatedly helpful to courts in identifying what is a patentable "process."
3. Although the "machine-or-transformation" test has always been a "useful and important clue" for determining patentability of processes, it has never been the "sole test."
4. The Court disagrees with *State Street Bank's* judgment that anything which produces a "useful, concrete, and tangible result" is patentable.[204]

[198] *Id.* at *3227.

[199] *Id.* at *3229.

[200] *Id.* at *3232, 3257 (Stevens, J., concurring).

[201] *Id.* at *3232.

[202] *Id.* at *3239-50.

[203] *Id.* at *3255.

[204] *Id.* at *3258-59 (Breyer, J., concurring) (citations omitted).

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