PATENT REFORM IN THE COURTS, THE CONGRESS, AND THE PATENT OFFICE

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"Change" is the buzzword of the current political season. But change has already come to the patent system, and the promise (or threat, depending on your perspective) of more change is in the air. Understanding the implications of recent and proposed patent reforms is essential for anyone engaged in technology development and commercialization. The significant recent developments and pending proposed patent law revisions are summarized and discussed in this report.

I. INTRODUCTION

The last several years have seen a flurry of patent reform activity. The Supreme Court has accepted nine patent cases for review in its last four terms,[1] and the United States Court of Appeals for the Federal Circuit has granted *en banc* review of several key patent law questions.[2] Comprehensive patent reform legislation has been proposed, revised, and debated during each of the present and immediate past congressional sessions.[3] And the United States Patent and Trademark Office (USPTO) has promulgated sweeping and controversial new prosecution rules.[4]

This report summarizes the changes that have already been implemented and highlights potential additional developments. It assesses their significance for universities and businesses engaged in or planning technology commercialization transactions. It discusses the prospects and motivations for additional changes to the U.S. patent system, particularly those affecting technology commercialization.

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[1] *See infra* note 6.

[2] *See, e.g., infra* Section II.C.

[3] *See, e.g.*, Patent Reform Act of 2007, S. 1145, H.R. 1908, 110th Cong. (2007); Patent Reform Act of 2006, S. 3818, 109th Cong. (2006); Patents Depend on Quality Act of 2006, H.R. 5096, 109th Cong. (2006); Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

[4] Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1). Implementation of the new rules, which would severely limit the use of continuation applications, has been enjoined. Tafas v. Dudas, 541 F.Supp.2d 805 (E.D. Va. 2008). The USPTO's appeal from that decision is currently pending at the Federal Circuit. *Id., appeal docketed*, No. 2008-1352 (Fed. Cir. May 8, 2008).

II. RECENT JUDICIAL REFORMS

The recent patent reform-related developments in the courts and efforts in the legislature have focused primarily on two goals: improving patent quality and limiting the potential for litigation abuse.[5] The Supreme Court has been active on both fronts.

As noted above, the Supreme Court has granted review in nine patent cases since the start of the 2004-05 term.[6] Four of the Court's decisions, in particular, have significant implications for organizations engaged in efforts to commercialize technologies. These decisions relate to the legal standard for determining whether an invention is unpatentable as "obvious," when a patent owner is entitled to a permanent injunction against an infringer, whether a licensee can challenge the validity of a licensed patent, and whether (or when) a patent owner can impose restrictions on purchasers of patented products.

A. Supreme Court Decisions Summarized

1. KSR Int'l Co. v. Teleflex Inc. (April 2007)

KSR Int'l Co. v. Teleflex Inc.[7] falls most definitively into the first of the two reform categories: improving patent quality. In *KSR*, the Supreme Court reviewed the test applied by the Federal Circuit for evaluating whether an invention claimed in a patent or patent application satisfies the statutory requirement of nonobviousness. The Federal Circuit, the appellate court with exclusive jurisdiction over appeals from court determinations in patent infringement lawsuits as well as USPTO decisions refusing to issue patents, had held that a challenger or the USPTO could only prove obviousness if

[5] Sarah M. King, *Clearing the Patent Thicket: The Supreme Court and Congress Undertake Patent Reform*, 19 No. 9 INTELL. PROP. & TECH. L.J. 13,13 (2007).

[6] The Supreme Court has decided eight patent cases during the last four terms. *See* Quanta Computer, Inc. v. LG Electronics, Inc., 128 S.Ct. 2109, 2122 (2008) (holding that "[t]he authorized sale of an article that substantially embodies a patent exhausts the patent holder's rights and prevents the patent holder from invoking patent law to control postsale use of the article"); Microsoft Corp. v. AT&T Corp., 127 S. Ct. 1746, 1751-52 (2007) (addressing the extraterritorial reach of U.S. patent law); KSR Int'l Co. v. Teleflex, Inc., 127 S. Ct. 1727, 1741-43 (2007) (revising the standard for establishing obviousness); MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764, 777 (2007) (expanding the availability of declaratory relief); eBay, Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 1841 (2006) (holding that district courts are to apply generally applicable equitable principles in deciding whether to grant injunctions in patent cases); Illinois Tool Works, Inc. v. Indep. Ink, Inc., 547 U.S. 28, 45-46 (2006) (rejecting the premise that a patent necessarily confers market power on its owner, and holding that "in all cases involving a tying arrangement, the plaintiff must prove that the defendant has market power in the tying product."); Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 546 U.S. 394, 406-07 (2006) (applying the requirements of Fed. R. Civ. P. 50(b) to foreclose review of the sufficiency of the evidence); Merck KGaA v. Integra LifeSciences I, Ltd., 545 U.S. 193, 206-08 (2005) (interpreting the patent statute's safe harbor provision relating to the development and submission of data to the Food & Drug Administration). The Court also granted certiorari in an ninth patent case during this period, but ultimately dismissed the writ of certiorari as "improvidently granted." Lab. Corp. of Am. v. Metabolite Lab., Inc., 126 S. Ct. 2921, 2921 (2006) (per curiam). Even the latter case, however, resulted in an opinion on the merits by three justices. Id. (Breyer, J., dissenting).

[7] 127 S.Ct. 1727 (2007).

"'some motivation or suggestion to combine the prior art teachings' can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art."[8] Critics argued that the Federal Circuit's inflexible application of this requirement set the patentability bar too low – that it made it too difficult for the USPTO or a patent challenger to reject or invalidate a patent claim.

The Supreme Court rejected the Federal Circuit's "rigid approach" and held that "[w]hat matters is the objective reach of the [patent] claim" – not the patentee's "motivation [or] avowed purpose."[9] The Court instructed that the obviousness analysis must take into account not only the particular problem the patentee was trying to address and the narrow, specific teachings of the prior art, but also the "ordinary creativity" and "common sense" of a person of ordinary skill in the relevant art, and what solutions would have been obvious for that person to try.[10] The effect of *KSR* on patent prosecution, litigation, and licensing strategy is considered below, following a brief discussion of the other significant recent Supreme Court decisions having general implications for entities engaged in technology commercialization efforts.

