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RESTORING THE BALANCE: THE SUPREME COURT JOINS THE PATENT REFORM MOVEMENT

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In the last several years, the Supreme Court of the United States has maintained an unusually high profile in the patent law arena. With a cluster of important recent decisions, the Court has joined the "patent reform" movement already underway in the other branches of government. The Court's opinions reflect a keen awareness of the issues facing the U.S. patent system, including what many (but by no means all) commentators believe is a proliferation of patents of questionable validity. In parallel with Congress and the PTO, the Supreme Court is endeavoring to re-balance a patent system that the Court may regard as too favorable to patent applicants and owners.

Section I of this article provides an overview of the Court's recent cases. Section II describes the unifying trends evident in the Court's rulings and places the Court's contributions in the context of the larger patent reform movement. Finally, Section III offers some predictions on the future direction of the Supreme Court's patent jurisprudence.

I. THE RECENT CASES: SUPREME COURT PATENT DECISIONS FROM 2005 TO 2007

In its last three terms, the Supreme Court has issued six significant decisions covering patent law issues. Certiorari in a seventh patent case was dismissed as improvidently granted, but several Justices offered a lengthy dissent explaining their views on the important topic of that case. In this section, we provide an overview of each of these cases. The policies and concerns underlying these decisions will be further explored in the next section.

A. *KSR v. Teleflex* – Refining the Obviousness Standard

The most highly anticipated of the Supreme Court's recent patent rulings came in *KSR International v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007). In a unanimous opinion delivered by Justice Kennedy, the Supreme Court rejected the Federal Circuit's longstanding "teaching, suggestion, or motivation" ("TSM") test as the exclusive means for proving that a patent is obvious in light of the prior art. Instead, the Court counseled a more flexible approach for determining obviousness, recognizing that persons of ordinary skill in the art are generally capable of combining available technologies to solve known problems, even without specific suggestions to do so in the prior art. Viewed from this perspective, the Court held that Teleflex's patented automobile pedal, all elements of which were revealed in the prior art, was obvious.

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Background

Section 103 of the Patent Act provides that a patent cannot be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made." 35 U.S.C. Section 103. In *Graham v. John Deere Co.*, 383 U.S. 1 (1966), the Supreme Court set forth four factors that are relevant to an obviousness determination: (1) the scope and content of the prior art; (2) the skill level of a person of ordinary skill in the art; (3) the differences between the invention and the prior art's teachings; and (4) any secondary considerations that support an inference of non-obviousness, such as the commercial success of the invention. Further development of the obviousness standard was left to the lower courts.

The Federal Circuit developed the TSM test in 1983 as a guard against using hindsight in evaluating obviousness. *See Orthopedic Equip. Co. v. United States*, 702 F.2d 1005 (Fed. Cir. 1983). Inventions that combine pre-existing elements in innovative ways may seem obvious in retrospect, even though they were not obvious at the time of their conception. Under the Federal Circuit's TSM test, a patent claim that combines elements from multiple prior art references is only obvious if some "teaching, suggestion, or motivation" would have led a person of ordinary skill to combine the references at the time of the invention. *See Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1323-24 (Fed. Cir. 1999). In practice, courts applying the TSM test generally looked in the prior art itself for a "teaching, suggestion, or motivation" to combine the references. Absent such an explicit suggestion in the prior art, a combination patent would ordinarily survive the obviousness inquiry.

The Federal Circuit relied on the TSM test to reverse a summary judgment ruling invalidating Teleflex's patented automobile pedal. In the Federal Circuit's view, the prior art did not contain a sufficient teaching, suggestion or motivation to lead a person of ordinary skill to combine the various pedal elements from the references. As a result, Teleflex's automobile pedal was not obvious, even though all of its parts were revealed in the prior art.

The Supreme Court's Decision

The Supreme Court rejected the Federal Circuit's "rigid" application of the TSM test, finding it inconsistent with the "expansive and flexible approach" to obviousness set forth in *Graham* and Section 103 itself. *KSR*, 127 S. Ct. at 1739. The Court reiterated its "earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art." As the Court explained:

> [A] "patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men."

Id. (quoting *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.,* 340 U.S. 147, 152 (1950)). The obviousness inquiry under *Graham* helps eliminate improper combination patents – i.e., those that combine "familiar elements according to known methods" to "yield predictable results." *Id.*

The Supreme Court faulted the TSM test for its "overemphasis on the importance of published articles and the explicit content of issued patents." *Id.* at 1741. Obvious techniques in a given field may receive little attention in the published literature, but might still be well known to persons of ordinary skill in the art. A person of ordinary skill will be able to combine familiar items to solve problems, even without explicit guidance from the prior art. As the Court noted, "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 1742.

In clarifying the obviousness standard, the Supreme Court envisioned a clear distinction between (1) inventions based on "real innovation" and (2) "advances that would occur in the ordinary course," arising from "ordinary skill and common sense." *Id.* at 1741-1742. The Court explained:

> Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress, and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

Id. at 1741. Proper application of the obviousness standard is critical to ensuring that the patent system rewards "real innovation," not predictable variations of existing technology.

Applying these principles, the Court held that the challenged claim was invalid as obvious.

B. *Microsoft v. AT&T* – Limiting Patent Coverage on Software Shipped Overseas

The Court's opinion in *Microsoft Corp. v. AT&T Corp.,* 127 S. Ct. 1746 (2007) examined the applicability of Section 271(f) of the Patent Act to computer software shipped overseas. Section 271(f) constitutes an exception to the general rule that U.S. patent protection does not apply to products made and sold overseas. Under 271(f), infringement occurs if "components" of a patented product are supplied from the U.S. for combination abroad. The Supreme Court held that software developed in the U.S. and shipped overseas on a master disk to be copied and installed on foreign computers did not qualify as a "component" under 271(f). Software code in the abstract, devoid of a physical medium, is not a "component" within the meaning of the statute. Since the master disk supplied from the U.S. was never itself installed on the foreign computers and all installable copies of the software were made overseas, Microsoft was not liable for the infringing use of its software on the foreign computers. Justice Ginsburg delivered the Court's opinion, joined in its entirety by Justices Scalia, Kennedy, and Souter. Justice Alito, joined by Justices Thomas and Breyer, filed an opinion concurring as to all but one footnote. Justice Stevens filed a dissenting opinion. The Chief Justice took no part in the decision.

Background

AT&T holds a patent covering an apparatus for digitally encoding and compressing recorded speech, which it asserted against Microsoft. Microsoft conceded that its Windows operating system, when installed on a computer, had the potential to infringe AT&T's patented apparatus. The parties settled their dispute concerning Windows used on computers in the U.S., but Microsoft denied liability for copies of Windows installed on foreign computers.

Windows is designed at Microsoft's headquarters in Redmond, Washington. Microsoft ships master versions of Windows to foreign computer manufacturers either on a master disk or via encrypted electronic transmission. The foreign manufacturers use the master version to generate CD-ROM copies of the software, which are then installed on foreign-made computers.

Section 271(f) of the Patent Act provides that infringement occurs when one "supplies . . . from the United States" the "components" of a patented invention for "combination" in another country. 35 U.S.C. Section 271(f). AT&T argued that by shipping Windows to foreign manufacturers, Microsoft was supplying a "component" of AT&T's patented apparatus for combination abroad. The district court and Federal Circuit found Microsoft liable for infringement under Section 271(f).

