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The Case Law Push Toward Real World Measures of Reasonable Royalties

By James W. Gould1

he trend to monetize patents, however they are obtained, has sometimes led to excessive damages. "Excessive" here is not defined as above some arbitrary dollar amount. Rather, it is a claim that is divorced from real world measures of value. Fortunately, the Federal Circuit's recent cases have been swinging the pendulum back to the real world.

To understand the context of this change, this article starts by describing the rights a patent provides and how various real world business models use those rights to maximize returns, whether by maintaining high profits through exclusivity in the marketplace or licensing. These models are then compared to the two forms of patent litigation damages: lost profits and reasonable royalty. With this background, the recent Federal Circuit cases will be deconstructed into their factors for determining the value of a patent, which provide guidance for litigation as well as for the real world.

Exclusivity Patent Business Models

People erroneously believe a patent confers the right to practice the subject invention. In fact, a patent provides the owner only the right to exclude others from using the invention. If the patent holder's own practice of the invention may infringe another patent, the patent holder must obtain rights from the other patent's owner or decide that the patent is invalid or not infringed and risk litigation for patent infringement. Such an analysis is often called assessing the "freedom to operate." As an initial step in the process of evaluating a patent, a patent holder should have its patent lawyer confer with its business and technical people as to the strength of the patent over the prior art and how difficult it is to "design around" the patent. An easily avoided patent does little to maintain market exclusivity.

A business model reflecting this patent right to exclude is for the patent holder to try for market exclusivity by keeping out all competitors and making "supra-competitive" profits on its own sales. This is not the easiest thing to do, because competitors tend to flock to compete with anything with high profit margins. For this approach to work, litigation (or at least the credible threat of it) may be needed. This model further requires that there be no acceptable non-infringing alternatives in the market. For example, an allergy drug

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Dear Fellow Members:

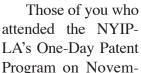
In my first President's Corner, I indicated that one of my objectives as President is to increase the opportunities for participation and networking among members of the Association. I am pleased to report that the Committee Co-Chairs and their Board liaisons have eagerly embraced this agenda. To date we have had a September CLE co-sponsored by the Women in IP Law and Meetings and Forums Committees and an October CLE co-sponsored by the Trademark and Meetings and Forums Committees.

The response to these co-sponsored programs has been extremely favorable. The programs have been very successful, both in terms of the content and quality of the programs and in terms of fulfilling my objective of increasing networking among the Association's committees. Again, if you have not already taken advantage of the opportunity to become an active member of an NYIPLA committee, I encourage you to contact the co-chairs of the committees that interest you and become an active committee member.

Thanks to all of the committees for these wonderful programs. Thanks also to the CLE Committee for a superb all-day series of panel discussions on November 3 at the NYIPLA's One-Day Patent Program. This all-day program provided in-depth analysis on a variety of patent topics. The caliber of the speakers and the content of their presentations were uniformly high. All of the panels had something to offer practitioners at all levels of experience. Even at my rather senior level of experience (where CLE programs often provide little that is notable), this program had content in each panel that was valuable to me. Not only were the many who attended afforded much useful CLE, but they also satisfied their ethics requirement.

In December the NYIPLA CLE luncheon will be co-sponsored by the Patent

Litigation and Meetings and Forums Committees. The program will be held on December 15, and Chief Judge Rader will be the speaker. I hope to see many of you there.





ber 3 were among the first to find out which of the Eastern District judges have opted to participate in the recently-implemented Pilot Patent Program, as Judge Seybert shared that list during her keynote luncheon address. Our thanks to Judge Seybert, both for letting the NYIPLA be among the first to know and for an entertaining and informative keynote address.

Another of our local jurists, Judge Colleen McMahon, has graciously agreed to be this year's keynote speaker at the 2012 Judges Dinner. She has also opted into the panel of Southern District judges who will participate in the Pilot Patent Program. We look forward to her speech at the Judges Dinner and to working with her as the pilot program evolves.

As you are undoubtedly aware, the Pilot Patent Program in the Eastern and Southern Districts of New York is now being implemented. The Rules Committees of the two districts are currently exploring what local patent rules should be implemented as part of this program. The NYIPLA is providing input into that process. Please contact an NYIPLA Board member if you have suggestions that you wish to have passed on to the Rules Committees.

I look forward to our continued work together this year.

With kind regards, Terri Gillis may be patented, but if there are many competing non-infringing allergy drugs, the patent holder may not be able to reap "supra-competitive" profits. Other business/technical/legal issues include how easy it is to design around the patent, whether the market is large enough for a new entrant to share it and still make a profit, and whether regulatory or market barriers to entry would discourage new entrants. Finally, from the litigation standpoint, if the infringers are small and numerous, the cost of suing enough of them to cause all of them to stop must be considered.

The law on patent lost profits damages reflects these realities of the exclusivity model as well as other real world factors. Lost profits, defined as the incremental profits the patent holder would make on its additional sales "but-for" infringement, includes both lost profits from unit sales and reduced profits on the sales still made, mirroring the actual business losses due to infringement. The law on lost profits also requires the absence of noninfringing alternatives.³ If such alternatives exist, then a market share analysis must be used.⁴ This reflects the business reality that even "but-for" infringement, some customers would choose an acceptable alternative to the patented product. The patent holder must also prove it had the manufacturing and marketing capacity to make the extra sales, another real world factor. Demand for the patented product due to the patent (and not due to something else such as a trademark, etc.) must also be proved. A patent holder claiming that infringement eroded its prices must also analyze elasticity of demand, i.e., analyze how increased prices would affect unit volume, and show that other market factors such as cheap imports or obsolescence did not cause the drop in price.⁵ A two-supplier market may avoid the need for proof on elasticity.⁶ The law on lost profits also requires real world "competition-in-fact" between the patent holder and the infringer, measured by comparing pricing tiers, classes of customers, and channels of distribution.⁷

The case law on lost profits damages thus applies a full range of real world factors that also apply to deciding whether the real world exclusivity business model is viable. This case law closely mirrors business and market realities, so it is not surprising that this area of the law has been fairly stable for years and is not involved today in the push for legal changes.

The Licensing Business Model and Trolls

The second patent business model is to license the patents. In this model, the threat of litigation may be viewed as a means to induce companies to sign up. A variant of this business model skips the licensing step, with the patent holder going straight to litigation, aiming for a large award. This variant is where much of the case law action is today.

Real world business licensing models are based on two approaches – carrot and stick. In the carrot licensing model, the license gives the targeted licensee added value, and the royalty is a portion of that value. An example of added value (from my chemical engineering days) is an improved petrochemical catalyst that increases the yield of a reaction and reduces cost to the licensee manufacturer. Another example is a company that has proven a pharmaceutical through FDA Phase I but does not have the money for Phases II and III or the ability to nationally market. The latter example is becoming a more common pharmaceutical research scenario. Another example is licensing prior generation technology in developing countries, which often includes non-patented know-how. DuPont did this some years ago with its older automobile paint technology, keeping the newest for itself. The polymerase chain reaction ("PCR") technology, a Nobel Prize winning technique widely used in molecular biology, 8 is another example.

Because carrot licensing generally focuses on the real added benefits to the licensee after considering available alternatives, there tend to be fewer false valuation problems. That is especially true if the licensor is smart enough to set the royalty at the sweet spot where the licensee can still make an acceptable profit after the royalty, and the royalty is lower than the cost of challenging the patent in court. With a well-designed and properly valued carrot license program, the industry will sign up and infringement suits will be avoided – a good model indeed.

