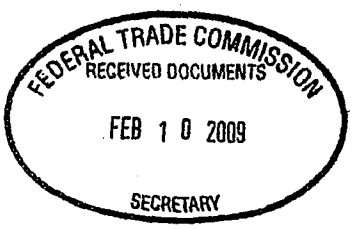
Billy Tauzin
PRESIDENT AND CHIEF EXECUTIVE OFFICER

PhRMA

February 10, 2009



BY HAND DELIVERY

The Honorable William E. Kovacic
Chairman, Federal Trade Commission
Office of the Secretary
600 Pennsylvania Ave., NW
Room H-135 (Annex I)
Washington, DC 20580

Re: Evolving IP Marketplace – Comment, Project No. P093900

Dear Chairman Kovacic:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to respond to the Federal Trade Commission's notice and questions concerning the Evolving Intellectual Property Marketplace, 73 Fed. Reg. 70645 (Nov. 21, 2008).

PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $44.5 billion in 2007 in discovering and developing new medicines. Industry-wide research and investment reached a record $58.8 billion in 2007.

The U.S. pharmaceutical and biotechnology sector make important economic contributions to the United States. Developing new medicines is a particularly risky, lengthy, and costly endeavor. Strong intellectual property protection is a fundamental element of an environment that fosters innovation and provides important incentives for the investment needed to seize the extraordinary opportunities for medical advances and economic growth offered by this 21st Century knowledge-based sector.

We appreciate your engagement in this important area and the thoughtful approach in which you are soliciting views from stakeholders on these issues. We look forward to continuing to work with you, your colleagues at the Federal Trade Commission, and other stakeholders, as you continue consideration of these and other important topics.

Sincerely,

Billy Tauzin

PhRMA

Evolving IP Marketplace – Comment, Project No. P093900

by

The Pharmaceutical Research and Manufacturers of America

Submitted to
The Federal Trade Commission
February 10, 2009

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PhRMA'S COMMENTS TO THE FEDERAL TRADE COMMISSION

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February 10, 2009

PhRMA'S COMMENTS TO THE FEDERAL TRADE COMMISSION

Since the Federal Trade Commission's ("FTC") 2003 report,[1/] strong patent protection has become more important to the biopharmaceutical industry due to the increasing expense and uncertainty associated with developing new medicines and bringing them to market. Biopharmaceutical companies range in size from small start-up research firms to multi-national, multi-billion dollar corporations, and encompass both research-based pharmaceutical and biotechnology companies. Regardless of their size, these companies face significant challenges relating to the discovery, development, testing, production, and commercialization of new medical treatments.

PhRMA's member companies are leading research-based pharmaceutical and biotechnology companies that are devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. In 2007, PhRMA's member companies invested an estimated $44.5 billion in research and development and were developing or seeking regulatory approval for 2,700 molecules that might eventually be used to treat U.S. patients. Development of new medicines is a long and high-risk process, and it has become more costly and complex over the last decade.

Recent medical advances—driven by scientific research and creative genius—would have been impossible without a system of laws that provide the structure, stability, and opportunity necessary to support the needed investment. As discussed more fully below, PhRMA's member companies face a number of challenges in the intellectual property ("IP") marketplace that reinforce and heighten the importance of strong intellectual property rights.

I. For The Biopharmaceutical Industry, Strong Patent Protection Has Become More Important Than Ever.

In the FTC's Federal Register notice for its Hearings on the Evolving IP Marketplace, the FTC asks a series of questions on various developments in the IP marketplace.[2/] The FTC's first question asks how the IP marketplace has changed in the last five to ten years and how those changes affect innovation. The biopharmaceutical industry is premised on strong intellectual property protections—including both patents and data exclusivity. For biopharmaceutical companies, patent protections provide the innovator with a time-limited, exclusive right to market a particular patented medicine once the medicine has been approved by FDA. Biopharmaceutical companies that bring products to market rely on such intellectual property rights, and the ability to enforce those rights, to justify the inherently risky, costly, complex, and lengthy R&D process that is necessary to successfully bring safe and effective medicines to market.

/1 Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf [hereinafter 2003 FTC Report].

/2 Federal Trade Commission, *Notice of Public Hearings Concerning the Evolving Intellectual Property Marketplace*, *available at* http://www.ftc.gov/os/2008/11/P093900ipwkspfrn.pdf. References to the FTC's questions in the present document are to these questions.

Patents are particularly important to the biopharmaceutical industry as compared to other industries. According to one commentator, without patent protection, an estimated 65 percent of pharmaceutical products would not have been brought to market, while the average across all other industries was 8 percent.[3] Indeed, it is well-established that patents are significantly more important to pharmaceutical firms than for firms in other sectors in part due to the very high costs of development.[4] In 2007, commentators found that patents are especially crucial to small biotechnology companies because they are "typically the only assets those firms possess that are sufficiently stable and valuable to attract the large amounts of capital they need to exploit promising research toward new drugs and diagnostics. Hence, the market valuation of startup biotechnology firms tends to reflect the scope and breadth of their patents."[5] Commentators also describe the "spillover" effect of patented innovation that provides knowledge and economic value to both patentees and competitors.[6] An example of this is a successful medicine used in research for testing, refining, and suggesting hypotheses in basic science.

A. Because the uncertainties associated with the development of new medicines are many and substantial, patent protection is essential to maintaining a vibrant and innovative biopharmaceutical industry.

Today, the United States is the clear global leader in biopharmaceutical investment, jobs, and product development, offering opportunities for high-quality and robust economic growth. However, the industry faces increasing challenges that reinforce the importance of robust patent protection to biopharmaceutical companies. These challenges include increasing regulatory requirements and heightened complexity of clinical trials for new drugs, both of which result in increased costs and greater uncertainty in drug development over time. Additionally, challenges to the validity of biopharmaceutical patents are increasingly occurring earlier in a drug's lifecycle. Finally, the effective patent life for pharmaceutical products is shorter than the effective patent life in other industries. Each of these developments will be discussed below.

First, the regulatory environment for biopharmaceutical products has grown increasingly complex since 2003. For example, enhanced post-market surveillance requirements and the creation of Risk Evaluation and Mitigation Strategies enacted as part of the Food and Drug Administration Amendments Act of 2007 increase investments in marketed products.[7] These increased investments, while appropriate to promote regulatory compliance, also enhance the importance of patent protection to help recoup increased costs for marketed drug products.

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[3] Edwin Mansfield, *Patents and Innovation: An Empirical Study*, Management Science (February 1986) at 173-181.

[4] Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 JOURNAL OF INT'L ECONOMIC LAW 849-60 (2002).

[5] John E. Calfee & Claude Barfield, *Biotechnology and the Patent System: Balancing Innovation and Property Rights* 27 (The AEI Press 2007).

[6] *Id.* at 28.

[7] *See generally* Pub. L. No. 110-85.

Second, the clinical trials necessary to develop the data to support product approval are growing increasingly complex, adding to development costs for biopharmaceutical products. Today, clinical trials are longer, have more participants (who are difficult to recruit and retain), and involve more demanding and complex trial design and clinical protocols (including more procedures per patient and difficult-to-measure clinical endpoints). In addition, there is an increasing challenge of developing new therapies for complex diseases and more testing against comparator drugs.[8/]

In addition, while the 1984 Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act") was designed to achieve a balance between increased generic competition while preserving sufficient patent exclusivity to ensure continued R&D development, the dramatic increase in generic competition and the increase in the number of Paragraph IV certifications[9/] challenging the validity of drug patents have created great uncertainty for pharmaceutical innovators. This risk and uncertainty is magnified when one also considers the increasing generic utilization rate and the increasingly rapid erosion of the brand market to generic drugs. In 2007, generics represented 67 percent of prescriptions filled in the United States, up from 19 percent in 1984.[10/] Thus, the significant investments needed to develop, seek approval of, and successfully market a medicine are supported by a smaller and smaller percentage of total U.S. prescriptions, and this trend can be expected to continue. This fact demonstrates that patent protections will continue to be even more essential to allow these significant investments to be recouped. When a generic version of a medicine becomes available for the first time, it can capture as much as 86 to 97 percent of the market within the first month.[11/] This dramatic and rapid impact on brand market share increases the risk and uncertainty involved in innovative drug development.

Commentators have found that the number of patent challenges associated with Paragraph IV filings has grown in recent years and that these legal challenges are occurring much earlier in a drug's lifecycle.[12/] Changes in the Food and Drug Administration's implementation of the 180-day exclusivity period resulted in it being awarded to the first

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/8 Tufts University Center for the Study of Drug Development, *Growing Protocol Design Complexity Stresses Investigators, Volunteers*, Tufts Impact Report (Jan./Feb. 2008), *available at* http://csdd.tufts.edu/_documents/www/Doc_309_65_893.pdf.

/9 Under the Hatch-Waxman Act, generic drug companies may submit Abbreviated New Drug Applications ("ANDAs") that rely upon the submissions in an innovator pharmaceutical company's approved New Drug Application. *See* 21 U.S.C. § 355(j). If an ANDA applicant seeks to market its drug before the Orange-Book-listed patents on the relevant innovator pharmaceutical expire, then under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) the generic drug company must certify that those patents are invalid or will not be infringed. Such certifications are commonly known as "Paragraph IV certifications."

/10 PhRMA tabulation of 1984-2000 data: IMS Health Inc., National Prescription Audit Plus™; IMS Health News Release, *IMS Health Reports U.S. Prescription Sales Grew 3.8 Percent in 2007 to $286.5 Billion* (Mar. 12, 2008), *available at* http://www.imshealth.com.

/11 Medco, *2008 Drug Trend Report* (2008) at 9, *available at* http://medco.mediaroom.com/file.php/162/2008+DRUG+TREND+REPORT.pdf

/12 Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 Managerial and Decision Economics 491, 492 (2007).

applicant to file an abbreviated application with a patent challenge, rather than requiring the generic challenger to prevail in the underlying court case in order to receive the grant of 180-day exclusivity.[13] According to one commentator, "[m]ost of these patent challenges now occur four years after market approval which is the earliest point in time that a generic firm can submit an ANDA filing with a paragraph IV certification."[14] Such "[e]arly patent challenges also can have a chilling effect on the development of new indications and formulations, given the uncertain time horizon concerning generic entry and the fact that new indications are developed and approved several years after the original approval."[15]

Lastly, pharmaceutical products have a much shorter effective patent life compared to the effective patent life in other industries. Commentators have examined this issue for a more recent sample of products experiencing initial generic competition.[16] They found the marketing exclusivity period (defined as the time from innovator approval to first generic entry into the market) for new molecular entities was in the range of 12 to 15 years, with products with larger sales at the time of first generic entry having lower average marketing exclusivity periods.[17] For medicines with annual sales of more than $100 million (which accounts for 90% of the sales of medicines exposed to generic competition) whose generic competitors entered the market in 2005, the average time on the market before generic competition was 11.5 years.[18] Continued erosion of the effective patent life of pharmaceutical patents may put future investments into new medicines at risk. According to the commentators, these "values for [market exclusivity periods] represent relatively short product life cycle return periods for products that typically take more than a decade to develop and whose sales revenues are critical to the returns to R&D for the overall portfolio of new drug introductions."[19] The continued erosion of pharmaceutical patent life could cause the rate of new product introductions to decline dramatically, to the detriment of both innovator companies and generic drug manufacturers.

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[13] For a discussion of the changes to the law, including elimination of the "successful defense requirement," see Erika Lietzan & David Korn, *Issues in the Interpretation of 180-Day Exclusivity*, 62 FOOD AND DRUG LAW JOURNAL 1, 54, 59 (2007).

[14] Henry G. Grabowski, *Data Exclusivity for New Biological Entities*, Duke University Department of Economics working paper (Jun. 2007) at 28, *available at* http://www.econ.duke.edu/Papers/PDF/DataExclusivityWorkingPaper.pdf [hereinafter Data Exclusivity for New Biological Entities].

[15] *Id.* at 29.

[16] Grabowski & Kyle, *supra*, at 491-502.

[17] *Id.*

[18] *Id.*

[19] *Id.* at 497.

B. Patent protection is increasingly important to innovating biopharmaceutical companies because the development of new medicines is a long, costly, and risky process and total development time has grown significantly.

In 2007, there were more than 2,700 molecules in development or awaiting approval for use by U.S. patients.[20/] Development of new medicines is a long and high-risk process, and it has become more costly and complex over the last decade. Without strong patent protection, biopharmaceutical companies could not afford to make the significant investments that are needed to develop these new medicines.