The Supreme Court's Decision

In reversing the Federal Circuit's ruling, the Supreme Court first examined the genesis of Section 271(f). The statute was enacted in response to the Court's holding in *Deepsouth Packing Co. v. Laitram Corp*., 406 U.S. 518 (1972). In that case, Deepsouth was sued for infringing Laitram's patent on a shrimp-deveining machine. Deepsouth did not dispute that its own deveining machine infringed Laitram's patent in the U.S., but denied liability for shipping the parts of its deveiner for assembly and use overseas. *Microsoft*, 127 S. Ct. at 1751. The Supreme Court agreed that Deepsouth was not liable for manufacturing the components of the deveining machine (which were not separately patented) and shipping those components abroad.

To close the loophole created by the *Deepsouth* decision, Congress enacted Section 271(f). The statute expands the definition of infringement to include supplying a patented invention's "components" from the U.S. for combination abroad. 35 U.S.C. Section 271(f).

After reviewing the origins of Section 271(f), the Court addressed two questions arising under the statute:

> (1) When, or in what form, does software qualify as a "component" under Section 271(f)?
> (2) Were "components" of the foreign-made computers involved in this case "supplie[d]" by Microsoft "from the United States"?

Microsoft, 127 S. Ct. at 1753-54.

As to the first question, the Court noted that "no one in this litigation argues that software can *never* rank as a 'component' under Section 271(f)." *Id*. at 1754 (emphasis in original). The disagreement was "over the stage at which software becomes a component." *Id*. Under the statute, a "component" must be amenable to "combination" once it arrives in the foreign country. Accordingly, software will only qualify as a "component" under Section 271(f) when it takes a physical form capable of being combined with a computer (i.e., installed). Abstract software, divorced from a physical medium, is uncombinable and, thus, does not qualify as a "component." The Court explained:

> Until it is expressed as a computer-readable "copy," e.g., on a CD-ROM, Windows software – indeed any software detached from an activating medium – remains uncombinable. It cannot be inserted into a CD-ROM drive or downloaded from the Internet; it cannot be installed or executed on a computer. Abstract software code is an idea without physical embodiment, and as such, it does not match Section 271(f)'s categorization: "components" amenable to "combination."

Id. at 1755. The Court held that software is a "component" only when embodied in "an actual, physical copy . . . delivered by CD-ROM or some other means capable of interfacing with the computer." *Id*. at 1756.

Addressing the second question, the Court concluded that Microsoft did not supply components of the foreign computers from within the U.S., because the actual copies of Windows installed on those computers were made outside the country. *Id*. at 1756. The master disk shipped by Microsoft was never itself installed on any computer, but was used only to make installable copies. As explained by the Court:

> [T]he very components supplied from the United States, and not copies thereof, trigger Section 271(f) liability when combined abroad to form the patented invention at issue. Here . . . the copies of Windows actually installed on the foreign computers were not themselves supplied from the United States.

Id. at 1757. The ease of making a software copy does not erase the distinction between a master disk supplied from the U.S. and copies made overseas. Only the installed copies qualified as "components" under Section 271(f), and those were not supplied from the U.S. Accordingly, Microsoft was not liable for the use of its software on foreign computers.

In the Court's view, any doubt as to whether Microsoft's conduct falls outside of Section 271(f) can be resolved by the presumption against extraterritorial extension of U.S. patent protection. *Id*. at 1758. AT&T's remedy against foreign copying lies not in the U.S. patent system, but in "obtaining and enforcing foreign patents." *Id*. at 1759. The Court acknowledged that its interpretation of Section 271(f) would be seen by some as an unfair "loophole" through which

software manufacturers can escape liability. *Id*. But the resolution of that issue "is properly left for Congress to consider." *Id*.

Justice Alito's concurring opinion (joined by Justices Thomas and Breyer) argued that even if Microsoft had shipped the installation copies from the U.S., it would still not be liable under Section 271(f). *Id*. at 1762. Since the installation disks never become physical parts of the foreign-made computers, they are not "components" of those computers under the statute.

Justice Stevens filed a dissenting opinion contending that "if a disk with software inscribed on it" was a component, then "the most important ingredient of that component" – the software itself – should also be a component. *Id*. at 1763. In his view, Section 271(f) is broad enough to cover "indirect transmission [of software] via a master disk." *Id*.

C. *MedImmune v. Genentech* – Enabling Declaratory Judgment Actions by Patent Licensees

On January 9, 2007, the Supreme Court issued its decision in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007), holding that a patent licensee need not breach or terminate its license before seeking declaratory judgment that the underlying patent is invalid, unenforceable or not infringed. The Court's opinion was delivered by Justice Scalia, joined by all Justices except Justice Thomas, who dissented.

Background

MedImmune manufactures Synagis, a drug used to prevent respiratory tract disease in infants and young children. In 1997, MedImmune took a license to an existing Genentech patent and a pending Genentech patent application, both for technology pertinent to Synagis. In 2001, Genentech's patent application issued as the "Cabilly II" patent. Genentech sent a letter to MedImmune asserting that Synagis was covered by the Cabilly II patent and that MedImmune was obligated to pay royalties under the license. Although MedImmune purportedly believed that the patent was invalid, unenforceable, and not infringed, it paid the demanded royalties to avoid the risk of a patent infringement suit. At the same time, it sought a declaratory judgment that the Cabilly II patent was invalid, unenforceable, and not infringed.

The district court dismissed MedImmune's declaratory judgment action for lack of subject matter jurisdiction, relying on the Federal Circuit's decision in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (2004). *Gen-Probe* held that unless a patent licensee breaches the license by refusing to pay royalties, there is no Article III case or controversy and the federal courts lack jurisdiction to entertain a declaratory judgment action. The Federal Circuit affirmed the district court's ruling.

The Supreme Court's Decision

In reversing the Federal Circuit's judgment, the Court held that a patent licensee has standing to bring a declaratory judgment action against the underlying patent, even while protected from the threat of an infringement action because it is still paying royalties under the license.

Under the Declaratory Judgment Act and the Article III case-or-controversy requirement, jurisdiction is proper if "there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune,* 127 S. Ct. at 771 (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.,* 312 U.S. 270, 273 (1941)). The Court observed that Genentech's letter asserting its patent and demanding royalties was viewed by MedImmune as a threat to enforce the patent and seek injunctive relief. Although MedImmune continued paying royalties in order to eliminate the imminent threat of litigation, it was still entitled to bring suit to resolve the underlying controversy of the patent's validity, enforceability, and scope.

Examining its precedents, the Court noted that "where threatened action by government is concerned, we do not require a plaintiff to expose himself to liability before bringing suit to challenge

the basis for the threat." *Id*. at 772. When a plaintiff refrains from violating the law, he "eliminates the imminent threat of prosecution, but nonetheless does not eliminate Article III jurisdiction" over the plaintiff's challenge. *Id*. Indeed, the Declaratory Judgment Act is designed to save a challenger from "the choice between abandoning his rights or risking prosecution." *Id*. at 773. In short, when faced with a "genuine threat of enforcement," a plaintiff need not violate the law before challenging it. *Id*. at 772-73 (emphasis in original).