A variant of this carrot model is a company that has a large patent portfolio covering its own products but is willing to license. An example is IBM, which sets the royalties for its massive portfolio low enough – five percent for the entire portfolio – that no one challenges. (IBM also offers one patent at one percent, two at two percent and three at three percent, due to a previous antitrust settlement. But because of the cost of determining the freedom to operate for all those thousands of patents, everyone takes the five percent license.) Of course, companies also like large patent portfolios to use for counterclaims when sued. (That is why such companies hate to be sued by patent trolls – since pure patent trolls have no business apart from making money from patents, there is no infringement counterclaim.) (A "troll" is defined here as an entity which does not practice its own patents; a "pure troll" is defined as an entity having patent monetization as its sole source of revenue.)

The stick licensing model arises where the target licensee is merrily making and selling product it developed in the lab and in the market, and then one fine day gets a demand letter to fork over a chunk of the money it has already been making. In other words, all subtraction, no addition to profits. This is the territory in which patent trolls dwell.

The stick licensing approach usually weighs projected royalties against the threat of litigation, with its attendant lawyers' fees and costs for discovery (especially e-discovery) and experts and possible damages awards. Patent trolls typically have few documents or employees with relevant knowledge, so this cost tends

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to be weighted towards the accused infringer. Since pure patent trolls' only assets are patents, their entire focus is maximizing return by buying patents cheaply during bankruptcy (or obtaining exclusive licenses that confer standing to sue) and in effect selling high via threat of, or actual, litigation. There is nothing inherently economically incorrect with the troll model. It is akin to buying distressed assets cheaply rather than finding value. In the hands of trolls, patents have become more like securities. This overall trend of securitization is also shown by patents being sold at public auctions by bankruptcy trustees and by private companies like Ocean Tomo.

This motivation to maximize return on investment has caused patent trolls (as well as some non-trolls) to overreach in some patent reasonable royalty cases. (Selling no products on which to claim lost profits, trolls' claims are limited to reasonable royalties.) The courts have responded by pushing back. To understand the push and counter-push, some background in reasonable royalty case law is needed.

Historical Reasonable Royalty Litigation Models and the Troll Model

Classical reasonable royalty approaches in litigation include the Georgia-Pacific hypothetical negotiation, incremental value or profits to the infringer due to the invention (sometimes called the "analytical method"), design-around alternative cost, and comparable license rates. All of these approaches have grounding in the real world. Licensing professionals use the Georgia-Pacific list of factors⁹ as a checklist in negotiating real world licenses. The analytical method¹⁰ focuses on real world value by, e.g., comparing profit margins for the patented product to industry averages. Similarly, the design-around alternative cost and comparable license rate approaches fundamentally reflect the real world. The problem thus is not with the theories per se, but rather with how they are used, especially in the interplay of the royalty base and royalty rate.

The "royalty base" is the dollar (or unit) sales to which the royalty rate is applied. Where the patent is essentially the product, as in the case of the active ingredient in a drug (although there may also be formulation and method claims), then using the entire sales price makes real world sense. But where the patent is one small feature or component of a much larger combination, some damages experts have played with the royalty base and royalty rate to expand the potential damages far beyond real world value.

One approach has been to claim a royalty base consisting of an entire combination (that is, a product that includes the patented feature plus other non-patented parts), then set a royalty of twenty-five percent of the profits of the entire combination under what is called the "25% Rule of Thumb" without investigating if the "Rule" made sense in the particular case. Experts

have argued that the entire combination is the base, noting that without the component the entire combination would not work. Using that logic, a patent on lug nuts for wheels on a car could use the entire car as the royalty base. Such absurd arguments do not succeed in real world licensing. But since patent trolls tend to accuse of infringement products having large sales, the result is sometimes hundreds of millions of dollars in damages, even on something that is a component of a component of a larger combination such as a computer server. Another approach has been to find other licenses with high rates in the field and simply apply them to the entire royalty base without analyzing whether they are truly comparable. As mentioned above, the fundamental problem is that these approaches are disconnected from real world measures of valuation.

In response to pressure from companies hit with large awards under these and other approaches, Congress sought for years to include changes to the law of patent damages as part of the larger effort to amend the Patent Laws. One approach under consideration was making the trial court an explicit gatekeeper to keep out unsupported damages theories, essentially following the ruling in Daubert v. Merrell Dow Pharmaceuticals. 11 Another was to amend the statutory basis for damages to require analysis of value. But the Federal Circuit did not wait for Congress to act. With Judge Rader leading the charge as detailed below, the Court has been introducing sound, real world economic valuation principles to limit excessive damages theories. In the author's view, these actions by the Federal Circuit are the primary reason the America Invents Act does not contain any changes to the law of patent damages.

Limiting the Royalty Base and the Entire Market Value Rule

To obtain royalty damages for a patent on a component or feature of a larger combination (where all the parts are sold and function together), the test has long been that the patented component or feature must be the basis for customer demand for the entire combination.¹² In the recent case of *Uniloc USA*, *Inc. v. Mi*crosoft Corp., 13 the Federal Circuit reiterated the alternate test from Rite-Hite, 14 namely whether the patented component "substantially created the value of the component parts [i.e., the unpatented components sold with the patented apparatus]." Whatever the test, this principle has been called the "Entire Market Value Rule." As stated, the Rule does have a solid relationship to reality, perhaps because it started with a case in which a patented plowshare was held to be the basis for demand for the entire plow and damages were awarded accordingly. The problem instead has been experts (testifying on behalf of patent trolls and others) not following the test to apply the Rule and opponents and courts failing to challenge experts not satisfying the tests.

The problem began to be addressed by the courts

when the Federal Circuit's Judge Randall Rader, sitting by designation as a trial judge in Cornell University v. Hewlett-Packard Co.,15 granted judgment as a matter of law ("JMOL") on damages and reduced the jury's \$184 million damages verdict to \$53.5 million. In that decision, Judge Rader reiterated the "basis for customer demand" test and excoriated the plaintiff's expert witness for failing to link customer demand for the asserted royalty base to the claimed invention. Judge Rader also suggested that demand curves or other economic or market evidence might have cured the defect. (The original royalty base offered by the expert was computer servers. After a Daubert ruling cutting that back, the expert then during trial tried to use central processing unit "bricks" of which the patented feature was still a small part. Judge Rader ultimately limited the damages to processors, the smallest component of the brick containing the accused infringement.)

Judge Rader struck again in *IP Innovation L.L.C.* v. *Red Hat, Inc.*, ¹⁶ this time sitting by designation as a trial judge in the Eastern District of Texas. In this case Judge Rader excluded the report of the plaintiff's damages expert because the report (1) did not determine the value of the one desktop patented feature relative to the thousand other components in the accused products, (2) "made no effort to even discern the percentage of users who would never enable or use the claimed feature," and (3) did not "show some plausible economic connection between the invented feature and the accused operating systems before using the entire product as the royalty base." ¹⁷

A few months before *IP Innovation*, the Federal Circuit affirmed a damages analysis, shedding light on the kind of economic analysis that might pass muster under a "real world" economic scenario. In *i4i Limited Partnership v. Microsoft Corp.*, ¹⁸ the court affirmed a \$200 million award. The royalty base portion of the decision approved of the approach of (1) excluding individual users, (2) surveying 988 large and small business users as to their actual use of the patented XML feature in certain Microsoft Word® products, and (3) using only the 1.5 percent positive survey responses as a measure of the royalty base. (How this case handles the royalty rate is addressed in the next section.)