2. eBay Inc. v. MercExchange, L.L.C. (May 2006)

The recent Supreme Court decision most closely identified with the second reform goal – curbing litigation abuse – is *eBay Inc. v. MercExchange, L.L.C.*.[11] In *eBay*, the Court rejected the Federal Circuit's "general rule . . . that a permanent injunction will issue once infringement and validity have been adjudged."[12] It unanimously held, instead, that the four-factor test that governs the availability of permanent injunctive relief generally[13] "appl[ies] with equal force to disputes arising under the Patent Act."[14]

This bottom-line holding was consistent with the Court's approach in several of its other recent patent-related decisions, where the Court held, in effect, that generally applicable litigation rules apply, as well, in patent cases.[15] According to the Court, its

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[8] *Id.* at 1734-35 (citing Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1323-24 (Fed. Cir. 1999)).

[9] 127 S.Ct. at 1741-42.

[10] *Id.*

[11] 126 S.Ct. 1837 (2006).

[12] *Id.* at 1841 (quoting MercExchange, LLC v. eBay Inc., 401 F.3d 1323, 1338 (Fed. Cir. 2005), *vacated*, 126 S.Ct. 1837 (2006)).

[13] "A plaintiff must demonstrate: (1) that it has suffered an 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." 126 S.Ct at 1839.

[14] *Id.*

[15] *See, e.g.*, Illinois Tool Works Inc. v. Independent Ink, Inc., 547 U.S. 28, 45-46 (2006) (rejecting the premise that a patent necessarily confers market power on its owner, and holding that "in all cases involving a tying arrangement, the plaintiff must prove that the defendant has market power in the tying

holding is also consistent with the language of the applicable statute, which "expressly provides that injunctions 'may' issue 'in accordance with the principles of equity.'"[16] However, because the essence of the patent right is the "right to exclude others from making, using, offering for sale, or selling" the invention,[17] the *eBay* decision is controversial. And, although the precise contours of the *eBay* doctrine will be refined over time, the decision, without a doubt, is significant.

3. Quanta Computer, Inc. v. LG Electronics, Inc. (June 2008)

Quanta Computer, Inc. v. LG Electronics, Inc.[18] is the most recent patent decision of the Supreme Court. This case concerned whether a patentee can control/restrict the rights of buyers of the patented product. The patentee, LG Electronics (LGE), had licensed Intel to "make, use, [or] sell" patented computer microprocessors and chipsets. Intel, in turn, sold those components to computer manufacturers. In accordance with its agreement with LGE, Intel notified the manufacturers that they did not have authorization to combine the licensed Intel components with non-Intel parts. The Supreme Court, in a re-affirmation of the "patent exhaustion" doctrine, held that LGE, the patent owner, had "exhausted" (extinguished) its patent rights – even as to its method claims – by authorizing the sale of products (microprocessors and chipsets) that "substantially embody the patents" asserted by the patentee (in its infringement suit against the buyer-computer manufacturer). Notably, the Court held that the exhaustion doctrine applies even where, as here, the patents at issue covered not the individual components Intel sold to its customers, but rather the final product manufactured by Intel's computer manufacturer customers. Critical to the Court's reasoning in this regard was that the licensed products – microprocessors and chipsets – were only useful once incorporated by the buyer-computer manufacturer with other computer components ("buses and memory") to yield a functioning computer. Thus, said the Court, the licensed products "substantially embodie[d]" the patents at issue.

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product"); Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 546 U.S. 394, 407 (2006) (applying the requirements of Fed. R. Civ. P. 50(b) to foreclose review of the sufficiency of the evidence). *See also* Gregory A. Castanias, Lawrence D. Rosenberg, Michael S. Fried & Todd R. Geremia, *Survey of the Federal Circuit's Patent Law Decisions in 2006: A New Chapter in the Ongoing Dialogue With the Supreme Court*, 56 AM. U. L. REV. 793, 814-815 (2007) (identifying, from "the recent dialogue between the Federal Circuit and the Supreme Court", the "lesson" that "[t]he same rules apply to litigation involving patents as in ordinary, non-patent litigation[,]" citing *Unitherm* and *MedImmune*).

[16] *eBay*, 126 S.Ct. at 1839 (quoting Injunction, 35 U.S.C. § 283 (1952)).

[17] 35 U.S.C. § 154(a)(1) (2002).

[18] 128 S.Ct. 2109 (2008).

4. MedImmune, Inc. v. Genentech, Inc. (January 2007)

A fourth recent Supreme Court decision with significant implications for patent licensors and licensees is *MedImmune, Inc. v. Genentech, Inc*.[19] The issue in *MedImmune* was whether a patent licensee must terminate or breach its license with the patentee before it can bring suit in the federal courts to request a declaration that the patent is not infringed, invalid, or unenforceable. The Federal Circuit had held that as long as the license was in force, the federal courts lacked jurisdiction to consider a challenge by the licensee because under such circumstances there was no actual controversy between the parties. The Supreme Court rejected the Federal Circuit's interpretation and held that even though a licensee-in-good-standing has no basis for fearing an infringement action on the part of the patentee, the fact that its license payments are made under the coercion of the patentee's rights creates a sufficient basis for jurisdiction over the licensee's claims that the patent does not cover the licensee's products, or is invalid or unenforceable.

B. Effects and Open Questions

Each of these decisions contributes to an overall shift in the balance of power from patent owners to licensees and potential licensees. *KSR* should make it easier for accused infringers and patent licensees to succeed with challenges to spurious patent claims. It should also, especially in combination with *MedImmune*, tend to discourage patent owners from trying to coerce potential infringers from taking licenses under such claims, since *MedImmune* facilitates court challenges by those who have been "offered" licenses, as well as those who have already signed up. *Quanta* reaffirms that purchasers of patented products, even components of a patented combination which "substantially embody" the patent at issue, are effectively licensed under the patent. It thus limits the opportunities for patentees to attempt to exact royalties from downstream purchasers. And by curbing the threat that a finding of infringement will automatically trigger a permanent injunction, *eBay* changes the dynamics of license negotiations, particularly when the patent is owned by a commercial entity which does not manufacture or sell the patented products.

