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Rebalancing Pay-for-Delay: Why the Hatch-Waxman Act Should Be Given More Weight in the Antitrust Analysis and What That Means for Reverse Payment Agreements

*By David Kurlander**

I. Introduction

Eli Lilly & Co., a $10.9 billion-per-year pharmaceuticals giant, created one of the best selling drugs in history – Prozac.[1] In 2000, the drug alone accounted for roughly one quarter of the company's revenue.[2] A year later, however, Lilly lost a legal battle with a generic manufacturer over the validity of the Prozac patent.[3] Seemingly overnight, the drug, which previously pulled in $2.6 billion per year, saw its quarterly sales drop sixty-six percent.[4]

Recognizing the potentially disastrous consequences of losing patents for blockbuster drugs, large pharmaceutical companies began settling patent battles by making large payments to potential generic rivals. In exchange, the generic manufacturers began to abandon lawsuits that may have allowed the entry of generic drugs into the market and increase competition in the health care industry. These agreements between brand-name pharmaceutical companies and generic manufacturers, however, do not exclude the generic product entirely. Rather, they postpone generic entry for an agreed-upon time frame. Still, these so-called "pay-for-delay" settlements have attracted the attention of antitrust enforcement authorities because of their potential to hinder competition. In the courts, the battles regarding these agreements have produced inconsistent results. A handful of circuit courts have upheld the validity of these settlements when the agreement was confined to the parameters of the patent, while others have condemned reverse payments as an illegal restraint of trade.[5] The United States Supreme Court, in a recent decision, held that reverse payments are subject to antitrust scrutiny under an approach that analyzes both the procompetitive and anticompetitive effects of the agreement.[6] As an academic matter, pay-for-delay agreements raise long-standing debates about the proper balance between patent rights and consumer access.[7]

II. Background

A reverse payment settlement involves three legal regimes – patent, antitrust, and food and drug laws.[8] On the one hand, the patent system grants innovators the right to exclude others from using the invention.[9] This right to exclude ultimately minimizes the gap between the value of the invention and the value that an inventor receives by allowing that inventor to charge a higher price for use of the invention.[10] The patent system, thus, incentivizes profit-motivated individuals to develop new technology and promotes technological progress.[11] On the other hand, antitrust law functions to maximize consumer

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NYIPLA

PRESIDENT'S CORNER

Development of innovative NYIPLA products presents unique approaches to traditional and emerging aspects of the law. In this respect, we are grateful for the participation of our members and other contributors to our ongoing CLE programs, events, and publications.

I am pleased to report that the early fall programs in September and October have proved to be quite successful. On September 24th the Young Lawyers Committee, chaired by Jonathan Auerbach, Michael Bullerman and Lauren Nowierski, held the first of a bi-monthly Young Lawyers Roundtable on legal writing. Panelists Paul A. Bondor of Desmarais LLP and Henry C. Dinger of Goodwin Procter LLP were extremely informative in reviewing briefs and providing suggestions as an assistance to young lawyers desiring to become more persuasive and compelling legal writers.

Board Member Jessica L. Copeland coordinated a September 26th CLE Program directed to Intellectual Property Considerations for Software and Mobile Apps at Hodgson Russ LLP's office in New York City. Panelists were Jeanine Ray-Yarletts of IBM Corporation and Al Cutaia and Rob Fluskey from Hodgson Russ LLP. A significant turnout of attendees was present for this excellent program.

On October 9, 2013, we held the first Presidents' Forum. The topic was "What to do about NPEs: Do We Risk Throwing The Baby Out With The Bath Water?" The goal was to promote an in-depth, high-level discussion among leaders in the field. We were fortunate to have Honorable Paul R. Michel, Retired Chief Judge for the Court of Appeals for the Federal Circuit; Hugh Hansen, Professor of IP Law at Fordham University School of Law; Alexander I. Poltorak, Chairman and CEO of General Patent Corporation; William H. Sorrell, Attorney General of Vermont; and Marian Underweiser, Counsel, IP Law Strategy & Policy of IBM, as discussion leaders. NYIPLA Past Presidents Marylee Jenkins and Melvin Garner facilitated a town-hall style discussion that was spirited and informative. Many thanks to Dorothy Auth, Annemarie Hassett, and Matt McFarlane, who spearheaded the event supported by a number of other NYIPLA past presidents.

The Association participated in an event, also on October 9th, called "Meet the Bar Associations." Young Lawyers Committee member Gary Yen of Kenyon & Kenyon LLP and a staff member from the NYIPLA Executive Office volunteered to attend on behalf of the NYIPLA. The goal was to educate law students about membership benefits with the NYIPLA. It proved to be a good interface for the Association with future attorneys.

On October 10th, Meetings & Forums Committee Co-Chairs Colman Ragan and Steven Lendaris hosted an event at New York Law School concerning "Diverse Careers in IP law and Strategies for Achieving Success." Panelists Tom Meloro, NYIPLA Immediate Past President, of Willkie Farr & Gallagher LLP; John Resek of Resek, Liang and Frank LLP; and Michael Chang of Kenyon & Kenyon LLP discussed how young lawyers can effectively communicate with partners and clients and how to navigate their career paths in a marketplace with diverse opportunities for intellectual property lawyers. The program was successful and nicely coordinated by the Co-Chairs, working diligently with the panel to satisfy the needs of the attendees.

On October 17th, the Corporate Committee under Co-Chair Frank Sedlarcik conducted an in-house counsel mixer with interaction between NYIPLA corporate members and prospective members about the benefits of NYIPLA membership and possible improvements in programming to satisfy specific needs. Feedback on the programming was positive, and there is definite interest in repeating the event.

On October 29th the Young Lawyers Committee hosted a program entitled, "Life as a Young IP Associate - Managing the Non-Legal Aspects of Your Practice," at Crowell & Moring LLP, which targeted another segment of the profession. Hoffmann & Baron, LLP hosted a continuing legal education program on November 7th entitled, "Understanding Recent Changes in Patent Law and Their Effect on Litigation," on Long Island to continue our efforts to geographically expand NYIPLA activities.

Clearly the CLE programs were diverse, interesting, and well received. In the coming months, we look forward to a similar success in providing informational and educational services to the intellectual property law profession.

Meanwhile, plans for the winter and spring events are well under way. In particular, with regard to the 2014 NYIPLA Judges Dinner, we are pleased to report that Judge Gregory M. Sleet, Chief Judge of the United States District Court for the District of Delaware, has agreed to accept the 2014 NYIPLA Outstanding Public Service Award. Judge Sleet's public

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service record is second to none, and, as a native New Yorker, he is a friend and supporter of the NYIPLA.

Finally, I would like to comment on some of the excellent components of the present Bulletin, which I urge members and recipients of this publication to peruse. For instance, we are publishing the Honorable William C. Conner Writing Competition First Place Winner's article by David Kurlander, a third-year student at Benjamin N. Cardozo School of Law. The article is entitled, "Rebalancing Pay-for-Delay: Why the Hatch-Waxman Act Should Be Given More Weight in the Antitrust Analysis and What That Means for Reverse Payment Agreements." It discusses the various tests applied by courts in analyzing "pay-for-delay" settlement agreements (i.e., "scope of patent" test, "rule of reason" test, and "quick-look rule of reason" analysis). Pursuant to the Association's request, David revised his original article to address the Supreme Court's recent decision in *FTC v. Actavis* on the test to be applied (i.e., "rule of reason") in analyzing reverse payment settlements.

A further article of interest being published is entitled, "The Patent Pilot Program: Reassignment Rates and the Effect of Local Patent Rules." This article by Ron Vogel discusses the Patent Pilot Program, the variation in the reassignment rates and the absence of a statistically significant correlation between the adoption of local patent rules and an increase in a district's caseload. Also included in this issue is an article submitted by Sandra Hudak, Charles Macedo and Michael Kasdan entitled, "The NYIPLA Advocates for Clarification on Patent-Eligible Subject Matter in an Amicus Brief to the Supreme Court Regarding *CLS Bank International v. Alice Corp*.," which is about the *CLS Bank* case and the NYIPLA amicus briefs submitted to the Court of Appeals for the Federal Circuit and the United States Supreme Court. All three of these articles are insightful and informative.

In closing, I would like to extend my condolences to the family and friends of NYIPLA past President John Tramontine, who recently passed away.

Charles R. Hoffmann

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benefit by protecting and promoting competition among firms.[12] Through the competitive free market, the consumer benefits from low prices, high quality, and technological progress.[13] The Supreme Court has described antitrust law generally, and the Sherman Act specifically, as the "Magna Carta of free enterprise."[14]

Congress began to construct federal food and drug law in an attempt to keep pace with pharmacological advancements and to set quality standards for both food and drugs.[15] The main statutory authority, the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), prohibits the sale of any new drug unless it is proven safe and effective.[16] In order for a manufacturer to produce and sell a drug product, 21 U.S.C. § 355(b) requires it to file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA"). The NDA requires copious amounts of information, including data from animal and laboratory testing and information about the chemistry and pharmacology of the drug.[17] 21 U.S.C. § 355(d) stipulates that the FDA may approve a drug when its safety has been demonstrated through "adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended or suggested. . . ." Thus, obtaining approval of an NDA is extremely costly and time-consuming.[18]

While the FDCA approval process was designed to protect consumers, it was not perfect. It required an NDA for all new drugs, including generics, even though generic drugs are "identical – or bioequivalent – to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use."[19] Since the NDA process was extremely costly, it became a major hurdle for cash-strapped generic manufacturers.[20] As a result, many generic drugs, which often serve as a catalyst for driving down the price of designer drugs, were unable to reach the market.[21]

Recognizing that generic drugs are estimated to save consumers between $8 billion and $10 billion each year, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act").[22] Designed as a complex regulatory scheme to increase generic competition in the pharmaceutical industry, the Act features mechanisms to streamline the entrance of generic alternatives into the marketplace and provides incentives for manufacturers of generic drugs to challenge the validity of patents on brand-name drugs.[23] One of the most important aspects of the legislation was the creation of an Abbreviated New Drug Application ("ANDA") for the bioequivalent form of a drug already approved for safety and effectiveness.[24] ANDAs speed up the approval process because the generic drug manufacturer is not required to reproduce the clinical studies that were conducted for the original product.[25] Instead, generic drug manufacturers must demonstrate that their product is bioequivalent to a previously approved product.[26]

After this first condition has been proven, the ANDA filer must certify that: (I) no patent was filed for the brand-name drug; (II) the patent for the drug has expired; (III) the patent will expire in the future and the generic drug will not be marketed until that date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug.[27] A filer that elects paragraph IV certification is required to notify each patent owner/NDA holder of its paragraph IV certification, stating that the listed patent is invalid or that its product does not infringe the patent.[28] Once the patent owner/NDA holder receives notification of the certification, the owner/NDA holder has forty-five days to bring a lawsuit for patent infringement against the ANDA filer.[29] If the patent owner/NDA holder brings a suit for patent infringement, it triggers an automatic thirty-month stay against

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approval.[30] The stay is lifted after the expiration of the thirty-month period or once a decision is issued by the district court as to the validity of the patent or the issue of infringement.[31]

To encourage generic manufacturers to challenge weak or invalid patents through paragraph IV certification, the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(B)(iv), offers the first successful paragraph IV filer the opportunity to market its generic drug exclusively for 180 days. This creates a duopoly between the brand-name drug and the generic drug for the 180-day period.[32] Notably, under 21 U.S.C. § 355(j)(5)(D) the 180-day exclusivity period is available *only* to the first paragraph IV filer. Consequently, if the first filer never becomes eligible to use its exclusivity period because it settles or withdraws the litigation, that potential benefit will not pass to subsequent filers.[33]

Recognizing the potentially disastrous effects that a lost patent could have on profits, some patent holders began to settle infringement suits with the ANDA filers.[34] These settlements often involve payments from the patent holder to the alleged infringer to drop its patent challenge and refrain from producing a generic drug for a negotiated period of time.[35] Since the payment flows from the patent holder to the would-be-generic manufacturer, these agreements are called "reverse payment agreements."[36] Commentators note that the reverse flow of money occurs because the Hatch-Waxman Act reallocates the risks and potential rewards between the litigants.[37] It is now the patent infringement plaintiff that stands to lose the most valued item – the patent. In contrast, the alleged infringer stands to gain the most – the right to enter the market. Thus, reverse payments are considered "a natural by-product" of the Hatch-Waxman regulatory design.[38]

The Hatch-Waxman Act passed with the primary intention of jumpstarting generic competition with brand-name pharmaceuticals.[39] The Act encourages the production of more low-cost generic drugs in two ways.[40] First, it created an expedited approval process by allowing the generic manufacturer to piggyback on the safety and effectiveness data submitted by the brand-name pharmaceutical company.[41] This allows the generic manufacturer to avoid the costly and time-consuming clinical trials necessary to establish the safety and efficacy of the generic drug.[42] Second, 21 U.S.C. § 355(j)(5)(B)(iv) encourages generic manufacturers to challenge potentially invalid drug patents by granting the first paragraph IV filer a 180-day period of market exclusivity.

At the same time, the Hatch-Waxman Act responded to the lobbying efforts of many pioneer drug companies.[43] Since there is a lengthy approval process for pioneer drugs, pioneer companies sought legislation to restore lost patent life.[44] Specifically, the Hatch-Waxman Act restored the amount of patent term equal to the "regulatory review period for the approved product."[45] There are a number of limitations to the restoration extension, but the overarching purpose of the extension was to mitigate the adverse impact that the rest of the Hatch-Waxman Act would have on the incentives for large brand-name pharmaceutical companies to invest in research and development of new drugs.[46]

Although some consider the legislation a compromise, Congress has followed its traditional path in the area of intellectual property, stimulating innovation in industry while explicitly promoting the public interest.[47] Nevertheless, the Hatch-Waxman Act principally serves the consumer interest. By extending the length of the patent, the Act continues to encourage large drug firms to invest in the research and development of new drugs, and the creation of new drugs ultimately benefits the consumer. Meanwhile, the ANDA approval process and paragraph IV certification operate to streamline the introduction of generic drugs into the marketplace and drive down the costs of health care – again, benefiting consumers.[48] Thus, the Act serves a singular purpose, to promote consumer welfare, through two parallel avenues.

III. Imbalance Between Intellectual Property Rights, Competition Law, and the Hatch-Waxman Act

The issue of reverse payments has been considered by a number of district and circuit courts, and the process of review has varied.[49] Some courts, under *per se* illegal analysis, examine the antitrust implications of the agreement at the expense of any patent consideration. Other courts, under scope of the patent analysis, focus extensively on the existence of a patent and ignore potential antitrust violations. The Supreme Court, over the October 2012 term, stepped in to address the issue in *F.T.C. v. Actavis, Inc.,* and concluded that both patent and antitrust law are relevant in determining the legality of a reverse payment. While some practitioners downplay the decision, stating that reverse payments are still viable so long as the procompetitive justifications are well documented, others declare that reverse payments are a "dangerous" activity.[50] Nevertheless, companies still engage in reverse payments, and, as a result, attorneys and companies are closely watching how the lower courts interpret *Actavis* on a case-by-case basis.[51] Accordingly, it is useful to analyze the various approaches employed by the courts to determine the costs and benefits of each method of review. This analysis leads to the conclusion that the courts have consistently neglected the Hatch-Waxman Act as a material part of the analysis.

A. The Per Se *Illegal Analysis*

Potential antitrust violations are generally reviewed under the "rule of reason."[52] That test directs a court to examine various factors that relate to the challenged action's impact on competition.[53] The rule of reason, however, provides little guidance on how those factors should be analyzed and, as a result, provides little predictability.[54] The *per se* illegal rule is an outgrowth of the rule of reason's lack of predictability.[55] Restraints that are deemed *per se* violations are those which judicial experience has found lack any redeeming procompetitive effect.[56] When

the *per se* rule applies, the plaintiff is not required to show that competition has been injured, and any procompetitive justification by the defendant is moot.[57]

Under the *per se* illegal rule, reverse payment settlements are conclusively presumed to be unreasonable restraints on trade and, as a result, are deemed unlawful and invalid without any further inquiry.[58] The Supreme Court has stated that a *per se* rule of invalidity is appropriate only when the agreement is "manifestly anticompetitive."[59] If the court can predict with confidence that the agreement would be invalidated under traditional antitrust analysis, then the *per se* rule may apply.[60] Thus, the *per se* rule applies when the agreement "would always or almost always tend to restrict competition and decrease output."[61]

Accordingly, the *per se* rule is not an appropriate framework for evaluating a reverse payment settlement because the underlying patent may be valid and infringed. If a valid patent does exist, then a settlement agreement is in accord with well-established patent principles.[62] Since the patent may be valid and infringed, it is impossible to conclusively determine at this early stage whether the agreement is plainly and inherently anticompetitive. Ultimately, the *per se* illegal analysis deems patent validity irrelevant and invalidates the agreement on *purely* antitrust grounds.

B. Scope of the Patent Analysis

On the other end of the spectrum is the scope of the patent test, which has developed into a *per se* rule of legality.[63] The current version of the scope of the patent test will find a reverse settlement agreement valid as long as a patent holder did not act in bad faith beyond the limits of the patent to restrain or monopolize trade.[64] The only exceptions to this rule occur where there is evidence that the patent was procured by fraud or that the brand-name pharmaceutical company's infringement suit was objectively baseless.[65]

Michael Carrier, Professor of Law at Rutgers School of Law-Camden, opines that the scope of the patent test has shred all nuance and evolved into a *per se* legal test.[66] He notes two major flaws. First, the test assumes away the question being litigated – whether the underlying patent is valid.[67] Professor Carrier notes, however, that the presumption of validity is merely procedural.[68] That is, the presumption of validity merely governs the order in which proof is presented during trial; it is not substantive evidence of validity.[69] Nevertheless, under the scope of the patent test, the courts have presumed that the patent is valid for the purposes of reviewing the settlement.[70] In doing so, there remains the potential that the patent is invalid. As a result, the scope of the patent test may help a brand-name pharmaceutical company exclude generic competition from the market even though it has no legal right to do so. Professor Carrier also notes that when a brand-name pharmaceutical company sues a generic company for infringement, the brand-name pharmaceutical company has the burden of proving infringement.[71] The scope of the patent test cannot resolve this issue because it does not require the brand-name pharmaceutical company to make any showing of infringement.[72] There remains the potential that the brand-name pharmaceutical company's patents are valid, but the generic company does not infringe the patents.

Ultimately, the scope of the patent test may help a brand-name pharmaceutical company preserve the exclusionary power of an invalid patent or help it exclude a non-infringing generic.[73] In doing so, the scope of the patent test allows a brand-name pharmaceutical company to undermine the Hatch-Waxman Act's regulatory procedure, which was designed to increase the number of generic products available to consumers on a timely basis. As a result, the consumer is denied the benefits of generic competition and suffers a high social cost.[74] Thus, the scope of the patent test fails to address the central question of a paragraph IV certification and ultimately undermines the ability of the Hatch-Waxman Act to promote the consumer interest.

Second, the test fails to address antitrust issues. According to the Supreme Court, whether a restraint qualifies as an unreasonable restraint, and therefore violates antitrust law, is normally evaluated under the "rule of reason."[75] Applying the rule of reason, "the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect."[76] The scope of the patent test does not consider any of these factors. Rather, it considers only "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."[77] Essentially, the scope of the patent test will consider a patent settlement agreement valid as long as a patent holder did not act in bad faith "beyond the limits of the patent monopoly" to restrain or monopolize trade.[78] The test merely applies antitrust scrutiny to any part of the agreement that exceeds the patent's range. The test does not consider that if the patent is invalid, the effect of the restraint is significant, especially given that the relevant market has cost consumers exorbitant amounts – to the point that Congress passed the Hatch-Waxman Act as a means to reduce health care costs.[79] A proper analysis would not bypass competition law so easily.