Hopefully future cases (and gun-shy experts) will take heed from these cases and rein in improper inflation of the royalty base.

Limiting the Royalty Rate

When reviewing royalty rates, the Federal Circuit recently reiterated the need to prove economic value. In *ResQNet.com*, *Inc. v. Lansa*, *Inc.*, ¹⁹ the Federal Circuit vacated the damages award and ordered a new trial because the district court's award "relied on speculative and unreliable evidence divorced from proof of economic harm linked to the claimed invention." The test the Federal circuit articulated was to "carefully tie proof of damages to the claimed invention's footprint in the

market place." ²¹ In this case, the issue was the definition of comparable licenses. The court rejected a slew of asserted "comparable" licenses as improper because they (1) were not for the patent in suit, (2) showed no discernable link to the claimed technology, and (3) were rebundled licenses involving software that was technologically and economically different from the subject matter of the patent in suit. ²²

In contrast, in *i4i*, the Federal Circuit approved the approach of (1) finding the market price of the closest feature, (2) multiplying that price by Microsoft's profit margin, (3) multiplying the result of step 2 by 25%, and (4) adjusting for the *Georgia-Pacific* factors. ²³ However, Microsoft's failure to file a pre-verdict JMOL motion on damages was held to waive its right to challenge this approach. ²⁴ Thus, the test on appeal was a "clear showing of excessiveness," *i.e.*, no evidence to support the verdict. ²⁵ This is a warning to practitioners not only to file *Daubert* motions to strike damages experts, but also to file Rule 50(a) and (b) motions to preserve damages issues on appeal.

But then, shortly after seemingly affirming the use of the 25 percent Rule of Thumb in i4i, the Federal Circuit took it away. In Uniloc, the Federal Circuit held that the 25 percent Rule was incorrect as a matter of law and inadmissible under *Daubert* and the Federal Rules of Evidence, even as a starting point for later adjustment.²⁶ The analysis repeated the need to look at (1) the importance of the patent to the profits of the products sold, (2) the potential availability of close substitutes or non-infringing alternatives, (3) "any other idiosyncrasies of the patent at issue that would have affected a real-world negotiation," and (4) ResQNet's "claimed invention's footprint in the market place."27 (A caveat here – in a hypothetical negotiation for a reasonable royalty, the patent must be assumed valid, enforceable and infringed. These assumptions are definitely not real-world.) Uniloc was careful to say that the Georgia-*Pacific* factors were still valid and singled out three as important: "factors 1 and 2 – looking at royalties paid or received in licenses for the patent in suit or in comparable licenses – and factor 12 – looking at the portion of profit that may be customarily allowed in the particular business for the use of the invention or similar inventions."²⁸ Finally, *Uniloc* reaffirmed that to apply the Entire Market Value Rule, the patent must be "the basis for customer demand" or "substantially create the value of the component parts."29

Putting it all Together

This article started by describing the business and economic realities of different business models for generating profits from patents. The exclusivity model closely matches a patent infringement lost profits case, and, not surprisingly, that match between reality and the law has meant a long period of stability in that area of the law. Similarly, the carrot licensing model has been relatively quiet legally, because the hypothetical

licensing negotiation is likely to reflect the real world. Only in the stick licensing model, especially as executed by patent trolls, has there been a problem. As the case analysis above shows, the Federal Circuit is doing a good job of insisting that even the stick licensing model reflects business and market realities and the true value of a patent.

To recap, the case law factors relevant to the real world exclusivity business model include (1) demand for the patented product; (2) the absence of acceptable non-infringing alternatives; (3) the licensor's marketing and manufacturing capacity to increase production and sales; (4) incremental profits from exclusivity; and (5) the degree of actual competition (same pricing, customer base and distribution channels).

For the licensing model, the case law factors applicable to the real world include (1) whether the patent covers the entire product or only a component or feature; (2) if only a component, whether the patent is the basis for customer demand or substantially creates the value of the component parts; (3) the invention's "footprint in the market"; (4) the profits of the accused product; (5) whether those profits are above average for the industry; (6) allocation of the product's profits between the contribution of the patent and the contributions of the infringer (including manufacturing and marketing); (7) the cost (or regulatory or market entry barriers) of design around alternatives; (8) rates for licenses to truly comparable technology; and (9) other market and economic factors showing value. Georgia-Pacific also adds business considerations, such as whether the licensor has been following an exclusivity or licensing model (Factor 4); whether the patent holder and infringer are competitors (Factor 5); and benefits to those who use the invention (Factor 10).

The Federal Circuit's message is getting out. As a patent litigator I am aware that damages experts know they need to conform to these new rulings. The catchphrase now used is "allocation of value" between the patent and the contributions of the accused infringers. (This focus on allocation of value is going back to the future – Georgia-Pacific Factor 13 describes apportioning profits between the invention and non-patented elements, manufacturing process, business risks, improvements and features added by the infringer. And the concept of allocation per se for patent damages is even older.³⁰) We can also expect this new legal reality to readjust the bargaining power of patent trolls, as did the eBay case,³¹ which appears to have led to more compulsory licenses and fewer injunctions, judging from the number of recent compulsory license cases.³²

This is all to the good – a strong patent system should be based on real value measured by real world business, market and economic factors. And entities (even patent trolls) that have valuable patents as judged by these real world factors have nothing to fear from this latest legal adjustment.



(Endnotes)

¹ James W. Gould has a B.S. in Chemical Engineering from Penn State and a JD from the University of Pennsylvania, with a stint in between doing research while in the U.S. Army. Since then he has been a litigator, for the last 30 years specializing in patent litigation in a wide range of technologies, including pharmaceuticals, medical devices, fine chemicals, catalysts, metallurgy, telecommunications,

computers, software and consumer products. He has a special interest in patent damages and the interplay of patent and antitrust law. Formerly with Morgan & Finnegan, he is now a partner with Locke Lord LLP

- ² Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir. 1978).
- 3 Id.
- ⁴ See State Indus., Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1577-80 (Fed. Cir. 1989).
- ⁵ Crystal Semiconductor Corp. v. TriTech Microelecs. Int'l, Inc., 246 F.3d 1336, 1357-60 (Fed. Cir. 2001).
- ⁶ Lam, Inc. v. Johns-Manville Corp., 718 F.2d 1056, 1067 (Fed. Cir. 1983).
- ⁷ BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc., 1 F.3d 1214, 1219 (Fed. Cir. 1993).
- ⁸ See, e.g., Carnegie Mellon Univ. v. Hoffman-LaRoche Inc., 541 F.3d 1115, 1129 n.4 (Fed. Cir. 2008).
- ⁹ Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).
- ¹⁰ See TWM Mfg. Co. v. Dura Corp., 789 F.2d 895, 899 (Fed. Cir. 1986).
- 11 509 U.S. 579, 589-97 (1993).
- ¹² Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1549 (Fed. Cir. 1995) (en banc).
- ¹³ 632 F.3d 1292, 1318 (Fed. Cir. 2011).
- 14 Rite-Hite, 56 F.3d at 1549.
- 15 609 F. Supp. 2d 279 (N.D.N.Y. 2009).
- ¹⁶ 705 F. Supp. 2d 687 (E.D. Tex. 2010).
- ¹⁷ *Id*. at 690.
- ¹⁸ 589 F.3d 1246 (Fed. Cir. 2009), withdrawn and reissued on petition for rehearing on other grounds, 598 F.3d 831 (Fed. Cir. 2010), aff'd on other grounds, 131 S. Ct. 2238 (2011).
- 19 594 F.3d 860 (Fed. Cir. 2010).
- 20 Id. at 868.
- ²¹ *Id*. at 869.
- ²² Id. at 870-71.
- ²³ *i4i*, 598 F.3d at 852-54.
- ²⁴ *Id*. at 856-57.
- ²⁵ *Id.* at 857.
- ²⁶ Uniloc, 632 F.3d at 1315.
- ²⁷ *Id.* at 1313, 1317.
- ²⁸ *Id.* at 1317.
- ²⁹ *Id.* at 1318.
- ³⁰ See Garretson v. Clark, 111 U.S. 120, 121 (1884).
- ³¹ eBay Inc. v. MercExchange, LLC, 547 U.S. 388 (2006).
- See, e.g., Telcordia Techs., Inc. v. Cisco Sys., Inc., 612 F.3d 1365,
 1378-79 (Fed. Cir. 2010); Paice LLC v. Toyota Motor Corp., 504
 F.3d 1293, 1315 (Fed. Cir. 2007).