Between 1960 and 2007, the average development time for new medicines increased from approximately eight years to between 10 and 15 years.[21/] At the same time, costs to bring new discoveries from bench to bedside have also increased. Recent analysis estimates the average cost to develop a new medicine to be more than $1.2 billion.[22/] This number includes the cost of the thousands of once-promising but ultimately failed initiatives—products that never made it to market. For every 5,000-10,000 compounds that enter the R&D pipeline, only 250 reach the pre-clinical stage. Of those compounds, only five progress to clinical study in humans, and ultimately only one receives regulatory approval.[23/] Figure 1 illustrates the research and development process.

/20 PhRMA, *Profile 2008* (2008), *available at* http://www.phrma.org/files/2008%20Profile.pdf.

/21 *Id.*; Joseph A. DiMasi, *New Drug Development in the U.S. 1963-1999*, 69 Clinical Pharmacology & Therapeutics 286, 292 (2001).

/22 Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 Managerial and Decision Economics 469, 477 (2007).

/23 PhRMA, *Drug Discovery and Development: Understanding the R&D Process* (2007), *available at* http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf.

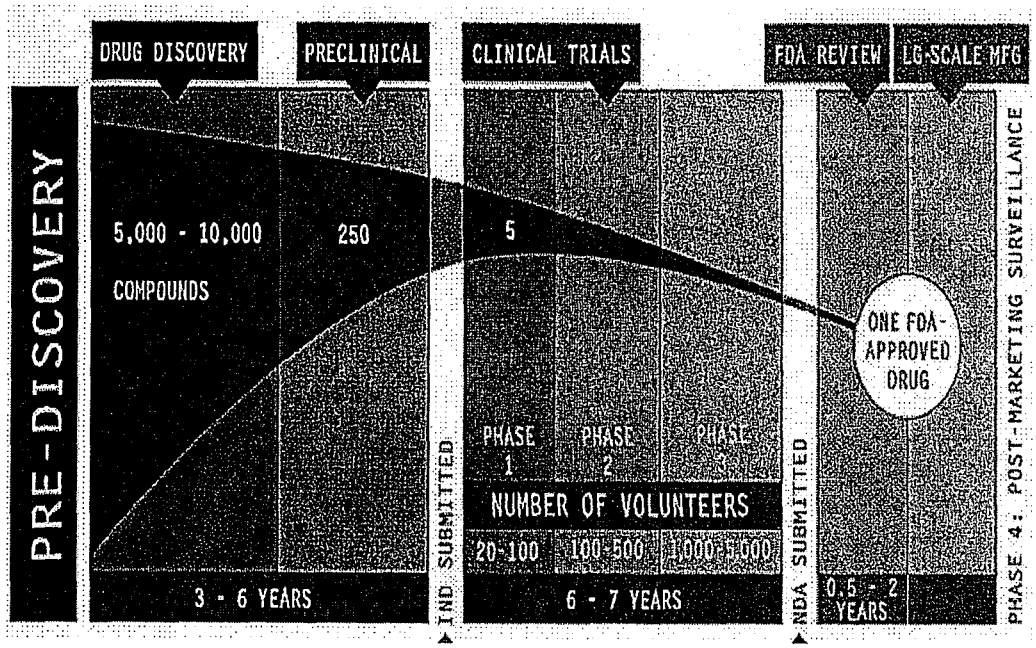

Figure 1. The Research and Development Process

Further, as discussed above, for those drugs or biologics that do reach human clinical trials, those trials have become lengthier, more complex and more costly to perform. In addition to increases in the number of clinical studies performed, the number of unique procedures per clinical protocol has grown, as have the criteria for enrollment and the time to conduct clinical trials.[24/] Moreover, only two in 10 approved medicines bring in enough revenue to recoup the average cost of development.[25/] These dynamics reinforce the importance of strong intellectual property protection and appropriate incentives to ensuring a vital, innovative biopharmaceutical sector.

C. Intellectual property rights play critical roles in the cycle of innovation for the biopharmaceutical industry.

Strong intellectual property rights serve important purposes throughout the drug development process. First, intellectual property rights protect early stage innovation, which is essential to the development of new treatments and cures. The ability to obtain intellectual property protection for early-stage research encourages research-based companies to make necessary fundamental investments.

Second, intellectual property rights enable the development of final, marketable drug products and make further, related innovation possible. Intellectual property protection of a

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/24 Tufts University Center for the Study of Drug Development. "Growing Protocol Design Complexity Stresses Investigators, Volunteers." *Tufts Impact Report* (Jan./Feb. 2008), *available at* http://csdd.tufts.edu/_documents/www/Doc_309_65_893.pdf.

/25 John Vernon, Joseph Golec & Joseph DiMasi, *Drug Development Costs When Financial Risk Is Measured Using the FAMA-French Three Factor Model* (Jan. 2008) (submitted to the Journal of Health Economics).

marketable drug product encourages not only development of that product but also makes possible further development of that innovation and related innovations to bring about improved therapies and cures.

Third, protection of intellectual property in marketed products gives their manufacturers the opportunity to benefit financially from the potential commercial promise created by the innovation. This provides incentives for further investment to support the research, development, and refinement needed for future treatments and cures.

Fourth, by providing incentives for the biopharmaceutical industry to develop cures and treatments and bring them to market, intellectual property protection plays an integral role in the creation of a biopharmaceutical market in which generic companies can compete with research companies following the expiration of intellectual property rights.

D. Patent rights are increasingly important to attracting direct investments in biopharmaceutical innovation from private investors.

The strength of intellectual property protection profoundly impacts investment in the biopharmaceutical industry. Substantial investments are needed to facilitate pharmaceutical innovations, and direct investors demand a potential return on their investment commensurate with the high costs and risks of drug development. These investors recognize that a "majority of their high risk early stage investments will fail ... [but] strong returns on a few successful projects are often enough to justify investments in high risk endeavors that entail many losses."[26] Indeed, every drug that ultimately is approved by the FDA is responsible for recouping the costs of the many other investigational drugs that never made it to market. Accordingly, the pharmaceutical industry depends on patents to provide its investors with returns that are commensurate with their significant up-front investments.

In addition, with collaboration and partnerships among traditional pharmaceutical companies, small biotechnology companies, and research institutions becoming an ever increasing component of bringing new medicines to patients, the need for venture capital in support of research is critical. Absent strong patent protection, venture capitalists, who have been essential in financing biotech and startup companies, likely would shift funding to other industries. In fact, one report found that between 2002 and 2006, venture capitalists became more risk averse and shifted their focus to later-stage, product-focused alliances.[27] This reflects an investment focus on expected returns within their investment horizons and may negatively impact the sectors and partnerships working on basic research. This trend would likely be exacerbated if patent protections are not maintained at a level that provides sufficient incentives for innovation.

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[26] Data Exclusivity for New Biological Entities, *supra*, at 14.

[27] Ernst & Young, *Beyond Borders: A Global Perspective* (2006).

E. The existence of non-practicing entities is not a significant change in the IP marketplace.

The FTC's second question asks about new business models involving IP and their impact on innovation. In considering this issue, it is important to recognize that so-called non-practicing entities ("NPEs") are not a new development in the IP marketplace but rather have been around since the dawn of the patent system.[28] NPEs include individual inventors, universities, pre-product companies, and companies inventing outside their product areas.[29] NPEs constitute only a small segment of patent holders, and generally are legitimate enterprises such as universities. In fact, Nathan Myhrvold, previously Microsoft Corporation's first chief technological officer, wrote that "[o]nly 2% of all patent lawsuits [involve] plaintiffs that have no ongoing product business. Of that 2%, the vast majority are perfectly legitimate companies or universities."[30]

The presence of NPEs in the IP marketplace also provides some distinct benefits. For example, one commentator has noted that many NPEs have the capital to create a credible threat of litigation to potential infringers and thus create economic value for inventions that represent important scientific advances.[31] In addition, NPEs create a more centralized market by coordinating exchange of patents, thus making patents more liquid.[32] NPEs thus can incentivize individual inventors and small entities to invent by increasing patent liquidity and decreasing risk.[33]

II. To Ensure That The Patent System Provides Proper Incentives For Innovation, The Existence Of Direct Competition Between The Patentee And The Infringer Nearly Always Should Support An Award Of Injunctive Relief.

The FTC's third question asks what economic evidence is relevant when analyzing whether to grant a permanent injunction following a finding of infringement. This issue is of

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[28] Marc Morgan, *Stop Looking Under the Bridge for Imaginary Creatures: A Comment Examining Who Really Deserves the Title Patent Troll*, 17 FED. CIR. B.J. 165, 168 (2007).

[29] Written Testimony of Peter Detkin before the Antitrust Modernization Commission, Hearings on Patent Law Reform 8 (Nov. 8, 2005), *available at* http://govinfo.library.unt.edu/amc/commission_hearings/pdf/statement_Detkin.pdf (hereinafter Detkin AMC Testimony); Morgan, *supra*, at 176.

[30] Nathan Myhrvold, *Inventors Have Rights, Too!*, WALL ST. J., Mar. 30, 2006, at A14; *see also Perspectives on Patents: Post-Grant Review Procedures and Other Litigation Reforms: Hearing before the Subcommittee on Intellectual Property of the S. Comm. on the Judiciary,* 109th Cong. at 10 (2006) (statement of Nathan Myhrvold, founder, Intellectual Ventures); *available at* http://www.intven.com/docs/NMyhrvoldTestimony052306.pdf.

[31] James F. McDonough III, *The Myth of the Patent Troll: An Alternative View of the Function of Patent Dealers in an Idea Economy*, 56 EMORY L.J. 189, 212 (2006); Morgan, *supra*, at 174.

[32] McDonough at 213-14; Testimony of Peter Detkin, *FTC Hearing on the Evolving IP Marketplace, Panel 1: Developing Business Models* 30 (Dec. 5, 2008), *available at* http://htc-01.media.globix.net/COMP008760MOD1/ftc_web/FTCindex.html#Dec5_08 [hereinafter Detkin FTC Transcript].

[33] McDonough, *supra*, at 223.

great importance to biopharmaceutical research companies as these businesses depend on the availability of injunctive relief against infringing competitors.

In *eBay, Inc. v. MercExchange, LLC*, the Supreme Court overturned the Federal Circuit's "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances."[34] Under *eBay*, patentees seeking a permanent injunction following a finding of infringement must satisfy the traditional four-factor test for injunctive relief.[35] Most patentees continue to be granted permanent injunctions under the *eBay* standard, as courts have identified numerous economic considerations that favor injunctive relief under the traditional four-factor test. The courts appropriately have focused on the existence of direct competition between the patentee and the infringer as the predominant consideration in the permanent injunction inquiry. However, under a four-factor test, there is no rule in favor of the issuance of injunctions, and courts could come out differently, creating uncertainty.

A. After the Supreme Court's decision in *eBay, Inc. v. MercExchange, LLC*, numerous economic considerations continue to support an award of injunctive relief following a finding of patent infringement.

In *eBay, Inc. v. MercExchange, LLC*, the Supreme Court held that the decision to award or deny injunctive relief in patent cases must be made in accordance with "traditional principles of equity."[36] Under those principles, a patentee seeking injunctive relief for patent infringement must show: "(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."[37] In so holding, the Court rejected the use of categorical rules as a substitute for a full analysis of this traditional four-factor test.[38]

Importantly, the Supreme Court also recognized in *eBay* that, under the Patent Act, "patents shall have the attributes of personal property," including "the right to exclude others from making, using, offering for sale, or selling the invention."[39] Further emphasizing the importance of a patentee's right to exclude, Chief Justice John Roberts observed:

> From at least the early 19th century, courts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases. This long tradition of equity practice is not surprising, given the difficulty of protecting a right to exclude through monetary remedies that allow an infringer to use an invention

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[34] 547 U.S. 388, 391 (2006) (citation omitted).

[35] *Id.*

[36] *Id.* at 394.

[37] *Id.* at 391.

[38] *Id.* at 393-94.

[39] *Id.* at 392 (quoting 35 U.S.C. §§ 261, 154(a)(1)).

> against the patentee's wishes—a difficulty that often implicates the first two factors of the traditional four-factor test.[40]

Accordingly, Chief Justice Roberts admonished that, when deciding whether to grant injunctive relief, courts should remember that "a page of history is worth a volume of logic."[41]

In the cases decided after *eBay*, district courts appear to be following Chief Justice Roberts' admonition. Indeed, courts have identified numerous economic considerations, rooted in competition, that support injunctive relief under the traditional four-factor test. Some of the most significant economic considerations include: direct competition, lost market share, lost sales, price erosion, reduction in the plaintiff's ability to create customer relationships, inability to calculate the plaintiff's future losses with precision, loss of brand name recognition and good will, the existence of an established policy not to license the patented technology at issue, damage to the plaintiff's reputation for innovation, and the relative contribution a patented invention makes to the infringing device.[42] Because so many equitable considerations commonly favor injunctive relief following a finding of infringement, permanent injunctions continue to be awarded in most patent cases. In fact, courts granted permanent injunctions following a finding of infringement in eighty percent of the cases decided in the two-year period after the *eBay* decision.[43]

B. The existence of direct competition between the patentee and the infringer is generally the focus of the district courts' application of the traditional four-factor test for injunctive relief.