C. The Rule of Reason Analysis

In *FTC v. Actavis*, two generic pharmaceutical companies filed ANDAs and paragraph IV certifications for a generic drug product.[80] In response, the brand-name pharmaceutical company initiated a patent infringement suit against the generic companies, which was later settled.[81] Pursuant to the settlement, the generic manufacturers agreed to refrain from bringing their products to market for a specified term.[82] As consideration, the brand-name pharmaceutical company agreed to pay millions to each generic company.[83] According to a lawsuit brought by the

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Federal Trade Commission ("FTC"), the payments were truly compensation for the agreement that the generic drugs would not compete against the brand-name drug for years.[84] The district court dismissed the complaint,[85] and the Court of Appeals for the Eleventh Circuit applied the scope of the patent test and affirmed the dismissal.[86] Because of a sizable circuit split, the Supreme Court granted *certiorari* to answer whether a reverse payment agreement could unreasonably restrict competition in violation of the antitrust laws.[87] The Court concluded that a reverse payment may, under certain circumstances, violate the antitrust laws.[88] Such a determination would be decided after a rule of reason analysis.[89]

The Court reasoned that it would be incongruous with Supreme Court jurisprudence to determine antitrust legality by measuring the anticompetitive effects of reverse payments solely against patent law policy; both antitrust and patent laws are relevant in determining the scope of the patent monopoly.[90] The Court went on to explain that it has consistently analyzed agreements between patentee and potential competitor by using "traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents."[91]

The rule of reason requires a court to engage in a complex inquiry to decide if a particular restraint is "unreasonable."[92] The first step in the analysis is to assess market power, which requires the court to define the relevant market.[93] However, "[d]efining the relevant market has become increasingly more difficult, with the globalization of the economy, making it more difficult to ascertain when reasonable substitutes exist and when they do not."[94] Also, as the widely respected antitrust scholar Professor Herbert Hovenkamp notes, "market definition questions in the pharmaceutical industry are particularly troublesome because of the high degree of product differentiation that distinguishes branded drugs from one another, notwithstanding considerable overlap in the treatment of certain conditions or symptoms."[95]

Market definition is just one factor. For example, market power, the relative size of the payment, and the entry ability of third parties are all considerations under the rule of reason.[96] Courts could weigh these considerations differently, which could lead to inconsistent results for similarly situated cases.

Professors Hovenkamp, Janis, and Lemley also note that the rule of reason is not designed to answer the relevant questions.[97] Specifically, the purpose of the rule of reason is to determine the competitive nature of a given practice, whereas patent law is "a set of judgments about the proper tradeoff between competition and the incentive to innovate over the *long* run."[98] The rule of reason "was not designed for such judgments and is not adept at making them."[99] The real question is whether the agreement is:

> one contemplated by the [intellectual property] laws as part of the supracompetitive incentive those laws give to innovation. For these queries, the burdens of production and proof properly rest with the antitrust defendants (or proponents of the settlement) because they typically control the information upon which resolution of the infringement issue will be made.[100]

Therefore, Professors Hovenkamp, Janis, and Lemley conclude that the rule of reason is not the optimal method of analysis in regard to reverse payment agreements.[101]

Also, the extensive and complex rule of reason analysis requires a significant amount of time and entails significant costs.[102] This increased burden on the FTC may lead the agency to attack only certain settlements, while allowing others to proceed. This would, in turn, increase the likelihood of false negatives – characterizing anticompetitive settlements as procompetitive or competitive neutral.

In addition, the pro-consumer effect of generic competition may be offset by delayed resolution of the case. The long and costly litigation period delays generic entry, during which time the brand-name pharmaceutical company can continue to collect monopoly profits. This issue is exacerbated by the rule of reason because the brand-name pharmaceutical company and the generic company do not have to prove that the agreement is not anticompetitive, despite being in the best position to explain the procompetitive benefits of the agreement. These issues suggest that the rule of reason is simply antitrust analysis applied to patent settlements, without a consideration of the Hatch-Waxman Act. Such a scheme is not in line with the objectives of the Act.

IV. The Hatch-Waxman Act Should Be Given More Weight in the Analysis

The courts, applying either the *per se* rule or the scope of the patent test, have elevated either patent or antitrust law, respectively, above the Hatch-Waxman Act at the expense of promoting the Act's purpose. Similarly, the rule of reason, which is a more balanced approach to analyzing pay-for-delay settlements, focuses solely on patent and antitrust and the interplay between these two bodies of law. Patent and antitrust laws, however, are large bodies of law that apply broadly to a number of industries. Thus, the Hatch-Waxman Act, which applies specifically to the health care industry, should be given the most weight in the analysis. Moreover, patent and antitrust laws have general aims while the Hatch-Waxman Act has a very specific purpose. Finally, the Hatch-Waxman Act is the most recent development related to competition in the pharmaceutical industry. Taken together, the Hatch-Waxman Act, its procedures, and its purpose must play a more dominant role in the analysis.

A. The Hatch-Waxman Act is Sector-Specific

Patent and competition laws are large, general bodies of law that encompass numerous industries. They can effectively reach every corner of the economy. For

example, a patent is the government grant of exclusive rights to an invention for a limited period that is awarded to an inventor in exchange for the public disclosure of the invention.[103] Governed by Title 35 of the United States Code, patents have a general set of legal rules that govern patentability in a wide variety of technologies.[104] It has been stated that those standards are so flexible that they can encompass "anything under the sun that is made by man."[105] As a result, patents have applied to numerous products, and processes, such as smartphones, tablet computers, teeth whiteners, and welding machines.[106]

Antitrust law is just as broad. Purposely designed to protect the public from the failures of the market, antitrust law directs itself against conduct that unfairly destroys or reduces competition.[107] Consequently, antitrust law condemns practices such as pricing agreements between competitors, mergers that result in conglomerates owning an unfair share of the market, and contracts between buyers and sellers that restrain trade.[108] Essentially, competition law is so broad and far-reaching that the doctrine applies to any anticompetitive activity that involves or affects interstate commerce. As such, violations of competition law have been found in a variety of industries such as mattress manufacturing, college sports, and dentistry.[109]

In contrast, food and drug law concerns itself with physical things that are put into or onto, or are used with, the bodies of humans or animals.[110] More specifically, the FDCA, which was later amended by the Hatch-Waxman Act, defines its jurisdictional terms as "food," "drug," "device," and "cosmetic."[111] Even more specific are the Hatch-Waxman Act amendments to the FDCA. Those amendments, codified at 21 U.S.C. § 355, extend the life of patent protection for brand-name pharmaceuticals and provide a mechanism for generic manufacturers to challenge the validity of the brand-name patents. The amendments apply directly to brand-name pharmaceutical manufacturers and their generic rivals in the pharmaceutical industry.

Interestingly, veterinary drug products are not included under the Hatch-Waxman Act's patent restoration provision. The inclusion of veterinary drug products was proposed at one point, but ultimately veterinary drug products were dropped from the final version of the Hatch-Waxman Act.[112] Thus, as Congress intended, the Hatch-Waxman amendments apply *only* to human drugs – a very specific sector of the economy.[113]

B. The Hatch-Waxman Act Has a Specific Purpose

The Hatch-Waxman Act should be given more weight in the analysis because the Act has a very specific purpose within this specific sector. Senator Orrin Hatch, one of the principal drafters of the Hatch-Waxman Act, stated that the purpose of the Act was to infuse generic competition into the pharmaceutical market sooner rather than later, thereby providing consumers with savings in the health care system.[114] The Act serves one fundamental purpose – to bring generic drugs to market quickly.[115]

Furthermore, the Hatch-Waxman Act indicates the means through which its purpose is to be carried out. The Act provides a mechanism for generic manufacturers to challenge brand-name patents and provides significant incentives for generic companies to initiate these challenges.[116] The Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(B)(iii), also allows a brand-name manufacturer to defend against these challenges by initiating a patent infringement suit. This design indicates that the drafters intended for these patent challenges to be litigated.[117] In addition, the legislative history shows that Congress intended to encourage generic manufacturers to challenge weak or invalid patents through the litigation process.[118] The means to quickly infuse generic competition into the pharmaceutical market, therefore, is to litigate the validity of the brand-name patents.[119] Thus, the purpose of the Act is specific, and the means that Congress specified to achieve that purpose are equally specific. As a result, the principles and objectives of the Hatch-Waxman Act should be given priority.

C. The Hatch-Waxman Act Marks a Recent Accomplishment in Health Care Law

Furthermore, the Hatch-Waxman Act is the most recent development. The Hatch-Waxman Act was a significant amendment to the 1938 FDCA.[120] Passed in 1984, the Hatch-Waxman Act was then amended as a part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[121] Since it was passed, the Act has played a significant role in health care law and the United States pharmaceutical market. One commentator notes that over the past few decades, pharmaceutical research, due in part to the Hatch-Waxman Act, has helped transform the health care industry.[122]

In contrast, Congress passed its first patent statute in 1790, and by 1836 all of the essential features of modern patent law were in place.[123] Despite periodic revisions, the basic structure of the patent system has remained unchanged.[124] Along a similar vein, the heart of federal antitrust law, the Sherman Antitrust Act, was passed in 1890.[125] The Legislature intended the Act to be a federal enactment of the common law of restraints of trade, with courts having wide discretion in framing its rules and guidelines.[126] Nevertheless, the Sherman Act is the main antitrust authority.[127]

V. The Quick-Look Rule of Reason is the Appropriate Test for Evaluating a Reverse Payment Agreement

Accepting that the Hatch-Waxman Act must play a significant role in the antitrust analysis of reverse payment agreements leads to the conclusion that reverse payments must face significant antitrust scrutiny without being inherently unlawful. Consequently, the quick-look rule of reason should be employed because it promotes the purposes of the Hatch-Waxman Act, lowers the cost of pharmaceuticals, and strikes a balance between patent and antitrust laws.

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Under a quick-look rule of reason analysis, courts consider the context and likely effect of the agreement before deciding to apply either the *per se* illegal rule or the rule of reason.[128] The analysis falls in between the rigid *per se* rule and the complicated rule of reason.[129] Typically, a restraint of trade falls within the quick-look category if it is highly suspicious, but some doubt exists as to the true effect of the restraint.[130] The quick-look rule of reason applies "in cases where *per se* condemnation is inappropriate, but where 'no elaborate industry analysis is required to demonstrate the anticompetitive character' of an inherently suspect restraint."[131] When it applies, the test presumes competitive harm, but allows the defendant to provide a procompetitive justification for the action.[132] Absent a reasonable procompetitive justification for the restraint, "the presumption of adverse competitive impact prevails" and the action is deemed a naked restraint in violation of antitrust law *per se*.[133] If the defendant offers a legitimate procompetitive justification, however, the court will proceed to apply the rule of reason.[134]

The quick-look test is appropriate for the evaluation of a reverse payment agreement. A reverse payment that occurs between two competitors is considered a horizontal restraint, and the potential for an adverse impact on competition is great.[135] No elaborate analysis is required to understand that an agreement between two horizontal competitors to refrain from competing in the relevant market is anticompetitive.[136] Thus, horizontal agreements are often considered *per se* violations.[137] A reverse payment, however, is complicated by the existence of a potentially valid and infringed patent. Accordingly, the patent holder may have lawful exclusionary rights. Thus, while the agreement itself is inherently suspect, *per se* condemnation is inappropriate. Whether the agreement is totally devoid of competitive effects is questionable.

Under the quick-look analysis, the existence of any payment from a brand-name patent holder to a generic patent challenger who in turn agrees to delay entry into the market is considered prima facie evidence of an unreasonable restraint of trade.[138] The patent holder can rebut that presumption by showing that the payment was for a purpose other than delayed entry or offers a procompetitive benefit.[139]

One important corollary is that settlement policy is not a justification.[140] Often, defendants argue that sound settlement policy favors upholding reverse settlements.[141] They argue that the purpose of a settlement is to provide the parties with certainty and finality and to help relieve the burden on a congested court system.[142] Consequently, they conclude that any rule that would deprive settlements of their finality or restrict the ability of the parties to enter into a settlement is contrary to sound settlement policy.[143] These arguments, while appealing, cannot rebut the presumption of an illegal restraint. The purpose of the quick-look test is to quickly ascertain whether the restraint tends to promote competition.[144] Sound settlement policy does not indicate anything about the procompetitive effects of the agreement.

In addition, Scott Hemphill, Professor of Law at Columbia Law School, argues that the Hatch-Waxman Act normally operates to balance innovation and competition, and any settlement favoring more innovation at the expense of consumer access disrupts this balance.[145] Taking that one step further, any settlement policy that favors the conservation of judicial resources and provides the parties with certainty and finality at the expense of consumer access is contrary to the purpose of the Hatch-Waxman Act.

A. The Quick-Look Rule of Reason Promotes the Purposes of the Hatch-Waxman Act

By creating the ANDA approval process and restoring lost patent life, the Hatch-Waxman Act is an effort "to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."[146] The quick-look rule of reason fosters these objectives best.

First, the quick-look test does not devalue the patent as far as the *per se* illegal test.[147] Making reverse payment agreements *per se* illegal reduces the value of the patent because it removes a method that the patent holder may use to protect its patent against infringement.[148] The quick-look test, however, does not fully strip the brand-name pharmaceutical company of this ability to defend its patent. While somewhat constricted, the brand-name pharmaceutical company can still settle the litigation so long as the payment is not for delay or as long as the payment promotes competition.[149] By granting the brand-name pharmaceutical company the opportunity to defend the settlement, the value of the patent is not reduced as significantly. Therefore, the quick-look test will not serve as a disincentive for brand-name pharmaceutical companies to invest further in research and development.

As mentioned previously, *per se* illegal treatment of reverse settlements may discourage generic manufacturers from filing ANDAs because it reduces the available settlement options.[150] The quick-look rule of reason, however, does not prevent all settlement. It merely requires that the settlement be for something other than delayed entry. If that is not possible, then the agreement must have legitimate procompetitive benefits. Thus, the potential that the test will reduce the number of ANDA filings is insignificant.

Furthermore, a settlement is still attractive as long as the brand-name and generic companies believe that they can rebut the presumption of settlement invalidity. As a result, pharmaceutical companies would only structure reverse settlement agreements if they were reasonably sure that it would not be anticompetitive. In an example provided by the Third Circuit, a reverse payment agreement that has an overall effect of increasing the amount of competition in the market would be "a modest cash payment that enables a cash-

starved generic manufacturer to avoid bankruptcy and begin marketing a generic drug."[151] In that sense, allowing for settlement in these rare situations fosters generic competition.

B. The Quick-Look Rule of Reason Advances the Ultimate Economic Goal of the Hatch-Waxman Act as Well as Patent and Antitrust Laws

The economic goal of patent and antitrust laws, and the Hatch-Waxman Act, is to maximize wealth by producing better items and producing items at a lower cost.[152] The three doctrines can achieve this goal by creating output expansion and avoiding output restriction.[153] Accordingly, antitrust law will permit anticompetitive activity, such as a monopoly, when that activity creates greater output.[154] Patent law finds its way into the mix when it provides something that consumers value, but could not otherwise obtain without affording the developer the protections of a patent.[155] This too is output expansion. The Hatch-Waxman Act cuts down the middle in that it effectively increases the potential value of a patent by increasing its duration while creating a mechanism by which generic manufacturers can compete against the patents. The result is creating output expansion by stimulating brand-name innovation and generic competition.

In contrast, a reverse payment has the potential to create substantial output restriction if the settlement protects an invalid or non-infringed patent. In this situation, a brand-name pharmaceutical company is able to keep the generic company at bay and make a substantial profit in an exclusive market even though the underlying patent is invalid or not infringed. These settlements would unduly restrict competition and, as a result, unnecessarily reduce consumer welfare.[156] While allowing a settlement that protects a patent that is not valid or infringed is more costly than condemning a settlement where the patent is valid and infringed, the latter should not be inherently illegal. A settlement that protects an invalid patent is the type of settlement agreement that must be avoided, but not completely at the expense of the second type of settlement.

The quick-look test, which presumes that the settlement is illegal, gives proper weight to the effect of output restriction.[157] It places a high burden to overcome the presumption and prove that the settlement does not reduce output. If the patent holder, however, can either prove that the agreement was for a purpose other than delayed entry or offers a legitimate procompetitive benefit, then the court can be assured that the settlement expands output rather than restricts it.[158] Since the patent holder is in the best position to offer justifications for the settlement, a failure on the part of the patent holder to do so strongly suggests that the agreement may restrict output. Ultimately, the more costly settlement, one that protects an invalid patent, will be avoided, but those rare settlements that increase competition will not be ignored.

C. The Quick-Look Rule of Reason Strikes a Proper Balance Between Patent and Antitrust Laws

Mark Lemley, Professor of Law at Stanford Law School, argues that in order to have a balance between patent and antitrust, strong patent rights must be coupled with strong antitrust enforcement.[159] In order to make this shift, Professor Lemley suggests that two processes must change. First, modern thinking has led to the conclusion that private decisions are efficient, not necessarily the free market.[160] Private decisions, however, produce efficient results only because they are disciplined by an unforgiving market.[161] Since the antitrust laws are designed to create a competitive and unforgiving market, private decisions require strong antitrust enforcement.[162] The quick-look rule of reason provides heightened antitrust scrutiny and allows for strong antitrust enforcement. Under the quick-look test, antitrust enforcement authorities have teeth to attack settlements that they view as restrictive. The test does not, however, fully render the brand-name pharmaceutical company defenseless. As a result, the brand-name pharmaceutical company can make a business decision to either see the infringement litigation through or settle. If the brand-name pharmaceutical company opts to settle, it is aware that it must settle in a manner that is not for delay or in a way that promotes competition. Consequently, the brand-name pharmaceutical company will make an efficient decision in response to the threat posed by enforcement authorities. If the brand-name pharmaceutical company fails to do so, it will be disciplined. Therefore, private decisions will be met with strong antitrust enforcement.

Second, Professor Lemley argues that "[w]hen patent rights get stronger, we want antitrust to get stronger to prevent abuses of the right."[163] In the pharmaceutical industry, drug patents are coupled with strong patent protection in order to allow for large profits.[164] Strong protection, however, poses high barriers for generic products to enter the marketplace.[165] In addition, the potential for patent abuse has increased from the passing of the Hatch-Waxman Act, which created the regulatory design that facilitates reverse payment settlements. Under the quick-look analysis, antitrust no longer merely polices the borders of the patent. As a result, it can prevent more settlements that protect invalid or non-infringed patents.

Furthermore, the quick-look rule of reason promotes fundamental principles of patent law. Patents do not immunize settlements from antitrust scrutiny, but, instead, patent law creates limited monopolies in order to encourage innovation. Invalid patents, however, do not promote innovation for the public good, and, as a result, they confer unlawful monopoly rights on their holders.[166] Consequently, the Supreme Court has stated that is of great importance to the public that worthless patents should not suppress competition.[167] The quick-look rule of reason tests the validity of patents and resolves questions surrounding the validity of the patent.[168] In resolving these important questions, the public can be assured that drug patents that survive actually promote

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innovation for the public good. On the other hand, if litigation finds that the patent is invalid, then the drug never had any lawful patent rights.

Ultimately, the quick-look rule of reason suggests a more balanced view between patent and antitrust. It examines where the strong patent rights of the pharmaceutical industry meet strong antitrust enforcement. Since there is an inherent conflict between patent and antitrust laws, having a balanced relationship between the two will serve to best promote the goals of the Hatch-Waxman Act.[169]

VI. Conclusion

The Hatch-Waxman Act is an ambitious and complicated legislative accomplishment. Given the potential for a massive drop in profits that is often coupled with the loss of a patent, many brand-name pharmaceutical companies have exploited weaknesses in the Act through reverse payment settlements. Judicial review of these settlements has swung full force with either antitrust or patent principles. The Supreme Court, in *FTC v. Actavis*, endorsed the rule of reason, blending antitrust and patent law. However, these methods of analysis have largely neglected the purpose of the Hatch-Waxman Act. The Act should be given the most weight in the analysis because it is aimed at a specific industry, embedded with a specific purpose, and representative of the most recent legislative accomplishment. Accepting that the Act must be given the most weight in the analysis has an important consequence. That is, reverse payment agreements should be subjected to a quick-look rule of reason analysis because the quick-look test promotes the dual purposes of the Hatch-Waxman Act, fosters the economic goals of patent law, antitrust law, and the Act, and strikes a proper balance between antitrust and patent laws. While the quick-look test is not perfect, it is a more balanced solution to a delicate problem.

(Endnotes)

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1 John Simons, *Lilly Goes Off Prozac*, Fortune, June 28, 2004.

2 *Id.*

3 *Id.*

4 *Id.*

5 *See, e.g.*, *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

6 *F.T.C. v. Actavis, Inc.*, 570 U.S. ___, 133 S. Ct. 2223 (2013).

7 *See* Gerald Sobel, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements*, 20 Fed. Cir. B.J. 47, 61-63 (2010); *cf.* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1597-04 (2006).