Retractable Technologies, Inc. v. Becton, Dickinson & Co.: The Federal Circuit's Debate over Claim Construction Methodology and Deference Rages On

by Megan T. Levine and John J. Molenda¹

I. Introduction

In an October 31, 2011 order rife with heated dissents, the Federal Circuit denied en banc rehearing in Retractable Technologies, Inc. v. Becton, Dickinson & Co., a case presenting a seemingly ideal opportunity for the court to review key aspects of its claim construction precedent. Judge Moore (joined by Chief Judge Rader) and Judge O'Malley issued dissenting opinions which together focused on two highly contentious claim construction issues at the Federal Circuit: (1) the proper use of the specification in interpreting patent claims and (2) the amount of deference, if any, that the Federal Circuit should afford to a district court's claim interpretation.³ Although the court refused to grant rehearing in this case, the dissenting voices have provided compelling arguments for the court to consider a serious reevaluation of its claim construction jurisprudence.

II. Background

The technology at issue in Retractable Technologies involved medical syringes with needles that retracted into the body of the syringe following use.4 The needle retraction feature served as a safety measure to prevent accidental needle pricks by unhygienic needles.⁵ Retractable Technologies, Inc. ("RTI") sued Becton, Dickinson & Co. ("BD") in the Eastern District of Texas, asserting that several models of BD's Integra syringe infringed certain claims of U.S. Patent Nos. 5,632,733, 6,090,077, and 7,351,224 (collectively the "patents-in-suit").6 The parties disputed the construction of several claim terms, one of which is the focus of the present discussion: whether the "body" limitation of the claimed syringe should be limited to covering a onepiece syringe body, or whether that term should also cover a multi-piece syringe body.7 The district court construed the "body" limitation to mean a "hollow outer structure that houses the syringe components," and further interpreted the term to encompass both one-piece and multi-piece syringe bodies.8 As a consequence of this construction, the jury ultimately found that BD's 3 mL Integra product, which possessed a multi-piece body, infringed the pertinent asserted patent claims.9 Subsequently, the district court denied BD's various post-trial motions, including BD's motion for judgment as a matter of law of non-infringement.10

III. Federal Circuit Opinions

A. Three-Judge Panel Opinions

On appeal, BD argued that the claim term "body" should be limited to a one-piece body. BD asserted that the specification notably characterized the invention as being a syringe with a one-piece body, but also criticized prior art syringes having two-piece bodies. 11 RTI responded that the ordinary meaning of "body" is not limited to a one-piece body but also includes a multi-piece body. 12 RTI argued that the doctrine of claim differentiation supports this construction, as some claims recited "body" while others recited the term "one piece body." Additionally, RTI argued that the preferred embodiment, a syringe with a one-piece body, was intended to illustrate manufacturing benefits, not limit claim scope. 14

1. Majority Opinion

The majority disagreed with the district court's claim construction holding that the disclosure in the specification dictated that the term "body" should be limited to a one-piece structure. 15 Judge Lourie's majority opinion rejected RTI's claim differentiation argument in view of the disclosure in the specification and the fact that no claims expressly recited a multi-piece body. 16 In addition, the majority cited the Summary of the Invention, which stated that the "invention is a retractable tamperproof syringe . . . featur[ing] a one piece hollow body."17 The majority also referenced the fact that all disclosed embodiments had a one-piece body and that the specification taught that the prior art had failed to appreciate a one-piece syringe body. 18 While acknowledging the tension between competing claim construction doctrines instructing judges to interpret claims in light of the specification on the one hand, but not import limitations into claims from the specification on the other hand, Judge Lourie appeared comfortable with erring on the side of disregarding the latter rule. He wrote, "In reviewing the intrinsic record to construe the claims, we strive to capture the scope of the actual invention, rather than . . . allow the claim language to become divorced from what the specification conveys is the invention."19

2. Concurring Opinion

In his concurring opinion, Judge Plager wholeheartedly agreed with Judge Lourie's view that the court should seek to construe claims in accordance with cont. from page 7

what the patentee actually invented instead of severing the claims from the invention disclosed in the specification. He stated, "However much desired by the claim drafters, who want claims that serve as business weapons and litigation threats, the claims cannot go beyond the actual invention that entitles the inventor to a patent." Acknowledging the fundamental *quid pro quo* of the patent system, Judge Plager noted that inventors should "make full disclosure of what is actually invented, and . . . claim that and nothing more."

3. Dissenting Opinion

Chief Judge Rader dissented in part, arguing that the claim language makes clear that the "body" limitation should not be limited to a "one-piece body," and that it is improper to import limitations from the specification into the claims.²³ He noted that under Phillips v. AWH Corp., 24 claim language is to be given its "ordinary and customary meaning."25 Chief Judge Rader continued that, in this case, there was no reason to depart from the claim term's ordinary and customary meaning, as no party had alleged that "body" had a special technical meaning in the field of art, and the specification did not include an express disclaimer of claim scope by merely describing a "one piece hollow outer body" in certain passages. 26 Chief Judge Rader further argued that the majority improperly ignored the doctrine of claim differentiation.²⁷ Quoting Phillips, he explained that claim differentiation "gives rise to a presumption that the limitation in question is not present in the independent claim," and that this "strong presumption" was not rebutted here. 28 To conclude, Chief Judge Rader again chastised the majority for improperly importing the "one-piece" limitation from the specification into the claims.²⁹

B. Petition for Rehearing

RTI subsequently sought rehearing *en banc* of the panel's decision. While the court denied RTI's petition, three Federal Circuit judges dissented from this denial in two separate opinions. Judge Moore's dissenting opinion vocalized two chief concerns: (1) the court's apparently inconsistent use of the specification in interpreting patent claims and (2) the Federal Circuit's lack of deference to district court claim constructions. Judge O'Malley's dissent focused exclusively on the issue of deference.

1. Judge Moore's Dissenting Opinion

Judge Moore's dissent, with which Chief Judge Rader joined, first addressed her concern that Federal Circuit panels employ the specification inconsistently when interpreting patent claims. Judge Moore asserted that the process of claim construction should not be confused with a validity determination,³⁰ and that claim terms should be given their plain and ordinary meaning unless "the inventor acted as his own lexicographer" or expressly disavowed claim scope.³¹ Because neither

exception applied in this case, Judge Moore argued that the majority's decision to depart from the plain and ordinary meaning in *Retractable Technologies* cannot be reconciled with the Federal Circuit's *en banc* precedent set in *Phillips*.³²

In further criticism of the majority's reasoning, Judge Moore asserted that the panel erred in rewriting the claims in accordance with the panel's own perception of what the invention "is." Judge Moore also reiterated a point made by Chief Judge Rader's dissent, namely that claim differentiation strongly militated against reading the "one-piece" limitation into the claims, and she viewed the majority's decision not to apply that doctrine as yet another way in which this case conflicted with *Phillips*. Finally, to underscore what she perceived to be conflicts in the court's claim construction methodology, Judge Moore pointed to the differing outcomes reached in several cases, including this one, despite the apparent similarity in fact patterns in the cases.