It has been widely recognized that, following the *eBay* decision, the existence of direct competition between the patentee and the infringer is one of the most important considerations in determining whether to grant injunctive relief.[44] Indeed, in the two-year period after the *eBay* decision, permanent injunctions issued in all but two of the twenty-six cases in which the district court found direct competition between the patentee and the infringer.[45] Conversely, during the

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[40] *Id.* at 395 (Roberts, C.J., concurring) (internal quotation marks omitted).

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

[42] *See* Douglas Ellis et al., *The Economic Implications (And Uncertainties) of Obtaining Permanent Injunctive Relief after eBay v. MercExchange*, 17 FED. CIR. B.J. 437 (2008); Bernard H. Chao, *After eBay, Inc. v. MercExchange: The Changing Landscape for Patent Remedies*, 9 MINN. J.L. SCI. & TECH. 543 (2008); Edward D. Manzo, *Injunctions in Patent Cases after eBay*, 7 J. MARSHALL REV. INTELL. PROP. L. 44 (2007).

[43] *See* Ellis et al., *supra*, at 441-42 & n.35-36 (collecting cases).

[44] *See, e.g., id.* at 442-43; Chao, *supra*, at 549-55; 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, 633 (2007); Gregory A. Castanias et al., *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, 812 (2007); Jeremy Mulder, *The Aftermath of eBay: Predicting When District Courts Will Grant Permanent Injunctions in Patent Cases*, 22 BERKELEY TECH. L.J. 67, 67 (2007); Darryl J. Adams & Victoria Wicken, *Permanent Injunctions after eBay v. MercExchange: The Year in Review*, 15 TEX. INTELL. PROP. L.J. 417, 422-25 (2007).

[45] Ellis et al., *supra*, at 442-43.

same period, when the district court found that the patentee and the infringer did not directly compete, injunctions were granted less than half the time.[46/]

The Federal Circuit has indicated that direct competition is key to the permanent injunction inquiry. For example, in *Acumed LLC v. Stryker Corp.*, the court held that "[a]dding a new competitor to the market may create an irreparable harm" even where the plaintiff had previously granted licenses to other parties.[47/] The court explained that while the grant of previous licenses tends to establish that the patentee could be compensated for ongoing infringement by money damages, "the identity of the past licensees, the experience in the market since the licenses were granted, and the identity of the new infringer," who was a direct competitor, all tended to favor injunctive relief.[48/]

In addition, many district courts have stated that direct competition weighs heavily in favor of granting injunctive relief. For example, in *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, the district court explained that while there is "no categorical presumption in favor of granting an injunction when an infringer is in direct competition with a patent holder . . . the fact that parties are direct competitors weighs heavily in determining the presence of irreparable injury."[49/]

C. The courts are correct to focus on direct competition between the parties as the key to the permanent injunction inquiry.

1. Focusing on direct competition emphasizes the most important economic considerations in the permanent injunction inquiry.

As one district court recently stated, "It is easy to understand why courts have continued to issue injunctions where the infringer will become a direct competitor."[50/] Indeed, direct competition implicates nearly all of the other economic considerations upon which courts typically rely when granting injunctions. When there is direct competition by an infringer, there is also likely to be, among other things, lost market share, lost sales, price erosion, reduction in plaintiff's ability to create customer relationships, inability to calculate plaintiff's future losses with precision, and loss of brand name recognition and good will.[51/]

/46 *Id.* at 443.

/47 — F.3d —, No. 2008-1124, 2008 WL 5397567, at *3 (Fed. Cir. Dec. 30, 2008).

/48 *Id.*

/49 No. 05-CV-1071, 2007 WL 5011980, at *6 (N.D. Ga. Feb. 23, 2007). *See also, e.g., Visto Corp. v. Seven Networks, Inc.*, No. 03-CV-333, 2006 WL 3741891, at *4 (E.D. Tex. Dec. 19, 2006) (noting that the parties "are direct competitors, and this fact weighs heavily in the court's analysis" of irreparable injury); *TiVo, Inc. v. EchoStar Commc'ns Corp.*, 446 F. Supp. 2d 664, 669-70 (E.D. Tex. 2006) (noting that direct competition "weighs heavily" in the permanent injunction inquiry and finding irreparable harm because the defendant's infringing products directly competed with the plaintiff's product and caused the plaintiff to lose market share).

/50 *Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 581 F. Supp. 2d 160, 212 (D. Mass. 2008).

/51 Ellis et al., *supra*, at 444-45.

For example, in one recent case, the district court explained that "*eBay* has changed little where a prevailing plaintiff seeks an injunction to keep an infringing competitor out of the market" and added that "[t]his case is no exception to that trend."[52] In particular, the court found that direct competition from the infringing product would cause the patentee to lose "profits, market share, and good will."[53] The court added that the infringer's "entry into the market, despite a judgment of infringement, could encourage other would-be infringers to attempt to gain access, resulting in significant litigation expenses and uncertainty about the value of [the patentee's] patents."[54] The court also found that direct competition from the infringer would cause the patentee's stock price to fall, "along with its ability to attract investment for research and development."[55] Based on these economic considerations, the court determined that direct competition from the infringer would cause the patentee "potentially immense and unquantifiable" irreparable harm "for which monetary damages are inadequate."[56] In addition, the court found that "the public's interest in a robust patent system that maintains incentives for pharmaceutical innovation outweighs the highly speculative, de minimis benefits that might occur as the result of a denial of an injunction."[57] Accordingly, the district court granted the patentee a permanent injunction.[58]

Similarly, in the preliminary injunction context, where courts also must consider evidence of irreparable harm,[59] economic considerations associated with direct competition have strongly favored awards of injunctive relief. For example, in *Sanofi-Synthelabo v. Apotex, Inc.*, the Federal Circuit affirmed an award of preliminary injunctive relief based on evidence that direct competition from the defendant's potentially infringing generic drug would result in "irreversible price erosion, loss of good will, potential lay-offs . . ., and the discontinuance of clinical trials that are devoted to other medical uses for [the patentees' drug]."[60] Likewise, in

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[52] *Amgen*, 581 F. Supp. 2d at 210.

[53] *Id.* at 212. *See also, e.g., Smith & Nephew, Inc. v. Synthes*, 466 F. Supp. 2d 978, 983 (W.D. Tenn. 2006) (noting that the parties were in direct competition and finding that the infringing competition caused the plaintiff to lose market share, profits, and brand name recognition—"injuries that are both incalculable and irreparable").

[54] *Amgen*, 581 F. Supp. 2d at 212.

[55] *Id.*

[56] *Id.*

[57] *Id.* at 210.

[58] *Id.* at 229; *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, No. 05-CV-12237 (D. Mass. Oct. 17, 2008) (Entry of Judgment). The district court entered the permanent injunction after the Federal Circuit affirmed, without opinion, the district court's decision to grant a preliminary injunction. *See Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, No. 2008-1300, 2008 WL 4532186 (Fed. Cir. Oct. 10, 2008) (per curiam).

[59] "The standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success." *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1364 (Fed. Cir. 2008) (quoting *Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 546 n.12 (1987)).

[60] 470 F.3d 1368, 1381-83 (Fed. Cir. 2006). *See also, e.g., Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001) ("Given the testimony of the likelihood of price erosion and loss of market position without corresponding market expansion from the introduction of [defendant's directly competing] product, we see no deficiency in the district court's finding of irreparable harm").

Everett Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc., the district awarded preliminary injunctive relief where the patentee showed that direct competition from the defendant's potentially infringing generic drug would result in lost sales, lost market share that "cannot be quantified," and loss of good will.[61]

2. Focusing on direct competition in the permanent injunction inquiry simultaneously promotes innovation, competition, and public access to products and technology.

Commentators have observed that focusing on direct competition between the patentee and the infringer in the permanent injunction inquiry promotes innovation without stifling competition. In particular, commentators argue that when the patentee competes with the infringer, the availability of an injunction maintains incentives for innovation by allowing the patentee to recoup the costs of its investment and profit directly from its invention.[62] Conversely, commentators argue that when the patentee does not compete with the infringer, the patentee generally will not suffer irreparable harms such as lost brand-name recognition or lost goodwill with customers.[63] In addition, Justice Anthony Kennedy has indicated that where the patentee and the infringer compete in the marketplace, there is little risk that the patentee is using the threat of an injunction only as "a bargaining tool to charge exorbitant [licensing] fees."[64]

Focusing on direct competition in the permanent injunction inquiry also helps to support public access to patented products and technology. When the patentee sells a product that competes with the infringer's product, the marketplace generally is not deprived of the patented product or technology if the patentee obtains an injunction.[65]

III. The Current Legal Rules Governing Patent Damages Result In Awards That Appropriately Compensate Patentees.

The FTC's fourth question asks whether the legal rules governing patent damages result in appropriate damages awards. The evidence shows that current legal rules are effective and appropriately flexible and that damages awards have remained constant for 13 years. Further, courts currently have appropriate discretion to overturn inappropriate or excessive jury awards. Because the determination of a reasonable royalty is unique to the nature of the invention, the value to the infringer of its unauthorized use, the industry, the competitive posture of the parties, prior licensing history, the availability of non-infringing substitutes, and other circumstances particular to the case, courts have long recognized "the immense variety of patents" prevents "any one rule of damages which will equally apply to all cases."[66]

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[61] 573 F. Supp. 2d 855, 867-69 (D.N.J. 2008).

[62] Chao, *supra*, at 553-54.

[63] Ellis et al., *supra*, at 444-45; Chao, *supra*, at 553-54.

[64] *eBay*, 547 U.S. at 396 (Kennedy, J., concurring).

[65] *See* Chao, *supra*, at 553-54.

[66] *Seymour v. McCormick*, 57 U.S. 480, 489 (1853).

Proposed legislative reforms that would dramatically alter the current legal framework and mandate so-called "apportionment" in every reasonable royalty analysis would lead to significant adverse consequences for patent holders in innovative industries. Such provisions, if enacted, would dramatically reduce the value of patents and introduce significant cost, uncertainty, and complexity into damages calculations.

A. The current legal framework for determining damages awards is effective.

The Patent Act requires that an award of damages for infringement must be "adequate to compensate for the infringement."[67] The Patent Act also provides that the patentee is entitled, at a minimum, to an award of a reasonable royalty.[68] The Federal Circuit has explained that "the purpose of this alternative is not to provide a simple accounting method, but to set a floor below which the courts are not authorized to go."[69] As the Supreme Court explained in *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, "The question to be asked in determining damages is how much had the Patent Holder and Licensee suffered by the infringement. And that question is primarily: had the Infringer not infringed, what would Patent Holder-Licensee have made?"[70] Thus, the general rule is that a patentee should be able to recover lost profits damages whenever the patentee would have made the sales but for the infringing competition.[71] As this well-reasoned precedent demonstrates, lost profits damages are critical to making patentees whole for patent infringement. Indeed, where patent holders and patent infringers are competitors in the marketplace, lost profits are the only measure of damages "adequate to compensate for the infringement."[72]

If a patentee cannot prove its entitlement to lost profits damages—i.e., cannot show that it would have made the sales but for the infringing competition—the court must award the patentee, at a minimum, a "reasonable royalty" for the infringement.[73] The amount of this reasonable royalty is often established by looking to the result of what the patentee (licensor) and infringer (licensee) would have agreed upon if they had engaged in arm's length negotiations at the time the infringement began.[74] More specifically, it is—

> [t]he amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both

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[67] 35 U.S.C. § 284.

[68] *Id.*

[69] *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1326 (Fed. Cir. 1987).

[70] 377 U.S. 476, 507 (1964) (internal quotation marks and citation omitted).

[71] *See, e.g., American Seating Co. v. USSC Group, Inc.*, 514 F.3d 1262, 1269 (Fed. Cir. 2008); *see also* Marion B. Stewart, *Calculating Economic Damages in Intellectual Property Disputes: The Role of Market Definition*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 321, 321 (1995) ("If . . . the plaintiff used (or would have used) the invention to increase its sales, lower its costs, or both, then it can be made whole only by an award that properly accounts for the profits lost as a result of the infringement.").

[72] 35 U.S.C. § 284.