8 Michael E. Clark, Pharmaceutical Law: Regulation of Research, Development, and Marketing 626 (7th ed. 2007).

9 35 U.S.C. § 154 (2006); *see also Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980).

10 John W. Schlicher, Patent Law, Legal and Economic Principles § 1:1 (2d ed. 2012).

11 *Id.*

12 John Miles, Health Care and Antitrust Law § 1:2 (2012).

13 *Town of Concord, Mass. v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990).

14 *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972).

15 *See* Julie C. Relihan, *Expediting FDA Approval of AIDS Drugs: An International Approach*, 13 B.U. Int'l L.J. 229, 234 (1995).

16 Federal Food, Drug, and Cosmetic Act, Pub. L. No. 717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-397 (2006)).

17 *Id.*

18 There has been testimony stating that the average cost of bringing a blockbuster drug to market is $800 million. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006).

19 U.S. Food and Drug Admin., Generic Drugs: Questions and Answers, http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm (last visited Oct. 10, 2013).

20 Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 Santa Clara Computer & High Tech. L.J. 489, 509 (2007).

21 *Id.*

22 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2006)); s*ee also* S. Rep. No. 111-123, at 2 (2010).

23 H.R. Rep. No. 98-857, pt. 1, at 14 (1984) ("The purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962.").

24 21 U.S.C. § 355(j).

25 Ethan N. Parvis, The Pharmaceutical Industry 81 (2002).

26 *Id.* The FDA considers bioequivalence as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in [generic drugs] becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R. § 320.1 (2012).

27 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV).

28 21 U.S.C. § 355(j)(2)(B). In addition, the filer must provide a "detailed statement of the factual and legal basis of the opinion of the [filer] that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv).

29 21 U.S.C. § 355(j)(5)(B)(iii).

30 *Id.* If the patent owner/NDA holder neglects to bring a suit, then the generic drug is automatically approved.

31 *Id.*

32 21 U.S.C. § 355(j)(5)(B)(iv); s*ee* Holman, *supra* note 20, at 509.

33 21 U.S.C. § 355(j)(5)(D).

34 *See Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 806 (D.C. Cir. 2001).

35 *See, e.g.*, *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

36 Holman, *supra* note 20, at 550.

37 *Id.*

38 *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003). Realizing the potential anticompetitive effects of reverse settlements, Congress amended the Hatch-

Waxman Act in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Those amendments require any reverse payment agreement to be filed with the FTC and the Department of Justice for antitrust review. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2066, 2461-64 (codified as amended at 21 U.S.C. § 355(j) (2006)).

[39] S. Rep. No. 111-123, at 23 (2010) (stating that the purpose of the Hatch-Waxman Act was to infuse the market quickly with generic competition thereby providing savings to consumers in the health care system).

[40] H.R. Rep. No. 98-857, *supra* note 23, at 14-15.

[41] Elizabeth S. Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 Antitrust L.J. 585 (2003).

[42] *Id.* at 585-86.

[43] Pioneer drug manufacturers pushed for patent term restoration bills every year from 1978 to 1984. *See* The Food and Drug Law Institute, Fundamentals of Law and Regulations 32 (David G. Adams et al. eds., 1997).

[44] *Id.*

[45] 35 U.S.C. § 156(c). Administration of the second half of the Hatch-Waxman Act is split between the FDA and the Patent and Trademark Office. 35 U.S.C. § 156(e).

[46] Weiswasser & Danzis, *supra* note 41, at 586.

[47] H.R. Rep. No. 98-857, *supra* note 23, at 30.

[48] *Id.* at 14-15.

[49] *See, e.g.*, *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (applying the *per se* illegal rule); *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) (applying a quick-look rule of reason test); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (applying the scope of the patent test).

[50] Terry Baynes, Lawyers at Odds Over Future of Pharma Patent Settlements (2013), *available at* Reuters Legal (July 19, 2013).

[51] Nanci Bompey, "Pay For Delay" Fight Moves To Pacts Barring Authorized Generics (2013), *available at* Westlaw Next 22192965.

[52] Herbert Hovenkamp, Federal Antitrust Policy: The Law of Competition and its Practice 263 (2005).

[53] *Nat'l Soc'y of Prof'l Engineers v. United States*, 435 U.S. 679, 688 (1978).

[54] Edward D. Cavanagh, *The Rule of Reason Re-Examined*, 67 Bus. Law. 435, 435 (2012).

[55] *Id.* at 436.

[56] John R. Phillips, *Things Your Mother Should Have Told You – A General Practitioner's Guide to U.S. Antitrust Law*, 64 Mich. B.J. 26, 26 (1985).

[57] Hovenkamp, *supra* note 52, at 263.

[58] *See* John Miles, Health Care and Antitrust Law § 2A:12 (2012); *see also Continental T. V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49-50 (1977) (explaining that when an agreement is *per se* illegal, it is conclusively presumed illegal without any further inquiry).

[59] *Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006).

[60] *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877, 887 (2007).

[61] *Id.* at 886.

[62] *See* Matthew B. Zisk, *Mediation and Settlement of Patent Disputes in the Shadow of the Public Interest*, 14 Ohio St. J. on Disp. Resol. 481, 486 (1999).

[63] Michael A. Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 16 Stan. Tech. L. Rev. 1, 5 (2012).

[64] *Id.*

[65] *Id.*

[66] *Id.*

[67] *Id.*

[68] *Id.* at 6.

[69] *Id.* at 5.

[70] *See, e.g.*, *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).

[71] Carrier, *supra* note 63, at 7.

[72] *Id.*

[73] Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. Rev. 11, 25 (2004).

[74] Hovenkamp, *supra* note 73, at 25; *see also* Scott A. Backus, *Reversing Course on Reverse Payment Settlements in the Pharmaceutical Industry: Has Schering-Plough Created the Blueprint for Defensible Antitrust Violations?*, 60 Okla. L. Rev. 375, 405 (2007).

[75] *See State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997).

[76] *Id.*

[77] *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1066 (11th Cir. 2005). An example of an action that exceeds the scope of the patent is an activity that serves as a device to circumvent antitrust law. *Id.* at 1067.

[78] *In re Tamoxifen*, 466 F.3d at 197.

[79] H.R. Rep. No. 98-857, *supra* note 23, at 17.

[80] *F.T.C. v. Actavis, Inc.,* 570 U.S. ___, 133 S. Ct. 2223, 2229 (2013).

[81] *Id.*

[82] *Id.*

[83] *Id.* $12 million in total to Paddock, $60 million in total to Par, and an estimated $19–$30 million annually, for nine years, to Actavis.

[84] *Id.* at 2230.

[85] *In re AndroGel Antitrust Litig. (No. II)*, 687 F. Supp. 2d 1371 (N.D. Ga. 2010).

[86] *F.T.C. v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012).

[87] *F.T.C. v. Watson Pharm., Inc.*, 133 S. Ct. 787 (Dec. 7, 2012) (No. 12-416).

[88] *Actavis*, 133 S. Ct. at 2238.

[89] *Id.*

[90] *Id.* at 2231.

[91] *Id.*

[92] *Ass'n of Retail Travel Agents, Ltd. v. Air Transp. Ass'n of Am.*, 623 F. Supp. 893, 898 (D.D.C. 1985).

[93] *Polk Bros., Inc. v. Forest City Enterprises, Inc.*, 776 F.2d 185, 191 (7th Cir. 1985).

[94] Peter Nealis, *Per Se Legality: A New Standard in Antitrust Adjudication Under the Rule of Reason*, 61 Ohio St. L.J. 347, 378-79 (2000).

[95] Herbert Hovenkamp, The Opening of American Law: Neoclassical Legal Thought, 1870-1970 (forthcoming: Oxford Univ. Press, 2014), *available at* http://www.ucl.ac.uk/laws/events/cledocs/ucl_hovenkamp_01 .pdf.

[96] *Actavis*, 133 S. Ct. at 2231.

[97] Herbert J. Hovenkamp, Mark D. Janis and Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1729 (2003).

[98] *Id.*

[99] *Id.*

[100] *Id.* at 1730.

[101] *Id.*

[102] *Arizona v. Maricopa County Med. Soc.*, 457 U.S. 332, 343 (1982).

[103] John Gladstone Mills, Donald C. Reilly, III and Robert C. Highley, Patent Law Fundamentals § 1:2 (2d ed. 2012).

[104] Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 Berkeley Tech. L.J. 1155, 1156 (2002).

[105] S. Rep. No. 82-1979 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399.

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[106] *See, e.g.*, *Apple, Inc. v. Samsung Electronics Co.*, 678 F.3d 1314 (Fed. Cir. 2012); *Ultradent Products, Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065 (Fed. Cir. 1997); *Gen. Elec. Co. v. Sciaky Bros, Inc.*, 415 F.2d 1068 (6th Cir. 1969).

[107] *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458-59 (1993).

[108] *See, e.g.*, *Arizona v. Maricopa County Med. Soc.*, 457 U.S. 332 (1982); *United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 327 (1963); *Mayer Hoffman McCann, P.C. v. Barton*, 614 F.3d 893, 896 (8th Cir. 2010).

[109] *See, e.g.*, *United States v. Sealy, Inc.*, 388 U.S. 350 (1967); *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Oklahoma*, 468 U.S. 85 (1984); *California Dental Ass'n v. F.T.C.*, 526 U.S. 756 (1999).

[110] The Food and Drug Law Institute, *supra* note 43, at 9.

[111] 21 U.S.C. § 321 (2006).

[112] The Food and Drug Law Institute, *supra* note 43, at 32.

[113] *Id.*

[114] S. Rep. No. 111-123, at 23 (2010).

[115] *Allergan, Inc. v. Alcon Laboratories, Inc.*, 200 F. Supp. 2d 1219, 1227 (C.D. Cal. 2002).

[116] *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

[117] H.R. Rep. No. 98-857, *supra* note 23, at 71.

[118] S. Rep. No. 107-167, at 4 (2002).

[119] *See* Hemphill, *supra* note 7, at 1614.

[120] The Food and Drug Law Institute, *supra* note 43, at 31.

[121] 21 U.S.C. § 355(j).

[122] Dr. Gregory J. Glover, *Hatch-Waxman Law Has Played Critical Role in Medical Advances*, 18 Andrews Pharma. Litig. Rep. 12 (2002).

[123] Burk & Lemley, *supra* note 104, at 1159.

[124] *Id.*

[125] 15 U.S.C. §§ 1-5 (2006).

[126] Michael A. Doyle & Michael P. Kenny, *The Statute of Limitations Applicable to Criminal Enforcement of the Sherman Act: Restraint of Trade or Enjoyment of the Spoils?*, 1986 Ariz. St. L.J. 183, 204 (1986).

[127] John H. Shenefield & Irwin M. Stelzer, The Antitrust Laws: A Primer 15 (4th ed. 2001).

[128] *Broadcast Music, Inc. v. Columbia Broadcasting Sys., Inc.*, 441 U.S. 1, 10 (1979).

[129] *In re K-Dur*, 686 F.3d at 209.

[130] Hovenkamp, *supra* note 52, at 265.

[131] *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993) (quoting *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Oklahoma*, 468 U.S. 85, 109 (1984)).

[132] *Id.*

[133] *Id.*

[134] *Id.*

[135] *Bus. Electronics Corp. v. Sharp Electronics Corp.*, 485 U.S. 717, 730 (1988).

[136] *See California Dental Ass'n*, 526 U.S. at 757.

[137] *Id.*

[138] *In re K-Dur*, 686 F.3d at 218.

[139] *Id.* Under this framework, arguments that the patent is strong would not be admissible.

[140] *See* Hovenkamp, *supra* note 52, at 265.

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[142] *Id.* at 22-27.

[143] *Id.* at 36-37.

[144] Hovenkamp, *supra* note 52, at 265.

[145] Hemphill, *supra* note 7, at 1614.

[146] *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1326 (Fed. Cir. 2001).

[147] *See supra* Part III.A.

[148] James Langenfeld & Wenqing Li, *Intellectual Property and Agreements To Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 Antitrust L.J. 777, 778 (2003).

[149] *See, e.g.*, *In re K-Dur*, 686 F.3d at 218.

[150] *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003).

[151] *In re K-Dur*, 686 F.3d at 218.

[152] *See id.* at 247-48.

[153] *Id.* at 248.

[154] Mark A. Lemley, *A New Balance Between IP and Antitrust*, 13 Sw. J. L. & Trade Am. 237, 255 (2007).

[155] *Id.* at 248.

[156] Lemley, *supra* note 154, at 253-54.

[157] Hemphill, *supra* note 7, at 1596.

[158] *In re K-Dur*, 686 F.3d at 218.

[159] Lemley, *supra* note 154, at 254.

[160] *Id.*

[161] *Id.* at 255.

[162] *Id.*

[163] *Id.*

[164] Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1581-83 (2003).

[165] *See Red Lion Med. Safety, Inc. v. Ohmeda, Inc.*, 63 F. Supp. 2d 1218, 1233 (E.D. Cal. 1999).

[166] *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892).

[167] *Id.*

[168] *Cf. Cardinal Chem. Co. v. Morton Int'l.*, 508 U.S. 83, 100-101 (1993) (noting the importance to the public at large of resolving questions of patent validity).

[169] *See* Lemley, *supra* note 154, at 254.

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The February/March 2014 issue of the NYIPLA Bulletin will be devoted to "Smartphones." Articles can encompass any of the intellectual property aspects of Smartphones, including patent (utility and design), trademark, and copyright, and also including damages, licensing, and technology standards. Articles may also discuss the parties involved, including phone manufacturers, such as Apple, Samsung, BlackBerry, Google, Motorola, Nokia, Microsoft, and HTC and service providers, such as AT&T, Sprint, Verizon, and T-Mobile.

Articles can be any length, but a length of 1700 to 2500 words is expected to be about average. Please submit the articles in Microsoft Word, 1997-2003 format (i.e. ".doc," not ".docx") and with endnotes rather than footnotes.

- Abstracts (1-2 paragraphs) due by **January 15, 2014** (for planning purposes)
- Final Articles due by **February 10, 2014**

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The Patent Pilot Program: Reassignment Rates and the Effect of Local Patent Rules

*By Ron Vogel**

I. Introduction

The Patent Pilot Program (the "Program") has been in operation for almost two years in fourteen U.S. district courts (the "patent districts"). To date, nearly a third of all patent cases assigned to non-patent judges in patent districts were reassigned to participating judges. The reassignment rates vary significantly by district and have been lowest in the Northern District of California, the Southern District of New York, the District of New Jersey, and the Central District of California—four busy districts where judges regularly deal with complex litigation. Whether the Program has met its stated goal of enhancing expertise in patent cases will become clearer as more data—including reversal rates on appeal—are collected.

Local patent rules are in place in twelve of the fourteen patent districts. An analysis of quarterly caseload data over the last decade shows that there is no statistically significant correlation between the adoption of local patent rules and an increase in a district's caseload. This is perhaps not surprising given that local patent rules vary across the adopting districts.

II. The Patent Pilot Program Has Been Operating for Over Two Years

On June 7, 2011, the Administrative Office of the U.S. Courts (AOUSC) announced that fourteen district courts were selected to participate in a pilot program designed to enhance expertise in patent cases among federal judges.[1] The ten-year program will "study the differences in reversal rates and disposition times between patent and non-patent judges."[2]

The districts were chosen based on either their busy patent dockets or their intention to adopt local patent rules.[3] The District of Delaware was the only patent-intense district not included in the Program. Twelve of the fourteen districts selected have already adopted local patent rules; some have been in place for over a decade, while others have been in place for a matter of months.

The Program works as follows: patent cases filed in participating district courts are randomly assigned to a district judge, regardless of whether that judge has been designated to hear such cases. A judge who is not a designee may decline to accept an assigned case. That case is then randomly assigned to one of the district judges designated to hear patent cases.[9] The AOUSC is statutorily required to make periodic reports to Congress, including analyzing if the Program has:[10]

- developed expertise in patent cases and improved the efficiency of the courts;
- created differences in designated and non-designated judges with respect to (i) reversal rates by the Federal Circuit on issues of claim construction and substantive patent law, and (ii) time elapsed from the filing of a case to the date on which trial begins or summary judgment is entered;
- encouraged litigants to select certain districts to ensure a given outcome; and
- been successful enough to be extended to other or all district courts.

III. In the First Two Years, One-Third of Patent Cases Have Been Reassigned by Non-Patent Judges

The Program was implemented in the fall of 2011, and a list of participating judges in Program districts is given in Appendix C. Between September 19, 2011 and October 10, 2013, 5,681 patent cases were filed in Program districts. Of those 5,681 patent cases, 2,037 were initially assigned to non-patent judges, and 649 of those 2,037 cases were reassigned. Reassignment rates varied significantly, and were lowest in the Northern District of California, the District of New Jersey, the Southern District of New York, and the Central District of California—four busy districts where judges regularly deal with complex litigation.

Table 1— DISTRICTS PARTICIPATING IN THE PATENT PILOT PROGRAM

	Patent Cases Filed[4]			Time to Trial,	Local Patent Rules
District	2011	2012	Through 10/29/13	years[5]	Adopted[6]
Eastern District of Texas	413	1,231	1,195	2.13	2/2/05[7]
Central District of California	309	503	324	2.47	—
Northern District of California	219	256	212	2.92	1/1/01
Northern District of Illinois	217	238	182	2.52	10/1/09
District of New Jersey	178	159	121	3.06	1/1/09
Southern District of New York	152	141	95	2.85	4/8/13
Southern District of California	79	143	174	2.48	4/3/06
Southern District of Florida	63	134	155	1.66	—
Northern District of Texas	46	57	67	2.26	5/1/07[8]
Eastern District of New York	33	30	38	3.28	4/8/13
District of Maryland	31	42	14	2.22	7/1/11
District of Nevada	30	30	37	2.39	8/1/11
Western District of Pennsylvania	11	39	19	—	1/1/05
Western District of Tennessee	2	31	14	—	9/19/11

In view of the wide range in the number of cases assigned to non-patent judges in each district (ranging from 9 to 601), the reassignment rates are best conveyed through the 95% confidence interval given in the last two columns of Table 2. As the Program matures, case reassignment rates can be compared with reversal rates to determine whether each district's outcomes have become more predictable.[16]

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TABLE 2 – REASSIGNMENT OF PATENT CASES IN PATENT PILOT DISTRICTS[11]

District	Patent Pilot Judges in District[12]	Patent cases assigned	Cases assigned to non-patent judges	Cases reassigned by non-patent judges	95% CI for Range of Cases Reassigned	
					Low	High
Eastern District of Texas	5 of 7	2,519	78	34	32.4%	55.3%
Central District of California	6 of 37	845	601	113	15.8%	22.2%
Northern District of California[13]	12 of 31	474	335	2	0.1%	2.1%
Northern District of Illinois	10 of 39	416	211	81	31.8%	45.3%
District of New Jersey	11 of 25	290	144	24	11.0%	23.8%
Southern District of New York	10 of 50	225	113	25	14.9%	30.9%
Southern District of California[14]	5 of 17	319	145	111	68.8%	83.2%
Southern District of Florida	3 of 25	210	194	108	48.4%	62.8%
Northern District of Texas	3 of 14	102	71	54	64.5%	85.4%
Eastern District of New York[15]	15 of 42	69	61	35	44.1%	70.0%
District of Maryland	3 of 18	45	36	20	38.1%	72.1%
District of Nevada	4 of 12	70	26	23	69.8%	97.6%
Western District of Pennsylvania	6 of 14	53	13	13	75.3%	100.0%
Western District of Tennessee	2 of 6	44	9	6	29.9%	92.5%

IV. Most Program Districts Have Adopted Local Patent Rules

Many district courts adopted local patent rules prior to implementation of the Program.[17] The Northern District of California was the first district to adopt local patent rules in January 2001. Twenty-eight other districts have followed suit, including twelve of the fourteen districts in the Program.[18]

Some IP commentators argue that district courts are interpreting their local patent rules in non-uniform ways in contravention of constitutional and congressional goals of having a uniform body of patent law and a uniform code of civil procedure.[19] For example, most local patent rules require the parties to provide early infringement and invalidity contentions.[20] Critics argue that this violates the spirit of the Federal Rules of Civil Procedure, which allow for notice pleading and liberal discovery.[21] Some courts limit the number of claim terms—typically ten—that they will construe.[22] This can force litigants to make key choices before they know how the court will construe any patent claims.[23] The local rules of patent districts are available online.[24]

One concern is that the continued Balkanization of the local rules will further encourage forum shopping. Recent Federal Circuit venue transfer jurisprudence may counter this trend; however, a number of commentators—including at least one federal judge—continue to call for creation of a single, national set of binding rules for patent case management.[25]

Local patent rules may not be the only way to achieve an efficient district court docket. Two notable patent "rocket-dockets," the Eastern District of Virginia and the Western District of Wisconsin, have not adopted local patent rules.[26]

V. There is No Correlation Between the Adoption of Local Patent Rules and an Increase in Case Volume

Plaintiffs generally look for several things when choosing a court: a high win rate, the ability to avoid summary judgment and get to a jury, low transfer and stay-pending-reexam rates, and fast, inexpensive proceedings.[27] Streamlined proceedings and predictable outcomes are coveted, and local patent rules potentially offer both. Defined due dates for exchanging infringement and invalidity contentions limit motion practice. This, along with rules regulating discovery and standard procedures for claim construction, makes it easier to predict case schedules and manage litigation budgets.[28] The rules must be enforced in practice, because lax or inconsistent enforcement of local patent rules would diminish any benefits, and could in fact generate more litigation.