With respect to her second concern, Judge Moore stated that *en banc* review should have been granted to address the issue of deference to district court claim construction determinations.³⁶ Judge Moore asserted that it is a "fallacy" to view claim construction as a pure question of law.³⁷ Rather, she argued that claim construction is a question of law with underlying facts, and the Federal Circuit should give deference to those factual determinations.³⁸

2. Judge O'Malley's Dissenting Opinion

Judge O'Malley's dissent focused on the issue of deference, including her desire that the Federal Circuit reverse its decision³⁹ in Cybor Corp. v. FAS Techs., Inc.,40 which held that claim construction determinations are purely legal and should be reviewed de novo.⁴¹ Judge O'Malley argued that in Cybor, the Federal Circuit misinterpreted the Supreme Court's decision⁴² in Markman v. Westview Instruments, Inc., 43 which held that claim construction is an issue of law for the court, not the jury, to decide.⁴⁴ Noting that the Supreme Court in Markman characterized claim construction as a "mongrel practice," Judge O'Malley contended that a correct reading of the decision is that claim construction is a mixed question of law and fact and that deference should be given to a district court's factual findings.⁴⁵ Judge O'Malley pointed to several reasons why she viewed such deference appropriate, including district court judges' resources and training, as well as their capacity to hear live testimony in hearings that, in some cases, last for several days. 46 She further noted that the lack of agreement among panel members on the claim construction issues in this case underscored the shortcomings of the Federal Circuit's de novo approach.⁴⁷ Lastly, Judge O'Malley argued that in cases such as this one, where "there is fair debate about the scope of the invention after application of Phillips's principles, we should defer to reasoned district court choices."48

C. Conclusion

While the Federal Circuit did not deem Retractable Technologies to be an appropriate vehicle through which to reassess the issues of claim construction methodology and deference, these issues may not remain dormant for long. As Judge O'Malley referenced in her dissent, five of the ten currently active judges on the court agreed in Amgen Inc. v. Hoechst Marion Roussel, Inc. 49 that the Federal Circuit should revisit its ruling in Cybor. 50 Five years after Amgen, the dissenting opinions in this case renew that call and additionally seek reexamination of the court's claim construction methodology. With one newly confirmed nominee and another nominee about to embark on the confirmation process,⁵¹ it would not be surprising if the court decides to revisit these issues in the near future.





(Endnotes)

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² Retractable Techs., Inc. v. Becton, Dickinson & Co., No. 2010–1402, 2011 WL 5222835 (Fed. Cir. Oct. 31, 2011) (Retractable Techs. III).

⁴ Retractable Techs., Inc. v. Becton, Dickinson & Co., 653 F.3d 1296, 1298 (Fed. Cir. 2011) (Retractable Techs. II).

⁶ The patents-in-suit share a common specification for the issues discussed in this case, so for simplicity we refer only to the specification of U.S. Patent No. 5,632,733 throughout this article. See id. at 1298, 1300 n.1. 7 See id. at 1304-05.

8 Id. at 1302 (citing Retractable Techs., Inc. v. Becton, Dickinson & Co., No. 2:07-CV-250, 2009 WL 837887, at *6-7 (E. D. Tex. Jan. 20, 2009) ("Retractable Techs. I Claim Construction Order")). See id. at 1298.

¹⁰ *Id*.

11 Id. at 1304.

 12 *Id*.

¹³ *Id*.

14 Id. at 1304-05.

15 See id. at 1305.

16 See id.

¹⁷ *Id.* (emphasis added).

²⁰ Id. at 1311 (Plager, J., concurring) (citing Majority Op. at 1305).

²² Id.

²³ Id. at 1312 (Rader, C.J., dissenting).

²⁴ Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

²⁵ Retractable Techs. \hat{II} , 653 F.3d at 1312 (Rader, C.J., dissenting) (citing Phillips, 415 F.3d at 1312).

²⁶ See id. at 1312-13.

²⁷ Id. at 1312.

²⁸ Id. (citing Phillips, 415 F.3d at 1315).

²⁹ *Id.* at 1313.

³⁰ Retractable Techs. III, 2011 WL 5222835, at *2 (Moore, J., dissenting).

³¹ *Id.* (citing *Phillips*, 415 F.3d at 1316).

³³ Id. at *3 (citing Retractable Techs. II, 653 F.3d at 1305).

³⁴ *Id*.

35 See id. at *4 (citing Arlington Indus., Inc. v. Bridgeport Fittings, Inc., 632 F.3d 1246 (Fed. Cir. 2011); Laryngeal Mask Co.. v. Ambu A/S, 618 F.3d 1367 (Fed. Cir. 2010); Fifth Generation Computer Corp. v. Int'l Bus. Mach. Corp., 416 F. App'x 74 (Fed. Cir. 2011)).

³⁷ *Id*. ³⁸ *Id*.

39 Id. at *5 (O'Malley, J., dissenting).

40 Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448 (Fed. Cir. 1998) (en

41 Id. at 1451, 1456.

⁴² See Retractable Techs. III, 2011 WL 5222835, at *5 (O'Malley, J., dissenting).

⁴³ Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996).

⁴⁵ See Retractable Techs. III, 2011 WL 5222835, at *5 (O'Malley, J., dissenting).

⁴⁶ Id.

⁴⁷ *Id.* at *6.

48 Id. at *7.

⁴⁹ Amgen Inc. v. Hoechst Marion Roussel, Inc., 469 F.3d 1039 (Fed. Cir.

⁵⁰ Retractable Techs. III, 2011 WL 5222835 at *7 (O'Malley, J., dissenting). ⁵¹ See Steve Tetreault, Former Las Vegas Attorney Confirmed as Appeals Judge, Las Vegas Review-Journal, Nov. 8, 2011, http://www.lvrj.com/ news/former-las-vegas-attorney-confirmed-as-appeals-judge-133451268. html?ref = 268.

Summary of October 4 "Meet the Bar Associations at New York Law School"

n October 4, 2011, Michael Bullerman, Co-Chair of the Young Lawyers Committee, represented the NYIPLA at New York Law School's Meet the Bar Associations event. The event was designed to allow students at NYLS to discover additional information concerning various bar associations through discussions with representatives from each organization. Throughout the two-hour event, more than two dozen law students visited the NYIPLA booth with questions about the NYIPLA, asking whether they could get involved prior to graduation and participating in general discussions concerning careers in intellectual property law. Available for NYLS students at the booth were membership applications and information on the NYIPLA and the NYIPLA's upcoming events. Few of the pamphlets remained at the end of event, as many students left with promises to join as student members and attend upcoming NYIPLA programs.

SUPREME COURT 2011 - 2012 IP CASE PREVIEW

by Mayer Brown LLP's Supreme Court & Appellate Practice

As of publication, the Supreme Court will review three patent cases during its October 2011 Term.

Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S, No. 10-844 (set for argument Dec. 5, 2011)

Issue: Hatch-Waxman Act – Counterclaims

Under the Hatch-Waxman Act, there are two ways in which manufacturers may seek FDA approval to market generic versions of patented drugs. The first, a "Paragraph IV certification," requires the generic manufacturer to certify that the patent is invalid or will not be infringed by the use of the drug. That certification is treated as a constructive act of infringement, which allows the brand owner to sue the generic manufacturer. The second method, a "Section viii statement," allows the generic maker to propose a "carve-out" label. These labels list only those FDA-approved uses for the drug that are not covered by the patent. Rather than interpret patents itself, the FDA, which evaluates proposed drug labels, relies on the patent holder to identify which "use codes" are patented. The Hatch-Waxman Act allows a manufacturer of generic drugs to challenge those use codes if sued for infringement by filing a counterclaim seeking an order "requiring the [patent] holder to correct or delete the patent information submitted by the holder" to the FDA. 21 U.S.C. § 355(j)(5)(C)(ii)(I). The Supreme Court granted certiorari to clarify the scope of generic makers' right to bring these counterclaims. The Court's decision will be important to manufacturers of both name-brand and generic drugs.

Caraco is a generic manufacturer that sought FDA approval to market the diabetes drug repaglinide, on which Novo Nordisk holds a patent. Caraco first filed a Paragraph IV certification, which prompted an infringement suit by Novo Nordisk. Caraco then filed a Section viii statement, which carved out certain uses of the drug from its proposed label. Based on the use code originally submitted by Novo Nordisk, the FDA approved the carve-out label. Novo Nordisk then revised its statement, including a less specific description of the patented use. That revision led the FDA to revisit its earlier decision and reject Caraco's proposed label, finding that the proposed uses were covered by Novo Nordisk's patent after all.

The district court in the infringement suit ordered Novo Nordisk to restore its original use code.

On interlocutory appeal (while the trial on patent validity and enforceability was stayed), a divided panel of the Federal Circuit reversed, holding that the counterclaim provisions of Hatch-Waxman are available only if the patent "does not claim any approved methods of using the drug," not when the use code is merely overbroad. 601 F.3d 1359, 1365. The court also held that the counterclaim may seek the correction only of "an erroneous patent number or expiration date," not an erroneous "use code narrative." *Id.* at 1366.

Mayo Collaborative Services v. Prometheus Laboratories, Inc., No. 10-1150 (set for argument Dec. 7, 2011).

Issue: Patent Law – Patentability under 35 U.S.C. § 101

Federal law allows inventors to patent "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. There are, however, "three specific exceptions to Section 101's broad patent-eligibility principles: laws of nature, physical phenomena, and abstract ideas." *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010). The Supreme Court granted certiorari in this case in order to examine the scope of these exceptions, as they apply to observed medical correlations between blood test results and patient health.

Prometheus's patent claims relate to tests for the efficacy and toxicity of thiopurine drugs used to treat autoimmune diseases, such as Crohn's disease. Prometheus's claims involve administering a thiopurine drug, determining the resulting level of certain metabolites of the drug in the blood, and considering what use, if any, to make of that information. In accordance with this patent, Prometheus markets a metabolite-concentration test. When Mayo announced its intent to market its own metabolite-concentration test, Prometheus brought suit alleging patent infringement.

Afederal district court invalidated Prometheus's patent under the natural laws/physical phenomena exceptions. The court held that the first two steps of Prometheus's method were merely "data-gathering" steps, and that the final step was merely a "mental step" in the mind of the treating physician.

At its core, according to the district court, Prometheus was attempting to patent the correlation between metabolite-concentration levels and concentration levels and patient health, preempting all practical uses of that biologic correlation. This correlation, as a natural law or physical phenomenon, was unpatentable.

The Federal Circuit reversed, finding that Prometheus's claims satisfied the "machine-ortransformation" test because both the administering of thiopurine and the subsequent testing of a blood sample were physically "transformative" and not merely "data-gathering" steps. Thus, the Federal Circuit reasoned, Prometheus's claims did not inappropriately "preempt all uses of the natural processes; they utilize them in a series of specific steps." 581 F.3d 1336, 1349 (Fed. Cir. 2009). Mayo sought certiorari, and the Supreme Court granted, vacated, and remanded in light of its decision in *Bilski*. On remand, the Federal Circuit adopted substantially the same analysis as before. 628 F.3d 1347 (Fed. Cir. 2010).

Mayo again petitioned for certiorari, arguing that the case presented an opportunity to address an issue left unresolved in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006). The LabCorp petition – which was ultimately dismissed as improvidently granted over the dissent of Justices Stevens, Breyer, and Souter – similarly addressed the patentability of a method that focused on a natural medical correlation. In their dissent, the three Justices argued that LabCorp's patent should be invalidated under the "law of nature" exception.

Disclaimer: Mayer Brown LLP is co-counsel to the petitioner, Mayo Collaborative Services, in this case.

The NYIPLA filed an amicus curiae brief in this case. *See* http://www.nyipla.org/images/nyipla/Documents/Amicus%20Briefs/MayovPrometheusNo2010-1150%20090811.pdf

Kappos v. Hyatt, No. 10-1219 (set for argument on Jan. 9, 2012)

Issue: Patent Act – Introduction and Review of Evidence in Challenges to Patent Denial

When the United States Patent and Trademark Office ("PTO") denies an application for a patent, the applicant may seek judicial relief in two different ways. The applicant may either seek review directly in the Federal Circuit or file a civil action against the PTO in federal district court, pursuant to 35 U.S.C. § 145. If an applicant files a civil ac-

tion in district court, he or she may offer evidence not previously submitted to the PTO. In *Kappos* v. *Hyatt*, the Supreme Court granted certiorari to consider the scope of evidence that may be introduced and the standard to be applied when reviewing the PTO's decision in light of that new evidence.

In the decision below, 625 F.3d 1320 (Fed. Cir. 2010), the Federal Circuit explained that a Section 145 action is no "different from a customary civil action" and that Section 145 does not establish "unique rules of evidence" that "limit an applicant's ability to introduce new evidence before the district court." *Id.* at 1327. Canvassing the pre-Patent Act history, the court concluded that in Section 145 proceedings, "Congress intended that applicants would be free to introduce new evidence . . . subject only to the rules applicable to all civil actions." *Id.* And new evidence, the court held, is subject to *de novo* review.

In its petition for certiorari, the United States contended that new evidence in Section 145 proceedings should be limited to material that could not reasonably have been presented to the PTO. The government grounded this argument in principles of agency exhaustion as well as pre-1952 practice, which the government contends was adopted by the Patent Act. The government further argued that when reviewing the PTO's decision to deny a patent application, courts should apply a deferential – rather than *de* novo – standard of review.

In *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238 (2011), the Supreme Court recently confirmed that a party challenging the validity of a patent in the course of an infringement suit must establish invalidity by clear and convincing evidence, even when the evidence supporting a claim of invalidity was not previously presented to the PTO during patent prosecution. Following *Microsoft*, the government filed a supplemental brief, arguing that the Federal Circuit's rule with respect to Section 145 "create[s] an unjustified asymmetry between judicial review of patent grants and review of patent denials." U.S. Supp. Br. at 3. The government urged review to "correct that disparity." *Id.* at 4.

Hyatt will thus delineate the scope of Section 145 actions with respect to both admissible evidence and the proper standard of review.

The NYIPLA filed an amicus curiae brief in this case. *See* http://www.nyipla.org/images/nyipla/Documents/Amicus%20Briefs/KapposvHyatt-No.10-1219.pdf



"As Time Goes By – Patent Reform Gone Awry"

by Dale Carlson

In summing up the America Invents Act ("AIA") in as few words as possible, GWU Law's Professor Hal Wegner put it thusly: "It's bad law, but it's the law. Get over it." A recent practitioner survey cited by the Patently-O blog suggested that fully seventy percent of patent practitioners surveyed agree with Prof. Wegner's assertion that it's bad law.