The Court acknowledged that its "jurisprudence is more rare regarding application of the Declaratory Judgment Act to situations in which the plaintiff's self-avoidance of imminent injury is coerced by threatened enforcement action of *a private party* rather than the government." *Id*. at 773 (emphasis in original). Nonetheless, the Court did find relevant authority in *Altvater v. Freeman*, 319 U.S. 359 (1943), which "held that a licensee's failure to cease its payment of royalties did not render nonjusticiable a dispute over the validity of the patent." *Id*. The Court in *Altvater* noted that the royalties "were being paid under protest and under the compulsion of an injunction decree." *Altvater*, 319 U.S. at 365. The *Altvater* Court concluded that "the requirements of [a] case or controversy are met where payment of a claim is demanded as of right and where payment is made, but where the involuntary or coercive nature of the exaction preserves the right to recover the sums paid or to challenge the legality of the claim." *Id*.

The fact that *Altvater* involved an actual injunction, as opposed to only a threat of injunction, did not distinguish it, in the Court's view, from MedImmune's circumstance. *MedImmune,* 127 S. Ct. at 774. The *Altvater* Court observed that "an 'actual or threatened serious injury to business or employment' by a private party can be as coercive as other forms of coercion supporting restitution actions at common law." *Id*. Whether a private party injunction is actual or threatened, it is still sufficiently coercive to create a case or controversy.

Genentech argued that the license agreement itself effectively settled any dispute between the parties concerning the patent, thereby barring any challenge by MedImmune. *Id*. at 775-76. The Court noted that "it is not clear where the prohibition against challenging the validity of the patents is to be found" in the license. *Id*. at 776. Moreover, even if the license agreement or the common law principle of licensee estoppel precluded MedImmune's suit, "the consequence would be that respondents win this case *on the merits – not* that the very genuine contract dispute disappears, so that Article III jurisdiction is somehow defeated." *Id*. (emphasis in original).

The Court concluded that MedImmune "was not required, insofar as Article III is concerned, to break or terminate its 1997 license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed." *Id*. at 777.

Justice Thomas filed a dissenting opinion, arguing that there was no justiciable case or controversy while MedImmune remained a licensee in good standing. *Id*. at 780. Since the license agreement had removed any threat of an infringement suit against MedImmune, there was no controversy in the context of which the courts could properly review MedImmune's affirmative defense of invalidity.

D. *eBay v. MercExchange* – Permanent Injunction is Not Automatic In Patent Cases

In *eBay, Inc. v. MercExchange, LLC*, 126 S. Ct. 1837 (2006), the Supreme Court rejected the Federal Circuit's "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances." *Id*. at 1839. Justice Thomas, in an opinion joined by all Justices (with two concurrences), concluded that the traditional four-factor test for evaluating a request for permanent injunction applied "with equal force to disputes arising under the Patent Act." *Id*.

MercExchange sued eBay for infringing a business method patent covering an electronic market of the kind that eBay operates. *Id*. A jury found the patent valid and infringed and MercExchange sought a permanent injunction. The district court denied MercExchange's request, but the Federal Circuit reversed, noting that permanent injunctions are generally granted to prevailing patentees in infringement suits.

In reversing the Federal Circuit, the Court observed that a plaintiff seeking a permanent injunction is always required to satisfy the traditional four-factor test: "A plaintiff must demonstrate (1) that it has suffered irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *Id*.

The Court found nothing in the Patent Act to exempt patent cases from these "well-established principles of equity" and allow for automatic issuance of permanent injunctions. *Id*. "To the contrary, the Patent Act expressly provides that injunctions 'may' issue 'in accordance with the principles of equity.'" *Id*.

The Court also stated that it would be inappropriate to categorically deny permanent injunctions to particular types of patent holders, such as those who seek to license their patents but do not practice the patented inventions. *Id*. at 1840. All prevailing patent holders must be given the opportunity to satisfy the four-factor test for injunctive relief. *Id*.

In a concurring opinion, Chief Justice Roberts (joined by Justices Scalia and Ginsburg) agreed that the traditional four-factor test for injunctive relief must be used in patent cases, but noted that "[f]rom at least the early 19th century, courts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases." *Id*. at 1841. The Chief Justice suggested that this historical practice arose from "the difficulty of protecting a right to *exclude* through monetary remedies that allow an infringer to *use* an invention against the patentee's wishes – a difficulty that often implicates the first two factors of the traditional four-factor test." *Id*. (emphasis in original). The Chief Justice encouraged courts to be mindful of this historical practice when ruling on injunctive relief in patent cases.

Justice Kennedy filed a separate concurring opinion (joined by Justices Stevens, Souter and Breyer) observing that the historical tendency to grant injunctions in patent cases may not be appropriate in certain types of patent disputes lately arising in the trial courts. *Id*. at 1842. In particular, he suggested that suits brought by so-called "patent trolls" ("firms us[ing] patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees") and suits involving "patents over business methods" might not merit injunctive relief. *Id*. For patent trolls, an injunction "can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent." *Id*. In these cases, "legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest." *Id*. As for business method patents, "[t]he potential vagueness and suspect validity of some of these patents may affect the calculus under the four-factor test." *Id*.

In the wake of *eBay*, district courts appear to be heeding Justice Kennedy's advice to deny injunctive relief to non-practicing patentees. For example, a permanent injunction was denied in four out of five of the most recent cases involving adjudicated infringers and patentees who do not practice the patented invention.[2]

E. *Illinois Tool Works v. Independent Ink* – No Presumption of Market Power in Tying Arrangements Involving a Patented Product

In a case of importance to both antitrust and patent law, the Supreme Court in *Illinois Tool Works, Inc. v. Independent Ink, Inc.,* 547 U.S. 28 (2006) overruled the longstanding presumption that a patent confers market power on the patentee, rendering any tying arrangement with the patented product a *per se* antitrust violation. In a unanimous opinion by Justice Stevens, the Court held that a patent does not presumptively confer market power on the patentee. Instead, a plaintiff must prove that market power exists in the relevant market.

2 *See z4 Techs., Inc. v. Microsoft Corp*., 434 F. Supp. 2d 437 (E.D. Tex. 2006); *Finisar Corp. v. DirecTV Group, Inc.*, 2006 U.S. Dist. LEXIS 76380 (E.D. Tex. July 7, 2006); *Paice LLC v. Toyota Motor Corp.*, 2006 U.S. Dist. LEXIS 61600 (E.D. Tex. Aug. 16, 2006); *Sundance, Inc. v. Demonte Fabricating Ltd.*, 2007 U.S. Dist. LEXIS 158 (E.D. Mich. Jan. 4, 2007); *but see Commonwealth Scientific and Industrial Research Organization v. Buffalo Tech. Inc.,* 2007 U.S. Dist. LEXIS 43832 (E.D. Tex. June 15, 2007) (injunction granted).

Illinois Tool Works and its subsidiary sold a printing system that included two patented components and a specially designed, but unpatented, ink. Buyers of the printing system had to agree to purchase ink exclusively from Illinois Tool Works. Independent Ink, a competing ink manufacturer, sued Illinois Tool Works seeking to invalidate its patents and accusing it of illegal tying in violation of Sections 1 and 2 of the Sherman Act. *Id.* at 31-32. The district court granted summary judgment to Illinois Tool Works on both Sherman Act claims, but the Federal Circuit reversed as to the Section 1 claim.