The possibility of more predictable outcomes, when combined with liberal jurisdiction rules that allow a plaintiff to file a case in almost any district,[29] suggests that a district's caseload should increase after the adoption of such rules. Table 3 below shows the number of cases per Program district per quarter before and after adoption of local patent rules (the shaded cells indicate the year the district adopted the rules).

Annual caseloads did increase; however, there are many potential reasons for the increase, including the marked rise in patenting activity, the proliferation of non-practicing entities, and the recently amended joinder rule that forces a patent holder to file separate lawsuits against similar defendants rather than bundling them into one action.[31]

TABLE 3—PATENT CASELOADS IN DISTRICTS AFTER ADOPTION OF LOCAL PATENT RULES[30]

	NDCA	EDTX	WDPA	SDCA	NDTX	DNJ	NDIL	DMD	DNV	WDTN
2001	148	35	19	65	48	104	126	28	22	7
2002	194	31	40	80	42	96	181	33	23	13
2003	168	52	20	54	54	133	145	30	22	4
2004	177	104	23	55	56	106	163	42	21	2
2005	179	151	18	60	53	102	136	28	28	11
2006	142	261	17	51	40	140	124	20	35	8
2007	132	359	18	59	42	196	141	24	19	7
2008	162	290	13	67	41	162	146	25	21	7
2009	165	235	16	70	36	145	134	29	15	1
2010	174	286	16	56	40	154	172	19	28	4
2011	219	413	11	79	46	178	217	31	30	2
2012	256	1,231	39	143	57	159	238	42	33	31
2013+	212	1,195	19	174	67	121	182	14	37	14

+As of 10/29/13

To determine whether there was a correlation between the adoption of local patent rules and caseloads, *quarterly* patent filing data from 49 districts were studied. In each patent district that adopted local patent rules, the average quarterly caseload before the adoption of local patent rules was compared to the average caseload after the adoption of local patent rules. The results show no statistically significant difference between caseload before and after the adoption of local patent rules.[32]

The analysis was also performed in the 39 largest non-patent districts to see if there was a trend in these districts.[33] The non-patent district caseloads were averaged before and after eight quarterly dates, where each date corresponded to a quarter in which a patent district adopted local patent rules. The analysis sought to determine if any of the independent factors discussed above contributed to an increase in patent filings at these eight points in time. In other words, was the increase in caseloads after the adoption of local patent rules in patent districts tied to some general trend in all districts? This is unlikely, for the analysis showed no statistically significant difference between the average quarterly caseloads before and after each time point in non-patent districts.

Based on these data, it can be concluded that average caseloads in patent and non-patent districts did not increase after adoption of local patent rules. This suggests that there is no correlation between the adoption of local patent rules and an increase in caseloads.

VI. Conclusion

The first two years of the Patent Pilot Program saw a significant number—31%—of case reassignments to participating judges and a continued trend towards adoption of local patent rules. The impact of these case reassignment rates is unclear. An updated analysis will be appropriate when more data—such as the Program's impact on reversal rates—become available.

The adoption of local patent rules has not led to a measurable increase in patent caseloads in all adopting districts, however. This is perhaps not surprising since, as discussed in Section IV above, local patent rules are not homogeneous, and certain district rules may be more appealing to a potential litigant based on the facts of his case. An across-the-board increase would be more likely if the local patent rules were uniform across districts.

Appendix A — Statistical Analysis of Caseloads Before and After the Adoption of Local Patent Rules

The quarterly district-by-district case filing data given in Table 4 were averaged before and after the adoption of local patent rules. Cases filed in the quarter of adoption were ignored.

TABLE 4—PATENT CASELOADS IN DISTRICTS AFTER ADOPTION OF LOCAL PATENT RULES[34]

	NDCA	EDTX	WDPA	SDCA	NDTX	DNJ	NDIL	DMD	DNV	WDTN
Mar-00	47	6	5	12	15	16	41	5	2	0
Jun-00	43	6	4	12	9	21	32	7	5	1
Sep-00	33	7	5	17	19	12	42	7	7	4
Dec-00	32	5	8	13	11	20	38	2	1	4
Mar-01	**30**	13	2	11	11	21	38	9	4	3
Jun-01	50	4	6	18	18	22	34	7	9	1
Sep-01	23	9	4	12	9	33	32	6	2	1
Dec-01	46	9	7	24	10	28	22	6	7	2
Mar-02	44	7	16	29	17	28	40	3	6	2
Jun-02	51	10	6	10	7	31	46	9	5	7
Sep-02	43	6	9	22	8	17	49	2	4	2
Dec-02	56	8	9	19	10	19	46	18	8	2
Mar-03	36	15	6	11	6	44	45	3	5	0
Jun-03	46	9	4	16	26	28	45	7	3	2
Sep-03	40	14	3	16	10	20	31	16	4	2
Dec-03	46	14	7	12	11	41	24	4	10	0
Mar-04	33	36	5	15	22	33	32	20	3	1
Jun-04	41	29	7	18	11	29	47	5	4	1
Sep-04	55	18	3	11	9	26	38	9	6	0
Dec-04	48	20	8	11	14	18	48	7	8	0
Mar-05	48	**26**	**1**	9	14	25	32	6	2	1
Jun-05	59	43	6	21	16	30	38	6	9	3
Sep-05	38	49	6	18	8	15	35	6	7	4
Dec-05	33	32	5	12	15	32	31	10	10	3
Mar-06	40	47	6	16	9	38	22	4	14	4
Jun-06	26	55	2	**11**	12	29	36	2	6	2
Sep-06	39	80	6	11	11	39	41	7	7	1
Dec-06	36	79	3	13	8	34	25	7	8	1
Mar-07	28	66	4	12	9	37	28	6	6	1
Jun-07	39	105	4	19	**8**	49	42	6	5	2
Sep-07	36	97	1	4	12	56	33	3	3	1
Dec-07	29	91	9	24	13	54	37	9	5	3
Mar-08	44	70	5	26	12	34	42	9	5	2
Jun-08	36	81	2	17	13	42	40	6	8	2
Sep-08	43	72	4	15	5	41	22	4	5	2
Dec-08	39	66	2	9	11	42	40	5	3	2
Mar-09	56	43	1	27	14	**51**	30	10	2	0
Jun-09	35	64	5	16	11	27	35	8	3	0
Sep-09	36	64	5	12	5	32	38	4	3	0
Dec-09	35	64	5	16	6	32	**28**	7	7	0
Mar-10	37	59	0	13	15	34	42	3	5	1
Jun-10	34	63	5	14	5	44	39	6	5	0
Sep-10	46	71	6	8	11	37	52	8	2	1
Dec-10	57	91	5	21	8	38	39	2	16	2
Mar-11	48	74	2	15	4	27	42	3	8	1
Jun-11	57	78	3	22	12	54	30	11	5	1
Sep-11	58	129	4	19	10	43	62	**7**	**9**	0
Dec-11	54	133	2	23	20	53	82	10	8	**0**
Mar-12	70	263	7	32	22	34	60	24	12	6
Jun-12	60	268	18	58	12	46	53	3	3	3
Sep-12	69	385	4	17	8	49	65	11	7	20
Dec-12	59	331	10	35	15	30	58	4	11	2
Mar-13	57	366	6	26	15	46	59	4	7	3
Jun-13	38	36	7	46	18	29	44	2	7	9
Sep-13	56	78	6	75	27	28	45	6	16	0

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The differences between the averages ("Delta" in the tables below) were then analyzed using a paired t-test, which evaluates whether the probability that the actual mean difference between the two data sets is zero. The paired t-test assumes that the differences between pairs are normally distributed, and the use of average caseloads supports this assumption.[35]

The paired t-test works as follows: the difference between the average quarterly caseloads before and after adoption of local patent rules was calculated for each district. The mean and standard deviation of these differences were also calculated, and used to generate a test statistic (according to the formula below) that is t-distributed with degrees of freedom equal to one less than the number of pairs, n.

$$t\ statistic = \frac{Mean_{Delta}}{Std.dev_{Delta} / \sqrt{n}}$$

The t-statistic was then compared against a tabulated critical value, t_0, at the appropriate significance level (α = 5%) to determine whether an increase in average caseloads after the adoption of local patent rules was statistically significant. The data are shown in Table 5 below.

TABLE 5 – PATENT CASELOADS BEFORE AND AFTER ADOPTION OF LOCAL PATENT RULES

	Average Quarterly Caseload Before	Average Quarterly Caseload After	Delta	Absolute Delta Rank
Northern District of California	38.8	44.7	5.9	6
District of New Jersey	30.7	37.9	7.3	9
Northern District of Illinois	36.3	29.2	-7.1	8
District of Maryland	6.7	8.0	1.3	2
District of Nevada	5.7	8.0	2.3	4
Western District of Pennsylvania	6.2	4.9	-1.3	3
Western District of Tennessee	1.6	6.1	4.5	5
Eastern District of Texas	12.3	108.6	96.4	10
Northern District of Texas	12.2	12.2	-0.1	1
Southern District of California	15.4	22.2	6.8	7

Paired T-test	Including EDTX	Excluding EDTX
Mean $_{Delta}$	11.6	2.2
Std. Dev. $_{Delta}$	30.1	4.6
T statistic	1.16	1.33
t_0 (α = 5%)	2.26	2.31
	Not Significant	Not Significant

Seven of the ten districts showed an increase in average quarterly caseloads after the adoption of local patent rules, including a large increase in the Eastern District of Texas (EDTX). Despite the EDTX's large caseload increase, the t-test was not significant at the 5% threshold.

To examine what effect an outlier had on the analysis, the EDTX data was removed and a second paired t-test performed on the remaining nine districts. This second test once again showed that there was no statistically significant increase in average caseloads after the adoption of local patent rules. This supports the conclusion that a district's patent caseloads did not increase because of the adoption of local patent rules.

A second analysis—the Wilcoxon signed-rank test—was performed to further confirm that the there was no statistically significant increase in caseloads.[36] The Wilcoxon signed-rank test is performed as follows. The differences between each district's before and after averages were calculated and the differences ranked according to increasing absolute value (neglecting the + and – signs). The smallest absolute difference score was ranked 1 and the largest ranked 10 (here, the sample size, n, is 10). The + or – symbols are reassigned to each of the ranks, and the Wilcoxon test statistic, W, is defined as the smaller of W+ (sum of the positive ranks) and W- (sum of the negative ranks). If the null hypothesis were true, one would expect to see similar numbers of lower and higher ranks that are both positive and negative (*i.e.*, W+ and W- would be similar). If the alternate hypothesis—that there was a substantial increase in average caseloads after the adoption of local patent rules in patent districts—were true, one would expect to see more higher and positive ranks (*i.e.*, W+ much larger than W-). The calculations yield W+ = 43 and W- = 12, and thus the Wilcoxon test statistic, W, is equal to 12.

A critical value of W is determined next such that if the observed value of W is less than or equal to the critical value, the null hypothesis is rejected.[37] When the critical values are tabulated,[38] for a one-tailed test at 5% significance, the critical value is 8. The null hypothesis is accepted—the change in quarterly caseloads is not significant because the test statistic W- is greater than 8.

Wilcoxon Signed-Rank test	
Sum of Positive Ranks (W+)	43
Sum of Negative Ranks (W-)	12
Critical Value (one-tailed, α = 5%)	8
	Not significant

Analysis of Non-Patent Districts

The same paired t-test analysis was performed on the 39 largest districts without local patent rules. The caseloads were averaged before and after eight quarterly dates, where each date corresponded to a quarter in which a patent district adopted local patent rules. The analysis sought to determine if there were any independent factors contributing to an increase in patent filings at these eight points in time. The null hypothesis was that there was no difference between the average before and after values.

The t-statistic was calculated as detailed above; however, the tabulated critical value was chosen at the 10% significance level instead of the typical 5% level to make rejection of the null hypothesis even more meaningful (*i.e.*, it would be easier to reject the null hypothesis at α = 10%). As shown in Table 6 below, there was no significant difference between the average quarterly caseloads in non-patent districts before and after each time point.

TABLE 6—CHANGES IN PATENT CASELOADS IN 39 NON-PATENT RULES DISTRICTS BEFORE AND AFTER ADOPTION OF LOCAL PATENT RULES IN PATENT PILOT DISTRICTS

Test Date	Average Delta	Std. Dev. Delta	T-statistic	t_0 (α = 10%)	Significant
1/1/01 (NDCA adoption date)	-1.6	7.5	-1.4	1.69	No
1-2/1/05 (WDPA and EDTX adoption date)	-1.4	9.2	-0.8	1.69	No
4/3/06 (SDCA adoption date)	-1.6	11.1	-0.8	1.69	No
5/1/07 (NDTX adoption date)	-2.0	12.7	-1.0	1.69	No
1/1/09 (DNJ adoption date)	-3.5	17.0	-1.3	1.69	No
10/1/09 (NDIL adoption date)	-4.4	19.6	-1.4	1.69	No
7-8/1/11 (DMD and DNV adoption date)	-8.3	33.7	-1.5	1.69	No
9/19/11 (WDTN adoption date)	-8.8	35.2	-1.6	1.69	No

This result does not rule out the possibility that these independent factors could have affected patent caseloads at time points that differed from ones chosen. The conclusion remains there is no statistically significant correlation between the adoption of local patent rules in a district and an increase in that district's patent caseloads.

Appendix B — Confidence Intervals for Patent Case Reassignment Rates

Between September 19, 2011 and October 10, 2013, 5,681 patent cases were filed in Program districts. Of those 5,681 patent cases, 2,037 were initially assigned to non-patent judges, and 649 of those 2,037 cases were reassigned. Given the wide range in the number of cases assigned to non-patent judges in each district (ranging from 9 to 601), the true accuracy of reassignment rates is best conveyed through a confidence interval. This interval has an associated confidence coefficient (95%), which can be interpreted as the probability that the given interval contains the true reassignment rate.

The 95% confidence intervals in Table 2 were calculated as follows. The reassignment probability, p, is calculated as x divided by n, where n is the number of cases assigned to non-patent judges and x is the number of cases reassigned. An exact confidence interval, based on the relationship between the binomial distribution and the F distribution, F, can be calculated as follows:[39]

$$\frac{1}{1+\frac{n-x+1}{x}F_{2(x-n+1),2x,\alpha/2}} \leq p \leq \frac{1+\frac{x+1}{n-x}F_{2(x+1),2(n-x),\alpha/2}}{1+\frac{x+1}{n-x}F_{2(x+1),2(n-x),\alpha/2}}$$

Because the value of the F distribution is built into most current spreadsheet programs, including Microsoft Excel, the exact confidence interval is easy to compute. The above equation requires adjustment of the lower endpoint to 0% if x = 0 and adjustment of the upper endpoint to 100% when x = n.

Appendix C — Participating Judges in Program Districts

Northern District of California (NDCA)

The participating District Judges in the Program are: Chief District Judge James Ware and Judges Ronald Whyte, Jeffrey S. White, Lucy Koh, and Edward Davila.[40] The Northern District allows Magistrate Judges to handle any case pursuant to consent by the parties, and plans to increase the number of patent cases assigned to the following judges: Chief Magistrate Judge Elizabeth Laporte and Magistrate Judges Joseph C. Spero, Laurel Beeler, Donna M. Ryu, Paul Grewal, Jacqueline Scott Corley, and Nathanael Cousins.[41]

Northern District of Illinois (NDIL)

The participating judges are: Chief Judge James F. Holderman and Judges Ruben Castillo, John W. Darrah, Gary S. Feinerman, Virginia Kendall, Matthew F. Kennelly, Joan Humphrey Lefkow, Rebecca R. Pallmeyer, Amy J. St. Eve, and James B. Zagel.[42]

District of New Jersey (DNJ)

The participating judges are: Judges Renee M. Bumb, Dennis M. Cavanaugh, Claire C. Cecchi, Mary L. Cooper, Stanley R. Chesler, Noel Hillman, Faith S. Hochberg, Joseph E. Irenas, Peter G. Sheridan, Jerome B. Simandle, and Susan D. Wigenton.[43]

Eastern District of Texas (EDTX)

The participating judges are: Judges Rodney Gilstrap, Richard Schell, Leonard Davis, Ron Clark, and Michael H. Schneider.[44]

Northern District of Texas (NDTX)

The participating judges are: Judges Barbara M.G. Lynn, David C. Godbey, and Ed Kinkeade.[45]

Southern District of California (SDCA)

The participating judges are: Judges Marilyn L. Huff, Dana M. Sabraw, Cathy Ann Bencivengo, Roger T. Benitez, and Janis L. Sammartino.[46]

District of Nevada (DNV)

The participating judges are: Chief Judge Robert C. Jones and Judges Philip M. Pro, Miranda M. Du, and Gloria M. Navarro.[47]

District of Maryland (DMD)

The participating judges are: Judges Marvin J. Garbis, William D. Quarles Jr., and Roger W. Titus.[48]

Western District of Pennsylvania (WDPA)

The participating judges are: Judges Gary L. Lancaster, Joy Flowers Conti, Arthur J. Schwab, Nora Barry Fischer, Cathy Bissoon, and Mark R. Hornak.[49]

Western District of Tennessee (WDTN)

The participating judges are: Chief Judge Jon P. McCalla and Judge S. Hardy Mays.[50]

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Southern District of New York (SDNY)

The participating judges are: Judges P. Kevin Castel, Denise Cote, Katherine B. Forrest, Thomas P. Griesa, John G. Koeltl, Colleen McMahon, Jed S. Rakoff, Shira A. Scheindlin, Laura Taylor Swain, and Robert W. Sweet.[51]

Eastern District of New York (EDNY)

The participating District Judges in the Eastern District are: Judges Brian M. Cogan, John Gleeson, William F. Kuntz, Kiyo A. Matsumoto, Joanna Seybert, and Jack B. Weinstein. The participating Magistrate Judges are: Judges Joan M. Azrack, Gary Brown, Marilyn D. Go, Steven M. Gold, James Orenstein, Cheryl L. Pollak, Ramon E. Reyes, Jr., Kathleen A. Tomlinson, and William D. Wall.[52]

Central District of California (CDCA)

The participating judges are: Judges S. James Otero, Andrew J. Guilford, Otis D. Wright II, John A. Kronstadt, James V. Selna, and George Wu.[53]

Southern District of Florida (SDFL)

The participating judges in the Southern District are: Judges Michael Moore, Donald M. Middlebrooks, and Patricia A. Seitz.[54]

(Endnotes)

* Ron Vogel is with Fish & Richardson P.C. Mr. Vogel was admitted to practice before the USPTO in 2011; his admission to the New York bar is pending and is expected in January 2014.

[1] Administrative Office of the United States Courts, *District Courts Selected for Patent Pilot Program* (June 7, 2011), http://www.uscourts.gov/news/newsview/11-06-07/District_Courts_Selected_for_Patent_Pilot_Program.aspx.

[2] Press Release, United States District Court for the Western District of Pennsylvania (June 8, 2011), http://ipspotlight.files.wordpress.com/2011/06/wdpa-patent_court_press_release.pdf.

[3] *District Courts Selected for Patent Pilot Program, supra* note 1. The AOUSC was required to select three district courts with at least ten judgeships in which at least three judges wanted to hear patent cases, and three district courts with fewer than ten district judgeships in which at least two judges wanted to hear patent cases.

[4] Data from Lex Machina as of 10/29/13, and includes only those cases with at least one claim for patent infringement, patent invalidity, or patent unenforceability. S*ee* www.lexmachina.com.