It is important to note that the import and influence of these very recent Supreme Court decisions are just beginning to percolate through the system, and that it will be years until we can competently assess their effects. It is possible, however, to make some preliminary observations about the reach and limits of these recent rulings.

First, as a general matter, *KSR* may have a greater impact on attempts to patent or license inventions in the mechanical or electrical arts than on new chemical compositions or advances in biotechnology. The latter, in general, are inherently unpredictable fields, and are, as a consequence, less susceptible to arguments that a given outcome could have or should have been expected.[20] *Quanta* limits a patent owner's ability to "sell one

[19] 127 S.Ct. 764 (2007).

[20] *See, e.g.,* Anthony Wilson, *Chemical and Life Sciences Patenting – New Considerations after the KSR vs Teleflex Decisio*n, available at http://ezinearticles.com/?Chemical-And-Life-Sciences-Patenting-New-

company a license and sue that company's customers", but patent holders can be expected to raise the price for licenses as a result.[21] Although *eBay* commands the courts to apply the same equitable considerations to determine the availability of injunctive relief in all patent cases,[22] and although patent holders who don't themselves sell patented products in competition with their accused infringers can now be expected to have difficulty qualifying for injunctive relief, the Court noted that some non-practicing patent owners, "such as universities or self-made inventors," may well be entitled to injunctions.[23] Thus, such patent holders may find their leverage in license negotiations largely unaffected by *eBay*.

Of the recent Supreme Court decisions, *MedImmune* most directly affects patent licensing, especially as to pre-existing license agreements negotiated and implemented under the old rules.[24] Licensees can use the threat of a validity challenge to compel renegotiation of the original deal.[25] And patent holders must tread lightly in their approaches to and discussions with potential licensees. Otherwise, they may find themselves in court defending an unanticipated validity challenge.[26] Interestingly, though, *MedImmune* may actually encourage potential licensees to take a license, if only to limit their exposure while they prepare to challenge the patents in question.[27]

Each decision leaves unanswered many significant questions. For example, was the Court's guidance in *KSR* clear and decisive enough to significantly and permanently alter the obviousness doctrine? Will non-profit research entities and independent inventors continue to enjoy the potent leverage of the potential injunction in license negotiations? And how will small startups seeking to raise venture capital and sign up licensees avoid being labeled as "trolls" presumptively ineligible for injunctive relief?

Quanta raises such questions as: (1) can a patentee avoid exhaustion and retain enforcement rights by imposing conditions on its licensee or customers? (2) If so, would the remedy for violations of those conditions lie in contract law or patent law? (3) When does (or not) a product "substantially embody" a patent (e.g., what if it is not an essential

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Considerations-After-The-KSR-VS-Teleflex-Decision&id=660176.

[21] *See, e.g.*, Sheri Qualters, *A Small Company Takes on Alleged 'Patent Trolls'*, NAT'L L.J., June 23, 2008, at 7.

[22] *eBay*, 547 U.S. at 391-92.

[23] *Id*. at 393.

[24] *See* Timothy J. Shea, Jr., *Patent Licensing in the Wake of MedImmune, eBay, KSR, and Microsoft*, available at http://www.westlegalworks.com/conferences/presentations/dnplb/Patent%20Licensing%20in%20the%20Wake%20of%20MedImmune.pps.

[25] *See id.*

[26] *See, e.g.*, Irfan A. Lateef and Joshua Stowell, *A Supreme End to Patent Trolls?*, 49 ORANGE COUNTY LAW. 18 (2007).

[27] *See* Shea, *supra* note 24.

element of the patented combination, or has reasonable uses outside of the patented combination)?[28] And *MedImmune* similarly directly affects the structuring of license deals, because it leaves unanswered the question of whether license provisions such as validity acknowledgements, provisions raising requirements and royalties in the event of a challenge, forum selection clauses, and provisions requiring advance warning of suit can be used to blunt its adverse impact on licensors.[29]

Research and technology development organizations cannot, of course, wait around to see how the law develops in the wake of these Supreme Court decisions. Fortunately, these cases suggest some potential prosecution, litigation, and licensing strategies for technology commercialization entities to consider implementing now. Some such strategies are presented below, following a discussion of potential legislative reforms.

C. Significant Federal Circuit Activity

In 2005**,** the Supreme Court agreed to hear a case presenting an issue concerning what types of inventions are eligible for patenting.[30] The Court subsequently declined to decide the case, but three justices issued an opinion calling into question the Federal Circuit's current standard for evaluating whether an invention constitutes patent-eligible subject matter.[31]

Since then, the USPTO has refused to issue patents on subject matter ineligibility grounds in a number of cases, including a case involving claims to an electronically "watermarked" signal (as in an electronically transmissible digital audio file "marked", for example, with copyright information),[32] and one where the applicant claimed "[a] method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price" – i.e., a hedging method, which method could be applied to any commodity and could be carried out entirely via mental steps.[33]

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[28] *See, e.g.*, Rufus Pichler, Paul E. Jahn, and William I. Schwartz, *Supreme Court Issues Ruling on Patent Exhaustion in Quanta v. LG Electronics*, MORRISON & FOERSTER LEGAL UPDATES & NEWS, June 2008, http://www.mofo.com/news/updates/files/13982.html.

[29] *See, e.g.*, Shea, *supra* note 24.

[30] Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc., 546 U.S. 975, 975 (2005).

[31] Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc., 548 U.S. 124, 125-38 (2006).

[32] In re Nuijten, 500 F.3d 1346, 1357 (Fed. Cir. 2007) (affirming the USPTO's holding that a signal is not patent-eligible subject matter).