The Supreme Court reversed the Federal Circuit's ruling. The Court observed that "[o]ver the years . . . this Court's strong disapproval of tying arrangements has substantially diminished," as the law has increasingly recognized "that tying arrangements may well be procompetitive." *Id.* at 35-36. Nonetheless, tying arrangements involving patented products continued to be regarded as *per se* antitrust violations, since a patent was presumed to confer market power over the patented product, enabling a patentee "to force a purchaser to do something that he would not do in a competitive market." *Id.* at 37 (citation omitted).

The presumption of market power in a patented product arose from the doctrine of patent misuse, under which it was "assumed that, by tying the purchase of unpatented goods to the sale of the patented good, the patentee was 'restraining competition' . . . or 'secur[ing] a limited monopoly of an unpatented material.'" *Id.* at 38 (citation omitted). This presumption "migrated from patent law to antitrust law in *International Salt Co. v. United States*, 332 U.S. 392 (1947)." *Id.* at 38-39. In 1988, Congress amended the patent code to eliminate the presumption of market power in the patent misuse context. *Id.* at 41-42. Consequently, the Supreme Court felt it necessary and appropriate to reappraise the presumption of market power over patented products in the antitrust context. *Id.* at 42.

"After considering the congressional judgment reflected in the 1988 amendment," the Court concluded that tying arrangements involving patented products should not be deemed *per se* antitrust violations, relying on a presumption of market power in the patented product. *Id.* at 42-43. Instead, any conclusion that a tying arrangement is unlawful "must be supported by proof of power in the relevant market."

F. *Merck v. Integra* – Expanding the Section 271(e)(1) Safe Harbor for Use of Patented Inventions in Connection with Drug Regulatory Submissions

The Supreme Court's decision in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), examined the scope of Section 271(e)(1) of the Patent Act, which states that it is not infringement to use a patented invention in connection with developing and submitting information under a federal law regulating the use of drugs. In a unanimous opinion delivered by Justice Scalia, the Court held that the "use of patented compounds in preclinical studies is protected under Section 271(e)(1) at least as long as there is a reasonable basis to believe that the compound tested could be the subject" of a regulatory submission, even if the results of the preclinical studies are not ultimately included in the submission.

Integra and the Burnham Institute (collectively, "Integra") own five patents related to the use of protein-like substances known as "RGD peptides." Merck conducted research aimed at developing drugs to inhibit angiogenesis, the process by which new blood vessels sprout from existing vessels. Part of that research involved preclinical experiments on RGD peptides, to evaluate their suitability as angiogenesis inhibitors and determine which peptides were the most promising candidates for human testing. Subsequently, Merck submitted one of its RGD peptides to the Food and Drug Administration to obtain approval for clinical trials (i.e., human testing).

Integra sued Merck for patent infringement, alleging that Merck's use of RGD peptides in its research violated Integra's patents. Merck answered that its experiments on RGD peptides did not infringe Integra's patents and that the research was protected by the Section 271(e)(1) safe harbor. A jury found that Merck infringed the Integra patents and had failed to show that its research was protected by Section 271(e)(1). The Federal Circuit affirmed the verdict as to Section 271(e)(1), stating that Merck's research "was not clinical testing to supply information to the FDA,

but only general biomedical research to identify new pharmaceutical compounds." *Id*. at 201 (citation omitted).

In reversing the Federal Circuit, the Supreme Court observed that Section 271(e)(1) "provides a wide berth for the use of patented drugs in activities related to the federal regulatory process." *Id*. at 202. The Court stated that "Section 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information" to the FDA, including "preclinical studies of patented compounds." *Id*.

The Court rejected Integra's argument that the FDA is only interested in preclinical data related to a drug's safety, noting that a drug's efficacy is also a concern for the FDA. Accordingly, preclinical research on drug characteristics other than safety is protected by Section 271(e)(1). *Id*. at 203.

The Court found that Section 271(e)(1) could also protect "(1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA," so long as the experiments, if successful, "would be appropriate to include in a submission to the FDA." *Id*. at 206-07. While the statute does not cover basic scientific research with no intent to develop a particular drug, it does protect experimentation designed to ascertain which drugs should be submitted for FDA approval. Such experimental, preclinical research is covered by Section 271(e)(1), even if it is not ultimately submitted to the FDA. *Id*.

G. *Laboratory Corporation v. Metabolite* (certiorari dismissed as improvidently granted) – Dissenters Would Have Invalidated Metabolite's Vitamin Deficiency Test Claim as an Unpatentable "Law of Nature"

Although the Supreme Court dismissed the writ of certiorari in *Metabolite* as improvidently granted, the dissent by Justice Breyer (joined by Justices Stevens and Souter) warrants some consideration as a possible indicator of the Court's future direction on the issue of patentable subject matter. *Laboratory Corp. of America v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006).

Metabolite addressed the validity of a patent covering a diagnostic test used to detect a certain type of vitamin deficiency in human beings. In the 1980s, three university doctors discovered a correlation between high levels of an amino acid called homocysteine in the blood and deficiencies of two essential vitamins. *Id*. at 2923. They developed new methods for testing homocysteine levels and obtained a patent on those methods. The patent also included a broader claim, Claim 13, covering *any test* used to measure homocysteine for the purpose of determining vitamin deficiency. The rights to the patent were eventually obtained by Competitive Technologies, Inc. and its licensee, Metabolite.

Laboratory Corporation ("LabCorp") took a license from Metabolite allowing it to use the specific homocysteine tests claimed in the patent. *Id*. Subsequently, LabCorp began using an alternative homocysteine test developed by Abbott Laboratories. As the Abbott test was not one of the specific tests described in the patent, LabCorp declined to pay royalties to Metabolite for use of the Abbott test. Metabolite sued LabCorp for infringing Claim 13, which covered any homocysteine test used to correlate an elevated homocysteine level with vitamin deficiency. *Id*. at 2923-24.

The lower courts found that Claim 13 was valid and infringed. LabCorp petitioned the Supreme Court for a writ of certiorari, which was initially granted on the following question: "Whether a method patent . . . directing a party simply to 'correlate' test results can validly claim a monopoly over a basic scientific relationship . . . such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result." *Id*. at 2925. The Court heard oral argument on March 21, 2006. Three months later, the Court voted to dismiss the writ as improvidently granted. From the questions posed at oral argument, it appears that the dismissal was based on LabCorp's failure to preserve the issue of patentable subject matter for review.[3]

3 Transcript of Oral Argument, *Laboratory Corp. of America v. Metabolite Labs., Inc.,* No. 04-607 (March 21, 2006) (http://www.supremecourtus.gov/oral_arguments/argument_transcripts/04-607.pdf).