How did we stumble upon this sad time for our patent system – a time that is the antithesis of the "golden age of patent law" that Past President Andrea Ryan hailed during her time as NYIPLA President? Perhaps we were waiting for another Judge Giles S. Rich to materialize, join our ranks, and set things right. That certainly didn't happen, at least not soon enough. More likely a myriad of factors were involved: a sense by some in the popular press that the patent system had gotten too big for its britches and that small patent players had developed too much clout for their size as users of the system; and a sense that the big patent players perceived a pressing need, and a once-in-a lifetime opportunity, to slant the system to their advantage using their lobbying clout.

In reflecting on this legislative sea change, there's good news and bad news. The good news is that the NYIPLA was not a significant force behind this change. The bad news is that the NYIPLA was not a significant force to counter this change, and to propose a better approach.

One's mind stumbles over the idea that the NYIPLA was "not a significant force" in addressing misplaced IP reform. That concept is shocking, particularly in light of the fact that the NYIPLA has played a key role several times in decades past in defending and strengthening our IP systems, and in propounding progressive IP legislation - legislation that actually advanced public policies underlying our nation's IP systems.

Consider the Lanham Act of 1946. Several members of our Trademarks Committee at the time, including Committee Chair Sylvester J. Liddy, testified before Congress in support of the Act. The end result was an Act that improved protection for trademarks.



Consider the Patent Act of 1952. At a meeting of the National Council of Patent Law

Dale Carlson, a partner at Wiggin and Dana, is NYIPLA Historian and its Immediate Past President. Associations (predecessor of the "NCIPLA") in 1950, NYIPLA Past President Giles Rich and GWU Law's Paul Rose were appointed as a two-person drafting committee for the Act, in coordination with the Patent Office's Pasquale Federico. The end result was an Act that improved our patent system in a myriad of ways.

What went awry with the patent bill drafting process, beginning in the mid-2000s, and leading up to the AIA's enactment? Most importantly, the NCI-PLA was abolished by the AIPLA, leaving the voice of local and regional IP law associations stuck in a virtual vacuum.

What needs to be set right? For one thing, ambiguities in the AIA's language are rampant. The words in the statute literally stumble over each other. Witness, for example, the phrases "inter partes reexamination," "inter partes review," and "post-grant review" as set forth in the statute. All three procedures are post-grant, and all three are inter partes. Needless to say, the conceptual overlap leads to confusion, even among the experts, and will doubtless befuddle users of the patent system. Confusion leads to uncertainty for patent users and practitioners alike.

As Federal Circuit Judge Pauline Newman, a former NYIPLA Board Member, stated in her dissenting opinion in *In re Bilski*: "Uncertainty is the enemy of innovation. These new uncertainties not only diminish the incentives available to new enterprise, but disrupt the settled expectations of those who relied on the law as it existed." The uncertainty caused by ambiguous, and sometimes retroactive, provisions of the AIA risks damaging our nation's patent system for decades to come.

How can things be set right? Legislation to supplement, or better yet supplant, the AIA is likely needed. PTO rulemaking is not up to the task for the simple reason that substantive changes are needed, and the PTO's authority is limited to procedural changes.

How do we, as an Association, become an agent for change to the AIA? The most straightforward way is to emulate our Association's past successes on the legislative front. Perhaps we can catalyze the formation of a new network of IP law associations - one that is separate and distinct from the national IP organizations. Come to think of it, "NNIPLA" has a nice ring to it, and the "NN" part of the acronym could serve double duty as "not national." Hopefully, we'll always be able to take pride in our Association's regional character, and its mettle too!

With kind regards, Dale Carlson

The views expressed herein are those of the author and do not reflect the views of his firm or the NYIPLA.



on 21 September 2011, the NYIPLA Committee on Meetings and Forums hosted a Continuing Legal Education (CLE) luncheon at the Union League Club. The program was titled "An In-House Perspective on IP Practice: Coordinating with Business Units and Legal Teams to Maximize Opportunities and Overcome Challenges." The program was co-sponsored by the NYIPLA Women in IP Law Committee. Sona De of Ropes & Gray LLP served as moderator.

The panel of speakers included Mony Ghose, IP Counsel at Becton, Dickinson and Company; Stephanie Monaco, Assistant General Counsel and Primary Care Unit Patent Lead at Pfizer, Inc.; Laura Sheridan, Patent Counsel at Google Inc.; and Paula Wittmayer, Senior Associate Director and IP Senior Counsel at Boehringer Ingelheim USA Corporation.

The speakers covered a range of topics on the role of an in-house attorney and how outside counsel can provide effective service, particularly in three interrelated areas: managing risk, communicating effectively, and managing cost. They highlighted two questions in-house attorneys ask outside counsel: "What is the probability of success?" and "Can we do more with less?"

The speakers offered practical advice for outside counsel working with business clients and their in-house attorneys:

- Learn the business to understand challenges facing the client
- Understand the client's timelines
- Respond to voicemails and e-mails promptly, even if only to indicate you have received the message
- It's OK not to give an immediate answer—if you need to do some research, say so
- Simplify the issues
- Help the in-house attorney manage risk; solve problems instead of merely identifying them
- Understand the organization, so when you need approval for something you can go to the right person
- Communicate in business language; make documents easy to read
- Always establish a budget before starting a project
- Think in terms of what the deliverable is, and the timeline for delivering it; often the simple, low-cost approach is best – "No need to buy a Cadillac when a Chevy will do"

My thanks again to all of the panelists and attendees.

-- Jay H. Anderson

on Meetings and Forums hosted a Continuing Legal Education (CLE) luncheon at the Union League Club. The program was titled "Recent Developments in U.S. Trademark and Unfair Competition Law" and was co-sponsored by the NYIPLA Trademark Law and Practice Committee. Ted Davis, a partner in the Atlanta office of Kilpatrick Townsend and Stockton LLP, was the featured speaker. Sabina Vayner, an associate at Kilpatrick Townsend and Stockton LLP, prepared the written materials with Mr. Davis.

Mr. Davis presented highlights of recent cases on establishing protectable rights in marks; proving infringement; the abandonment defense to infringement; remedies; and registration practice. Here is a brief summary:

Establishing protectable rights

The Federal Circuit confirmed that registration on the Supplemental Register cannot serve as evidence of a mark's validity. Courts differed on the evidentiary value of a non-incontestable registration on the Principal Register (e.g., a registration that has not reached its fifth anniversary). Some courts held that such a registration shifts the burden of proof of invalidity to the challenger of

a mark; others held that it shifts only the burden of production of evidence. The Seventh Circuit held that presumption of validity "evaporates" as soon as evidence of invalidity is presented, and that even an incontestable registration merely shifts the burden of production.

The Federal Circuit addressed the issue of when a mark's inherent distinctiveness should be measured, and held that it should be at the time of registration (as opposed to the time of first use).

In cases dealing with the nonfunctionality requirement for a valid mark, two opinions found colors to be functional (one for aesthetic reasons, the other for utilitarian reasons). In cases involving incontestably registered marks and related utility patents, three opinions found that disclosure of the utility patent weighed against nonfunctionality of the mark.