[73] *Id.*

[74] *Georgia-Pacific Corp. vs. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

> had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention—would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who is willing to grant a license.[75]

The case law makes clear that the pretext of the hypothetical negotiations is that there is a license being sought to practice the patented invention, and also that the license is negotiated at the time infringement began.[76] As uniformly applied by the courts, the patent is therefore assumed to be valid, enforceable, and infringed for purposes of the hypothetical negotiations.[77]

The assumption that the patent is valid, enforceable and infringed is, of course, a predicate to a damages award. These assumptions are also appropriate to avoid the pretense that infringement never happened. As explained by Judge Howard T. Markey, who later became the first chief judge of the U.S. Court of Appeals for the Federal Circuit:

> The setting of a reasonable royalty after infringement cannot be treated . . . as the equivalent of ordinary royalty negotiations among truly "willing" patent owners and licensees. That view would constitute a pretense that the infringement never happened. It would also make an election to infringe a handy means for competitors to impose a "compulsory license" policy upon every patent owner.
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> . . . [T]he infringer would have nothing to lose, and everything to gain if he could count on paying only the normal, routine royalty non-infringers might have paid. As said by this court in another context, the infringer would be in a "heads-I-win, tails-you-lose" position.[78]

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[75] *Id.* at 1120.

[76] *See Wang Labs. Inc. v. Toshiba Corp.*, 993 F.2d 858, 870 (Fed. Cir. 1993) (hypothetical negotiation "speaks of negotiations as of the time infringement began") (citation omitted); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1554 (Fed. Cir. 1995) (court must "envision the terms of a licensing agreement reached as the result of a supposed meeting between the patentee and the infringer at the time infringement began").

[77] *See, e.g., St. Clair Intellectual Prop. Consultants, Inc. v. Canon Inc.*, No. 2003-241, 2004 WL 2213562, at *3 (D. Del. Sept. 28, 2004) ("Patents are presumed valid, enforceable, and infringed in the context of an expert's formulation of an opinion on damages in a patent trial."); *Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.*, 216 F. Supp. 2d 1188 (D. Colo. 2002) ("A hypothetical negotiation employed after litigation assumes that the patent is valid."); *Northlake Mktg. & Supply, Inc. v. Glaverbel*, S.A., 72 F. Supp. 2d 893, 902 (N.D. Ill. 1999) ("Such a reasonable royalty is determined based upon a hypothetical negotiation between the patent owner and the infringer . . . with both parties to the negotiation assuming that the patent is valid and would be infringed but for the license."); *TP Orthodontics, Inc. v. Prof'l Positioners, Inc.*, No. 72-C-697, 1991 WL 187189, at *11 (E.D. Wis. July 2, 1991) ("Any negotiation is based on the assumption that the patent was valid and infringed."), *modified on other grounds*, 1992 WL 189670 (E.D. Wis. Jan. 29, 1992), *aff'd*, 980 F.2d 743 (Fed. Cir. 1992).

[78] *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1158 (6th Cir. 1978); *see also Proctor & Gamble Co. v. Paragon Trade Brands, Inc.*, 989 F. Supp. 547, 614 (D. Del. 1997) (to create "fiction" associated with hypothetical reasonable royalty includes assumption that "patented claims at issue are deemed unquestionably valid and enforceable and will be infringed by the products of the licensee in the absence of a negotiated license.").

In addition, courts typically consider fifteen factors, first set out in *Georgia-Pacific Corp. v. United States Plywood Corp.*,[79] when determining an appropriate and reasonable royalty to compensate for infringement.[80] The *Georgia-Pacific* multi-factor test provides courts with suitable guidance to determine reasonable royalty rates. As the Department of Commerce recently noted: "It appears that the courts have adequate guidance through *Georgia-Pacific* and, as a general matter, do in fact consider numerous factors in determining royalty rates."[81]

The law on reasonable royalty damages developed by the courts is "highly stable and well understood by patent litigators as well as judges."[82] The flexibility of the current framework allows court and juries to distinguish among patents and focus on the most pertinent considerations for the patented invention at issue. For example, patents in the biotechnology and pharmaceutical industries are different in nature and purpose from those in information technology industries.[83] As discussed above, pharmaceutical and biotechnology products have long development life cycles and require substantial investments in research and development.[84] Individual patents are critical to these industries because many pharmaceutical and biotechnology products are covered by only one or a few patents.[85] These differences can affect the amount of damages that are appropriate under the circumstances, and courts can accommodate the differences by instructing juries accordingly.[86] Notably, this hypothetical negotiation approach is also incorporated into a bill passed by the Senate in September 2008 that would place a limitation on judicial remedies in copyright infringement cases involving orphan works.[87]

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[79] *Georgia-Pacific*, 318 F. Supp. at 1120.

[80] *Minks v. Polaris Indus., Inc.*, 546 F.3d 1364, 1372 (Fed. Cir. 2008).

[81] Letter from John J. Sullivan, General Counsel of the U.S. Dep't of Commerce to the Hon. Howard L. Berman, Chairman, Subcommittee on Courts, the Internet, and Intellectual Property, Committee of the Judiciary, House of Representatives at 6 (May 16, 2007), *available at* http://www.uspto.gov/web/offices/dcom/olia/harmonization/j_sullivan.pdf.

[82] Clarisa Long, *Our Uniform Patent System*, 55-FEB. FED. LAW. 44, 47 (2008) (quoting Chief Judge Michel of the Court of Appeals for the Federal Circuit).

[83] *Id.*

[84] R. Polk Wagner, *When the "One Size Fits All" U.S. Patent System Doesn't Fit All*, PAT. L. & POL'Y (Spring 2008), *available at* http://www.law.upenn.edu/blogs/polk/patents/archives/2008/04/when_the_one_si.html.

[85] *Id.*

[86] *Id.*

[87] *See* S. 2913, Shawn Bentley Orphan Works Act of 2008 (110th Cong. Engrossed as Passed by Senate) (defining "reasonable compensation" as "the amount on which a willing buyer and willing seller in the positions of the infringer and the owner of the infringed copyright would have agreed with respect to the infringing use of the work immediately before the infringement began").

B. The size of patent damages awards has remained consistent over time.

Some commentators have suggested that damages awards have increased sharply in recent years,[88] yet the empirical data shows otherwise. According to a study conducted by PricewaterhouseCoopers ("PwC") in 2008, median damages awards have remained constant over the last 13 years when adjusted for inflation.[89] PwC's analysis showed that from 1995 to 2000, the median damages award was $3.9 million, and from 2001 to 2007, the median damages award was $3.8 million.[90]

Moreover, in those cases where a jury's damages award is inappropriate, the district court or the Federal Circuit can, and routinely does, correct it.[91] In recent years, various stakeholders and commentators have trumpeted specific cases as evidence that damages awards are excessive. For example, during a congressional hearing in 2007, Professor John R. Thomas relied on ten cases to support his contention that damages awards do not fairly reflect the patent's contribution to the infringing product.[92] More detailed analysis of the ten cases, however, revealed that the damages awards appropriately compensated the patentee for infringement.[93]

For example, *Lucent Techs., Inc. v. Gateway, Inc.* has been cited widely as evidence that new damages rules are needed. In *Lucent*, the jury awarded $1.5 billion in damages to Lucent, split evenly between two patents.[94] Yet on a motion for judgment as a matter of law, the district court held that Lucent lacked standing to sue on one patent and that Microsoft did not infringe

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[88] *See, e.g.*, Viet D. Dinh, *Yes to the Patent Reform Act*, AMERICAN SPECTATOR (Dec. 3, 2007), *available at* http://spectator.org/archives/2007/12/03/yes-to-the-patent-reform-act; Sarah M. King, *Clearing the Patent Thicket: The Supreme Court and Congress Undertake Patent Reform*, 19 INTELL. PROP. & TECH. L.J. 13, 16 (2007); Cecil D. Quillen, Jr., *Innovation and the U.S. Patent System*, 1 VA. L. & BUS. REV. 207, 217-18 (2006).

[89] PricewaterhouseCoopers, 2008 Patent Litigation Study: Damage Awards, Success Rates and Time-to-Trial 1-2, *available at* http://www.pwc.com/extweb/pwcpublications.nsf/docid/EBC144CF6220C1E785257424005F9A2B/$file/2008_patent_litigation_study.pdf.

[90] *Id.* at 2.

[91] *See, e.g., TruePosition Inc. v. Andrew Corp.*, 568 F. Supp. 2d 500, 525 (D. Del. 2008) (reducing the jury damages award of $45.3 million to $18.6 million, finding that the evidence did not reasonably support the jury's award because of its speculative nature); *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys. LLC*, 350 F.3d 1327, 1345-46 (Fed. Cir. 2003) (vacating lost profit damages award where the district court based the award on evidence of sales of a device that embodied infringing and non-infringing features); *Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 871-72 (Fed. Cir. 2003) (vacating district court's damages award of $15 million because it was not supported by the evidence of record and instructing the district court to consider on remand the effect of stacking royalties in arriving at the appropriate damages award), *rev'd. on other grounds*, 545 U.S. 193 (2005); *Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1311-12 (Fed. Cir. 2002) (vacating jury's reasonable royalty award of $8.7 million based on the value of the entire oil platform where the patent was directed to a method of anchoring offshore oil rigs without mud mats).

[92] Professor John R. Thomas, Hearing on The Patent Reform Act of 2007 before the U.S. House of Representatives Subcommittee on Courts, the Internet, and Intellectual Property 3-5 (April 26, 2007), *available at* http://judiciary.house.gov/hearings/April2007/Thomas070426.pdf.

[93] William C. Rooklidge, *Patent Damages Reform: The AIPLA Response to Professor Thomas*, *available at* http://www.patentsmatter.com/press/pdfs/Patent_Damages_Reform_ Rooklidge.pdf.

[94] No. 02-CV-2060, slip op. at 8 (S.D. Cal. Feb. 22, 2007).

the other patent.[95] The court further held that the jury misapplied the entire market value rule in determining damages and that the jury's reasonable royalty award was against the clear weight of the evidence.[96] The Federal Circuit affirmed the holding of no standing and non-infringement and thus did not reach the damages issues.[97] Given that this case was resolved favorably for the alleged infringer—with no damages award ever paid—this case cannot support an argument that current damages law is broken. Other cases cited by proponents of statutory reform to the calculation of patent damages similarly cannot withstand a closer look.[98]

C. Mandating apportionment in every case would decrease the value of patents and introduce substantial costs, uncertainty, and complexity into the patent system.

Recent legislative proposals, if enacted, would alter dramatically the way reasonable royalty damages are calculated. Under the current *Georgia-Pacific* framework, one of the fifteen factors that may be considered in determining a reasonable royalty is the "portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements. . . ."[99] This so-called "apportionment" test forms the basis of many recent congressional proposals on damages in patent cases. Although they vary in their particulars,

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[95] 509 F. Supp. 2d 912, 924, 927-28 (S.D. Cal. 2007).

[96] *Id.* at 938, 940.

[97] 543 F.3d 710 (Fed. Cir. 2008).

[98] For example, during the FTC's hearing on December 5, 2008, Professor Thomas referenced *Monsanto Co. v. McFarling*, 488 F.3d 973 (Fed. Cir. 2007), as an example of an excessive damages award. John R. Thomas, FTC Hearing on the Evolving IP Marketplace, Panel 1: Developing Business Models (Dec. 5, 2008). Yet a closer look at this case reveals that the damages award is supportable under the particular circumstances.

In *Monsanto*, the Federal Circuit affirmed the district court's reasonable royalty award to Monsanto Company for infringement by a farmer that planted its patent-protected herbicide resistant ("Roundup Ready") seed without purchasing the seed from a seed company licensed or owned by Monsanto. *See generally Monsanto*, 488 F.3d at 973. In calculating the reasonable royalty, the district court looked for evidence of an established royalty by considering license agreements that Monsanto had with other farmers. *Id.* at 978-79. As part of those license agreements, the farmers agreed to pay Monsanto a Technology Fee ($6.50 per 50-pound bag of Roundup Ready seed) and to refrain from planting Roundup Ready seed saved from the previous season's crop or from selling saved seed to others, instead purchasing seed annually from an authorized seed store. *Id.* at 979. The seed companies imposed an additional cost on the farmers of $19 to $22 per bag of seed. *Id.*

In affirming the award, the Federal Circuit reasoned that the Technology Fee and the per-bag fee alone did not fairly estimate the established royalty because it failed to take into account the clause in the license agreement requiring that the seed be repurchased from a seed company every year, a requirement that had independent value to Monsanto because, *inter alia*, it allowed Monsanto to control the quality of its products year-after-year. *Id.* at 980. In addition, the court considered expert testimony that the use of Roundup Ready seeds increased the yield of soybeans in an amount of $14 to $25 per acre and reduced the costs of weed control in an amount of $26 to $36 per acre. *Id.* at 980-81. Based on the evidence presented at trial, the Federal Circuit concluded that the jury's award of $40 per bag of seed was not unreasonable. *Id.* at 981.