[5] Average times for cases resolved at district court level for years 2000-2010. *See* Mark A. Lemley, *Where to File Your Patent Case,* 38 AIPLA Q.J. 401, 415-18 (2010).

[6] Local Patent Rules (http://www.localpatentrules.com/adoption-dates).

[7] In 2001, Judge Ward adopted his own patent rules based on modifications to the Northern District of California's local rules, ushering in the Eastern District's "rocket docket." Alfonso Garcia Chan, *Proposed Patent Local Rules for Adoption by Texas' Federal District Courts, 7* Comp. L. Rev. & Tech. J. 149, 151 (2003).

[8] Rules adopted in the Dallas Division of the NDTX.

[9] *District Courts Selected for Patent Pilot Program, supra* note 1.

[10] United States District Court for the Northern District of Illinois, *Patent Pilot Project in the Northern District of Illinois* (Sept. 19, 2011), http://www.ilnd.uscourts.gov/home/_assets/_news/Patent%20Pilot%20Program%20(09-19-11).pdf.

[11] Data as of October 10, 2013. Data from September 19, 2011 to October 22, 2012 were supplied by the clerk of the court for each district, except for the S.D.N.Y, S.D. Cal., W.D. Tenn., and E.D.N.Y. These data were supplied by LegalMetric. Data from October 23, 2012 to October 10, 2013 were supplied by LegalMetric. All data from the N.D. Cal. from 2011 through 2013 were supplied by the clerk of the court.

[12] The list of non-patent pilot district court judges was obtained from the Federal Judicial Center website. S*ee* http://www.fjc.gov/public/home.nsf/hisj. Magistrate judges were included for the E.D.N.Y and N.D. Cal. and sourced from the court websites.

[13] Includes magistrate judges.

[14] The Program judges were designated in September 2012; all judges may have participated in the Program before that date.

[15] Includes magistrate judges.

[16] The number of cases assigned to non-patent judges may be inflated due to these judges accepting other related cases.

[17] District courts have adopted local patent rules based on the authority given to them under Federal Rule of Civil Procedure 83. Arthur Gollwitzer III, *Local Patent Rules—Certainty and Efficiency or a Crazy Quilt of Substantive Law?* Engage Vol. 13, Issue 1 (Mar. 2012), http://www.fed-soc.org/doclib/20120517_GollwitzerEngage13.1.pdf.

[18] Local Patent Rules, *supra* note 6.

[19] *Id*. Rule 83 limits the district courts' rule-making authority consistent with the Rules Enabling Act's prohibition against rules that affect substantive rights: "[a] local rule must be consistent with—but not duplicate—federal statutes and rules adopted under 28 U.S.C. §§ 2072 and 2075." Fed. R. Civ. P. 83(a)(1).

[20] Gollwitzer, *supra*, note 17 (citing N.D. Ill. L.P.R. §§ 2.2, 2.3; N.D. Cal. Patent L.R. 3-1, 3-3; E.D. Tex. P.R. 3-1, 3-3). Some courts, such as the Eastern District of Texas and the Northern District of California, require a patentee to provide infringement contentions within days of the initial case status conference, and hold that the parties' contentions cannot be modified without demonstrating good cause. *Id*. (citing N.D. Cal. Patent L.R. 3-1 and 3-6; E.D. Tex. P.R. 3-1 and 3-6). The EDTX is more relaxed in its requirements for the requisite "good cause." A few material documents produced after the original contentions are submitted or a 30(b)(6) deposition would be sufficient—this is why plaintiffs routinely delay discovery.

[21] *Id*. (citing Fed. R. Civ. P. 8, 26; *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-57 (2007) (holding that federal notice pleading requires a short plain statement of a plausible claim for relief)).

[22] *See, e.g*. N.D. Ill. L.P.R. § 4.1(b); N.D. Cal. Patent L.R. 4-1(b).

[23] Gollwitzer, *supra* note 17. In these cases, parties often select their ten claim terms from the independent claims and forego disputes over terms that appear only in dependent claims—even though the court's eventual claim construction could focus on the initially-ignored dependent claims.

[24] *See* Local Patent Rules, *supra* note 6.

[25] Peter C. Schechter, *Cutting the Costs of Patent Litigation*, New York Law Journal (June 11, 2012) (citing James Ware and Brian Davy, *The History, Content, Application and Influence of the Northern District of California's Patent Local Rules,* 25 Santa Clara Computer & High Tech. L.J. 965, 1018 (2009)).

[26] *Id*. The W.D. Wisc. and the E.D. Va. were ranked first and second out of the 33 district courts with significant volume of patent litigation in time to resolution from 2000 to 2010, with an average of 0.67 and 0.96 years to trial, respectively.

[27] Richard Brophy, *The Ever Increasing Concentration of Patent*

Cases in Plaintiff-Favored Venues: Can We Avoid Critical Mass?, St. Louis Bar J. 12 (Winter 2012). The Northern District of Texas saw the highest win rate for plaintiffs (55.1%) in a study of patent cases between 2000 and 2010. Plaintiffs fared fourth best in Nevada (46.2%) and sixth best in East Texas (40.3%). Plaintiffs won approximately a third of the time in the Southern District of New York (37.0%), Central District of California (36.3%), and the Northern District of Illinois (32.6%). Success rates were lower in Southern California (27.3%), Northern California (26.0%), Maryland (25.0%), and New Jersey (21.0%). *See* Lemley, *supra* note 5.

[28] Gollwitzer, *supra* note 17.

[29] Roy Strom, *Location, location, location: Patent litigators choose their courts*, Chicago Lawyer (Sep, 1, 2012), http://www.chicagolawyermagazine.com/Articles/2012/09/01/Patent-Reform.aspx. The Federal Circuit, however, has reversed several decisions from the Eastern District of Texas for refusing to transfer patent cases out of the district. *Id*. (citing *In re Genentech, Inc*., 566 F.3d 1338 (Fed. Cir. 2009) (holding that it was an abuse of discretion for a district court to fail to consider geographic convenience, including the location of witnesses and easy access to sources of physical evidence.); *In re TS Tech USA Corp*., 551 F.3d 1315 (Fed. Cir. 2008)).

[30] Data from Lex Machina website. *See* note 4, *supra*. Shaded cells indicate year of adoption of local patent rules.

[31] *See* 35 U.S.C. § 299.

[32] The data were analyzed using both a paired t-test and Wilcoxon signed-rank test. *See* Appendix A for details.

[33] These 39 non-patent districts had the most cases filed over the period between 2001 and 2012. Each district had at least 100 cases filed in that span.

[34] Data created by manual quarterly calculations of annual case data from Lex Machina as of 9/30/13, and includes only those cases with at least one claim of patent infringement, patent invalidity, or patent unenforceability. Shaded cells indicate quarter of adoption of local rules.

[35] The Central Limit Theorem states that the distribution of an average tends to be normal, even when the distribution from which the average is computed is non-normal.

[36] The Wilcoxon signed-rank test does not require an underlying normal distribution, and requires only that the differences are approximately symmetric. However, the signed-rank test is almost as powerful, even under conditions appropriate to the paired t-test. *See* http://sphweb.bumc.bu.edu/otlt/MPH-Modules/BS/BS704_Nonparametric/BS704_Nonparametric6.html.

[37] The appropriate test is one-tailed because the alternative hypothesis is that the difference between average caseloads before and after adoption of local patent rules is greater than zero.

[38] *See* http://facultyweb.berry.edu/vbissonnette/tables/wilcox_t.pdf.

[39] *See* Jeffrey T. Morisette & Siamak Khorram, *Exact Binomial Confidence Interval for Proportions*, 64 (4) Photogrammetric Engineering & Remote Sensing 281-83 (April 1998).

[40] United States District Court for the Northern District of California, *Patent Pilot Program Becomes Active January 1, 2012*, http://cand.uscourts.gov/news/63.

[41] *Id*. Chief District Judge James Ware retired on August 31, 2012, http://www.cand.uscourts.gov/news/82.

[42] United States District Court for the Northern District of Illinois, *supra* note 10.

[43] United States District Court for the District of New Jersey, *Appendix T. Procedures For Patent Pilot Project Cases* (Revised Sept. 14, 2012), http://www.njd.uscourts.gov/sites/njd/files/APPT.pdf.

[44] Michael C. Smith, *Judge Gilstrap Added to Eastern District of Texas Patent Pilot Project*, EDTXweblog.com, http://mcsmith.blogs.com/eastern_district_of_texas/2012/01/judge-gilstrap-added-to-eastern-district-of-texas-patent-pilot-project.html. Judge Gilstrap replaced the retired Judge T. John Ward, who created the Eastern District's patent rocket docket. Judge Folsom retired from the federal bench in March 2012, http://www.jw.com/David_Folsom.

[45] United States District Court for the Northern District of Texas, *Special Order No. 3-287*, http://www.txnd.uscourts.gov/pdf/sp_order3/03-287_7-26-11.pdf.

[46] United States District Court for the Southern District of California, *General Order No. 598-C* (Jul. 30, 2013), http://www.casd.uscourts.gov/uploads/Rules/General%20Orders/GO_598-C.pdf. The following judges signed Order 598, which announced the Patent Pilot Program, but did not specifically identify the designated judges: Chief Judge Irma E. Gonzalez, Barry T. Moskowitz, Marilyn L. Huff, Larry A. Burns, Dana M. Sabraw, William Q. Hayes, John A. Houston, Roger T. Benitez, Janis L. Sammartino, Michael M. Anello, and Anthony J. Battaglia. The roster was adjusted on January 1, 2013, before the recent change on July 30, 2013, http://www.casd.uscourts.gov/uploads/Rules/General%20Orders/GO_598B.pdf.

[47] United States District Court for the District of Nevada, *General Order No. 2011-03* (Sept. 19, 2011), http://www.nvd.uscourts.gov/Files/General%20Order%202011-03.pdf.

[48] United States District Court for the District of Maryland, *Announcement of Pilot Program for Patent Cases*, http://www.mdd.uscourts.gov/news/news/PilotPatentProgram.pdf.

[49] United States District Court for the Western District of Pennsylvania, *Misc. Order No. 11-283* (May. 9, 2012), http://www.pawd.uscourts.gov/Documents/Forms/OrderDesignatingAdditionalPatentJudgeHornak.pdf.

[50] United States District Court for the Western District of Tennessee, *Patent Pilot Program* (June 9, 2011), http://www.tnwd.uscourts.gov/pdf/adminorders/12-06.pdf.

[51] Press Release, United States District Court for the Southern District of New York, *Ten SDNY Judges To Participate In Patent Pilot Program Starting November 26* (Nov. 3, 2011), http://www.nysd.uscourts.gov/file/news/ patent_pilot_program_press_release.

[52] *Id*. Press Release, United States District Court for the Eastern District of New York, *EDNY Implements Patent Pilot Program* (Feb. 7, 2012), http://www.nyed.uscourts.gov/sites/default/files/local_rules/PatentPilotProject-NYEDPressRelease.pdf.

[53] Press Release, United States District Court for the Central District of California, *Judges Participating in the Patent Pilot Program*, http://www.cacd.uscourts.gov/judges-requirements/court-programs/judges-participating-patent-pilot-program.

[54] United States District Court for the Southern District of Florida, *In re: Establishment of Pilot Project and Assignment of Patent Cases* (Jul. 5, 2011), http://www.flsd.uscourts.gov/wp-content/uploads/2011/07/2011-53-In-re-Establishment-of-Pilot-Project-and-Assignment-of-Patent-Cases-06-30-11.pdf.

The NYIPLA Advocates for Clarification on Patent-Eligible Subject Matter in an Amicus Brief to the Supreme Court Regarding *CLS Bank International v. Alice Corp.*

*By Sandra A. Hudak, Charles R. Macedo, and Michael J. Kasdan**

In a world that now relies on computers for everyday tasks, the area of software and computer-implemented inventions has become essential for innovation. However, it is difficult to define what falls within the scope of a patent-eligible computer-implemented invention under the current legal guidance. Indeed, even the appeals court dedicated to providing uniform standards on patent law, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit"), is having a difficult time applying the well-established "abstract idea" exception to patent-eligible subject matter.

In an *en banc* rehearing, the full court at the Federal Circuit remained highly divided as to the proper approach to take in analyzing whether a computer-implemented invention is patent eligible under 35 U.S.C. § 101. *See CLS Bank Int'l v. Alice Corp.*, 717 F.3d 1269 (Fed. Cir. 2013) ("*CLS III*"). Unpredictability in the patent system is harmful to the U.S. economy as well as the patent system as a whole. Judicial clarity and reliability are important parts of a functioning patent system. For these reasons, although it did not take a position on the ultimate validity of the claims at issue, the NYIPLA submitted an *amicus curiae* brief in support of Alice's petition for a writ of certiorari to urge the Supreme Court to clarify the abstract idea exception to patent eligibility as applied to computer-implemented inventions.

Patent Eligibility of Computer-Implemented Inventions Under Section 101

The Supreme Court has been developing jurisprudence on the "abstract idea" exception as applied to computer-implemented inventions since before personal computers were available for widespread use.

In *Bilski v. Kappos*, the Supreme Court reaffirmed the general principles that govern patent-eligible subject matter under Section 101, as synthesized in *Diamond v. Diehr*. The Court has consistently framed the inquiry based on the following two questions:

1. Does the claimed subject matter fall within one of the four statutory categories of patent-eligible subject matter: (i) process, (ii) machine, (iii) manufacture, or (iv) composition of matter (or any improvement thereof)?
2. If so, is the claimed subject matter directed to one of three so-called "fundamental principles," *i.e.*, laws of nature, natural phenomena or abstract ideas, which are exceptions to patent-eligible subject matter?

See Bilski v. Kappos, 561 U.S. __, 130 S. Ct. 3218, 3225 (2010); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (harmonizing, *inter alia, Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980), *Parker v. Flook*, 437 U.S. 584, 589 (1978), and *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

However, there has been much debate as to how to apply this second step; in other words, how to analyze whether claims are directed to one of the three judicially enumerated fundamental principles, which are not patent eligible. In the case of computer-implemented inventions, the question is whether the claims are precluded from patent eligibility as preempting an "abstract idea."

In *Bilski v. Kappos*, the Supreme Court reaffirmed its previous precedent in *Diehr* and rejected the machine-or-transformation test as the sole test for deciding whether an invention is a patent-eligible "process." Instead, it recognized that: (1) the machine-or-transformation test is a useful, but not dispositive, tool, (2) while a claim that preempts an abstract idea is not patent eligible, the *application* of an abstract idea may be patent-eligible subject matter, and (3) claims should be considered as a whole for abstractness. *Bilski*, 130 S. Ct. at 3227, 3230 (citing *Diehr*, 450 U.S. at 187-88).

Although the Court in *Bilski* declined to use the machine-or-transformation test exclusively, it openly encouraged the Federal Circuit to continue to try to delineate other limiting criteria to patent-eligible subject matter. *Id.* at 3231. Since *Bilski*, however, the Federal Circuit has yet to develop a definitive and consistent approach to this Section 101 analysis and, as a result, judicial analysis of "abstract ideas" has become muddled.

The Federal Circuit's variability in its approaches to Section 101 stems from a divergence of views at the Federal Circuit regarding how much of a bar patent eligibility should be to obtaining a claim:

1. Some judges have required that claims must be "manifestly abstract" in order to be patent ineligible

under Section 101. *See e.g.*, *MySpace, Inc. v. GraphOn Corp.,* 672 F.3d 1250, 1264 (Fed. Cir. 2012); *Classen Immunotherapies, Inc. v. Biogen Idec*, 659 F.3d 1057, 1065-66 (Fed. Cir. 2011); *Ultramercial, LLC v. Hulu, LLC*, 657 F.3d 1323, 1327 (Fed. Cir. 2011), *cert. granted, vacated and remanded*, 132 S. Ct. 2431 (2012), *rev'd and remanded*, 722 F.3d 1335 (Fed. Cir. 2013), *petition for cert. pending* (U.S. Aug. 23, 2013) (No. 13-255); *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 868 (Fed. Cir. 2010).

2. Other judges have used Section 101 as a "fine sieve," searching for abstractness by parsing out the claim or insisting on a "robust application" of Section 101 prior to analysis under Sections 102, 103, or 112. *See, e.g.*, *Bancorp Services, L.L.C. v. Sun Life Assurance Co. of Canada*, 687 F.3d 1266, 1279 (Fed. Cir. 2012); *MySpace,* 672 F.3d at 1269 (Mayer, J., dissenting) ("[a] robust application of section 101 is required to ensure that the patent laws comport with their constitutionally-defined objective."); *see also Highmark, Inc. v. Allcare Health Mgmt. Sys.*, 687 F.3d 1300, 1324 (Fed. Cir. 2012), *cert. granted on other grounds*, No. 12-1163, 2013 U.S. LEXIS 5130 (U.S. Oct. 1, 2013) ("Where, as here, a patent describes an abstract idea, but discloses no new technology or "inventive concept," … for applying that idea, a robust application of section 101 at the summary judgment stage will save both courts and litigants years of needless litigation.") (Mayer, J., dissenting).

3. Still other Federal Circuit judges have taken a middle approach: using Section 101 as a "coarse filter" under which abstractness still must be "manifestly evident," but under which the claims are also broadly evaluated for "meaningful limits," such as meeting the machine-or transformation test or including more than a mere field-of-use restriction. *See*, *e.g.*, *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1331, 1333-34 (Fed. Cir. 2012); *Cybersource Corp. v. Retail Decisions, Inc.*, 654 F.3d. 1366, 1375 (Fed. Cir. 2011).

The diverse positions underlying these various opinions helps explain why, as the Federal Circuit openly admits, "[d]efining 'abstractness' has presented difficult problems." *Ultramercial*, 722 F.3d at 1342.

Proceedings in *CLS Bank v. Alice*

The tensions among the Federal Circuit judges in divining the correct approach to a Section 101 analysis became especially apparent within the six opinions issued in *CLS III*, all with varying rationales supporting their conclusions as to whether the claims at issue were patent eligible. On September 4, 2013, seven years after CLS Bank International ("CLS") brought suit against Alice Corporation ("Alice"), seeking a declaratory judgment of non-infringement, patent invalidity, and patent unenforceability, Alice filed a petition for a writ of certiorari with the Supreme Court. The four patents at issue involve system, method, and computer-readable media claims concerning a computerized trading platform.

In 2011, the U.S. District Court for the District of Columbia granted CLS's motion for summary judgment, finding all of the claims at issue patent ineligible under Section 101. 768 F. Supp. 2d 221. Alice appealed to the U.S. Court of Appeals for the Federal Circuit, where a split judicial panel reversed the District Court decision to find all of the claims patent eligible. 685 F.3d 1341 (2012).

After granting CLS's petition for rehearing the case *en banc*, the Federal Circuit in *CLS III* affirmed the District Court decision that all of the claims were directed to patent-ineligible subject matter. The *CLS III* decision consisted of a *per curiam* opinion, in which a majority of the court agreed that the method and computer-readable media claims were patent ineligible, but remained split as to the subject matter eligibility of the asserted system claims. The *per curiam* opinion was accompanied by six separate opinions spanning 128 pages of divergent supporting reasoning.

There was no clear majority rationale as to the validity of the claims under Section 101 or the approach to a Section 101 analysis generally. The plurality opinion written by Judge Lourie supports an analysis that identifies the fundamental concept in the claim and then evaluates the claim "to determine whether it contains additional substantive limitations that narrow, confine, or otherwise tie down the claim so that, in practical terms, it does not cover the full abstract idea itself." *CLS III*, 717 F.3d at 1282 (Lourie, J., concurring). This suggested methodology was met with resistance from other judges, who thought the identification of the fundamental concept in the claim was akin to "hunting for abstractions by ignoring the concrete, palpable, tangible limitations of the invention the patentee actually claims," and that it adds an improper "inventiveness" factor to the inquiry. *Id.* at 1298, 1302 (Rader, C.J., concurring-in-part, dissenting-in-part); *id.* at 1313, 1315 (Moore, J., dissenting-in-part). Judge Newman expressed disappointment with the "judicial deadlock," and proposed a return to the statutory language of Section 101, and thus an abandonment of the judicial exceptions to patent-eligible subject matter. *Id.* at 1321, 1326 (Newman, J., concurring-in-part, dissenting-in-part). Judge Rader also insisted on a return to the statute, explaining that Section 101 "offers a patent to both inventions and discoveries," and should not be used as an

cont. on page 22

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invalidity defense to infringement. *Id.* at 1335 (Rader, C.J., additional reflections).