[33] *See e.g.*, Michael J. Schallop, *Hedging on the Scope of Patentable Subject Matter for Business Methods – The Potential Broader Implications of In re Bilski*, INTELLECTUAL PROPERTY TODAY, July 2008, *available at* http://www.iptoday.com/articles/2008-7-schallop.asp.

The Federal Circuit agreed with the USPTO about the signal claims,[34] raised patent eligibility concerns on its own in another case involving claims to a "business method",[35] and decided to hear the appeal in the case involving the hedging method claims "*en banc*", in other words to have the full court decide the case as opposed to the usual three-judge panel.[36] The court also requested that the parties and other people, groups and companies interested in providing the court with their views submit briefs on such broad questions as "[w]hat standard should govern in determining whether a process is patent-eligible subject matter . . ." and "[w]hether a method or process must result in a physical transformation of an article or be tied to a machine to be patent-eligible subject matter . . .?"

This case – *In re Bilski* – could result in a ban on the patenting of business methods. It seems more likely, however, that the court will tighten the existing standards and effectively require that patented business methods be tied to and implemented through computer hardware or computer-readable software media. But as of this writing, the outcome and its potential implications are uncertain. The Chief Judge of the Federal Circuit recently announced that the decision in *In re Bilski* will be "very significant," and that "[i]t will probably have a broader scope than [the other patent eligibility cases the court has recently decided],"[37] so it appears that the court has decided to use this case to significantly affect the future patenting of business methods.

III. LEGISLATIVE PATENT REFORM PROPOSALS

The U.S. patent system is a victim of its own success. It has worked to encourage the patenting of new technologies – too well, say its critics. The Federal Circuit's generous application of the Patent Act's remedy provisions have, in some cases, inspired abusive litigation, and the potency and perhaps-too-expansive availability of patents have led to a crush of applications which threaten to drown the USPTO.[38]

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[34] *Nuijten*, *supra* note 32, at 1357.

[35] In re Comiskey, 499 F.3d 1365, 1380-81 (Fed. Cir. 2007) (declining to decide whether the USPTO properly concluded that the claimed method was unpatentable as obvious over the prior art, because the patent application, in the court's opinion, claimed ineligible subject matter).

[36] In re Bilski, 264 Fed.Appx. 896, 897 (Fed. Cir. 2008).

[37] Eileen McDermott, *The View From the Federal Circuit*, AIPPI CONGRESS NEWS, Sept. 9, 2008, at 14, *available at* http://www.managingip.com/pdfs/02_AIPPI_Chicago_Tue.pdf.

[38] "The backlog of pending patents is approaching a record 800,000, and average approval time has stretched to 31 months. . . . Patent quality has suffered as overburdened and underpaid examiners have granted protection to broad and seemingly obvious business-process 'inventions,' such as Amazon.com's checkout cart for online shopping." Ann Therese Palmer, *Will Congress Slam Small Inventors?*, CNNMONEY.COM, June 19, 2007, http://money.cnn.com/2007/06/18/magazines/fsb/patent_reform.fsb/index.htm.

These factors have led to calls for change,[39] and members of Congress have responded by introducing comprehensive patent reform bills in both houses during the last several years. One bill – H.R. 1908 – was approved by the House of Representatives in September 2007, but the corresponding Senate bill, S. 1145, died in April of this year.[40] Nevertheless, there is no indication that the proponents of "change" have given up. Consequently, we are likely to see patent reform proposals taken up for consideration in the new Congress. Those proposals will likely mirror or echo what had gathered momentum in the current legislative session, including the key changes discussed below.

A. Patent Reform Provisions Advanced in the 110th (2007-08) Congress

1. First Inventor to File

In every patent-issuing country except the United States, the issue of which of two (or more) persons who independently invents the same invention at around the same time has priority is resolved by awarding the patent to the one with the earliest filing date.[41] In contrast, where priority of invention is contested, U.S. law currently awards the patent to the first to have invented the subject matter in question.[42]

The most recent congressional patent reform proposals would convert the U.S. from a "first-to-invent" to a "first-inventor-to-file" system, subject, perhaps, to certain changes in the law of other major patent-awarding countries to create a pre-application "grace period" similar to that available to inventors under U.S. law.[43] This is a long-debated issue, including as to whether such a change would disproportionately disadvantage independent inventors, small companies, and universities. Proponents of the change argue that it would reduce costs, increase certainty, and promote innovation by liberating resources currently invested in proving invention dates. In addition to concerns about fairness to small entities, opponents argue that patent application quality will suffer as applicants rush to file.[44]

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[39] *See, e.g.,* George Best, Benjamin Berkowitz, & Stephen Mabius, *How Damaged is the Patent Reform Act?: Dispute Over How to Calculate Awards is Just the Latest IP Debate Slowing Down this Bill*, 16 LEGAL TIMES, July 7, 2008, *available at* http://www.law.com/jsp/dc/PubArticleDC.jsp?id=1202422685963; Ted Frank, *There is a Role for Congress in Patent Litigation Reform*, 1 LIABILITY OUTLOOK, at 1, February 2008, *available at* http://www.aei.org/publications/pubID.27550/pub_detail.asp.

[40] *See, e.g.,* Emily Berger & Richard Esquerra, *Patent Reform Act Stalls in the Senate*, ELECTRONIC FRONTIER FOUNDATION, May 2, 2008, http://www.eff.org/deeplinks/2008/05/patent-reform-act-stalls-senate.

[41] *See* John R. Thomas & Wendy H. Schacht, *Patent Reform in the 110th Congress: Innovation Issues*, CONGRESSIONAL RESEARCH SERVICE REPORT FOR CONGRESS, at 15, Jan 10, 2008, *available at* http://ipmall.info/hosted_resources/crs/RL33996_080110.pdf (hereinafter CRS Report).

[42] *Id.*

[43] *Id.*

[44] *Id.* at 16.