[99] *Georgia-Pacific Corp.*, 318 F. Supp. at 1120.

both the House and Senate bills from the 110th Congress would essentially mandate apportionment of damages in all cases and elevate this one factor above all others.[100/]

This approach would substantially decrease the value of patents. A recent study prepared for the Manufacturing Alliance on Patent Policy found that focusing on apportionment in damages assessments would reduce U.S. patent value between $34.4 billion and $85.3 billion and reduce the value of U.S. public companies between $38.4 billion and $225.4 billion.[101/] The study found that such devaluation, in turn, would reduce research and development investment between $33.9 billion and $66 billion.[102/] These dramatic effects could have serious repercussions on the global economy.

An apportionment-focused approach to calculating damages also would introduce substantial costs, uncertainty, and complexity into the patent system.[103/] Many of the proposals would re-focus the court's or jury's reasonable royalty inquiry to determining and valuing the "inventive features" of the patented invention, a "prior art subtraction" concept that is not defined, is not part of patent law today, and has been controversial. Such proposals generally require a jury to reevaluate a patent claim (after finding it to be valid and enforceable) to determine which portion of the claim is truly "inventive," usually by subtracting out its elements which are found in the prior art. Then, the jury needs to place a value on the identified "inventive" feature, if any. This proposed methodology is problematic, in part because at some level all inventions can be considered combinations of old elements, albeit ones that are combined in a new way. A forced dissection of a claimed invention into its individual parts would inevitably result in grossly undervaluing the invention. Moreover, such approaches necessarily require the analysis to be done when the invention was made, rather than when the infringement began. Finally, many of these proposals would shift the burden of determining the methodology to be employed for assessing damages to the courts (even in jury cases), thereby depriving plaintiffs and defendants alike their opportunity to present those damages theories that they believe will most appropriately compensate for the infringement.

The Honorable Paul R. Michel, Chief Judge of the Court of Appeals for the Federal Circuit, has criticized the apportionment proposals as a "massive undertaking for which [the]

/100 For example, H.R. 1908 and S. 1145, the Patent Reform Act of 2007 (as introduced Apr. 18, 2007), would require a judge to conduct a mandatory apportionment analysis to ensure "that a reasonable royalty is applied only to that economic value properly attributable to the patentee's specific contribution over the prior art." H.R. 1908, the Patent Reform Act of 2007 (as passed Sept. 7, 2007) contains this language as well. Under S. 1145 (as reported in Senate, Jan. 24, 2008), in the absence of an established royalty based on marketplace licensing, the reasonable royalty inquiry must determine the economic value of "claimed invention's specific contribution over the prior art."

/101 Scott Shane, Ph.D., Professor Economics, Case Western Reserve University, *The Likely Adverse Effects of an Apportionment-Centric System of Damages* (Jan. 14, 2009), *available at* http://www.mfgpatentpolicy.org/images/Apportionment_of_Damages_Adverse_Effects_Jan14_09.pdf.

/102 *Id.*

/103 William C. Rooklidge & Alyson G. Barker, *Reform of a Fast-Moving Target: The Development of Patent Law Since the 2004 National Academies Report* 21-33 (2009) [hereinafter Rooklidge & Barker] (providing a highly informative discussion about the intense criticism of proposals to require mandatory apportionment of damages awards), *available at* http://www.patentsmatter.com/issue/20090205_rooklidge_barker.php.

courts are ill-equipped."[104] Today, consideration of prior art is limited to patentability and invalidity proceedings, during which patent valuation is not at issue. Prior art should not be revisited during damages determination proceedings. Chief Judge Michel observed that such an inquiry would require "extensive, complex economic valuations" calling for "massive amounts of data" and leading to "extra weeks of trial in nearly every case."[105] Particularly in instances in which the prior art was not reduced to practice and therefore was never embodied in any product sold on the market, it may be extremely difficult to determine the economic value of the "inventive" feature of the patented invention.

The unintended consequences of mandatory apportionment can be understood by considering the following two hypotheticals. First, suppose that a chemical compound containing a hydroxyl group is known in the prior art, but not sold commercially as a pharmaceutical. A patentee discovers that if the hydroxyl group is replaced with a methoxyl group, the new chemical compound has a valuable pharmaceutical property. Under some views of the proposed mandatory apportionment legislation, the patentee's damages would be limited to the value attributable to the difference between the methoxylated compound and the hydroxylated compound. However, since the hydroxylated compound had never been sold commercially, it would be extremely difficult (if not impossible) to assign an appropriate value to the inventive step of substituting the methoxyl group for the hydroxyl group in order to arrive at an apportioned damages award.

Second, suppose that an active pharmaceutical compound is known in the prior art. A patentee has discovered a formulation, with small independent value of its own, that stabilizes the active compound in a new way so as to make it substantially more effective as a therapeutic drug. Under some views of the proposed mandatory apportionment legislation, the patentee would be entitled to recover damages equal only to the value of the formulation. Because this does not reflect the true value of the patentee's invention, the patentee likely would be undercompensated.

In addition to the many adverse consequences that would arise from mandating apportionment in every case, such a dramatic change in the law is unnecessary because the hypothetical negotiation approach is well-suited to deal with circumstances where the patent at issue covers only a small part of the infringing product or process. In those circumstances, a reasonable royalty would be determined by assessing the value to the infringer of using the patented invention over the closest non-infringing substitute. Here, the closest non-infringing substitute would be the infringing product without the infringing component. Also, under existing case law, courts have discretion to "apportion" damages where appropriate,[106] but they rightly calculate a reasonable royalty according to a broad range of factors that may impact the patent's market value. Numerous stakeholders have concluded that radical changes to damages

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[104] Letter from Hon. Paul R. Michel, Chief Judge of the U.S. Appeals Court for the Federal Circuit, to Sen. Patrick Leahy and Sen. Orrin Hatch 2 (May 3, 2007), *available at* http://www.patentsmatter.com/media/issue/legislation/20070503_Michel.pdf.

[105] *Id.*

[106] *Georgia-Pacific*, 318 F. Supp. at 1120 ("The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.").

law are not needed, including more than 430 organizations in all 50 states.[107] The Department of Commerce likewise has taken the position that there is no reason to change the current law, which gives courts the discretion to evaluate the relevant facts of each case and the flexibility to award appropriate damages on a case-by-case basis.[108] Chief Judge Michel noted he is "unaware of any convincing demonstration" of the need for proposed provisions mandating apportionment of damages in patent reform legislation.[109]

IV. The Federal Circuit's *In re Seagate* Decision Represents A Sea Change In The Willfulness Doctrine That May Address The Concerns Raised By The FTC In Its 2003 Report And Should Be Allowed To Develop Further In The Courts.

The FTC's fifth question asks whether changes in the willfulness doctrine have changed the behavior of patentees and potential infringers and whether these changes adequately address concerns identified by the FTC in its 2003 report.[110] Under 35 U.S.C. § 284, after a finding of patent infringement, a district court has discretion to award the patentee up to three times the amount of actual infringement damages. The Federal Circuit has interpreted § 284 to allow enhanced damages only when the patentee establishes that the defendant's infringement was willful.[111] As the sole basis for an award of enhanced damages for patent infringement, the willfulness doctrine plays a vital role in maintaining respect for patent rights among competitors.

In its 2003 report, the FTC found that the willfulness doctrine, while important in protecting the rights of patentees, was discouraging competitors from reading each other's patents for fear that reading a competitor's patent would constitute "notice" of that patent.[112] The FTC recommended reforming the willfulness doctrine to address this concern.[113] As the FTC observed, "[f]ailure to read competitors' patents can jeopardize plans for a noninfringing

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[107] Letter from Advanced Medical Technology Association, et al., to Hon. Harry Reid, Majority Leader, U.S. Senate, and Hon. Mitch McConnell, Minority Leader, U.S. Senate (Oct. 23, 2007), *available at* http://www.innovationalliance.net/files/G-430_Senate_Letter.pdf (signed by a diverse group of industries, including agriculture, alternative energy, biotechnology, chemicals, computer hardware, computer software, computer networking, cosmetics, entertainment, financial services, food/beverage, health care, heavy industry, life sciences, manufacturing, medical devices, material science, nanotechnology, optics, pharmaceuticals, security, semiconductors, space systems, startup incubation, telecommunications, venture capital, and internet-based businesses).

[108] Letter from Nathaniel F. Wienecke, Assistant Secretary for Legislative and Intergovernmental Affairs, Department of Commerce, to Hon. Patrick Leahy, U.S. Senate, (Feb. 4, 2008), *available at* http://www.usa-canada.les.org/pdfs/whitehouse08Patent.pdf (discussing the problems with the proposed patent reform legislation because it provides an inflexible approach to calculation of damages, whereas judges and juries should have the flexibility to apply all relevant factors in determining a reasonable royalty based on the circumstances of a particular case); *see also* Letter from Carlos M. Gutierrez, Secretary of Commerce, to Hon. Patrick Leahy 2 (Apr. 3, 2008), *available at* http://www.ogc.doc.gov/ogc/legreg/letters/110/ s1145Apr0308.pdf (opposing legislative reform that would limit courts' discretion in calculating reasonable royalty awards).

[109] Letter from Hon. Paul R. Michel (May 3, 2007), *supra*.

[110] 2003 FTC Report, *supra*, Executive Summary at 16-17.

[111] *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007) (en banc) (citing *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 923 F.2d 1576, 1578 (Fed. Cir. 1991)).

[112] 2003 FTC Report, *supra*, Executive Summary at 16-17.

[113] *Id.* (Recommendation 9).

business or research strategy, encourage wasteful duplication of effort, delay follow-on innovation that could derive from patent disclosures, and discourage the development of competition."[114] At the same time, the FTC emphasized that it was important to "retain a viable willfulness doctrine that protects both wronged patentees and competition."[115]

By dramatically revising the legal standard for a finding of willfulness, the Federal Circuit in *In re Seagate*[116] may have addressed the FTC's concerns. However, the Federal Circuit left it "to future cases to further develop the application" of the new willfulness doctrine.[117] This process is ongoing in the federal courts and should be given time to develop. As the case law develops, it will be important to monitor whether the new willfulness standard maintains viable protections against willful infringement, as the FTC's 2003 report expressly recommended.

A. In *Seagate*, the Federal Circuit replaced the affirmative duty of care standard for willful infringement with an objective recklessness standard.

At the time of the FTC's 2003 report, the willfulness doctrine provided that once a potential infringer learned of another party's patent rights, he had "an affirmative duty to exercise due care" to determine whether he was infringing.[118] In *Seagate*, the Federal Circuit rejected this affirmative duty of care standard and held that "proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness."[119] To satisfy the new objective recklessness standard, the plaintiff must show that "the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent" and that this risk "was either known or so obvious that it should have been known to the accused infringer."[120]

B. The *Seagate* decision likely has addressed the problems with the willfulness doctrine identified by the FTC in its 2003 report.

First, by abandoning the affirmative duty of care standard, the *Seagate* decision eliminated any disincentive to read patents. According to the FTC, under the previous standard, competitors feared that by reading an adversely held patent they might inadvertently trigger a duty to avoid infringement and liability for treble damages for willful infringement.[121] Not only

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/114 *Id.*

/115 *Id.* at 17.

/116 497 F.3d 1360 (Fed. Cir. 2007) (en banc).

/117 *Id.* at 1371.

/118 *Id.* at 1368-69 (discussing the willfulness standard adopted in *Underwater Devices Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1389-90 (Fed. Cir. 1983)).

/119 *Seagate*, 497 F.3d at 1371.

/120 *Id.*

/121 2003 FTC Report, at 16-17.

does *Seagate* eliminate this disincentive, it could also provide an incentive to read patents, as competitors may now be found to have acted willfully if they "should have . . . known" that their actions constituted an objectively high likelihood of infringement.[122]

Second, the *Seagate* decision addresses the advice of counsel dilemma faced by defendants under the previous willfulness standard. Before *Seagate*, defendants often had to choose either (1) to risk a willful infringement finding by not raising an advice of counsel defense or (2) to rely on an opinion of counsel on noninfringement or invalidity, thereby waiving attorney-client privilege and work-product protection. The *Seagate* decision addresses this dilemma by establishing that raising an advice of counsel defense does not waive attorney-client privilege or work product protection with respect to trial counsel.[123]

C. Further development of the case law is needed in order to assess the full implications of the new willfulness standard.