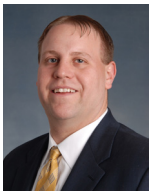
CLS III is a prime example of how the Federal Circuit's recent decisions on Section 101 "'spend page after page revisiting [its] cases and those of the Supreme Court, and still [the judges] continue to disagree vigorously over what is or is not patentable subject matter.'" *Accenture Global Servs. v. Guidewire Software, Inc.*, 728 F.3d 1336, 1348 (Fed. Cir. 2013) (Rader, C.J., dissenting) (quoting *MySpace, Inc. v. GraphOn Corp.*, 672 F.3d 1250, 1259 (Fed. Cir. 2012)).

The NYIPLA Amicus Brief

The NYIPLA previously submitted an amicus brief to the Federal Circuit in *CLS III*, arguing that the mere presence of a computer in a claim should not alter the fundamental analysis as to whether the claim as a whole preempts an abstract idea. In the face of the resulting highly divisive *en banc* decision, the NYIPLA recently filed another amicus brief regarding the case, to support Alice's petition for a writ of certiorari in the hope of obtaining some clarifying guidance from the Supreme Court on the application of a Section 101 analysis to computer-implemented claims.

In its latest amicus brief for the Supreme Court, the NYIPLA offered no opinion on the merits of the claims at issue, but explained how the law on patent eligibility has become confused, as exemplified by the fractured *en banc* Federal Circuit opinion and confusion in the district courts. The brief pointed to cases like *Zillow, Inc. v. Trulia, Inc.*, which had deferred ruling on a Section 101 issue in anticipation of the *en banc* decision in *CLS III*. Because the *CLS III* decision did not achieve "the hoped for clarity with respect to the test the court should apply" in analyzing patent eligibility under Section 101, the district court in that case continued to delay deciding the Section 101 issue until after claim construction. *Zillow, Inc. v. Trulia, Inc.,* No. C12-1549JLR, 2013 U.S. Dist. LEXIS 127606, at *5 (W.D. Wash. Sept. 6, 2013). Several other cases decided after *CLS III* demonstrate that district courts have been left without guidance as to how to pick from the various proffered approaches, with each approach potentially leading to a different outcome. For instance, in *Planet Bingo, LLC v. VKGS, LLC*, the district court explained that "despite the seeming futility of adopting one of the non-precedential approaches from *CLS Bank*, [it would] endeavor to follow the law as it sees it." *Planet Bingo, LLC v. VKGS, LLC,* No. 1:12-CV-219, 2013 U.S. Dist. LEXIS 116898, at *11 (W.D. Mich. Aug. 19, 2013). These early examples of uncertainty regarding the proper application of a Section 101 analysis emphasize the need for guidance by the Supreme Court.

The NYIPLA brief argued that Supreme Court clarification is necessary in this area of the law because patents play a vital role in the economy and courts need consistent precedent to follow to preserve judicial resources and provide reliable judgments. It concluded by stressing that the Federal Circuit's decision to rehear this case *en banc*, the demonstrated widespread interest in the outcome of the case, and the plethora of opinions on the issue make this case particularly appropriate for Supreme Court review.



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Moving UP ▲ & Moving ON ➤➤➤

➤ Wan Chieh (Jenny) Lee, formerly of King & Spalding, has joined Fay Kaplun & Marcin LLP as Counsel.

➤ Trevor Cook, a partner at Bird & Bird LLP in London, will be joining the New York office of Wilmer Cutler Pickering Hale and Dorr LLP as of January 1, 2014, as a partner in its Intellectual Property Group.

The Bulletin's Moving Up and Moving On feature is for the Association's members. If you have changed your firm or company, made partner, received professional recognition, or have some other significant event to share with the Association, please send it to the Bulletin editors: Mary Richardson (mary.e.w.richardson@gmail.com) or Robert Greenfeld (rgreenfeld@mayerbrown.com).

October/November 2013 IP Media Links

*Edited by Jayson Cohen**

Non-Practicing Entities and Patent Reform

The debate about what to do with patent trolls/non-practicing entities (NPEs) has expanded significantly in 2013 beyond the IP community and Congress to other branches of government, including the executive branch, and the mass media.

On June 4, 2013, the White House issued its news release, "White House Task Force on High-Tech Patent Issues," which presented the report, "Patent Assertion and Innovation," and announced a vision of patent policy aimed, in part, at curtailing NPE activity. The news release made seven legislative recommendations, announced five executive actions, and triggered media reaction worldwide. (http://www.whitehouse.gov/the-press-office/2013/06/04/fact-sheet-white-house-task-force-high-tech-patent-issues; http://www.whitehouse.gov/sites/default/ files/docs/patent_report.pdf). The *New York Times*' Editorial Board, in an op-ed titled "Fighting 'Patent Trolls,'" reacted to the White House release with a cautionary tale of a PTO that has "struggled to keep up and granted many patents that were poorly documented or too broad." The Board applauded bi-partisan commitments to "innovation, not litigation," but wondered how Congress and the President intended to provide the PTO with the resources it needs to improve patent quality and to reduce the backlog of applications to be examined. (http://www.nytimes.com/2013/06/06/opinion/obamas-promising-reforms-to-fight-patent-trolls.html?_r=0).

In *PandoDaily*, Hamish McKenzie reported that the "Proposed FTC study on patent trolls pushes reform one step closer." The article suggests that the FTC's involvement, and the eventual FTC report that will issue as a result, signals how serious Washington is getting about patent litigation reform intended to stymie NPE activity. McKenzie cites Application Developers Alliance president Jon Potter's insight that the FTC's involvement may also indicate the FTC's view of NPEs as raising consumer protection and antitrust issues. Potter sees the FTC's subpoena power and its authority to investigate and collect data on NPEs as valuable tools to get a glimpse behind the curtain of secretive (and/or closely-held) NPEs. (http://pandodaily.com/ 2013/09/30/proposed-ftc-study-on-patent-trolls-pushes-reform-one-step-closer).

Op-ed pieces — by those in the IP community who are already invested, on one side or the other, in the debate about NPEs — also play a role in educating the public. For example, in August Charles Duan wrote an op-ed for the *Los Angeles Times*, "Down With the Patent Trolls," aimed at explaining the costs of NPEs to the consumer and to small businesses. (Mr. Duan is the director of the Patent Reform Project at Public Knowledge, a nonprofit dedicated to an open Internet.) He stated that "when a troll waves the specter of a lawsuit or an overly broad patent in front of a tech startup, it is not uncommon for the startup to drop features from products, drop products altogether or even fold up shop." Duan, who presented the patent system in his op-ed as having the noble goals of rewarding inventors and incentivizing innovation, nevertheless sees our patent system as one gone wrong, concluding that "[a]s consumers, we must demand patent reform to protect that promise of the future." (http://www.latimes.com/opinion/commentary/la-oe-duan-troll-patent-abuse-consumer-20130822,0,2827107.story).

Copyright Litigation in the Entertainment World

Nationally circulated newspapers continue to report on interesting stories involving copyright litigation and unique issues of copyright law. Copyright battles that involve the entertainment world, in particular, continue to fascinate mass media, the public, and the IP community. The following stories from the *New York Times* are representative.

On October 1, 2013, Adam Liptak of the *New York Times* reported on the Supreme Court's decision to grant *certiorari* in a case from the Ninth Circuit called *Petrella v. Metro-Goldwyn-Mayer, Inc.* The case concerns the boxer Jake LaMotta and his friend, Frank P. Petrella (Paula's father), with whom LaMotta allegedly collaborated on the copyrighted works underlying the 1980 movie "Raging Bull." The issue on appeal is the lower court ruling that the equitable doctrine of laches, and not any statute of limitation, bars Petrella's possible recovery for copyright infringement. The Court granted *certiorari* on the issue: "[w]hether the non-statutory defense of laches is available without restriction to bar all remedies for civil copyright claims filed within the three-year statute of limitations prescribed by Congress, 17 U.S.C. § 507(b)." (The statutory three-year limitation period renews with each act of infringement.) The Circuits are split on the role of laches in cases for copyright infringement, and this case appears to

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represent a vehicle for the Supreme Court to decide the issue. (http://www.nytimes.com/2013/10/02/us/politics/justices-agree-to-hear-raging-bull-copyright-case.html; http://www.scotusblog.com/case-files/cases/petrella-v-metro-goldwyn-mayer-inc).

In September, Larry Rohter reported in the *New York Times* about singer-songwriter Victor Willis. Thirty-plus years ago, Willis was a pop superstar—the lead singer for the band Village People. (In case you are curious, Willis was the policeman.) Willis wrote the lyrics for iconic late-1970s pop songs like "YMCA," "Macho Man," and "In the Navy," but, at that time, artists like Willis normally signed over their copyrights to their studio. Now, thanks to a 1978 law allowing artists to terminate prior transfers of rights after thirty-five years (codified at 17 U.S.C. § 203), Willis is litigating to regain control of 33 of the works he wrote from the Village People catalog. He has won the first round in federal court in Los Angeles, but we will see what happens on appeal. (http://www.nytimes.com/2013/09/11/arts/music/a-copyright-victory-35-years-later.html).

Also in September, Ben Sisario reported on a lawsuit with enormous implications for satellite radio in particular and digital music broadcasts more generally in the story, "Record Labels Sue Sirius XM Over the Use of Older Music." Sony/Universal/Warner filed suit against Sirius XM, seeking damages for broadcasting pre-1972 songs without permission. The date Feb. 15, 1972, is central to the suit. That is the date that federal copyright protection began for musical recordings. It was thought that musical recordings before that date are not protected and need not be licensed, but the record companies are arguing, for example, that state law protects those earlier recordings from broadcast unless the broadcaster has permission from the rights holder. (http://www.nytimes.com/2013/09/12/business/media/big-record-labels-file-copyright-suit-against-sirius-xm.html?_r=0).

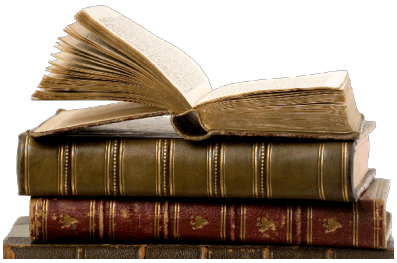
Trademark Stories

What turned out to be a faux trademark battle in London provides a good reason to take a look across the pond, to *The Guardian*'s Word of Mouth blog. On September 25, Jay Rayner opened his post "The Vietnamese pho war – can you trademark a soup?" with the following enticing introduction: "When a small Vietnamese cafe in London [Mo Pho] announced that it had been asked to change its name because another firm had trademarked the word 'pho', there was an uproar. Can one restaurant 'own' a country's national dish?" In this instance Twitter pressure caused the trademark owner, Pho Holdings, to capitulate, and Mo Pho got to keep its name. (The London restaurant, Mo Pho, has no affiliation with this writer's employer, Morrison & Foerster LLP.) (http://www.theguardian.com/lifeandstyle/wordofmouth/2013/sep/25/vietnamese-pho-trademark-soup-cafe).

"Don't Mess with Texas." In mid-September Manny Fernandez reported in the *New York Times* about Texas' vigilant protection of its state trademarks, including "Don't Mess with Texas" and "Remember the Alamo." The "Don't Mess with Texas" slogan was coined for a state anti-littering campaign in the 1980s and has stuck. Texas apparently wants to keep the mark tied to its original meaning, as a symbol of Texas' sustained commitment to fighting littering. In the process, the state has fought to maintain its marks' integrity against, among others, a romance novelist and an enterprising bar owner hoping to sell t-shirts with the decal "I Can't Remember the Alamo." (http://www.nytimes.com/2013/09/15/us/not-to-be-um-trifled-with-texas-guards-its-slogans.html?pagewanted=all).

* Jayson L. Cohen is an associate at Morrison & Foerster LLP, where his practice focuses on patent litigation. He is a member of the Publications Committee of the NYIPLA.

ATTENTION: NYIPLA Members



If you have any NYIPLA historical records, specifically Bulletins (1967-1981), Greenbooks (prior to 1951), and Judges Dinner booklets (1973 & prior to 1971), please contact Bill Dippert at wdippert@eckertseamans.com or 914.286.2813

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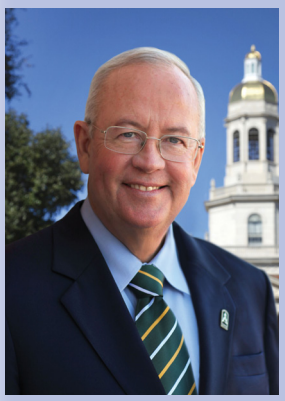

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Chief Judge Carol Bagley Amon

United States District Court for the Eastern District of New York

Panel 1: EXPLOITING PATENT RIGHTS – ANTITRUST AND VALUATION ISSUES
- Antitrust issues and the FTC
- Patent/Antitrust concerns arising in corporate transactions
- Valuation of patent portfolios

Panel 2: LITIGATION INVOLVING NPES
- Legislative proposals for addressing abuses by NPEs
- NPE litigation strategies for patent owners and accused infringers
- Ethical issues in NPE litigation

Panel 3: CURRENT ISSUES IN PATENT PROSECUTION
- Pre-grant activities: Procedural options to maximize your ability and minimize an opponent's ability to obtain a patent
- Post-grant proceedings: How often are they used and how well are they working
- Prosecution ethics issues

Panel 4: LEGAL UPDATE
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SUPREME COURT 2013-2014 IP CASE PREVIEW

by Mayer Brown LLP's Supreme Court & Appellate Practice

As of publication, the Supreme Court will review five intellectual property cases during its October 2013 Term.

Medtronic, Inc. v. Boston Scientific Corp., No. 12-1128 (cert. granted May 20, 2013, argued Nov. 5, 2013)

Issue: Patents – Actions Seeking Declaration Of Noninfringement – Burden Of Proof

In *MedImmune v. Genentech, Inc.*, 549 U.S. 118, 137 (2007), the Supreme Court ruled that a patent licensee that believes that its products do not infringe the patent, and accordingly are not subject to royalty payments, is "not required . . . to break or terminate its . . . license agreement before seeking a declaratory judgment in federal court that the underlying patent is . . . not infringed." On May 20, 2013, the Court granted *certiorari* in *Medtronic, Inc. v. Boston Scientific Corp.*, No. 12-1128, to decide whether, in a declaratory-judgment action brought by a licensee seeking a declaration of noninfringement of a patent, the licensee (i.e., the plaintiff) has the burden to prove that its products do not infringe the patent, or whether the patentee (i.e., the defendant) has the burden to prove infringement.

In 1991, petitioner Medtronic entered into a license agreement with the predecessor-in-interest of Guidant Corporation (a wholly owned subsidiary of Boston Scientific), which was the exclusive licensee of patents owned by respondent Mirowski Family Ventures, LLC ("MFV"). Under the license agreement, Medtronic had the right to practice certain patents, and Medtronic agreed to pay royalties for any products subject to the license. In 2007, MFV sent letters to Medtronic accusing seven Medtronic devices of infringing 29 claims of the patents and demanding royalties. Believing that its devices did not infringe, Medtronic began paying royalties into escrow and filed an action against Guidant, Boston Scientific, and MFV seeking a declaration of noninfringement. Following a bench trial, the district court entered judgment for Medtronic, rejecting defendants' contention that Medtronic bore the burden of proof regarding infringement and finding that defendants had failed to prove that Medtronic's products infringed the patents.

The U.S. Court of Appeals for the Federal Circuit reversed the district court's ruling for Medtronic on the burden of proof. *Medtronic, Inc. v. Boston Scientific Corp.*, 695 F.3d 1266 (Fed. Cir. 2012), *reh'g and reh'g en banc denied* (Dec. 14, 2012). The appeals court explained that the dispute between Medtronic and the defendants required the court to determine "the proper allocation of the burden of persuasion in the post-*MedImmune* world, under circumstances in which a declaratory judgment plaintiff licensee seeks a judicial decree absolving it of its responsibilities under its license while at the same time the declaratory judgment defendant is foreclosed from counterclaiming for infringement by the continued existence of that license." *Id.* at 1272. It concluded that, in this "limited circumstance," the licensee "bears the burden of persuasion." *Id.* at 1274. This result is appropriate, the appeals court reasoned, because Medtronic was "unquestionably the party now requesting relief from the court." *Id.* at 1273. It noted that Medtronic "already has a license; it cannot be sued for infringement; it is paying money into escrow, and it wants to stop," whereas MFV wanted "nothing more than to be discharged from the suit and be permitted to continue the quiet enjoyment of its contract." *Id.* According to the court of appeals, in these limited circumstances – where the licensee is the party seeking to "disturb the status quo ante" – the licensee "must present evidence showing that it is entitled to such relief." *Id.*

The Supreme Court's decision in this case will be important to both patent licensees and licensors in declaratory-judgment actions.

Lexmark International, Inc. v. Static Control Components, Inc., No. 12-873 (cert. granted June 3, 2013; set for argument on Dec. 3, 2013)

Issue: Trademarks – Standing to Bring False-Advertising Claim Under the Lanham Act

Section 43(a) of the Lanham Act (15 U.S.C. § 1125(a)) creates a federal private cause of action for false advertising and unfair competition. This cause of action encompasses, among other things, false statements made by competitors about each other's products. Section 43(a) grants standing to bring a claim to "any person who believes that he or she is or is likely to be damaged" by the allegedly false advertising or unfair

competition. 15 U.S.C. § 1125(a)(1)(B). Although the grant of standing appears quite broad on first reading, it has been circumscribed to varying degrees by courts applying prudential limitations to its scope. On June 3, 2013, the Supreme Court granted *certiorari* in *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, No. 12-873, to resolve a circuit split concerning the proper test for determining whether a plaintiff has standing to bring a claim under Section 43(a).

The case arises from a lawsuit that Lexmark filed against Static Control alleging that Static Control was infringing Lexmark's patents covering microchips in toner cartridges for laser printers. Static Control counterclaimed under Section 43(a), alleging that Lexmark falsely told Static Control's customers that Static Control's microchip was infringing Lexmark's patents. Lexmark moved to dismiss Static Control's claim, arguing that Static Control lacked standing under Section 43(a).

The district court granted Lexmark's motion to dismiss Static Control's Section 43(a) claim, following the Third, Fifth, Eighth, and Eleventh Circuits in holding that the test for standing to bring a false advertising claim is the same rigorous five-factor test used in analyzing standing to sue for antitrust violations under the Sherman and Clayton Acts as set forth by the Supreme Court in *Associated General Contractors of California, Inc. v. California State Council of Carpenters,* 459 U.S. 519 (1983).

The Sixth Circuit vacated and remanded. *See Static Control Components, Inc. v. Lexmark Int'l, Inc.*, 697 F.3d 387 (6th Cir. 2012). The court rejected the five-factor test, as well as the so-called "categorical approach," used by the Seventh, Ninth, and Tenth circuits, which requires that the plaintiff be in competition with the alleged false advertiser. The Sixth Circuit instructed the district court on remand to apply the less rigorous "reasonable interest" test employed by the Second Circuit, under which the plaintiff must show only (1) a reasonable interest in being protected against the allegedly false advertising and (2) a reasonable basis for believing that that interest is likely to be damaged by the allegedly false advertising.

The Supreme Court granted review in order to resolve this circuit split.

The Supreme Court's decision in this case will be significant for businesses because Section 43(a) claims have been raised and litigated with increasing frequency against businesses across a wide spectrum of industries. The decision has the potential to greatly expand or limit the universe of potential plaintiffs in these actions.

Octane Fitness, LLC v. Icon Health & Fitness, Inc., No. 12-1184 (cert. granted Oct. 1, 2013); *Highmark Inc. v. Allcare Health Management Sys., Inc.*, No. 12-1163 (cert. granted Oct. 1, 2013)

Issue: Patents – Attorney Fees for Exceptional Cases

The Patent Act allows courts to "award reasonable attorney fees to the prevailing party" in "exceptional cases." 35 U.S.C. § 285. On October 1, 2013, the Supreme Court granted *certiorari* in two separate cases – *Octane Fitness, LLC v. Icon Health & Fitness, Inc.*, No. 12-1184, and *Highmark Inc. v. Allcare Health Management Sys., Inc.*, No. 12-1163 – to clarify when such awards are appropriate and when they should be upheld. Octane concerns the proper test for determining whether an infringement claim is "exceptional," while *Highmark* involves the standard of review applied by the Federal Circuit to a district court's ruling on exceptionality.