Surprisingly, the data on whether moving to a "first-inventor-to-file" system would benefit or disadvantage independent inventors, universities, and small businesses are mixed. A 2002 study found that the current system has not benefited small entities,[45] and has, during one recent period, at least, harmed independent inventors.[46] Furthermore, large entities can use the current system to challenge the patent rights of small entities.[47] On the other hand, when priority (as opposed to patentability) is the issue upon which these proceedings are resolved, "the first to invent is quite frequently not the first to file."[48]

It is worth noting that globalization is pulling the U.S. in the direction of first-inventor-to-file, not only because of harmonization pressure from other countries, but also because, for those seeking protection in multiple countries, operating under two systems can be expensive.

2. Post-Grant Review

Two major recent patent reform studies called for the institution of post-grant review proceedings in the USPTO.[49] Current law provides for "reexamination" of issued patents by the USPTO under limited circumstances, but critics of the current system argue that existing opportunities for post-grant challenge have limited effectiveness.[50]

Concerns about patent quality are spurring calls for expanded post-grant review opportunities in the U.S. At a series of 2005 "Town Meetings on Patent Reform", presented by the American Intellectual Property Law Association and the sponsors of the two patent reform studies referenced above – the Federal Trade Commission and the National Academies' Board on Science, Technology, and Economic Policy – "the problem" was described as the "[r]apid growth in patent applications leading to [a l]arge increase in patent office workload [and h]igher grant rates in the US . . . [s]uggest[ing] a decline in the standard of patentability."[51] The identified "possible causes" of a decline in

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[45] Gerard J. Mossinghoff, *The First-to-Invent System Has Provided No Advantage to Small Entities*, 88 J. PAT. AND TRADEMARK OFF. SOC'Y 425, 428 (2002).

[46] *Id.* at 427-28.

[47] Mark A. Lemley & Colleen V. Chien, *Are U.S. Patent Priority Rules Really Necessary?*, 54 HASTINGS L.J. 1299, 1323 (2003).

[48] *Id.* at 1309.

[49] NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 95 (Stephen A. Merrill et al. eds., 2004), *available at* http://books.nap.edu/catalog.php?record_id=10976; FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 7 (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

[50] *See, e.g.*, CRS Report, *supra* note 41 (citing Mark D. Janis, *Inter Partes Reexamination*, 10 FORDHAM INTELLECTUAL PROPERTY, MEDIA & ENTERTAINMENT L.J. 481 (2000)).

[51] Fed. Trade Comm'n, et al., *Town Meeting on Patent Reform* (2005), http://cyberlaw.stanford.edu/attachments/Complete%20slides_San%20Jose.ppt.

quality included an "overburdened patent office", a "lack of expertise in the relevant areas", a "lack of prior art databases", and the "weakening of the non-obviousness test, partly through court decisions."[52]

In addition to concerns about quality, advocates of expanded post-grant review opportunities in the U.S. point to the high cost and limited availability of the alternative review route – litigation in federal district court – as well as the availability of post-grant opposition proceedings in other major patent-granting countries.[53] The potential drawbacks of new post-grant review procedures include the imposition of new costs, delays, and uncertainty on patent holders, and new burdens on an already-overburdened USPTO.[54] And advocates for small entity patent owners argue that such proceedings present opportunities for harassment by larger concerns.[55]

The real debate about expanded post-grant review in the United States relates to when during the life of a patent should such opportunities be available.[56] In Europe, for example, an opposition may only be filed during the nine months following the issuance of the patent.[57] Traditional beneficiaries of strong patent rights, such as pharmaceutical

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[52] *Id.* As noted *supra* notes 7-10 and accompanying text, the Supreme Court's decision in *KSR* has since revised the obviousness standard.

[53] *See, e.g.,* Matthew Sag & Kurt Rhode, *Patent Reform and Differential Impact*, 8 MINN. J.L. SCI. & TECH. 1 (2007) ("the high cost of federal court litigation shields bad patents from scrutiny in many cases," but "[p]ost-grant review will address this by providing a low cost method of challenging patents."); Michele A. Cimbala & John M. Covert, *Let Opposing Forces Gather: Post-grant Process Could Fix Questionable Patents Faster*, LEGAL TIMES, Mar. 15, 2004, *available at* http://www.sternekessler.com/media/news/news.131.pdf ("Europe and Japan already permit post-grant oppositions," and under post-grant review process "[t]hird parties would be able to challenge a patent before they had spent major costs on a product that might infringe."); Peter F Corless & George W Neuner, *Taking the USPTO Route to Challenging a Patent*, 172 PATENT WORLD 12 (2005) ("[a]lthough found in other countries, there is no practical post-allowance or -grant opposition procedure in the United States…" Additionally, "in the U.S. litigation may not be a realistic strategy for many parties, as it can be notoriously expensive and protracted."); Stuart J.H. Graham & Dietmar Harhoff, *Can Post Grant Reviews Improve Patent System Design? A Twin Study of US and European Patents* (Governance and the Efficiency of Economic Systems, Discussion Paper No. 38, 2006), *available at* http://www.gesy.uni-mannheim.de/dipa/38.pdf**;** Bronwyn H. Hall, et al., *Prospects for Improving U.S. Patent Quality via Post-grant Opposition* (NBER Working Paper No. W9731, 2003), at 8-13, *available at* http://ssrn.com/abstract=410657 (comparing post-grant procedures and patent litigation in the European Union to the U.S.); Hal Wegner, *On Patent Review in US vs. Japan*, Dec. 7, 2006, http://www.ipeg.com/_UPLOAD%20BLOG/December%207%20Patent%20Review,%20Research%20Exemption.pdf (comparing patent review in Japan versus the U.S.).

[54] *See* Town Meeting, *supra* note 51.

[55] *See, e.g.,* Stephen G. Kunin & Anton W. Fetting, *The Metamorphosis of* Inter Partes *Examination*, 19 BERKELEY TECH. L.J. 971, 982 (2004) ("the post-grant review forum should be open to all issues for a limited time" because there "is the potential for harassment engendered by the relative ease and minimal cost of initiating post-grant review proceedings."); Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 967-68 (2004) ("[p]ost-grant patent revocations could be "misused by firms who simply want to slow down or injure a patentee-firm.").