The Federal Circuit has applied the new objective recklessness standard for willfulness in a limited number of cases. Thus far, the court has held that the new standard precludes a finding of willful infringement when the defendant's arguments for noninfringement or invalidity are "reasonable," "legitimate," or "credible."[124] The district courts also have been consistent in following this approach. For example, in *ResQNet.com, Inc. v. Lansa, Inc.*, the district court held that the defendant's infringement was not willful because the defendant's arguments for noninfringement and invalidity "were substantial, reasonable, and far from the sort of easily-dismissed claims that an objectively reckless infringer would be forced to rely upon."[125]

If this trend continues, the *Seagate* decision will have established a willfulness doctrine that discourages truly willful behavior, while protecting competitors who make credible challenges to infringement or validity.[126] In this way, *Seagate* also may have struck the right balance in helping to maintain patent quality while discouraging frivolous and costly litigation.

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[122] *Seagate*, 497 F.3d at 1371.

[123] *Id.* at 1374, 1376.

[124] *See, e.g., Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1374 (Fed. Cir. 2008) (holding that the defendant's infringement was not willful because a disputed claim term "was susceptible to a reasonable construction under which [the defendant's] products did not infringe"); *Black & Decker, Inc. v. Robert Bosch Tool Corp.*, Nos. 2007-1243, 2007-1244, 2008 WL 60501, at *7 (Fed. Cir. Jan. 7, 2008) (holding that "both legitimate defenses to infringement claims and credible invalidity arguments" negate a willfulness finding).

[125] 533 F. Supp. 2d 397, 420 (S.D.N.Y. 2008). *See also Pivonka v. Central Garden & Pet Co.*, No. 02-CV-02394, 2008 WL 486049, at *2 (D. Colo. Feb. 19, 2008) (granting summary judgment of no willfulness because the defendant raised "colorable" arguments of invalidity); *TGIP, Inc v. AT&T Corp.*, 527 F. Supp. 2d 561, 579 (E.D. Tex. 2007) (finding no willfulness because the defendant's position on invalidity "was hardly objectively unreasonable" and because the infringement issue was "a very close question").

[126] *See* Rooklidge & Barker, *supra*, at 18-19. In this paper, Rooklidge and Barker conclude that "without resorting to legislative action, the very court whose prior case law had created an atmosphere resulting in increased litigation costs and decreased predictability has addressed the willfulness problem in a constructive way. While *Seagate* may or may not have solved the willfulness problem, Congress should at least wait to see the extent to which the willfulness problem survives, and if so in what form, before considering further efforts in the area." *Id.*

It will be important to monitor this trend as the case law develops to ensure that the willfulness doctrine continues to protect "both wronged patentees and competition," as the FTC recommended.[127/]

V. Recent Supreme Court Decisions In *KSR*, *eBay*, And *MedImmune* May Prove To Play Important Roles In The IP Marketplace.

The FTC's sixth question asks how changes in patent law caused by Supreme Court and Federal Circuit decisions in the past five years affect the value of patents, the operation of the IP marketplace, and, more generally, innovation and competition. Three recent Supreme Court decisions may influence patent law in important ways. First, in *KSR Int'l Co. v. Teleflex Inc.*, the Supreme Court analyzed the standard to be applied in determining whether an invention is obvious over the prior art.[128/] The new approach to obviousness articulated by the Court may help to address one of the concerns raised by the FTC in its 2003 report. Second, as discussed above, in *eBay, Inc. v. MercExchange, LLC*, the Supreme Court overruled the Federal Circuit's general rule that a permanent injunction will issue following a finding of patent infringement, requiring courts to apply the traditional equitable test for injunctive relief.[129/] Third, in *MedImmune, Inc. v. Genentech, Inc*, the Supreme Court considered the scope of district courts' jurisdiction over declaratory judgment actions.[130/] These decisions are being developed and implemented in the district courts and the Federal Circuit. Their full implications for the IP marketplace, the value of patents, innovation, and competition therefore remain to be seen.

A. The Supreme Court's decision in *KSR* has altered the way courts handle challenges to the validity of patents based on obviousness.

In *KSR*, the Supreme Court rejected the Federal Circuit's rigid application of the teaching, suggestion, motivation ("TSM") test in evaluating obviousness.[131/] The Court held that the determination that an invention is obvious does not require precise teachings in the prior art to combine two references or to add an element missing a single reference. Rather a finding that a patent is obvious may be based on inferences about the creative steps employed by a person of ordinary skill in the art.[132/]

The Supreme Court's decision in *KSR* may help to address the FTC's concern about questionable patents raised in its 2003 report.[133/] In particular, it may respond directly to the FTC's recommendation to tighten certain legal standards used to evaluate whether a patent is

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/127 2003 FTC Report, at 17.

/128 127 S.Ct. 1727 (2007).

/129 547 U.S. 388 (2006).

/130 549 U.S. 118 (2007).

/131 127 S.Ct. at 1739.

/132 *Id.* at 1741.

/133 *See* FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 5 (2003), http://www.ftc.gov/os/2003/10/ innovationrpt.pdf.

obvious.[134/] The FTC expressed concern that in order "[t]o show that a claimed invention is obvious, some cases seem to require the PTO to point to particular items of prior art that concretely suggest how to combine all of the features of a claimed invention. . . . Requiring concrete suggestions beyond those actually needed by a person with ordinary skill in the art, and failing to give weight to suggestions implicit from the art as a whole and from the nature of the problem to be solved, is likely to result in patents on obvious inventions . . . ." Some commentators have speculated that as a result of *KSR*, the bar for showing nonobviousness has become higher.[135/]

The *KSR* decision has affected the PTO's approach to obviousness determinations.[136/] Following *KSR*, the PTO issued new guidelines on the application of the obviousness standard to pending patent applications.[137/] Emphasizing the flexible approach to obviousness mandated by *KSR*, the PTO's guidelines state that the "proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts."[138/] The *KSR* decision also had an immediate impact on the approach to obviousness at the PTO's Board of Patent Appeals and Interferences. For example, in *Ex parte Kubin*, the Board stated that, "[u]nder KSR, it's now apparent 'obvious to try' may be an appropriate test in more situations than we previously contemplated."[139/] In *Kubin*, the Board then held that the claimed invention was obvious on the ground that it "was 'the product not of innovation but of ordinary skill and common sense.'"[140/] In addition, as the legal standard for overcoming an obviousness rejection has changed, the rate at which the PTO grants patent applications has declined sharply.[141/] In fact, Jon W. Dudas, former Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office, testified before Congress in February 2008 that the "allowance rate for patent[applications] is currently 44%. This is in contrast to allowance rates in excess of 70% just eight years ago."[142/] Due at least in part to these changes at the PTO,

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/134 *Id.* at 10-12.

/135 *See, e.g.*, Randy Lipsitz, et al., *A Patent Primer for the Communications Lawyer*, 25-JUL COMM. LAW. 1, 27 (2008); John R. Trembath, *KSR International Co. v. Teleflex Inc.—Obviousness Revisited*, 37-APR COLO. LAW. 35, 44 (2008); Joshua D. Sarnoff, *Bilcare, KSR, Presumptions of Validity, Primary Relief, and Obviousness in Patent Law*, 25 CARDOZO ARTS & ENT. L.J. 995, 1036 (2008); Ronald A. Bleeker & Nikolas J. Uhlir, *A Small Charge of Infringement: Strategic Alternatives for Nanotech Patent Defendants*, 4 NANOTECHNOLOGY L. & BUS. 433, 444-45 (2007).

/136 *See* Rooklidge & Barker, *supra*, at 14-15.

/137 *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526 (Oct. 10, 2007)

/138 *Id.* at 57528.

/139 2007-0819, 2007 WL 2070495, at *5 (B.P.A.I. May, 31, 2007).

/140 *Id.*

/141 *See Oversight Hearing on the U.S. Patent and Trademark Office Before the Subcommittee on Courts, the Internet and Intellectual Property of the H. Comm. on the Judiciary*, 110th Cong.(Feb. 27, 2008) (Statement of Jon W. Dudas, former Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office).

/142 *Id.*

patents are now more difficult to obtain across industries, and this may discourage some investment in innovation.

Consistent with these developments at the PTO, since the Supreme Court's decision in *KSR*, the Federal Circuit has also invalidated a number of patents, including pharmaceutical and biotechnology patents, based on obviousness. For example, in *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, the Federal Circuit held that a composition comprising a substantially pure stereoisomer was obvious over a mixture of different stereoisomers. [143] In so holding, the court explained that to require an explicit teaching to purify one stereoisomer from the mixture is "precisely the sort of rigid application of the TSM test that was criticized in KSR." [144] Certain district courts also have found claims directed to a compound obvious under this new standard.[145]

However, since *KSR*, the Federal Circuit also has rejected a number of obviousness challenges to the validity of pharmaceutical and biotechnology patents, based in large part on the inherent unpredictability in the pharmaceutical and biotechnology arts. For example, in *Eisai Co. v. Dr. Reddy's Labs., Ltd.*,[146] the Federal Circuit upheld a finding that a patent directed to the chemical compound, rabeprazole, was nonobvious. Applying the *KSR* standard, the Federal Circuit could find no motivation for one of skill in the art to select the lead compound based on the presence of a particular substituent, and then remove the very substituent that made it a good choice as a lead compound in the first place.[147] The court concluded that "post-*KSR*, a prima facie case of obviousness for a chemical compound still, in general, begins with a reasoned identification of a lead compound."[148] And, the court noted that because the chemical arts are

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[143] 499 F.3d 1293 (Fed. Cir. 2007)

[144] *Id.*; *see also, e.g., Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254 (Fed. Cir. 2007) (holding that method of topically administering ofloxacin to treat bacterial ear infections was obvious because ofloxacin is a close relative of ciprofloxacin, which was known to be effective in treatment of ear infections); *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007) (holding that method for isolating and cryopreserving human umbilical cord blood from an infant and introducing it into an adult to effect hematopoietic reconstitution was obvious because it was reasonable to infer from the prior art that there were high concentrations of hematopoietic stem cells in umbilical cord blood, and that the inventors merely used routine research methods to prove as much).

[145] *See, e.g., Novartis Pharm. Corp. v. Teva Pharm. USA, Inc.*, No. 05-CV-1887, 2007 WL 2669338, at *6 (D.N.J. Sept. 6, 2007) (denying a request for a preliminary injunction and finding that selection of lead compound was of ordinary skill and common sense), *aff'd*, 2008 WL 2369849 (Fed. Cir. June 9, 2008); *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 532 F. Supp. 2d 666 (D.N.J. 2007) (holding that plaintiffs failed to establish a likelihood of success at the preliminary injunction stage because the defendants raised a substantial question that it was obvious to try a combination of the prior art and that this combination was a predictable variation of the prior art).

[146] 533 F.3d 1353 (Fed. Cir. 2008).

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

[148] *Id.* at 1359.

unpredictable, the identification of "predictable solutions" as emphasized in *KSR* may present a difficult hurdle.[149]

The nonobviousness of the lead compound was also the basis for the Federal Circuit's affirmance of the district court in *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*[150] In addition, several other recent holdings of nonobviousness by the Federal Circuit are likewise premised on the unpredictability in the chemical arts, including the holdings in *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*,[151] *Forest Labs., Inc. v. Ivax Pharms., Inc*,[152] and *Abbott Labs. v. Sandoz, Inc.*[153] In sum, although the determination of obviousness depends on a close analysis of the facts in each case, after *KSR* the Federal Circuit has recognized that the unpredictability of the chemical arts is an important consideration that may help to establish nonobviousness.

The *KSR* standard is in the process of being implemented and developed by the federal courts.[154] It is therefore too soon for a definitive assessment of the implications of this decision on the value of patents and the IP marketplace. To the extent that courts have been invalidating more patents based on obviousness since the *KSR* decision, the decision could have an effect on the value of patents, and thus on innovation.

B. The Supreme Court's decision in *eBay* has decreased the value of patents by creating uncertainty about the availability of injunctive relief following a finding of infringement.

The Supreme Court's decision in *eBay* represents a sea change in the law of permanent injunctions in patent cases. As discussed above, following *eBay*, patentees can no longer rely on the general rule that an injunction will be granted upon a finding of infringement. Uncertainty

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/149 *Id.*

/150 492 F.3d 1350 (Fed. Cir. 2007) (concluding that it would not have been obvious to select the lead compound out of the hundreds of millions of compounds disclosed in the prior art and further that there was no suggestion in the prior art to make either of the required chemical modifications to the lead compound to arrive at the claimed compounds).