Justice Breyer, joined by Justices Stevens and Souter, issued a written opinion dissenting from the dismissal. These three Justices would have found Claim 13 invalid as an improper attempt to patent a "law of nature." *Id.* at 2928. Justice Breyer's opinion began by reciting the principle that patent protection excludes "laws of nature, natural phenomena, and abstract ideas." *Id.* at 2922. "[T]he reason for the exclusion is that sometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection." *Id.* (emphasis in original). While patent protection is intended to encourage research "by providing monetary incentives for invention," too much protection can discourage research "by forcing researchers to avoid the use of potentially patented ideas . . . and by raising the costs of using the patented information, sometimes prohibitively so." *Id.*

To help strike the right balance, patent law excludes from the scope of patentable subject matter fundamental scientific, mathematical, and technological principles. *Id.* at 2922-23. That exclusion reflects both "'the enormous potential for rent seeking that would be created if property rights could be obtained in [those basic principles] and . . . the enormous transaction costs that would be imposed on would-be users.'" *Id.* (quoting W. Landes & R. Posner, *The Economic Structure of Intellectual Property Law* 305 (2003)).

Justice Breyer concluded that Claim 13 was an invalid effort to patent a "phenomenon of nature." *Id.* at 2926-27. There was "little doubt that the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a 'natural phenomenon.'" *Id.* at 2927. Metabolite defended the claim as a patentable "*application* of a law of nature" involving a physical transformation of matter – the alteration of a blood sample during the homocysteine test. *Id.* (emphasis added). But Justice Breyer observed that Claim 13 was not a specific process for testing blood – the homocysteine level could be determined using any blood test at all. Instead, the claim described the mental process of correlating a test result showing an elevated homocysteine level with vitamin deficiency. *Id.* at 2928. A doctor could infringe the claim merely by thinking about the relationship between homocysteine and vitamin deficiency after looking at the test result. In Justice Breyer's view, the claimed correlation was "an unpatentable 'natural phenomenon.'" *Id.*

II. CONNECTING THE DOTS: THE SUPREME COURT'S CONTRIBUTIONS TO PATENT REFORM

Ideas for "reforming" the U.S. patent system have been percolating in both the executive and legislative branches for many years. Perceived problems with the current system were closely examined by the Federal Trade Commission and the Department of Justice in 2002. The PTO has recently proposed and implemented several important rule changes and Congress has been mulling sweeping patent reform legislation for several years. Motivating this reform activity is the increasing perception in some industries that the current patent system is unbalanced, perhaps stacked too heavily in favor of patent applicants and patentees. The inherent limitations of the PTO's examination process, in this view, may have resulted in the issuance of numerous patents of questionable validity. An abundance of such patents in the U.S. economy would hobble, rather than promote, innovation, and needlessly increase the costs of patent compliance. Others, however, think the perceived problems are exaggerated, and that examples of problematic patents are anomalies or outliers. They assert that the patent system overall works well, and promotes investment in risky R&D activities that produce innovation and technology jobs in the United States.

The Supreme Court's recent patent law jurisprudence seems to reflect a sharp awareness of the "patent reform" movement and the problems that have been identified in the current patent system. A majority of the Court appears to have embraced the arguments of the patent reformers. There is little doubt that the Supreme Court has been paying greater attention to patent law in the last several years, culminating with its heavy 2007 output. In the new millennium, the Supreme Court has issued rulings in eight cases involving patent law issues, six of which were decided in just the last three years (*see* Table 1). In five out of the last six cases, the Court's decisions cut against the patentee and effected a narrowing of patent rights in some manner. In all but one of the last eight patent cases, the high court reversed the ruling of the Federal Circuit.

Table 1	
2007	*KSR; Microsoft; MedImmune*
2006	*eBay; Illinois Tool Works*[4]
2005	*Merck*
2004	None
2003	None
2002	*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*[5]
2001	*J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*
2000	None[6]

Examining the decisions from 2005 to 2007, at least two unifying themes can be discerned. First, the Court has recognized and is endeavoring to mitigate the problem of "questionable patents." *KSR* will make it more difficult for patent applicants and patentees to clear the obviousness hurdle, whether in front of the PTO or in litigation. *MedImmune* will increase the number of challenges to patent validity by removing the jurisdictional barrier formerly facing patent licensees. And if Justice Kennedy's concurrence in *eBay* gains traction, owners of business method patents (which are criticized for "vagueness and suspect validity") and patentees who do not themselves use their patents may find it difficult or impossible to obtain injunctions, arguably reducing the value of those patents.

The second theme evident in the Court's recent cases is the desire to avoid patent rules that would drive research and development activities offshore. Had the Court in *Microsoft* extended patent coverage to American-developed software shipped overseas, U.S. software manufacturers would have had additional reason to move their software development offshore. The same logic might underlie the Court's decision in *Merck* – i.e., a broad construction of the Section 271(e)(1) safe harbor gives more leeway to American drug researchers and avoids pushing research overseas.

A. *Patent Reform Efforts in the PTO and Congress*

Before examining the Supreme Court's jurisprudence any further, it will be helpful to take a quick look at the efforts of the other branches of government to change the patent system.

In 2002, the Federal Trade Commission ("FTC") and Department of Justice ("DOJ") held hearings to "examine the current balance of competition and patent law and policy."[7] Input was obtained from more than 300 panelists, including business representatives, and leading patent and antitrust organizations, practitioners, and scholars. *Id*. at 3-4 (Executive Summary). In an October 2003 report, the FTC concluded that although most of the patent system worked well, modifications were needed to maintain a proper balance of competition and patent law and policy. *Id*. at 4-5. In particular, the FTC observed that the number of "questionable patents" issued by the PTO raised significant competitive concerns and posed a threat to innovation. *Id*. at 5. The FTC defined a "questionable patent" as "one that is likely invalid or contains claims that are likely overly broad." *Id*. The FTC noted that the high cost of patent litigation might lead competitors to forgo research and development in the area covered by the questionable patent, rather than challenge the patent's validity. *Id*. at 5-6. This reduces competition in the covered market and deters follow-on innovation.

The FTC reported that in certain industries, such as the computer hardware and software sectors, the constant emergence of incremental technological innovations has produced a large number of overlapping patents that companies must confront when developing their products. *Id*. at

4 Although the underlying litigation in *Unitherm Food Systems, Inc. v. Swift-Eckrich, Inc.*, 546 U.S. 394 (2006) was an action for declaratory judgment of patent invalidity and unenforceability, the Supreme Court's opinion did not address issues of patent law, but was directed solely to a question of federal civil procedure.

5 *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002) addressed the issue of Federal Circuit jurisdiction over patent law counterclaims, but did not cover substantive patent law issues.

6 The underlying litigation in *Nelson v. Adams USA, Inc.*, 529 U.S. 460 (2000) involved claims for patent infringement, but the Supreme Court's opinion was limited to civil procedure issues.

7 *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Report by the FTC (October 2003) (http://www.ftc.gov/os/2003/10/innovationrpt.pdf).

6. To strengthen their bargaining position, firms devote considerable effort to obtaining "defensive patents," adding to the volume of overlapping rights. The FTC stated that questionable patents contribute significantly to the "patent thicket" in these industries. *Id*. at 7.

To improve patent quality, the FTC made a number of reform recommendations, including:

* Create an administrative procedure for post-grant review and opposition to patents, allowing third parties more robust involvement (including cross-examination and discovery opportunities) than the current re-examination process. *Id*. at 7-8.

* Change the standard for proving patent invalidity from "clear and convincing evidence" to "preponderance of the evidence." *Id*. at 8-10.

* Tighten the obviousness standard to "assume an ability to combine or modify prior art references that is consistent with the creativity and problem-solving skills" of a person of ordinary skill in the art. *Id*. at 11-12.