[56] *See, e.g.,* Best et al., *supra* note 39.

[57] *Id.*

and biotechnology industry members, argue that such limits are necessary to safeguard the incentives which motivate their substantial research investments.[58] But some argue there should be a "second window" for opposition that would open when the patent owner asserts infringement and close following a reasonable opportunity for the threatened party to consider an administrative challenge.[59] This divide is one of the sticking points holding up comprehensive legislative reform.[60]

3. Prior Art Searching

Both H.R. 1908 and S. 1145 would impose (or authorize the USPTO to impose) a new duty on applicants to conduct and submit the results of a pre-filing prior art search, and the Senate version would also authorize the USPTO to require the submission of an "analysis relevant to patentability."[61] This latter requirement, in particular, is quite controversial, because it would significantly increase the cost of preparing patent applications.[62] And because it would require applicants to "go on the record" with affirmative statements characterizing the claimed invention, the content of the prior art, and how they differ, it would also greatly increase the risk that alleged infringers would one day assert – possibly successfully – that the patent was procured via "inequitable conduct", a violation of the applicant's "duty of candor" to the USPTO.[63]

4. Limitations on Venue, 18-Month Publication, and Other Potential Changes

Some proposed reforms are less controversial. For example, both H.R. 1908 and S. 1145 would limit patent owners' options regarding where to file infringement actions.[64] And both would require the publication of all pending patent applications,[65] although the bills differ somewhat on the precise timing of pre-issue publication.[66]

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[58] *Id.*

[59] *Id.*

[60] Harold Wegner, *Berman H.R. 1908, Patent Reform Bill, Pronounced D.O.A.*, Apr. 29, 2007, http://www.ipfrontline.com/depts/article.asp?id=14909&deptid=4 (arguing that there had been a "total impasse from the last Congress over 'second window' post-grant review and that the [then] current legislation as introduced is dead in the water" because it called for a 'second window'); Thomas Kelton, Policy Considerations Behind Post-Grant Patent Oppositions, http://www.fulbright.com/images/publications/Policy%20Considerations%20Behind%20Post-Grant%20Patent%20Oppositions.pdf (last visited Sept. 30, 2008) (arguing that "compromise reform would be easier to pass" because "pharma" would be "expect[ed to] fight second window legislation vigorously.").

[61] *Id.* at 38-39.

[62] *See, e.g.*, Best et al., *supra* note 39.

[63] *See id.*

[64] CRS Report, *supra* note 41, at 35-37.

[65] Under current law, most U.S. patent applications are published 18 months after filing. 35 U.S.C.

Other potential changes include clarification and limitation of the law of willful infringement,[67] expanded opportunities for the public to submit prior art pertinent to pending applications,[68] a ban on patenting "tax planning method[s]",[69] revision of the inequitable conduct and best mode doctrines,[70] an expansion of USPTO rule-making authority.[71]

5. Limitations on Damages

Each of the above-summarized legislative proposals has its critics. But none is as controversial as the proposal relating to how damages for infringement would be calculated.

Many infringement actions involve claims that a patent covers a component of a marketed product. For example, a patented component of an audio speaker may be sold as part of a complete stereo system.[72] Under current law, when the patented component is the basis for the market demand for the product, courts may apply the "entire market value rule" to award damages based on the sales of the product.[73] Critics argue that this principle can over-reward patent owners and burden innovation.[74]

Both of the most recent congressional patent reform bills would authorize courts to "apportion" damages.[75] While courts could still apply the entire market value rule in certain circumstances, in many cases they would be required to award damages based on the "economic value" of the patented feature's "specific contribution over the prior art."[76]

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§ 122(b)(1)(A). Applicants can prevent publication by certifying that "the invention disclosed in the application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication of applications 18 months after filing." 35 U.S.C. § 122(b)(2)(B)(i).

[66] CRS Report, *supra* note 41 at 32-33.

[67] *Id.* at 26.

[68] *Id.* at 33.

[69] *Id.* at 34.

[70] *Id.* at 39-43.

[71] *Id.* at 43.

[72] *See* discussion in CRS Report, *supra* note 41, at 23.

[73] *Id.*

[74] *Id.*

[75] *See id.* at 23-24.

[76] *See* Best, et al., *supra* note 39.

The result would, in many cases, be a lower damage award than is available under current law. Beyond that, however, there is great concern that the apportionment analysis would add cost and complexity to already-complicated and expensive patent litigation.[77]

This aspect of the proposed reform legislation was the most contentious,[78] and the issue which ultimately killed this patent reform bill for 2008.[79]

B. Dueling Coalitions and the Prospects for Legislative Reform

The proponents and opponents of patent reform have invested significant money and effort in lobbying members of Congress.[80] Two key factions have emerged, split largely along industry lines.[81] Large high-tech companies and financial services firms generally support the proposed reforms, while smaller tech vendors, pharmaceutical and biotechnology companies, traditional manufacturing concerns and labor unions tend to oppose the proposed legislation, on the ground that many of the provisions, in their view, would undermine strong patent protection.[82] The fundamental schism lies between businesses – those in the latter group – which depend heavily on intellectual property rights and those whose business models depend on the agile adaptation of fast-developing technologies.[83] The split also derives from the basic nature of the products marketed by the major players in these two coalitions. Medical drugs and devices often embody only a single patent, whereas the high-tech companies sell products – including software –

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[77] *See id.* It now costs, on average, $4 million to litigate a patent case from filing to trial. *See* Joe Mullin, *Never a Dull Moment*, 7/2008 IP LAW & BUSINESS 39 (July 2008).

[78] *See* Chris Frates, *Patent Reform Contest Heads to Senate Floor*, POLITICO, Apr. 7, 2008, http://www.politico.com/news/stories/0408/9425.html.

[79] Corey Boles & Patrick Yoest, *US Patent Bill Appears To Be Dead, Says Sen Judiciary Chmn*, DOW JONES NEWSWIRES, *available at* http://agoracom.com/ir/patriot/messages/807268 (reporting that Senator Orrin Hatch "acknowledged that the stumbling block" was the damages portion of the legislation).