Because the Court's resolution of these cases is likely to clarify the circumstances under which fees may be awarded to defendants in meritless lawsuits for patent infringement, the two decisions together may prove significant for all businesses potentially involved in patent litigation – particularly for those that aggressively pursue infringement litigation or are the targets of questionable infringement actions.

Octane. The petitioner in Octane successfully defended against a suit alleging that its elliptical machines infringed the respondent's patent. The district court denied Octane's request for attorney fees. The court applied Federal Circuit precedent holding that, absent any misconduct in the prosecution or litigation of the infringement claim, a case qualifies as "exceptional" only if it was both "brought in subjective bad faith" and "objectively baseless." *Icon Health & Fitness, Inc. v. Octane Fitness, LLC,* 2011 WL 3900975, at *1 (D. Minn. Sept. 6, 2011). The district court held that Octane had not satisfied either prong of that test.

On appeal, Octane argued both that it had shown the case to be exceptional and that the Federal Circuit should discard the subjective prong of the exceptionality test. The Federal Circuit rejected both arguments and affirmed the district court, expressly declining to "revisit [its] settled standard for exceptionality." *Icon Health & Fitness, Inc. v. Octane Fitness, LLC*, 496 F. App'x 57, 65 (Fed. Cir. 2012). Octane's petition for *certiorari* argued that the Federal Circuit's test is unduly stringent and fails to deter meritless infringement suits.

Highmark. The petitioner in *Highmark* sought attorney fees after defending against a claim that it had infringed a health-care patent. The district court concluded that the case was exceptional, both because two

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of the infringement claims were baseless and because of litigation misconduct.

A divided panel of the Federal Circuit affirmed in part and reversed in part. The panel majority applied a recent Federal Circuit precedent holding that *de novo* review, rather than review under the deferential clear-error standard, applied to a district court's conclusion that an infringement action was objectively baseless. *See Highmark, Inc. v. Allcare Health Mgmt. Sys., Inc.*, 687 F.3d 1300, 1309 (Fed. Cir. 2012). Using the *de novo* standard, the majority concluded that only one of the infringement claims at issue was frivolous and that the "alleged litigation misconduct" did not render the case exceptional. *Id.* at 1316. It remanded the case to the district court for a determination of "the amount of attorneys' fees apportionable to" that claim. *Id.* at 1318. The dissenting judge argued that the deferential clear-error standard of review should apply to all aspects of an exceptionality determination and that the district court's decision should be affirmed under that standard. *Id.* at 1319 (Mayer, J., dissenting).

The Federal Circuit then denied rehearing *en banc*. *See Highmark, Inc. v. Allcare Health Mgmt. Sys., Inc.*, 701 F.3d 1351 (Fed. Cir. 2012) *(per curiam)*. Five judges dissented, arguing that applying a *de novo* standard of review to determinations that a suit was objectively baseless "is squarely at odds with the highly deferential review adopted by every [other federal court of appeals] and the Supreme Court" when reviewing awards of either sanctions for misconduct or attorney fees under other statutes. *Id.* at 1357 (Moore, J., dissenting).

Amicus briefs in support of the petitioners in both *Octane* and *Highmark* will be due on December 2, 2013, and amicus briefs in support of the respondents will be due on January 17, 2014.

Petrella v. Metro-Goldwyn-Mayer, Inc., No. 12-1315 (cert. granted Oct. 1, 2013; set for argument on Jan. 21, 2014)

Issue: Copyrights – Infringement – Laches

On October 1, 2013, the Supreme Court granted *certiorari* in *Petrella v. Metro-Goldwyn-Mayer, Inc.*, No. 12-1315, to resolve a circuit split concerning the availability of the laches defense in copyright infringement cases. The Court's decision on this issue will be important to businesses and individuals in the media and entertainment industries.

The federal Copyright Act contains a statute of limitations barring civil actions commenced more than three years after the claim accrued. 17 U.S.C. § 507(b). This limitations period applies separately to each act of infringement, even if prior acts of infringement began before the three-year period. The equitable defense of laches, however, may bar claims when a plaintiff's unreasonable delay in commencing a lawsuit causes prejudice to the defendant. The courts of appeals have split over the availability of laches as a defense to copyright infringement claims, particularly when the defendant's allegedly infringing conduct had been going on for more than three years before the plaintiff filed suit.

In *Petrella*, the plaintiff sued MGM and other defendants for copyright infringement related to the defendants' sale and distribution of the 1980 movie *Raging Bull*, which was allegedly based on works written by the plaintiff's deceased father (who also allegedly participated in the production of the film). The plaintiff had been aware of her potential claims against the defendants since 1991, but she did not file suit until 2009. In recognition of the statute of limitations, she sought damages solely for infringements occurring during the three years before she filed suit; she also sought prospective injunctive relief. The district court granted summary judgment in favor of the defendants, holding that laches barred all the claims because the plaintiff's delay in commencing the action was unreasonable and had prejudiced the defendants. The Ninth Circuit affirmed, holding that the plaintiff's 18-year delay was unreasonable and that the defendants, who spent millions of dollars marketing and distributing the film, had suffered expectations-based prejudice.

In a concurring opinion, Judge Fletcher recognized "a severe circuit split on the availability of a laches defense in copyright cases." In particular, while laches may bar all relief in copyright claims filed in the Ninth Circuit, the defense is completely unavailable in copyright actions in the Fourth Circuit. *Lyons P'ship, L.P. v. Morris Costumes, Inc.*, 243 F.3d 789, 797-98 (4th Cir. 2001). Other circuits apply laches to copyright claims only in the most "extraordinary" or "compelling" circumstances *(see Peter Letterese & Assocs., Inc. v. World Inst. of Scientology Enters., Int'l*, 533 F.3d 1287, 1320 (11th Cir. 2008); *Chirco v. Crosswinds Cmtys., Inc.*, 474 F.3d 227, 233 (6th Cir. 2007)), or to bar only certain types of relief (*see New Era Publ'ns Int'l v. Henry Holt & Co.*, 873 F.2d 576, 584-85 (2d Cir. 1989)).

Recognizing the split of authority, the Supreme Court granted *certiorari* on the question "whether the non-statutory defense of laches is available without restriction to bar all remedies for civil copyright claims filed within the three-year limitations period prescribed by Congress."

Absent extensions, amicus briefs in support of the petitioner will be due on November 22, 2013, and amicus briefs in support of the respondents will be due on December 23, 2013.

HISTORIAN'S CORNER

As Time Goes By: Of Babies and Bathwater*

You may have noticed that the topic of the recent Presidents' Forum, "What to do about NPEs: Do We Risk Throwing the Baby Out With the Bath Water," had a familiar ring about it. The title appears to echo that of a paper by Matthew Dowd that won 1st Prize in our Association's 2006 Conner Writing Competition: "Elimination of the Best Mode Requirement: Throwing the Baby Out with the Bathwater."

As far as patent reform legislation is concerned, various factors play a role in the likelihood of throwing out the good with the bad. Political concerns are often paramount. For example, when it came to the legislative debate over best mode prior to the AIA, a Congressional tipping point came in 2007 when the Chair of the Senate Judiciary Committee, Senator Leahy, mustered ten votes to defeat, by a single vote, a patent reform amendment before the Committee that would have repealed the best mode disclosure requirement.[1]

At the time, Senator Leahy apparently was concerned, and perhaps rightly so, that repeal would harm the quality of disclosure provided in patent applications. Indeed, one might reasonably conclude that repeal would harm both the quality and the quantity of such disclosure.

As a result, the best mode disclosure requirement was not repealed under the AIA. Instead, the AIA severely weakened the efficacy of the requirement by eliminating the opportunity for a defendant in a patent infringement action to assert best mode as an invalidity/unenforceability defense to alleged patent infringement.

Patent lawyers appear to be squarely stuck between a rock and a hard place in terms of providing counsel to their inventor clients regarding best mode under the AIA. On the one hand, we need to be able to explain that the obligation to disclose the client's best mode is mandated by the statute, and thus needs to be provided. On the other hand, in the interest of full disclosure, so to speak, we might add that there is little likelihood that the requirement can, or will be, enforced. The net result is that the quality and quantity of disclosure in patent applications will likely be diminished – effectively weakening the patent system without repealing the disclosure requirement.

Some colleagues in the IP field have told me that they don't care whether we have a strong patent system or a weaker one. They apparently believe that they will continue to do well, at least economically-speaking, either way. Nonetheless, such a view appears short-sighted because a weaker patent system may lead to disuse, and that would presumably have serious economic consequences for all concerned.

Dale Carlson, a partner at Wiggin and Dana, is NYIPLA Historian and a Past President.

The current debate over non-practicing entities ("NPEs"), often pejoratively referred to as "patent trolls," perhaps sets a new standard for murkiness. As you may recall, "patent troll" was coined by Peter Detkin back in 1999, while he was Intel's patent counsel, as a way to negatively characterize certain patent holders opposing Intel. The tables turned, however, when Mr. Detkin left Intel to co-found Intellectual Ventures, which some may consider to be an example of a patent troll in Detkin-speak.

[Thomas Murner's Woodcut (circa 1512)]

The moniker "NPE" is often applied to patent owners who do not have products in the marketplace, but rather rely on their patent portfolio as a source of revenue. Consider the Wright Brothers. Would they properly be labeled as NPEs/patent trolls using today's verbiage?

In a speech at DePaul University College of Law on October 15, 2013, former Chief Judge Paul Michel decried legislative efforts to attack NPEs/patent trolls in bills currently pending in Congress, which he collectively referred to as "AIA II."[2] In light of Judge Michel's comments and the plain language of the bills themselves, it might be reasonable to conclude that AIA II, if enacted, will have the effect of discriminating against, and disadvantaging, one class of patent holders vis-a-vis another, more well-funded, class of patent holders.

Perhaps well-funded companies would like us to forget that, when they got their start, they too were non-practicing entities. Patent lawyers, however, are hard-pressed to forget that all patentees are stake-holders in the patent system. It makes logical sense for them to be treated equally to ensure that innovation will continue to survive and thrive.

With kind regards,

Dale Carlson

* The opinions expressed herein are solely those of the author and are not to be attributed to the NYIPLA or its Board of Directors.

[1] IPO Daily News, July 20, 2007, at www.ipo.org.

[2] "Judge Michel: Patent Reform Bills Would Weaken the Patent System," Olivia T. Luk, at www.ipwatchdog.com, posted October 16, 2013.

Notable Trademark Trial and Appeal Board Decisions

By Stephen J. Quigley[*]

(Unless noted otherwise, all decisions are precedential.)

Application Voided Because the Mark Was Not in Use

A use-based application was declared void *ab initio* because the mark was not in use in commerce at the time the application was filed to register the mark for electronic equipment, namely, an electrolysis cell for use in the manufacture of various ionic solutions.

The applicant's display of its goods on a website was mere advertising, and the Board dismissed the applicant's claim that he sells only about one product per year at a cost between $200,000 and $2,000,000 as irrelevant because the law clearly requires "use in commerce" at the time a use-based application is submitted to the Patent and Trademark Office.

The Clorox Company v. Hermilo Tamez Salazar, 108 USPQ2d 1063, 2013 TTAB LEXIS 484 (TTAB 2013).

SUPERJAWS Is Merely Descriptive

The Board affirmed the refusal to register SUPERJAWS for machine tools and hand tools that included jaws and metal vice jaws.

Although the goods include tools other than "jaws" or gripping devices, if the mark describes only one of the products listed in an application, the mark is merely descriptive. Moreover, because SUPER is laudatory, whether it will be regarded as suggestive or merely descriptive will depend on the context in which it is used in conjunction with the other term or terms in the mark. Generally, however, when SUPER is used in connection with the actual name of a product, it will be regarded as merely descriptive and hence unregistrable.

In re Positec Group Limited, 108 USPQ2d 1161, Serial No. 77/920,346 (TTAB 2013).

FOOTLONG Is Generic for Sandwiches

The fast food company Subway cannot claim trademark rights in FOOTLONG for sandwiches. Although approved for registration, the Board sustained an opposition brought by Sheetz, a chain of gas stations and convenience marts.

While Subway argued that FOOTLONG denotes the fact that it "purveys a type of sandwich that is approximately one foot long," Sheetz submitted numerous examples of third-party uses of "footlong" to identify sandwiches. The Board agreed with Sheetz's position finding that "footlong" identifies a type or category of sandwich that includes 12-inch sandwiches. Therefore, it is generic for sandwiches. The Board noted that the extensive advertising and commercial success of Subway's FOOTLONG sandwiches are not necessarily indicative of acquired distinctiveness. Instead, consumers are much more likely to consider this term as referring to sandwiches of a specific size, rather than as a trademark.

Sheetz of Delaware, Inc. v. Doctor's Associates Inc., 108 USPQ2d 1341, Opposition No. 91192657, 2013 TTAB LEXIS 468 (TTAB 2013).

Design for Handbags and Shoes Is Not Aesthetically Functional

The weave design used by the applicant on footwear and leather goods is neither aesthetically functional nor mere ornamentation in view of its acquired distinctiveness.

Noting that an applicant has a "heavy burden" to prove acquired distinctiveness, the Board found that

Bottega Veneta International submitted a significant amount of evidence including use on handbags beginning in 1975, use on more than 80% of its goods, sales from 2001 through 2007 totaling $275 million, and advertising expenditures during this period of $18 million. In addition, the applicant's catalogs and advertisements featured products with the design, as well as references to the "intrecciato wave design." Particularly compelling were customer comments referring to or describing third-party products as looking like the applicant's design.

In re Bottega Veneta International S.a.r.l., Serial No. 77219184, 2013 TTAB LEXIS 541 (September 30, 2013) [not precedential].

Belgian Village Name is Not Geographically Descriptive

In reversing the Examining Attorney's refusal to register, the Board held that ACHOUFFE for beer is not primarily geographically descriptive even though the product emanated from the Village of Achouffe in Belgium.

The Board found that Achouffe is "very much an obscure location and would be relatively unknown to the relevant American consumer." For this reason, the mark does not fit the definition of geographic descriptiveness, i.e., a geographic location that is generally known to the relevant consuming public.

In re Brasserie D'Achouffe, Société Anonyme, Serial No. 79107741, 2013 TTAB LEXIS 517 (September 26, 2013) [not precedential].

* Stephen J. Quigley is Of Counsel to Ostrolenk Faber LLP, where his practice focuses on trademark and copyright matters. He is also a member of the NYIPLA Board of Directors.

CALL FOR NOMINATIONS!

2014 NYIPLA INVENTOR OF THE YEAR AWARD

Deadline: Wednesday, December 11, 2013

We invite you to nominate an individual or group of individuals who, through their inventive talents, have made a worthy contribution to society by promoting the progress of Science and useful Arts.

2014 Call for Nominations – Inventor of the Year

See the rules and details on www.nyipla.org.

Should you have any questions, feel free to contact David Leichtman at **212.980.7401,** **dleichtman@rkmc.com** or Eric H. Yecies at **212.513.3254,** **eric.yecies@hklaw.com**

The 2014 Inventor of the Year will be honored at the Association's Annual Meeting and Awards Dinner to be held at The Princeton Club of New York on Tuesday, May 20, 2014.

2014 NYIPLA HONORABLE WILLIAM C. CONNER INTELLECTUAL PROPERTY LAW WRITING COMPETITION

Deadline: Friday, March 7, 2014

The Winner will receive a cash award of $1,500.00
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Awards to be presented on May 20, 2014 NYIPLA Annual Meeting and Awards Dinner at The Princeton Club in New York City

The competition is open to students enrolled in a J.D. or LL.M. program (day or evening). The subject matter must be directed to one of the traditional subject areas of intellectual property, i.e., patents, trademarks, copyrights, trade secrets, unfair trade practices and antitrust. Entries must be submitted electronically by March 7, 2014 to the address provided below.

See the rules for details on www.nyipla.org.

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Voices from the Presidents' Forum

NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION · 1922

Compiled by
Matt McFarlane and Isaac Chao

On October 9, 2013, more than 45 leaders from private practice, industry, government, and academia gathered at the offices of Goodwin Procter LLP to attend the NYIPLA Presidents' Forum, the first in a series of invitation-only discussions on important topics in intellectual property law. Participants in the Forum addressed one of the most hotly-contested topics today in patent law: patent assertion by non-practicing entities ("NPEs"), sometimes identified using the more colorful term, "patent trolls." The Forum discussed what, if anything, should be done about the current situation, and "do we risk throwing the baby out with the bath water?"

FRAMING THE DISCUSSION

NYIPLA Past Presidents Melvin C. Garner and Marylee Jenkins introduced the Forum to the topic for discussion.

Although difficult to identify as a discrete class, NPEs, generally speaking, own patent rights covering subject matter invented by others and seek royalties from target companies allegedly making, using, or selling products that use those patented inventions.

Mr. Garner pointed out that monetization of patent rights is far from a new phenomenon. Several Forum participants pointed to Jerome H. Lemelson's enforcement activities. Lemelson was an inventor and entrepreneur who sued countless companies, ultimately obtaining more than $1 billion in licenses over the decades – perhaps paving the way for patent monetization in the modern era. Also, large companies like Texas Instruments and IBM, although not NPEs *per se*, heavily license their patent holdings, with revenues from licensing often exceeding that of product sales.

But, in the past few years, the number of suits filed by NPEs has increased steadily. NPE lawsuits accounted for roughly 4,700 patent lawsuits filed in 2012 – an uptick of 29% from two years earlier. Because many NPEs have no actual operations other than patent assertion, it is no surprise that these corporate entities choose plaintiff-friendly jurisdictions to bring suit. This litigation strategy has been successful, as historically, NPEs have won over 40% of their cases before the Eastern District of Texas and the District of Delaware, compared to less than 25% of their cases nationwide.

NPEs and their supporters fall back on the law: a patent is transferable personal property that entitles its owner to the full bundle of property rights – including the right to enforce and seek remedies such as damages adequate to compensate for infringement.

Detractors, on the other hand, believe that assertions by NPEs frustrate the patent system. Critics often highlight unorthodox strategies of NPEs to support their position: for example, NPEs extracting settlements from small entities that cannot afford the high cost of defending a patent litigation. Whereas a more well-heeled defendant might challenge a patent of questionable validity, others might opt for the certainty of settlement rather than undertake the considerable risk of damages. In addition, critics note that institutional patent owners maintain extensive patent portfolios for both offensive and defensive purposes: to assert against a competitor and mitigate exposure via cross-licensing. NPEs, by definition, are not vulnerable to such defensive strategies and inherently have more leverage at the negotiating table than traditional plaintiffs that practice inventions.

Ms. Jenkins then presented the Forum with an overview of various steps underway to address NPE activity. Congress is considering proposals for legislation that would heighten pleading standards for infringement and limit discovery—steps generally thought to make litigation less "friendly" for NPEs. In February 2013, Reps. Peter DeFazio and Jason Chaffetz introduced the SHIELD Act, which would require NPEs that lose in court to pay the legal costs and fees of the defendant. Because the cost-shifting proposed by the SHIELD Act applies only when the plaintiff is an NPE, the bill includes a mechanism that allows for defendants to move for a ruling before the court that the plaintiff is an NPE. According to the proposed legislation, if a court determines that the plaintiff is an NPE, the plaintiff will be required to post a bond to cover the defendant's legal costs. If implemented in its current form, the SHIELD Act has the potential to disrupt the NPE business model by making it prohibitively expensive for an NPE to file concurrent actions against a large number of defendants.

But Congressional reform is only one front in the battle against NPE activity, as other government agencies have begun to assert their authority. The Federal Trade Commission recently initiated a Rule 6(b) investigation into "patent assertion entity" activity, calling for public comment on proposed questions to pose to about 25 such entities. Among the information the FTC seeks is to understand the number of patent infringement demands,

time spent analyzing actual infringement before filing them, and the license agreements and revenue obtained. Several state governments have likewise targeted NPEs using those states' fair competition and deceptive practices statutes. And, on the same day as the Forum, a startup company, FindTheBest.com, Inc., filed a federal Racketeering Influenced and Corrupt Organizations Act (RICO) lawsuit in the Southern District of New York, alleging that individuals and companies associated with a "patent troll," Lumen View Technology LLC, conspired to extort licensing fees through baseless patent infringement lawsuits.

Perhaps most importantly, the issue has recently captured the attention of President Obama, who, in June, announced several executive orders "to protect innovators from frivolous litigation" by NPEs. Clearly, the increased exposure to aggressive enforcement entities has escalated patent issues to catch the attention of executives within companies, which has, in turn, led to increased political action and lobbying.