* Require patent applicants to submit statements upon request explaining the relevance of prior art submitted for review. *Id*. at 13.

* Enact legislation requiring publication of all patent applications eighteen months after filing. *Id*. at 15.

The FTC's report and its recommendations were widely publicized at the time. The report undoubtedly came to the attention of the Court at some point, as it was cited in Justice Kennedy's concurrence in *eBay*. *eBay*, 126 S. Ct. at 1842.

In recent years, the PTO has proposed and implemented several rule changes aimed at improving its examination process, a key concern for patent reformers. For example, in July 2006, the PTO proposed a rule change requiring applicants to explain the relevance of prior art references submitted for review.[8] This proposed change was designed to discourage applicants from overburdening the examiner with too much prior art documentation, thereby obscuring the most pertinent information. *Id*. This change was among the recommendations in the FTC's report. In August 2007, the PTO announced a final rule placing certain restrictions on the number of claims in a patent application, as well as the number of continuation applications an applicant can file.[9] The stated intention of this rule was to improve the quality of the PTO's examination process.[10]

In the last several years, Congress has taken an active interest in patent reform. Patent reform bills contemplating substantial changes to the patent system have been introduced in both houses, including H.R. 1908, passed by the House of Representatives in September 2007.[11] H.R. 1908 embodies a great number of reform proposals championed over the years by certain business interests, as well as patent practitioners and scholars. Highlights of the bill include:

* First-to-file system: Patents would be awarded to the first inventor to file an application, rather than the first to invent the claimed innovation. This change would bring the U.S. patent system in line with other jurisdictions.

* Damages: Reasonable royalty calculations could be based on (1) the economic value of the accused product attributable to the patent's specific contribution over the prior art, (2) the entire market value of the product if the patented

8 Changes to Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38808 (July 10, 2006) (summary and link at http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/focuspp.html).

9 Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46716 (August 21, 2007) (summary and link at http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html).

10 In April 2008, the United States District Court for the Eastern District of Virginia found that the new rule exceeded the PTO's rulemaking authority. *Tafas v. Dudas*, Case No. 07-846-JCC (E.D. Va. Apr. 1, 2008). The PTO has appealed that decision.

11 H.R. 1908, 110th Congress (2007) (http://www.rules.house.gov/110/text/110_hr1908.pdf).

invention was the predominant reason for the product's market demand, or (3) other factors as defined by the courts.

* Post-Grant Review: A post-grant review procedure would be created, allowing broader involvement for third parties than the current re-examination process. An unsuccessful attempt to invalidate a patent during the post-grant review proceeding would preclude the challenger from asserting invalidity on the same grounds in litigation.

* Willful Infringement: Makes "willfulness" the sole reason for awarding treble damages and heightens the standard for proving willfulness. The Federal Circuit's decision in *In re Seagate Tech*., 497 F.3d 1360 (Fed. Cir. 2007), may have the same effect as the House bill, but the legislation offers a more precise structure for determining willfulness.

* Venue: Imposes venue limitations to discourage forum-shopping by plaintiffs.

The Senate is also considering a patent reform bill, S. 1145, with many of the same features as the House bill, including the first-to-file system, refinement of the reasonable royalty calculation, heightening of the willful infringement standard, and post-grant review proceedings.[12]

B. *The Supreme Court Tackles "Questionable Patents"*

The Supreme Court's most dramatic contribution to patent reform came in *KSR*, with the refinement of the obviousness standard. By scaling back the Federal Circuit's TSM test and placing greater reliance on the "ordinary creativity" of a person of skill in the art, the Court has made it easier to invalidate patents on grounds of obviousness. *KSR*, 127 S. Ct. at 1742. This will raise the hurdle for patent applicants and patentees defending their claimed inventions during PTO examination, on re-examination, or in litigation.

KSR will have an especially heavy impact on those industries with large numbers of patents covering small, incremental advances in technology. As described in the 2003 FTC report, the computer hardware and software sectors, as well as consumer electronics, automotive, and similar industries, progress through a continual accretion of small technological improvements designed to give products a competitive edge. Many such improvements are obvious combinations of pre-existing techniques and devices. In a rapidly developing market, the published literature may never mention the possibility of these small improvements, even while they are well-understood by persons of skill in the art. It is for this reason that *KSR* advises courts against overemphasizing the published prior art to find a teaching, suggestion or motivation to combine pre-existing elements. *Id*. at 1741.

KSR reflects an awareness of different types of innovation in different industries. Rapidly moving, high-tech industries may not require much patent protection to thrive. Some argue that incremental advances in electronic technologies would emerge with or without patent rights, as companies strive to stay on top in a quickly evolving marketplace. Advocates of this view suggest that the profits to be captured by the first company to bring a new feature to market are sufficient incentive to spur many advances. This is especially true if the investment costs are low and development time short.

The Supreme Court drew a sharp distinction between "real innovation" and advances in the "ordinary course," the former of which is the intended beneficiary of patent law. The Court observed that "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility." *Id*. at 1741. While "real innovation" typically requires exceptional creativity and high development costs, advances in the "ordinary course" arise routinely with much less effort and expense. *KSR* dealt with a patent covering an ordinary advance in

12 S. 1145, 110th Congress (2007) (http://www.govtrack.us/congress/billtext.xpd?bill=s110-1145).

automotive technology, but that is hardly the only industry experiencing a proliferation of such patents. Under *KSR*, advances in the "ordinary course" are more easily excluded from patent protection through application of the obviousness test.

Along with *KSR*, the Court's decision in *MedImmune* may also help to reduce the volume of questionable patents in effect. *MedImmune* clears the way, on a jurisdictional level, for use of the "pay and sue" strategy by licensees. Under this approach, a licensee eliminates the risk of being sued for infringement by paying royalties under the license, while simultaneously attacking the underlying patent's validity. Before *MedImmune*, some alleged infringers preferred to pay royalties even on a patent they believed to be invalid, rather than challenge the patent and risk the potentially crippling effect of an injunction and patent infringement damages. These licensees were often the only parties with an interest in attempting to invalidate the patent. *MedImmune* makes it easier for interested parties to challenge questionable patents. Removing such patents from circulation, if indeed they are invalid, benefits the industry to which they pertain and the economy at large.

Of course, *MedImmune's* impact may be blunted by changes in patent licensing practice. One obvious solution for patentees is to include a license provision prohibiting validity challenges or penalizing the licensee for bringing one. Traditionally, courts have held such "no-challenge" clauses to be unenforceable. *See, e.g., Bendix Corp. v. Balax, Inc.*, 471 F.2d 149 (7th Cir. 1972). But the *MedImmune* opinion seems to contemplate the inclusion of no-challenge clauses in patent licenses. In rejecting the patentee's argument that the contract barred a validity challenge, the Court noted that the license lacked a no-challenge clause, but did not suggest that such a clause would be unenforceable. *MedImmune*, 127 S. Ct. at 776. Another alternative is for patentees to demand a lump sum payment up front as opposed to ongoing royalty payments. This arrangement would remove any incentive the licensee might have to subsequently challenge the validity of the patent.