/151 520 F.3d 1358 (Fed. Cir. 2008) (claimed sulfamate compounds were nonobvious over the prior art because there were not a small and finite number of easily traversed alternatives to screen through, in arriving at the claimed compounds, to support an inference of obviousness).

/152 501 F.3d 1263 (Fed. Cir. 2007) (patent claims to a substantially pure (+)-enantiomer of citalopram were not obvious because one of skill in the art would not have had a reasonable expectation of success in resolving citalopram given that many had tried and failed to separate enantiomers from their racemates).

/153 544 F.3d 1341 (Fed. Cir. 2008) (holding that patentee likely to prevail on nonobviousness with patent claims to formulation of the antibiotic, clarithromycin, even though the prior art taught formulations containing another erythromycin derivative; concluding that it would not have been obvious to substitute one for the other because there were differences in chemical and biological properties as well as *in vitro* and *in vivo* data between the two compounds).

/154 *See, e.g.*, David K. Barr, *Patentability of Active Pharmaceutical Ingredients*, 944 PLI/PAT 11, 30 n.77 (2008); R. Polk Wagner, *The Supreme Court and the Future of Patent Reform*, 55-FEB FED. LAW. 35, 41 (2008); George V. Novak, *An Overview and Primer on Intellectual Property for the Insurance Industry*, 902 PLI/COMM 859, 868 (2008); Kevin R. Davidson, *Retooling Patents: Current Problems, Proposed Solutions, and Economic Implications for Patent Reform*, 8 HOUS. BUS. & TAX L.J. 425, 437 (2008).

about whether an injunction will issue impacts the value of patent rights in the marketplace, particularly when licenses are negotiated or settlement discussions take place.

Certain types of patentees may be particularly impacted by the decision in *eBay*. For example, as discussed above, following *eBay* patentees that do not compete directly with the infringer may have difficulty obtaining a permanent injunction.[155] It follows that non-practicing entities may also have difficulty obtaining permanent injunctions following *eBay*.[156] As another example, following *eBay*, patentees may have difficulty obtaining a permanent injunction when their invention constitutes a relatively "small component" of the infringing product or is not a significant basis of consumer demand for the infringing product.[157] It may take more time to determine the full impact of this case.

C. *MedImmune* expanded district courts' declaratory judgment jurisdiction.

In *MedImmune, Inc. v. Genentech, Inc.*,[158] the Supreme Court considered whether the limitation on federal courts' jurisdiction to "cases and controversies" under Article III of the U.S. Constitution requires a patent licensee to terminate or be in breach of its license agreement in order to seek a declaratory judgment that the patent is invalid, unenforceable, or not infringed.[159] The Court held that in order to establish declaratory judgment jurisdiction the proper standard is "whether the facts alleged, under all the circumstances, show there is a substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."[160] In so holding, the Court implicitly rejected the Federal Circuit's "reasonable apprehension of suit" test.[161] Even though the patent licensee was under no threat of suit as long as it continued to pay royalties, the Court held that the licensee was not required to breach or terminate the license in order to seek a declaration of its legal rights.[162]

The Federal Circuit first applied *MedImmune* in *SanDisk Corp. v. STMicroelectronics, Inc.*,[163] where the parties did not have a license agreement, but instead were engaged in license negotiations.[164] During the negotiations, the patentee presented a detailed infringement analysis and asserted that the other party's products infringed its patents, while the other party maintained

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/155 Ellis et al., *supra*, at 471; Chao, *supra*, at 549-55.

/156 Ellis et al., *supra*, at 459-61.

/157 *See, e.g., z4 Technologies, Inc. v. Microsoft Corp.*, 434 F. Supp. 2d 437, 440 (E.D. Tex. 2006); *see also* Chao, *supra*, at 558-59.

/158 549 U.S. 764 (2007).

/159 *Id.* at 120-21.

/160 *Id.* at 127.

/161 *Id.* at 132 n.11.

/162 *Id.* at 137.

/163 480 F.3d 1372 (Fed. Cir. 2007).

/164 *Id.* at 1382.

that it did not need to pay royalties.[165] The court held that under these circumstances there was "a substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality" to give rise to declaratory judgment jurisdiction.[166] The court further held that a statement by the patentee that it would not sue the alleged infringer did not eliminate the controversy.[167]

Many commentators have speculated that the combined effect of *MedImmune* and *SanDisk* will be to increase the number of declaratory judgment actions and to cause patent holders to become more reluctant to engage in license negotiations.[168] Some argue that by making it easier for alleged infringers to bring a declaratory judgment action, patent holders may be disinclined to engage in license negotiations for fear that they will lose control over any subsequent patent infringement suit should the licensing negotiations break down.[169] The effect of these cases may be to increase the number of declaratory judgment actions brought by licensees who entered into license agreements before the decisions issued. The impact of these cases on license agreements made after the decisions issued is unclear, as prospectively parties to license agreements may seek to address these issues in their written agreements.[170]

Since *MedImmune*, the Federal Circuit's application of the Supreme Court's all-the-circumstances test reflects that the existence of declaratory judgment jurisdiction depends on the facts of each case. The Federal Circuit has found that district courts lack declaratory judgment jurisdiction in many circumstances, including in *Benitec Australia, Ltd. v. Nucleonics, Inc.*,[171] and *Prasco, LLC v. Medicis Pharm. Corp.*[172] *MedImmune*'s effect on cases in the Hatch-Waxman context has varied. In some cases, such as *Teva Pharm. USA, Inc. v. Novartis Pharm.*

/165 *Id.*

/166 *Id.*

/167 *Id.* at 1382-83.

/168 Lawrence K. Nodine et al., *Declaratory Judgment Jurisdiction and Injunctions in Patent Cases after MedImmune and eBay*, 948 PLI/PAT 599, 602 (2008); Jennifer Saionz, *Declaratory Judgment Actions in Patent Cases: The Federal Circuit's Response to MedImmune v. Genentech*, 23 BERKELEY TECH. L.J. 161, 192 (2008); Roderick R. McKelvie, *Forum Selection in Patent Litigation: A Traffic Report*, 19 INTELL. PROP. & TECH. L.J. 1, 8 (2007).

/169 Saionz, *supra*, at 192; Robert P. Taylor, *Patent Law in Flux: Echoes of the Supreme Court*, 947 PLI/PAT 93, 125-127 (2008).

/170 *See, e.g.*, Steven D. Porter, Jr., *Estimating Hypothetically Negotiated Royalty Rates After MedImmune, Inc. v. Genentech, Inc., et al.*, 14-MAR J. LEGAL ECON. 43, 46 (2008); Ronald A. Bleeker & Michael V. O'Shaughnessy, *One Year After MedImmune: The Impact on Patent Licensing & Negotiation*, 17 FED. CIR. B. J. 401, 432-35 (2008).

/171 495 F.3d 1340 (Fed. Cir. 2007) (holding that district court lacked jurisdiction over invalidity and unenforceability counterclaims after patentee moved to dismiss the complaint because there was no "substantial controversy...of sufficient immediacy and reality to warrant issusance [sic] of a declaratory judgment," as required under *MedImmune*).

/172 537 F.3d 1329 (Fed. Cir. 2008) (holding that district court lacked jurisdiction over declaratory judgment action brought by pharmaceutical company against its competitor when it had not yet begun to market its product; concluding, after considering all the circumstances, that the evidence did not indicate "a substantial controversy ... of sufficient immediacy and reality" to establish declaratory judgment jurisdiction).

Corp.[173] and *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*,[174] the Federal Circuit determined that the district court had declaratory judgment jurisdiction to hear the generic drug manufacturer's challenge to the validity of certain patents. In at least one other case, *Janssen Pharmaceutica, NV v. Apotex, Inc.*, the Federal Circuit held that the district court lacked declaratory judgment jurisdiction.[175]

Because the holding in *MedImmune* is in the process of being developed and implemented by the lower federal courts, the full implications of it on the patent system and the IP marketplace are uncertain.

VI. The Doctrine Of Inequitable Conduct Is A Major Source Of Uncertainty In The IP Marketplace.

The FTC's seventh question asks about existing sources of uncertainty in the IP marketplace and the implications of that uncertainty. One significant source of uncertainty for patent holders is the legal doctrine of inequitable conduct, under which a court can render an entire patent unenforceable based on a finding that the patentee withheld or misrepresented any material information with the intent to deceive the U.S. Patent and Trademark Office (PTO).

Courts have stated that the original purpose of the inequitable conduct doctrine was to prevent patentees from enforcing patents that were acquired by fraud.[176] Over the years, however, the courts have significantly weakened the requirements for proving inequitable conduct and strayed far from the important purpose of the doctrine. Using malleable and vague legal standards, the Federal Circuit has upheld inequitable conduct findings based on litigation-inspired second-guessing of minor mistakes made during patent prosecution that have no bearing on patent validity. Such cases make the application of the inequitable conduct doctrine highly unpredictable. This uncertainty, coupled with the devastating consequence of a judgment of unenforceability, significantly undermines the ability of innovating companies to attract investors, value patents under consideration to be purchased, and make long-term plans for business development.

A. There is growing recognition that developments in the inequitable conduct doctrine have increased both the uncertainty and the costs of patent litigation.

In 2004, the National Research Council of the National Academies of Science, after a thorough and independent analysis of the patent system, criticized the inequitable conduct doctrine as one of several "subjective elements of patent litigation" that require reform to "increase predictability of patent dispute outcomes and reduce the cost of litigation."[177] In 2008,

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[173] 482 F.3d 1330 (Fed. Cir. 2007).

[174] 527 F.3d 1278 (Fed. Cir. 2008).

[175] 540 F.3d 1353 (Fed. Cir. 2008).

[176] *See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F. 3d 1357, 1365-66 (Fed. Cir. 2008).

[177] National Research Council, *A Patent System for the 21st Century*, at 117-18 (2004).

Federal Circuit Judge Randall Rader criticized the inequitable conduct doctrine for creating a "litigation tactic" that "opens new avenues of discovery; impugns the integrity of the patentee, its counsel, and the patent itself; excludes the prosecuting attorney from trial participation (other than as a witness); and even offers the trial court a way to dispose of a case without the rigors of a claim construction and other complex patent doctrines."[178] In 2007, Federal Circuit Judge Pauline Newman lamented that the Federal Circuit was "encouraging unwarranted charges of inequitable conduct, spawning . . . opportunistic litigation."[179] Indeed, Federal Circuit judges and commentators have referred to the prevalence of inequitable conduct charges as a "plague" on the patent system.[180] Likewise, Senators Arlen Specter and Orrin Hatch agree that the inequitable conduct defense "has proven to be irresistible for litigants" and "has become a convenient and frequently raised litigation tactic that is overpled and a quick route to taking down otherwise valid and commercially valuable patents."[181]

Additionally, in 2007, then Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office Jon W. Dudas testified before Congress that "the inequitable conduct standard is uncertain and the potential penalties severe. . . . [and inequitable conduct] is frequently alleged."[182] Under Secretary Dudas further observed that the unpredictability of the inequitable conduct doctrine "results in counterproductive behavior before the [PTO]" that reduces the quality of patent prosecution.[183] He explained that the inequitable conduct doctrine creates an environment that discourages applicants from explaining their submissions, for fear of making a misrepresentation, and encourages applicants to disclose an excessive number of prior art references, for fear of omitting a material reference.[184] By reducing the quality of patent prosecution, and thus the quality of issued patents, the unpredictability of the Federal Circuit's inequitable conduct doctrine further undermines the efficiency of the patent system in promoting innovation.

/178 *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J., dissenting) (*Aventis II*).

/179 *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 926 (Fed. Cir. 2007) (Newman, J., dissenting).

/180 *See, e.g., Aventis II*, 525 F.3d at 1350 (Rader, J., dissenting); *McKesson*, 487 F.3d at 926-27 (Newman, J., dissenting); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1196-97 (Fed. Cir. 2006) (Newman, J., dissenting); James E. Hanft & Stacey S. Kerns, *The Return of the Inequitable Conduct Plague: When "I Did Not Know" Unexpectedly Becomes "You Should Have Known,"* 19 NO. 2 INTELL. PROP. & TECH. L.J. 1 (2007); John A. O'Brien, *Inequitable Conduct—Is the Federal Circuit Reviving the "Plague" Of The Past?*, 884 PLI/Pat 467 (2006); Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERK. TECH. L.J. 147 (2005). Referring to the prevalence of inequitable conduct charges as a "plague" on the patent system dates back to the Federal Circuit's opinion in *Burlington Industries, Inc. v. Dayco Corp.*, when the court observed that "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague." 849 F.2d 1418, 1422 (Fed. Cir. 1988).