[80] *See* Frates, *supra* note 78 (noting that the push has involved traditional corporate and grass-roots lobbying efforts).

[81] *See, e.g.*, King, *supra* note 5, at 16.

[82] *See e.g.*, Dan Slater, *Patently Stalled*, WSJ LAW BLOG, Apr. 18, 2008, http://blogs.wsj.com/law/2008/04/18/patently-stalled/ (noting that Cisco Systems, Apple Corp., Bank of America and Goldman Sachs Group support the proposed legislative reform, while drug manufacturers, Caterpillar and Dow Chemical are opposed); Grant Gross, *Software Companies Want Patent Reform by Congress*, PC WORLD, March 9 2008, http://www.pcworld.com/article/143246/software_companies_want_patent_reform_by_congress.html ("Many large tech vendors, including [Business Software Alliance] members Microsoft, Symantec and Apple, say it's too easy for patent holders to claim that a small piece of a tech product infringes a patent and to collect huge court awards.").

[83] In the fifteen months between January 2007 and the end of April 2008, the "Coalition for Patent Fairness", comprised of companies including Cisco and Palm, reportedly spent $2.5 million for a "small army of lobbyists", while "[a] rival group, the Coalition for 21st Century Patent Reform", which includes "pharmaceutical and biotech companies like Genzyme, Lilly, Merck and Pfizer" has reportedly paid $1.8 million to lobbyists. Robert Pear, *Patent Bill is Bonanza to Lobbyists*, N.Y. TIMES, April 30, 2008, at C1.

which may be covered by dozens or even hundreds of individual patents.[84] The latter companies, in particular, tend for this reason to see strong patents as an impediment.

As noted above, it appears that the current congressional term will not produce patent reform. But the jockeying for the next session has already begun. On September 24, 2008, Senator Jon Kyl (R-AZ), introduced an alternate bill – S. 3600 ("Patent Reform Act of 2008") – which is similar in some respects and quite different in others from the most recent other House and Senate bills, discussed above.[85] Given recent developments affecting the financial markets,[86] and the pending presidential and congressional elections, there will likely be no further action on any of these bills this year. But the introduction of the Kyl bill is significant nonetheless, because it sends the message that (1) there will be a competing bill (to the Leahy-Hatch-backed proposals of 2007) in the next congress, and (2) that the "opposition" – the pharmaceutical and biotech companies (the "strong patents coalition") has awakened and is prepared to challenge the high-tech companies' pursuit of more limited patent protection.[87]

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[84] *See* Dana Blankenhorn, *Patent Reform Dead for 2008*, ZDNET, May 15, 2008, http://blogs.zdnet.com/open-source/?p=2435.

[85] *See, e.g.*, Kevin E. Noonan, *BIO Praises Senator Kyl's Patent Reform Bill*, PATENT DOCS, Sept. 26, 2008, http://www.patentdocs.net/patent_docs/2008/09/bio-praises-sen.html; Gene Quinn, *Senator Kyl Introduces Patent Reform*, IPWATCHDOG, Sept. 25, 2008, http://www.ipwatchdog.com/2008/09/25/senator-kyl-introduces-patent-reform/.

In brief, the Kyl bill would establish a first-inventor-to-file system, provide for "two windows" for post-grant review, authorize the USPTO to offer incentives to applicants to encourage the submission of search reports and patentability analyses, limit where patent infringement actions may be filed, and impose limits on the courts' calculation of what constitutes a reasonable royalty.

[86] David M. Herszenhorn & Carl Hulse, *Congress Nears a Bailout in Intense Push*, N.Y. TIMES, Sept. 28, 2008, at A1.

[87] One other factor may prove significant: the new congressional session:

> [The possibility exists] that several key players negotiating the current bill could change jobs. [Rep. Howard] Berman [(D-Ca.), chairman of the Judiciary Subcommittee on the Courts, the Internet and Intellectual Property] is expected to give up the gavel of his subcommittee to lead the House Foreign Affairs Committee, while [Senator] Leahy [(D-Vt.)] could move from head of the Senate Judiciary Committee to take over the Appropriations Committee for the ailing Sen. Robert Byrd (D-W.Va.). Another unknown factor is the health of [Senator Arlen] Specter [(R-Pa.), ranking Republican Judiciary Committee member], who is battling a recurrence of cancer.

Charlene Carter, *Conflicting Views Mire Patent Reform*, ROLL CALL, June 19, 2008, http://www.rollcall.com/issues/53_155/news/26052-1.html?CMP=OTC-RSS.

IV. IMPACT OF REFORMS AND PROPOSED REFORMS ON TECHNOLOGY COMMERCIALIZATION

As discussed above, the changes which have thus far occurred have been in the direction of weakening protections for patent owners and strengthening the bargaining position of licensees and potential licensees. Patents are harder to get and more difficult to keep, and patent owners' enforcement opportunities are more limited.[88]

But it is important to take care not to overstate the effects of the recent judicial determinations. For example, some have argued that the effects of the *KSR* decision are limited, particularly with respect to its effects on chemical and biotechnology inventions.[89] *eBay* has teeth, but so far has resulted in injunction denials primarily in cases involving non-manufacturing patentees who are not engaged in basic research.[90]

The Supreme Court's decisions in *MedImmune* and *Quanta* are probably the most significant for technology commercialization entities – regardless of technology area. As noted above, *Quanta* leaves a significant number of open questions about whether and to what extent patent owners can impose restrictions upon the authorized buyers of products embodying their patented technologies. Patent owners and their counsel are still coming to grips with what limits *Quanta* does and does not impose. But we know that, even as to

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[88] *See supra* Section II.