The Court's decision in *eBay* may also play some role in curbing questionable patents, particularly if the viewpoints in Justice Kennedy's concurrence gain wider acceptance. In Justice Kennedy's opinion, injunctive relief may be less appropriate for certain types of patents and patentees. *eBay*, 126 S. Ct. at 1842. Justice Kennedy was especially concerned about patent trolls ("firms [which] use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees") and business method patents. *Id.* In his view, injunctive relief is largely unnecessary for the so-called "patent trolls," who are not seeking to block use of the patented invention, but rather to obtain royalties on it. In these situations, patent damages are sufficient to compensate for the infringement. *Id.* To capture damages from ongoing infringement, some district courts in the wake of *eBay* have effectively imposed compulsory licenses after declining to issue a permanent injunction. *See, e.g., z4 Techs., Inc. v. Microsoft Corp.*, 434 F. Supp. 2d 437 (E.D. Tex. 2006) (requiring Microsoft to provide sales information quarterly to allow damages calculation).

As for business method patents, Justice Kennedy seemed to doubt the propriety of such patents as a class. He stated that the "potential vagueness and suspect validity of some of these patents" may have an effect on the injunctive relief decision. *eBay*, 126 S. Ct. at 1842. The meaning of this comment is not entirely clear, given that decisions on permanent injunction occur only after a patent has already been found valid and infringed. But the remark certainly suggests an underlying skepticism of business method patents, which often amount to obvious computer automations of known business techniques. Whether these patents as a group qualify as "questionable patents" will require a much closer definition of "business method" in the patent context, something the concurring opinion did not provide.

C. *The Court Avoids Disadvantaging American Research and Development*

The Court's decisions in *Microsoft* and *Merck*, while outwardly arising from the intricacies of statutory interpretation, may also have been informed by economic considerations. The attractiveness of the United States as a location for research and development is influenced by numerous factors, including the labor market, educational system, immigration structure, and overall legal and regulatory environment. Certain provisions of American patent law could also play a decisive role in whether a company undertakes its R&D in the U.S. or elsewhere. *Microsoft* and *Merck* addressed two such important provisions.

Had the Court in *Microsoft* construed Section 271(f) to impose liability for software developed in America and sold overseas, Microsoft and other American software developers would have faced a competitive disadvantage vis-à-vis their foreign counterparts. Under this scenario, liability for foreign software sales would depend entirely on where the software was developed – write the software in the U.S. and you infringe U.S. patents; write it elsewhere and you don't. Such a rule would motivate software companies to move their development activities offshore. The domestic software industry has already seen an outflow of business activity to India, China, and other foreign destinations. By correcting an unfavorable patent rule, the Supreme Court in *Microsoft* avoided exacerbating the offshoring problem.[13]

Similar economic logic might have informed the decision in *Merck*. Through an expansive reading of the Section 271(e)(1) safe harbor, the Court gave some relief to American pharmaceutical researchers faced with patent concerns. While the Court made clear that the Section 271(e)(1) safe harbor exempts only research related to regulatory submissions, not basic scientific research (*Merck*, 545 U.S. at 205-06), the heavy regulation of the pharmaceutical industry means that most research will have some relation to a regulatory submission. Accordingly, the Court's broad reading of Section 271(e)(1) may bring virtually all drug research into the protection of the safe harbor.

Such wide protection creates a friendlier environment within the United States for drug research. It does not substantially weaken the rights of patentees, who can still take action against any product incorporating their patented compounds, if not against the research making use of those compounds. Of course, patented inventions whose only use is for research purposes on products subject to the FDA process – i.e., "research tools" – would lose much of their value under a broad research exemption, as the Court acknowledged in *Merck*. *Id*. at 205 n.7. While the Court declined to address this issue, a proper construction of Section 271(e)(1) would need to exclude "research tools" from its ambit.

III. THE CRYSTAL BALL: THE FUTURE OF THE SUPREME COURT'S PATENT JURISPRUDENCE

We conclude with a few projections on the future direction of patent reform in the Supreme Court. The Supreme Court heard one patent case during the October 2007 term, pertaining to the doctrine of patent exhaustion. Several writ petitions (either pending or denied) raised other important patent law issues that the Court is likely to address in the near future.

On September 25, 2007, the Court granted certiorari in *Quanta Computer, Inc. v. LG Electronics, Inc.* (No. 06-937), a case involving the doctrine of patent exhaustion. The following question is presented in *Quanta*: "Whether the Federal Circuit erred by holding, in conflict with decisions of this Court and other courts of appeals, that respondent's patent rights were not exhausted by its license agreement with Intel Corporation, and Intel's subsequent sale of product under the license to petitioners." The patent exhaustion doctrine provides that an authorized first sale of a patented article exhausts the patentee's rights in that specific article, precluding the patentee from controlling or imposing conditions on the use or resale of the article.

LG Electronics owns a portfolio of patents covering combinations of microprocessors with other computer components. Intel took a license to the LG patents permitting Intel to make and sell its microprocessors. The license expressly excluded Intel's customers from its coverage. LG filed infringement suits against several computer manufacturers that use Intel's microprocessors in their computers, including Quanta. The manufacturers argued that the doctrine of patent exhaustion precludes LG from pursuing computer manufacturers for use of the purchased Intel chips. The district court agreed, but the Federal Circuit reversed, finding that the patent exhaustion doctrine was superseded by the express terms of the license. *LG Electronics, Inc. v. Bizcom Elecs., Inc.*, 453 F.3d 1364, 1369-70 (Fed. Cir. 2006). While the license permitted Intel to make and sell its chips, it did

13 The present discussion of the competitive disadvantages of U.S. patent law assumes a less restrictive patent environment in at least some competing nations. It is recognized, of course, that U.S. patent protection may be equaled in many jurisdictions, eliminating any competitive disadvantages that would otherwise exist.

not cover the use of those chips by Intel's customers. The license specifically required Intel to notify its customers that their use of the chips was not covered. Given the conditional nature of the sale, patent exhaustion did not apply and LG was entitled to pursue Intel's customers for patent infringement. *Id*.

During oral argument before the Supreme Court, several justices appeared skeptical that patent exhaustion could be avoided merely by giving notice to customers that subsequent use of the purchased article was not authorized.[14] Intel's sale of microprocessors to its customers was fully authorized under the license, a fact that would ordinarily trigger the exhaustion of LG's patent rights as to those microprocessors. The LG/Intel license did not prohibit Intel from selling its microprocessors to computer manufacturers. Instead, it required Intel to notify the manufacturers that they were not authorized to use the microprocessors in the computers they built. As noted by several Justices, however, that is the only real use the microprocessors have. This led some Justices to ask whether the manufacturer's use of the microprocessors was covered by an implied license, if the patent exhaustion doctrine did not apply. On the whole, the Court did not seem supportive of LG's infringement claims and its efforts to avoid the patent exhaustion doctrine.

In addition to the issues raised by *Quanta*, several writ petitions submitted during the October 2007 term posed other questions that remain undecided in the wake of the Supreme Court's recent cases. Two of the more intriguing questions are highlighted below.

A. *Whither the Presumption of Validity?*

Under 35 U.S.C. Section 282, "[a] patent shall be presumed valid" and the "burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." This presumption of validity is premised on the supposition that the PTO has approved the claims after thoroughly reviewing the patent application and prior art. *See KSR*, 127 S. Ct. at 1745. As patent practitioners and litigators are well aware, the PTO's examination of the prior art is often exceedingly limited, sometimes missing critical pieces of prior art. The patent applicant is only required to disclose prior art known to him (*see* 37 C.F.R. 1.56) and has no obligation to locate other pieces of relevant art. Once the patent issues, it is entitled to a statutory presumption of validity against all prior art, whether or not the art was examined by the PTO.