/181 S. Rep. No. 110-259, at 60, 62 (2008) (Additional views of Senators Arlen Specter and Orrin Hatch on the Inequitable Conduct Defense, S. 1145).

/182 *Patent Reform: The Future of American Innovation: Hearing Before the S. Judiciary Comm.*, 110th Cong. (June 6, 2007) (testimony of Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office).

/183 *Id.*

/184 *Id.*

These negative effects of the uncertainty caused by the inequitable conduct doctrine are of great concern to the biopharmaceutical industry, as the resurgence of inequitable conduct charges is particularly pronounced. Indeed, with respect to cases arising under the Hatch-Waxman Act decided by the Federal Circuit between 2004 and 2006, inequitable conduct was raised in 63 percent of such cases—and in 75 percent of such cases in 2006 alone.

B. Since the FTC's 2003 report, the Federal Circuit has created uncertainty in the inequitable conduct doctrine in significant ways.

First, the Federal Circuit frequently has conflated the intent requirement of inequitable conduct with the materiality requirement.[185] Some cases conflate the materiality and intent requirements expressly, stating: "The more material the omission or misrepresentation, the less intent that must be shown to elicit a finding of inequitable conduct."[186] Other cases allow intent to be inferred if the court finds that the applicant "should have known" that undisclosed information was material and fails to provide a credible reason for the omission.[187] Such decisions effectively reduce the scienter requirement of inequitable conduct to mere negligence. As a result, even patentees who prosecuted their patent applications in good faith cannot be certain that their patents will be enforced against infringers.

Although recent Federal Circuit decisions have weakened the intent requirement, the court historically has held that mere negligence alone—even gross negligence—"does not of itself justify an inference of intent to deceive."[188] Indeed, some recent Federal Circuit decisions continue to follow this precedent.[189] Although these cases properly emphasize the intent requirement, they do little to eliminate the overall uncertainty regarding the court's inequitable conduct doctrine when so many other cases "emphasiz[e] materiality almost to the exclusion of any analysis of the lofty intent requirement."[190]

Second, the Federal Circuit has held that the materiality requirement can be met by making any one of five different showings of materiality.[191] The Federal Circuit's five standards include the PTO's current definition of materiality at 37 C.F.R. § 1.56, the PTO's previous

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[185] S. Rep. No. 110-259, at 32 (finding that "some courts collapse the issue of intent into the issue of materiality, so that intent to deceive is often inferred from materiality").

[186] *Aventis II*, 525 F.3d at 1344 (quoting *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1375 (Fed. Cir. 2006)).

[187] *See, e.g., Monsanto Co. v. Bayer Bioscience, N.V.*, 514 F.3d 1229, 1241 (Fed. Cir. 2008); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313-14 (Fed. Cir. 2008); *Ferring*, 437 F.3d at 1191.

[188] *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant part).

[189] *See, e.g., Star Scientific*, 537 F. 3d at 1368 (holding that the "patentee need not offer any good faith explanation [for failing to disclose material information] unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence"); *see also Cohesive Technologies, Inc. v. Waters Corp.*, 543 F.3d 1351, 1366 (Fed. Cir. 2008) (finding "no independent evidence of specific intent" and emphasizing that intent "is a separate and essential component" of the inequitable conduct analysis).

[190] *Aventis II*, 525 F.3d at 1350 (Rader, J., dissenting).

[191] *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006).

definition of materiality, and three additional common law definitions unrelated to the PTO's definitions.[192] A withheld reference can be deemed material under any one of those five standards, even if the court finds that the same information was not material under the others.[193] The application of such varied standards for materiality creates great uncertainty for patentees, as it is difficult to predict whether something will be found in hindsight to be material, and, as a result, whether a patent will be held unenforceable.[194]

Third, the Federal Circuit has significantly lowered the standard for materiality in some cases, leaving patentees uncertain whether they will lose the right to enforce their patents due to minor mistakes during prosecution. For example, in *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, the Federal Circuit affirmed an inequitable conduct finding where the patent applicant had favorably compared his inventive drug compound with a prior art compound, but failed to disclose that the comparison was not as favorable at the same dosage levels.[195] The court held that the failure to disclose the dosage levels was a material omission because it denied the examiner an opportunity to determine whether the differences between the compounds were significant.[196] However, in a subsequent reissue application, the applicant was granted a reissue patent on the same compound despite having omitted the favorable comparison altogether.[197] Thus, the Federal Circuit affirmed the trial court's finding that the undisclosed information was material even though it was unnecessary to establish patentability.[198]

Another important example of the lowered standard for materiality at the Federal Circuit is *Ferring B.V. v. Barr Laboratories, Inc.*[199] During the prosecution of the patent-in-suit in *Ferring*, the PTO requested declarations "from a non-inventor" to support patentability.[200] The applicant provided the declarations from non-inventors, as requested.[201] Importantly, these non-inventor declarants had no direct financial stake in the patent application.[202] Nonetheless, the Federal Circuit found that the applicant had committed inequitable conduct in submitting these declarations because he did not disclose that the declarants previously received funding from or

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/192 *Id.*

/193 *Monsanto*, 514 F.3d at 1237 n.11.

/194 *See* S. Rep. No. 110-259, at 32 ("Having multiple materiality standards is hardly helpful to the district courts that are charged with making inequitable conduct determinations in the first instance, and patent holders are left with less than clear guidance about what they should disclose to the [PTO].").

/195 No. 2005-1513, 2006 WL 925278, at *3-*5 (Fed. Cir. Apr. 10, 2006) (*Aventis I*).

/196 *Id.* at *3.

/197 *Aventis II*, 525 F.3d at 1352 (Rader, J., dissenting).

/198 *Id.*

/199 437 F. 3d 1181 (Fed. Cir. 2006).

/200 *Id.* at 1184.

/201 *Id.* at 1185.

/202 *Id.* at 1188.

worked for his company.[203] On the basis of this omission alone, the court affirmed the district court's ruling that the entire patent was unenforceable.[204] In so holding, the court disregarded the absence of any evidence that the declarations supporting patentability were false or misleading.[205] In addition, the court disregarded the fact the PTO had only requested declarations from non-inventors—not parties without a significant relationship to the applicant.[206] Moreover, by holding that courts can infer deception from an applicant's relationship to a declarant *per se*, the court ignored the practical reality that inventors commonly interact with scientists and professionals in their field.[207] The *Ferring* case is thus another example of the Federal Circuit arbitrarily lowering the threshold for materiality to include minor omissions that are insignificant to the patentability determination.

Fourth, the Federal Circuit has expanded the reach of the inequitable conduct doctrine to include minor transgressions that have no bearing on patentability. For example, the Federal Circuit has twice held that improperly claiming "small entity status," which allows the patentee to make smaller maintenance fee payments relating to a patent, but which has no bearing on the patentability of an invention, can constitute inequitable conduct.[208] In addition, the Federal Circuit has held that the materiality standard can be met if false statements were made in a "petition to make special," a mechanism used only to accelerate review of a pending patent application.[209] The expansion of the inequitable conduct doctrine into such new areas creates considerable further uncertainty for inventors.

In sum, since the FTC's 2003 report, the lack of clarity in the standards for inequitable conduct has created enormous uncertainty in the IP marketplace. This uncertainty in forecasting the strength of patent protection makes it difficult for patent holders to make long-term business plans, to attract investors, and to value patents under consideration to be purchased. In addition, the Federal Circuit's expansion of the inequitable conduct doctrine has reduced the quality of patent prosecution, driven up litigation costs, and unfairly punished innocent actors. These changes to the inequitable conduct doctrine have thus decreased the value of patents and the rewards for innovation.

VII. The IP Marketplace Has Become More Transparent Than Ever.

The FTC's eighth question asks about the transparency of the current IP marketplace. In recent years, patents and patent applications have become more accessible than ever. In particular, the United States Patent and Trademark Office (PTO) unveiled Public PAIR (Patent

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/203 *Id.* at 1187-90.

/204 *Id.* at 1195.

/205 *Id.* at 1199 (Newman, J., dissenting).

/206 *Id.*

/207 *Id.* at 1200.

/208 *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1231 (Fed. Cir. 2007); *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1146 (Fed. Cir. 2003).

/209 *See Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1374 (Fed. Cir. 2008) (citing *General Electro. Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994)).

Application and Information Retrieval), making the prosecution of pending applications from the time of pre-grant publication to final disposition fully transparent to the public.[210] In addition, issued patents are now published every Tuesday in the Electronic Official Gazette.[211]

Both published applications and issued patents can be searched without charge on the PTO's website.[212] Several other websites also provide easy access to patents and facilitate searching for patents for free.[213] A number of companies offer more sophisticated fee-based on-line patent search systems.[214]

Several agencies have required that patents be reported. For example, since 2005, the U.S. Securities and Exchange Commission has required that key patents be identified by companies filing forms under the Securities Act of 1933, Securities Exchange Act of 1934 and Energy Policy and Conservation Act of 1975.[215] For pharmaceutical companies, the Federal Food, Drug, and Cosmetic Act requires that all applicants submitting new drug applications to the Food and Drug Administration (FDA) identify certain patents that claim the drug or a method of using the drug that is the subject of the application.[216] Upon approval of the drug, the numbers and expiration dates of the patents are published in the Electronic Orange Book, along with any extensions in patent term due to FDA regulatory review.[217]

Patent litigation statistics likewise have become more readily available in the last few years, facilitated in part by several law schools. Since 2000, the University of Houston Law Center has operated an on-line database, providing litigation statistics on over forty major issues in patent law.[218] Last year, Stanford University developed an on-line database, which provides

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[210] *See* United States Patent and Trademark Office, Press Release 04-12: Internet Access to Patent Application Files Now Available, Aug. 2, 2004, *available at* http://www.uspto.gov/web/ offices/com/speeches/04-13.htm.

[211] Electronic Official Gazette, *available at* http://www.uspto.gov/web/patents/patog/; *see* Office of Patent Publication FAQs, *available at* http://www.uspto.gov/web/patents/pubs/faq. htm#ogqa1.

[212] PTO Search Collections, *available at* http://www.uspto.gov/main/search.html.

[213] *See, e.g.*, Google Patent Search, *available at* http://www.google.com/patents; Free Patents Online, *available at* http://www.freepatentsonline.com/.

[214] *See, e.g.*, Westlaw, *available at* www.westlaw.com; LexisNexis, *available at* www.lexisnexis.com; Delphion, *available at* www.delphion.com; Thomson Reuters PatentWeb, *available at* http://thomsonreuters.com/products_services/scientific/PatentWeb; PatentMax, *available at* www.patentmax.com; PatBase, *available at* www.patbase.com; QPAT, *available at* www.qpat.com.

[215] *See* 17 C.F.R. 229.101(c)(1)(iv) (2005) (requiring that description of business include "[t]he importance to the segment and the duration and effect of all patents, trademarks, licenses, franchises and concessions held").

[216] 21 U.S.C. § 355(b)(1).

[217] Electronic Orange Book, *available at* http://www.fda.gov/cder/ob/.

[218] U.S. Patent Litigation Statistics, *available at* http://www.patentstats.org.

data on the number and outcome of patent litigation filings in each U.S. jurisdiction.[219] In the pharmaceutical area, a specialized online publication tracks patent litigation developments.[220]

Finally, current developments in patent law are easier to follow than ever before. The number of on-line patent journals has increased in recent years.[221] Furthermore, there are an ever-increasing number of patent blogs that report and analyze recent Federal Circuit opinions and other developments in patent law.

While many patent rights remain closely guarded,[222] advances in information technology discussed above have facilitated enhanced transparency of patents, patent law, and patent litigation. This trend has proved invaluable to pharmaceutical and biotechnology companies, allowing them to be more aware of the market in which they are operating, to avoid unnecessary litigation, and to evaluate the strength of their litigation positions.

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[219] IP Litigation Clearinghouse, *available at* http://lexmachina.stanford.edu/ cases/map.

[220] *See* Paragraph Four Report®, *available at* www.paragraphfour.com.

[221] *See, e.g.*, HARVARD J.L. & TECH., http://jolt.law.harvard.edu; STANFORD TECH. L. REV., http://stlr.stanford.edu ; Berkeley Tech. L.J., www.btlj.org; RICHMOND J.L. & TECH., http://law.richmond.edu/jolt/index.asp; SANTA CLARA COMPUTER & HIGH TECH. L.J., http://www.chtlj.org; DUKE L. & TECH. REV., http://www.law.duke.edu/journals/dltr.

[222] For example, patent litigation can be subject to protective orders and patent licenses can have confidentiality provisions.