[89] Kevin E. Noonan, *Implications of the Supreme Court's KSR v. Teleflex Decision for Biotechnology*, PATENT DOCS, May 4, 2007, http://patentdocs.typepad.com/patent_docs/2007/05/implications_of.html ("...it is likely that biotechnology claims should be spared the greatest burdensome effects of the *KSR* decision."); Courtenay C. Brinckerhoff, *KSR: A Bump in the Road for Biotech?: Changes in Assessing Obviousness of Patents Shouldn't Affect the Industry*, 27 GENETIC ENG'G & BIOTECH. NEWS, July 1, 2007, *available at* http://www.genengnews.com/articles/chitem.aspx?aid=2150 ("KSR may not have as much of an impact on the biotech industry as it will on other fields."); J. Peter Fasse, What the U.S. Supreme Court's *KSR v. Teleflex* Decision Means for Biotech, 3 INDUS. BIOTECH. 129 (2007) ("…the impact of the *KSR* decision, both on obtaining and defending patents, is appreciably lower for inventions in the areas of biotechnology and chemistry (the so-called 'unpredictable' arts) than for inventions in other areas of technology").

[90] Benjamin H. Diessel, Note, *Trolling for Trolls: The Pitfalls of the Emerging Market Competition Requirement for Permanent Injunctions in Patent Cases Post*-Ebay, 106 MICH. L. REV. 305, 318 (2007) ("In cases where courts denied plaintiffs injunctions, plaintiffs did not practice their invention and did not compete in the market in the area covered by the patent."); Andrew Beckerman-Rodau, *The Aftermath of Ebay v. MercExchange, 126 S.Ct. 1837 (2006): A Review of Subsequent Judicial Decisions*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 631, 655-56 (2007) ("In almost every case in which a court denied a permanent injunction for patent infringement the patent owner was a non-practicing entity," but noting the potential exception for non-practicing patentees who are "non-profit enterprises such as universities and research institutes"); Robert J. Garrey & John M. Jackson, *The Permanent Injunction Threat in Patent Cases: Has Ebay v. MercExchange Changed the Landscape for Patent Litigation in Texas District Courts?* (2006), http:// images.jw.com/com/publications/626.pdf (while "it appears that plaintiffs that use their patents to produce goods and services are far more likely to obtain injunctive relief against competitors adjudged to infringe their patents than are plaintiffs who merely license their patents," "district court opinions [in post-*eBay* injunction decisions] took their cue from the distinction Justice Kennedy's concurring opinion in *eBay* made between 'university researchers or self-made inventors' and firms that 'use patents not as a basis for producing and selling goods but, instead, primarily for obtaining license fees.'").

components of patented combinations, and even as to methods of using those components in patented combinations, the fundamental principle that the first authorized sale "exhausts" the patent has been reaffirmed. To what extent skillful contract drafting can modify those limits has yet to be determined.

The same is true regarding the post-*MedImmune* landscape. Patent owners can no longer rest once their licensees have "signed up." A patent license is no longer the culmination of licensor-licensee negotiations; it may be just a step along the path to a licensee challenge to the applicability and/or validity of the licensor's patent. It remains to be seen whether and to what extent the license terms can limit the licensee's ability to terminate or rewrite its obligations to the patentee.

Assessing the potential effects of proposed legislative reforms is more difficult, because those changes have yet to take shape. However, it seems likely that the U.S. will move, if not immediately, then ultimately, to a "first-inventor-to-file" system, that issued patents will be subject – for some period(s) and under some condition(s) – to post-grant review in the USPTO, that more will be required of applicants than is currently asked with respect to prior art searching and participation in the examination process, and that more restrictive standards will govern patent damages awards. And additional changes – from 18-month publication of all applications, to greater public participation in the examination process, to expanded USPTO rule-making authority (which will lead to limitations on the filing of continuation applications and requirements that applicants assist examiners in the identification and applicability of the closest prior art), are likely.

V. CONCLUSION: SOME SUGGESTED STRATEGIES IN THE WAKE OF IMPLEMENTED CHANGES AND IN ANTICIPATION OF THOSE TO COME

While the implications of recent judicial decisions are yet to be fully clear, and we will likely not see legislative reform until some time into the next congressional term, if then, the changes and potential changes suggest some strategies for consideration by those engaged in technology commercialization:

For licensors and potential licensors:

- Scrutinize and reconsider investments in patent filings on marginally patentable inventions.

- Avoid aggressive solicitations of potential licensees.

- Include license terms designed to discourage validity challenges, or seek up front lump sum payments instead of royalties.[91]

- If a licensee validity challenge is likely, consider termination of the agreement.[92]

- In appropriate situations, consider restricting a licensee's right to sell.[93]

- Revamp patent filing procedures to file early where possible.

For licensees and potential licensees:

- Consider taking a license before bringing a patent validity challenge.[94]

- Revise license negotiation strategies to take advantage of the leverage afforded by the recent Supreme Court decisions discussed above.

- Where the licensed patent is of questionable validity, consider requesting renegotiation of the existing terms.

Finally, all entities engaged in the business of technology commercialization should continue to follow patent-related developments. We are in a time of tremendous and wide-ranging change, but those who carefully monitor the key legal developments will be in the best position to take advantage of favorable changes and to adopt measures to ameliorate the effects of those which are disadvantageous.

[91] *See, e.g.*, Gregory L. Clinton & James G. McEwen, *Licensing Strategies After* Medimmune, STEIN MCEWEN & BUI LLP, Jan. 2007, at 6-7, http://www.smbiplaw.com/pdf/LICENSING%20STRATEGIES%20AFTER%20MEDIMMUNE.pdf.

[92] *See, e.g.*, Shea, *supra* note 24.

[93] *See, e.g.*, *Townsend Client Alert: Supreme Court Opinion in* Quanta Computer, Inc. v. LG Electronics, Inc., TOWNSEND AND TOWNSEND AND CREW, LLP, June 11, 2008, http://www.townsend.com/resource/publication.asp?o=8623; *Does Your Licensing Strategy Still Work? The Supreme Court Clarifies Patent Exhaustion Doctrine*, FOLEY & LARDNER LLP, June 9, 2008, http://www.foley.com/publications/pub_detail.aspx?pubid=5088.

[94] *See, e.g.*, Townsend, *supra* note 93, at 7.