The Supreme Court's opinion in *KSR* suggests a future change to the presumption of validity as applied to unexamined prior art. A crucial prior art reference in *KSR* was the Asano patent, which had not been disclosed to the PTO. *KSR*, 127 S. Ct. at 1745. In addressing the presumption of validity as against the Asano patent, the Court stated:

> We need not reach the question whether the failure to disclose Asano during the prosecution of Engelgau voids the presumption of validity given to issued patents, for claim 4 is obvious despite the presumption. We nevertheless think it appropriate to note that the rationale underlying the presumption – that the PTO, in its expertise, has approved the claim – seems much diminished here.

Id. From this statement, it appears that the Court is interested in addressing whether the presumption of validity should be limited, in appropriate cases, only to examined prior art.

At least two writ petitions submitted during the October 2007 term asked the Court to consider the presumption of validity vis-à-vis examined and unexamined prior art. The petition in *PharmaStem Therapeutics Inc. v. ViaCell Inc.* (No. 07-888, cert. denied 3/17/08) asked whether the presumption of validity is strengthened when the PTO has examined the prior art in question. The petition in *Microsoft Corp. v. z4 Techs. Inc.* (No. 07-1243, petition dismissed 5/8/08) posed the opposite question – is the presumption of validity weakened when the prior art was not examined by the PTO? While neither petition was granted, this issue will likely come before the Court again.

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14 Transcript of Oral Argument, *Quanta Computer, Inc., v. LG Electronics, Inc.,* No. 06-937 (January 16, 2008) (http://www.supremecourtus.gov/oral_arguments/argument_transcripts/06-937.pdf).

Applying the presumption of validity only to examined prior art, as suggested in *KSR*, would be eminently sensible and beneficial to the patent system. It would encourage applicants to research and submit more relevant prior art to the PTO, since only examined art (and the technical teachings they contain) would be given a presumption of validity. Unexamined prior art containing non-cumulative teachings would not be entitled to the presumption. With more relevant art, PTO examiners would be better able to identify and reject obvious claims, thereby improving the quality of issued patents. Of course, applicants might attempt to hide relevant prior art by flooding the examiner with weak or cumulative references. The PTO's proposed rule requiring applicants to explain submitted prior art might help protect examiners from such abuse, even though the rule would greatly burden the applicant. *See supra*, note 8.

Some scholars have proposed more radical reform with respect to the presumption of validity.[15] Under one proposal, the PTO would cease to examine submitted claims for patentability over the prior art.[16] Instead, the patent would simply be "registered" with the PTO and issued without a presumption of validity. *Id*. The PTO could still check an application for form requirements under 35 U.S.C. Section 112 and other applicable sections, but would not review prior art to determine validity under Sections 102 and 103. This approach avoids the fundamental limitations of PTO examination by eliminating it altogether. If and when a patent is litigated, the parties would then sort out the validity issues, with the burden of establishing validity resting with the patentee. This would enhance the efficiency of validity determinations, as explained by one scholar: "Because so few patents are ever asserted against a competitor, it is much cheaper for society to make detailed validity determinations in those few cases than to invest additional resources examining patents that will never be heard from again."[17] Of course, such significant changes would be a matter for Congress, not the Supreme Court.

B. ***Patentable Subject Matter***

Another issue that the Court may wish to revisit in the near future is the scope of patentable subject matter under 35 U.S.C. Section 101. Some method claims covering medical, scientific, and business techniques may be pushing the line between abstract ideas and concrete inventions. The Court heard arguments on one such claim in *Metabolite*, before dismissing that writ as improvidently granted. But the dismissal appears to have been based on defendant's failure to preserve the Section 101 issue for review, not a disinclination to decide the underlying question of patentable subject matter. Indeed, three Justices were fully prepared to decide the issue and clarify the boundaries of patentable subject matter. *Metabolite*, 126 S. Ct. 2921 (Breyer, J., dissenting from cert. dismissal, joined by Stevens, J., and Souter, J.). At least one other Justice expressed similar concerns during oral argument.[18] The fundamental issue in *Metabolite* – the patentability of a biological correlation attached to an otherwise non-novel method – may arise before the Court again, with the issue properly preserved for review.

Some of the Justices on the Court also appear to be skeptical about the patentability of software-related or "business method" inventions, as evidenced by questions raised at oral argument in *eBay* and *KSR*. The PTO and the Federal Circuit seem to be cognizant of the Justices' concerns over patentable subject matter, resulting in a stricter policing of the issue. For example, in *In re Comiskey*, 499 F.3d 1365 (Fed. Cir. 2007), the Federal Circuit found that a "method for mandatory arbitration resolution" was not patentable subject matter, under Section 101. *Id*. at 1379. The method did not involve a machine of any kind and did not alter the composition of matter. It was, instead, an unpatentable method for applying human intelligence. By contrast, the court determined that the same method performed using a computer, as described in some of the claims, did constitute patentable subject matter. *Id*.

15 *See* F. Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 B.C. L. Rev. 55 (2003); Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495 (2001).
16 Kieff, *supra* note 11, at 71.
17 Lemley, *supra* note 11, at 1497.
18 Transcript of Oral Argument, *Laboratory Corp. of America v. Metabolite Labs., Inc.,* No. 04-607 (March 21, 2006) (Justice Scalia posed several questions evincing skepticism of the method's patentability) (http://www.supremecourtus.gov/oral_arguments/argument_transcripts/04-607.pdf).

In another recent ruling on Section 101, the Federal Circuit concluded that "digital watermarks" (i.e., electromagnetic or electrical signals designed to mark electronic data files) were unpatentable, because they did not fit within the categories of patentable subject matter set forth in Section 101. *In re Nuijten,* 500 F.3d 1346, 1357 (Fed. Cir. 2007). A writ petition was filed in *Nuijten* on May 9, 2008. *Nuijten v. Dudas* (No. 07-1404, review sought 5/9/08).

Most recently, the Federal Circuit, sitting *en banc*, heard oral argument in *In re Bilski* (No. 07-1130), in which the patentability of a business method, untethered to any machine, is at stake. Bilski's patent covers a method for managing risks associated with commodities trading. As in *Comiskey*, the method does not involve the use of a machine or the transformation of matter. In addition to the specific question of whether Bilski's method is patentable, the court inquired as to whether its ruling in *State Street Bank,* upholding the patentability of business methods, remains good law. *See State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1369 (Fed. Cir. 1998). The outcome of *Bilski* may decide the fate of thousands of patents. Whichever way the case is decided, an appeal to the Supreme Court is almost certain to follow, providing the Justices another opportunity to resolve the concerns over patentable subject matter raised in *eBay* and *KSR.*

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Supreme Court experts and commentators have suggested that the Court will continue to scrutinize certain areas of Federal Circuit patent law based on a belief by some Justices that U.S. patent law is out-of-balance in significant respects and needs correction. It is important that the Justices remain closely tuned to the ongoing patent policy debates and strike the right balance between patent rights and competition. Unless and until Congress passes significant patent legislation, the Supreme Court will likely remain the most important driver of change in the U.S. patent system.