OPINIONS OF FEATURED SPEAKERS

Against this backdrop, participants in the Forum then heard position statements from five featured speakers approaching the issue from different perspectives.

"He who pays the piper calls the tune."

Alexander Poltorak, Founder, Chairman, and CEO of General Patent Corporation, questioned why so much attention is being paid to NPEs now. After all, Mr. Poltorak stated, an NPE acquires patents, which are essentially personal property that can be transferred. An NPE asserts patents against a third party, which is the only right granted in a patent: the right to exclude another from practicing an invention. As to an NPE not practicing an invention, that cannot be a problem, as society does not require a songwriter to sing her own song, or an architect to live in the house he designed. Mr. Poltorak challenged the audience to consider that maybe the problem is caused by a few bad actors, which is not a reason to overhaul the entire patent enforcement system. As to the increased attention paid to NPEs at the highest echelons of government, Mr. Poltorak suggested that the lobbying efforts of large companies with deep pockets have taken hold, and as always in politics, "he who pays the piper, calls the tune."

"States will act to protect their citizens."

Vermont Attorney General William Sorrell explained that Vermont takes an aggressive stance against NPEs as bad actors. Attorney General Sorrell explained that Vermont recently passed legislation targeting bad faith assertion of patent infringement, recognizing the pressure that NPE lawsuits have had on Vermonters. Vermont also filed the first state action against an NPE resident of a foreign state: a September

2012 lawsuit against NPHK LLC, a Texas corporation, which threatened litigation against Vermont non-profits and small businesses, like coffee shops, alleging infringement of four patents related to scanning and emailing documents. The state also filed a lawsuit in May 2013 against an NPE alleging a violation of Vermont's Consumer Protection Act. That case was removed to federal court, but Vermont is fighting to move the case back to Vermont state court. Taken together, Attorney General Sorrell explained how Vermont's efforts evidence a strong desire by states to curtail bad faith attempts by an entity to sue for patent infringement, an activity it recognizes as harmful to the commercial activities of its citizens.

"NPE issues should be dealt with 'In The Family.'"

Professor Hugh Hansen from Fordham University School of Law suggested that the NPE issue arose because something went wrong "In The Family," referring to patent practitioners and scholars, and "The Family" has ceded control of the discussion to other non-patent interests. Professor Hansen noted that NPEs have gained so much attention that outside players (and their non-patent interests) now dominate the completely polarized landscape, with academics and some non-governmental organizations declaring the patent scheme irreparably broken, and patent bar associations staunchly defending the status quo. In short, "The Family" has let the NPE issue become one highly visible battle in the larger war for and against intellectual property generally. Professor Hansen suggested that neither Congress nor the Executive Branch is equipped to help "The Family" address perceived problems, leaving the courts as the most promising forum for meaningful progress.

"Don't blame the patent system, curb abusive litigation practices."

Marian Underweiser, Intellectual Property Counsel at IBM, brought the perspective of a large corporation to the table. Ms. Underweiser stated her disapproval of the good versus evil approach that is often used to frame the NPE issue. She said that the root of the problem does not lie with patents themselves, but with the behavior driving business decisions. She

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believes that the U.S. patent system is very robust and that innovators like IBM will continue to rely on the patent system to protect ideas for many decades, in part because it will continue to evolve to address any challenges, including those posed by bad litigation practices. Ms. Underweiser suggested that alternatives to the patent system are insufficient to give innovators security, so practitioners must work together to curb litigation abuses and shore up patents' foundation as the main protector of technological progress in the future.

"Abusive litigation behavior is an equal opportunity practice."

The Honorable Paul R. Michel, former Chief Judge of the Court of Appeals for the Federal Circuit, called patenting "an important right that must be preserved because of its beneficial effects on the economy and scientific progress." He said in no uncertain terms that a "strong patent system directly affects the income of individuals. If we can make the system right, it will make everyone better off." The Judge noted that the U.S. patent system, in particular, is the best on the planet, but that domestic forces are acting to weaken it. Abusive litigation behavior is an equal opportunity practice and is not unique to patent litigation. While Judge Michel did note that patent litigation was too costly, slow, unpredictable, and has too high of an error rate, he attributed inefficiencies in the system to aggressive litigation practices, not the fact NPEs are the plaintiffs. Counseling and warning against a prescription that would not cure the disease, Judge Michel was optimistic that the courts themselves are taking useful steps to streamline litigation not directed at NPEs (*e.g.*, discovery reforms and local patent rules). In the face of this progress, Judge Michel implored Congress to tread carefully, avoid micromanaging the courts, properly fund the courts and end fee diversion at the U.S. Patent and Trademark Office.

CONSENSUS OF THE FORUM

After considering the views of the featured speakers, the Forum—the audience—engaged in a nearly two-hour open conversation about NPEs and paths forward from the current state. From this discussion, three essential points of consensus emerged.

Abusive litigation practices must be controlled.

The Forum generally agreed that NPEs themselves are not the problem, but that the litigation system has not been effective in limiting NPEs' exploitation of lax rules to suit their business goals. Some in the audience lauded reform efforts like the SHIELD Act, but others remained skeptical about its implementation and questioned which entities would qualify as an NPE.

The Forum agreed that the challenge is not about NPEs versus other plaintiffs, but rather to sort out frivolous lawsuits from meritorious ones. To this end, efforts to streamline litigation were generally viewed positively. For example, proposals for an earlier *Markman* hearing, earlier cutoff date of discovery, and a preliminary determination of whether potential damages are large enough to justify allowing the litigation to proceed would all help remedy the phenomenon of frivolous lawsuits clogging up the courts. The Forum rejected the notion currently popular in some quarters that lawsuits brought by NPEs are inherently suspect, if not patently frivolous.

The judiciary already has the tools it needs to address litigation problems.

The second point of consensus among the Forum was that courts are already equipped with the mechanisms to handle abusive litigation, and that there is nothing that Congress can do to "fix" the NPE issue without causing unintended consequences.

Many noted that Rule 11 of the Federal Rules of Civil Procedure requires attorneys to certify that a pleading is not presented for a frivolous purpose and allows for attorney fees as sanctions. As for 35 U.S.C. § 285, however, which permits enhanced damages or an award of attorney fees for exceptional cases, most participants felt that the Federal Circuit's recent interpretation limiting that avenue for relief set too high a standard, and welcomed the Supreme Court's agreeing to take up this issue in *Octane Fitness, LLC v. ICON Health & Fitness, Inc.* (No. 12-1184) and *Highmark Inc. v. Allcare Health Management System, Inc*. (No. 12-1163).

Forum participants also discussed whether the Patent Trial and Appeal Board ("PTAB") could offer solutions for problematic NPE activity, given that the PTAB is now staffed with 169 Administrative Law Judges with backgrounds in patent law. Cheaper, faster, and more efficient proceedings before the PTAB may also relieve pressure on federal district courts, but whether NPEs avail themselves of this mechanism remains to be seen.

The NPE issue prevents discussion about other fundamental issues in patent law.

A third point of consensus is that NPE litigation is merely the flavor of the month in patent litigation. Most participants recognized that the spotlight has become brighter due to the intense lobbying efforts of affected companies in certain technological areas. This lobbying effort has reduced the debate to an overly simplistic dualism—whether or not NPEs should be permitted to freely enforce the patents they have purchased. Politicians desperately need to hear from interested parties that the current system can work – only those views can interject a reasoned voice into the discussion.

Even so, Forum participants recognized that the question of whether NPEs are "good" or "bad" has prevented fair consideration of more far-reaching ideas that could potentially impact the patent system in more profound ways. Two examples of such far-reaching ideas, presented at the Forum, were adoption of a tiered patent system like Germany's and publication of patent royalties to eliminate the case-by-case determination of a reasonable royalty. Shackled by the present debate over NPEs, however, it seems unlikely that those more radical approaches will gain traction.

CONCLUSION

Most Forum participants seemed to lament the fact that a discussion of substantive issues concerning patent litigation has devolved into a discussion of "patent trolls." Some questioned whether NPEs were not the real problem at all, but really represented problems with litigation generally. Almost all participants cautioned against Congress or the Executive Branch applying "broad brush" and "sledgehammer" approaches to a problem of limited pervasiveness.

Perhaps all could agree on one point: prescribing the wrong medicine will not only fail to cure the patient, but could actually make the patient sicker. Given that the patient in this instance is a thriving patent system, Forum participants shared the desire to act wisely and with moderation, pursuing only those changes that will foster protection for future technological innovation and economic development.

Bar associations must continue to be vocal advocates for intelligent change. The NYIPLA is proud to support the Presidents' Forum as a crucible in which critical ideas can be discussed and converted to positive action in support of our community's shared goals.

Suggested reading:

- U.S. Accountability Office, GAO Report to Congressional Committees, *Assessing Factors That Affect Patent Infringement Litigation Could Help Improve Patent Quality* (August 2013)
- Layne-Farrar, Anne, *The Brothers Grimm Book of Business Models: A Survey of Literature and Developments in Patent Acquisition and Litigation* (March 12, 2012)
- Bessen, James E. and Michael J. Meurer, *The Direct Costs From NPE Disputes* (June 28, 2012)
- Lu, Jiaqing "Jack", *The Economics And Controversies Of Nonpracticing Entities (NPEs): How NPEs And Defensive Patent Aggregators Will Change The License Market* (June 2012)
- Love, Brian J., *An Empirical Study Of Patent Litigation Timing: Could A Patent Term Reduction Decimate Trolls Without Harming Innovators?*, 161 U. PA. L. REV. 1309 (2013)
- Ewing, Tom and Robin Feldman, *The Giants Among Us*, 2012 STAN. TECH. L. REV. 1
- Lemley, Mark A. and A. Douglas Melamed, *Missing the Forest for the Trolls* (May 23, 2013). Columbia Law Review, Forthcoming; Stanford Law and Economics Olin Working Paper No. 443. *Available at* SSRN: http://ssrn.com/abstract=2269087 or http://dx.doi.org/10.2139/ssrn.2269087
- Chien, Colleen V., *Patent Assertion And Startup Innovation*, New America Foundation, Open Technology Institute (September 5, 2013)
- Transcript of Proceedings, Patent Assertion Entities Activities Workshop (hosted by Federal Trade Commission and U.S. Department of Justice, December 10, 2012)
- Intellectual Ventures, *The Red Herring of Transparency*, IV Insights Blog (December 6, 2012)
- *Tracking PAE Activity: A Post-script to the DOJ Review,* http://www.rpxcorp.com/index.cfm?pageid=14&itemid=27
- *Why do patent trolls love East Texas and Delaware? They win more there, The Washington Post* (Sept. 19, 2013), http://www.washingtonpost.com/blogs/the-switch/wp/2013/09/19/why-do-patent-trolls-love-east-texas-and-delaware-they-win-more-there/

CLE PROGRAMS

Young Lawyers Roundtable: Legal Writing

By Jonathan A. Auerbach

On September 25, 2013, the Young Lawyers Committee hosted the second Young Lawyers Roundtable at Desmarais LLP. Paul Bondor, partner at Desmarais, and Henry Dinger, partner at Goodwin Procter LLP, led an interesting discussion on legal writing. Paul and Henry began the Roundtable by providing their best tips for junior lawyers. They then conducted a live editing session of two post-trial briefs from a major patent infringement case to demonstrate the practical application of the earlier discussion. The Committee plans to host its next Roundtable in January, relating to oral advocacy.

Intellectual Property Considerations for Software and Mobile Apps

By Jessica L. Copeland

On Thursday, September 26, 2013, Jessica L. Copeland hosted "Intellectual Property Considerations for Software and Mobile Apps" at Hodgson Russ LLP's office in Times Square. The attendees included outside counsel, in-house counsel, and business executives from the NYC metro area. This CLE presentation and reception was the second in a series of mobile app-focused presentations—the first presentation took place in Buffalo, New York on April 24, 2013. The event featured a riveting discussion on developing and protecting software and mobile applications by Robert J. Fluskey, Jr., a partner and IP litigation attorney at Hodgson Russ LLP; Alfonzo I. Cutaia, a senior associate and IP litigation and prosecution attorney at Hodgson Russ LLP; and Jeanine S. Ray-Yarletts, Application and Integration Middleware (AIM) & Industry Solutions (ISN) Division IP Counsel from IBM. Ms. Ray-Yarletts offered a dynamic industry perspective on the development of mobile apps based on her depth of knowledge and experience at IBM in this field. The audience was not only receptive to the topic, but was actively engaged in the panel's discussion throughout the CLE.

Diverse Careers in IP Law and Strategies for Achieving Success

By Colman Ragan

On October 10, 2013, the Meetings & Forums Committee and the Young Lawyers Committee hosted their second in a series of networking events and panels aimed at creating an open dialogue with young lawyers addressing the variety of career options currently being presented in today's changing marketplace. This time, the panel discussion and networking reception were held at the New York Law School. The panel consisted of Tom Meloro of Willkie Farr & Gallagher LLP; John Resek of Resek, Liang & Frank LLP; and Michael Chang of Kenyon & Kenyon LLP. The panel was moderated by Colman Ragan, Co-Chair of the Meetings & Forums Committee.

The panel discussion focused on how young intellectual property lawyers can take charge of their careers and avoid the pitfalls that befall many young (and not so young) attorneys. Tom

Meloro was able to provide perspective on how senior partners view young associates, what is expected of a young associate to succeed in the law firm dynamic, and how young associates can meet those expectations. John Resek provided a unique perspective addressing how his career started in science, moved to working at major law firms, then in-house at a major pharmaceutical company, back to major law firms, and finally to starting his own firm with colleagues he met along the way. Michael Chang provided the much-needed perspective of someone much closer to the audience and still growing into the practice of law while deciding his career path.

The panel was formatted as an open dialogue, with the audience participating in the discussion as it progressed. A common theme that came from the audience and was addressed by the panel was how to start networking at such an early stage, including the ever-challenging goal of learning to communicate with actual and potential clients. After the panel discussion concluded, pizza was served, and the panel members had a chance for lively one-on-one conversations with the audience, which consisted largely of young lawyers and current law students. Plans are already in the works to reprise the panel, in February at Fordham University School of Law.

Corporate Committee In-House Counsel Mixer

By Frank Sedlarcik

The Corporate Committee, co-chaired by Frank Sedlarcik and Jeffrey Butler, hosted a mixer for in-house counsel (both active and prospective NYIPLA members) on October 17, 2013 at Latitude Bar in Manhattan. About twenty in-house counsel attended but many more now regret not making time to be there. It was a great kick-off to what we're hoping will be a great year! All those in attendance were excited to connect (and in some instances re-connect) with other in-house counsel through the NYIPLA, sharing thoughts and ideas for future programs of particular interest to our corporate members. The Corporate Committee would like to thank both the Board for its support and the fantastic NYIPLA administrators that made Frank and Jeffrey look good. See you at future events!

Life as a Young IP Associate – How To Market Yourself To Your Clients; How To Incorporate Pro Bono Work Into Your Practice

By Jonathan A. Auerbach

On October 29, 2013, the Young Lawyers Committee hosted a panel discussion for young IP associates at Crowell & Moring LLP. Steven Skelley (Dickstein Shapiro LLP), Vicki Franks (Frommer Lawrence & Haug LLP), Ed Tulin (Skadden, Arps, Slate, Meagher & Flom LLP), and Preetha Chakrabarti (Crowell & Moring LLP) served as panelists, with Committee Co-Chair Jonathan Auerbach (Goodwin Procter LLP) moderating. The panelists discussed how young attorneys can incorporate pro bono work into their practice, achieve work/life balance, and market themselves within their own firms and externally.

Minutes of September 10, 2013
Meeting of The Board of Directors of
The New York Intellectual Property Law Association

The Board meeting was called to order at Union League Club, 38 East 37th Street, New York, NY at 7:33 p.m. by President Charles Hoffmann. In attendance were:

Dorothy Auth	Annemarie Hassett
Jessica Copeland	Anthony Lo Cicero
Raymond Farrell	Denise Loring
Bruce Haas	Matthew McFarlane
Walter Hanley	Stephen Quigley

Attending by telephone were Kevin Ecker and Wanli Wu. Feikje van Rein, Lisa Lu, and Elena Suarez were in attendance from the Association's executive office.

Charles Hoffmann called the meeting to order. The Board approved the Minutes of the July 9, 2013 Board meeting.

Treasurer Denise Loring reported that the organization continues to be in a strong financial position, noting that (compared to 2012) assets and expenses are up, and income is flat. The Treasurer further reported on the various investment options available to the Association that might improve yield on the Association's financial assets while maintaining a reasonable degree of safety and adequate liquidity of the funds. The Board determined to hold in reserve some funds, over and above the amount of the annual operating expenses, and to invest the remainder. Ms. Loring also noted that Loeb & Troper LLP recommended that the Association adopt an investment policy based on an endowment fund model.

The Board discussed various options for using its resources to add value to membership in the Association. Raymond Farrell, Dorothy Auth, Walter Hanley, and Bruce Haas were asked to develop a 3-year strategic plan for the Association.

The Board reviewed and approved the list of new applicants for membership. The Board noted that the new members represented several new firms and that the overall number of active members in the 3+ category had substantially increased compared to 2012.

The Board approved the arguments proposed by the Amicus Brief Committee for filing an amicus brief in support of Alice Corp.'s Petition to the U.S. Supreme Court for a Writ of Certiorari in *Alice Corp. v. CLS Bank Int'l.* On behalf of the Amicus Brief Committee, Matthew McFarlane reported on cases on the horizon for potential amicus submissions, and noted the schedule for the submissions.

Dorothy Auth reported, on behalf of an ad hoc committee, on the progress of planning for the inaugural Presidents' Forum on October 9. A number of prominent speakers have agreed to participate. Marylee Jenkins and Mel Garner will facilitate the discussion.

The Board discussed and approved Mr. Hoffmann's proposal for the 2014 recipient of the Association's Public Service Award.

Raymond Farrell reported on the development of a webinar presentation by the Copyright Committee. Jessica Copeland noted that the webinar format would enable greater participation by attorneys outside the NYC metropolitan area. President Charles Hoffmann encouraged the Association to ensure good video and audio quality for any webinars it presented. Feikje van Rein said that the Association's executive office personnel were experienced in implementing such presentations.

The Board discussed and approved a suggestion from the Website & Records Committee that the Association's website include a job bank to link potential employers and prospective employees. Non-members may list employment opportunities, but only members may search for employment positions.

The meeting was adjourned by Charles Hoffmann at 8:50 p.m.

NYIPLA Calendar www.nyipla.org

How Can You Avoid Paying the Other Side's Attorney Fees? - Amicus Brief Discussion

EARN NY/NJ 1.0 PROFESSIONAL CLE CREDIT

➤ WEDNESDAY, DECEMBER 4, 2013 5:30 PM – 8:30 PM ◄

Orrick (CBS Building), 51 West 52nd Street, New York, NY

December CLE Luncheon

EARN NY/NJ 1.0 PROFESSIONAL CLE CREDIT

Speaker **Circuit Judge Kathleen M. O'Malley**

United States Court of Appeals for the Federal Circuit

➤ MONDAY, DECEMBER 16, 2013 12:00 PM – 2:00 PM ◄

The Union League Club, 38 East 37th Street, New York, NY

One-Day Patent CLE Seminar

EARN NY/NJ 7.0 CLE CREDITS INCLUDING 2 ETHICS CREDITS

Keynote Speaker **Chief Judge Carol Bagley Amon**

United States District Court for the Eastern District of New York

➤ THURSDAY, JANUARY 16, 2014 8:30 AM – 5:30 PM ◄

The Princeton Club, 15 West 43rd Street, New York, NY

January Young Lawyers' Roundtable: Oral Argument

February Young Lawyers' Roundtable: Claim Construction

February NYIPLA Presidents' Forum

Diverse Careers in IP Law and Strategies for Achieving Success

➤ THURSDAY, FEBRUARY 27, 2014 12:40 PM – 1:45 PM ◄

Fordham University School of Law, 140 West 62nd Street, New York, NY

"Day of the Dinner" CLE Luncheon

EARN NY/NJ 2.0 PROFESSIONAL CLE CREDITS

FOLLOWED BY

92nd Annual Dinner in Honor of the Federal Judiciary (Judges Dinner)

➤ FRIDAY, MARCH 28, 2014 ◄

The Waldorf Astoria New York Hotel, 301 Park Avenue, New York, NY

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