Proving infringement

A Second Circuit district court confirmed that its applicable likelihood-of-confusion factors would apply with equal force to claims for forward and reverse confusion. The same opinion confirmed that a sequential array survey should not be used if the parties' goods were not sold side-byside; a monadic survey should be used instead.

cont. on page 14

Two cases showed that technicalities matter when seeking to prove counterfeiting: The plaintiff's complaint must establish that the goods sold by the defendant were covered by plaintiff's registration. To be considered a "counterfeit mark," a mark must be identical to or substantially indistinguishable from a registered mark.

In cases relating to the likelihood of dilution, two opinions found that a showing of identity or near-identity of marks was not a prerequisite for a finding of likely dilution.

Defenses based on claims of abandonment

Courts examined two theories of abandonment: use of a mark discontinued by its owner without an intent to resume use; and "naked licenses" under which the mark owner does not control the nature and quality of the goods and services. A Second Circuit district court found that an owner's use of the term "formerly" in conjunction with a mark evidences a lingering use, precluding a finding of abandonment. The Seventh Circuit held that by failing to monitor or control licensee's use of a mark during the term of a license agreement, the mark owner granted a naked license when the agreement expired. The Second Circuit held that a naked license does not result in loss of all the licensor's rights, but only in geographic areas where the mark loses its significance.

Remedies

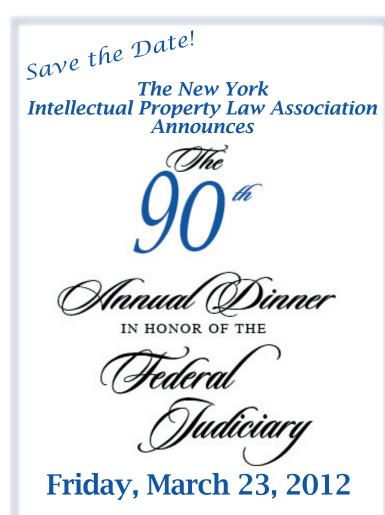
Several courts questioned the viability of the rule that if a mark owner demonstrates likely confusion, there is a presumption of irreparable harm that warrants injunctive relief. Nevertheless, opinions dispensing with the presumption often issued injunctive relief anyway (for example, where plaintiff presented proof that sale of defendant's lower-priced goods would result in unquantifiable lost sales).

Registration practice

Where a registrant admitted it had sold only some of the goods covered by its registration, the Trademark Trial and Appeal Board found that the averment of actual use had been false, but nevertheless did not find fraud on the USPTO. The Board used its authority to restrict the registration rather than cancelling it in its entirety.

In two other cases, the Board found that the test of an applicant's bona fide intent to use a mark is an objective one; the applicant must have contemporaneous, documentary evidence of its intent.

-- Jay H. Anderson



The Waldorf=Astoria Hotel, New York City

Keynote Speaker



Honorable Colleen McMahon United States District Judge for the Southern District of New York

More information at www.nyipla.org

U.S. Bar – JPO Liaison Council Report

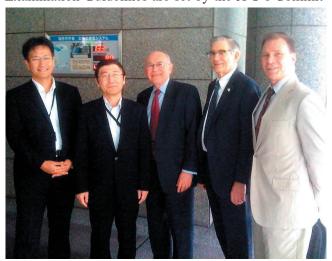
By John B. Pegram, NYIPLA Delegate

The U.S. Bar – JPO Liaison Council visited Tokyo on June 1, 2011 for its annual meeting with the Japan Patent Office. Eleven delegates of U.S. bar groups (including several members of the NYIPLA) and three American guests met with nine JPO representatives led by Deputy Commissioner Koichi Minami, the top career official. As usual, the meeting consisted of an exchange of presentations on current Japanese and U.S. patent issues. The Japanese presentations and responses to questions are summarized here.

Following introductory remarks, Deputy Director Yuichiro Nakaya of the International Affairs Division provided current JPO statistics and explained an amendment to the Japanese Patent Act that was passed by the Diet on May 31, 2011. Over the past two years there has been a slight decrease in the number of JPO filings and the trend on the backlog of cases awaiting first action is steadily decreasing. The new law creates "derivation" actions under which an award of a derived patent or application can be transferred to the inventor from whom the invention was derived.

Director of the Examination Policy Planning Office, Kosuke Minami, announced a new Patent Prosecution Highway (PPH) initiative called the "MOTTAINAI Model." Under this proposal, PPH programs would be based on the allowance of claims in any patent office, not just the "Office of First Filing" (OFF). Shortly after our meeting, the USPTO announced a pilot program of this type, effective July 15, 2011. Mr. Minami also reported on the US-JP and JP-US PPH programs, noting that Japanese applicants are making much more use of the PPH than US applicants.

In the afternoon, the Director of the JPO Examination Standards Office, Ms. Reeko Imamura, explained how the JPO examiners apply the inventive step requirement during examination. Ms. Imamura explained that Examination Guidelines are set by the JPO's Commit-



Intl. Affairs Dir. Sawai, Deputy Commissioner Minami with US Council Members Helfgott, Pegram and Guetlich

tee on Examination Standards, noting the February 17, 2010 Case Study on Inventive Step, available on the JPO website (www.jpo.go.jp/shiryou/kijun/kijun2/pdf/tuku-jitu_casestudy/progre_en.pdf).

Later, Ms. Imamura explained how JPO Examiners apply the written description, support, and enablement requirements during examination. She noted that these examination guidelines were under review, but she did not anticipate any drastic changes.

The meeting concluded with a question-and-answer period. The JPO representatives indicated that the JPO generally favored the WIPO's proposed Patent Law Treaty (PLT). With respect to search reports, they noted that the JPO outsources much of its prior art searching. Applicants can have the JPO's outsourcing partners conduct the prior art search in advance and provide the report to the JPO when filing their applications. When asked about compulsory licensing, the JPO reported there are no plans currently being developed by the JPO to require that. The JPO representatives requested the US Council Members' opinions regarding the "double track" system in contesting patent validity in Japan, under which JP patent validity can be contested either during an infringement action in court or in an invalidity proceeding at the JPO. U.S. delegates noted the similarity to a "double track" in the United States consisting of patent litigation in the courts and Reexamination proceedings at the USPTO. The then-pending U.S. Patent Law Reform legislation provides for expanded USPTO review proceedings of issued patents. The general view expressed was that proceedings before patent offices were generally less time consuming and less expensive than litigation. However, it was also noted that the double-track type proceeding could cause delays and piece-meal resolution of issues, which often are factors considered by US judges in deciding whether or not to stay a litigation in favor of a USPTO proceeding.

On June 2, 2011, US Council Members visited the

Japan IP High Court, where they met Chief Judge Nakano and colleagues from all four of the Court's Divisions, as well as judges of the IP Division of the Tokyo District Court. The Judges provided presentations on the structure of the Court and recent decisions regarding inventive step. Two examples of inventive step decisions were contrasted; one finding inventive step and the other finding no inventive step. The decisions appeared to be much in line with Federal Circuit opinions and the Court expressed its high regard for the reasoning in US appellate and Supreme Court decisions.



John B. Pegram is a Past President of the NYIPLA and a Senior Principal of Fish & Richardson, P.C.



MINUTES OF JULY 12, 2011

MEETING OF THE BOARD OF DIRECTORS OF THE NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION

The meeting of the Board of Directors was called to order at the offices of Mayer Brown, 1675 Broadway, New York, New York at 12:00 P.M. by President Terri Gillis.

In attendance from the Board:

Theresa Gillis Walter Hanley
Thomas Meloro Bruce C. Haas
Anthony Lo Cicero Jeffrey Butler Ira Levy

John Moehringer
Annemarie Hassett
Sue Progoff

Kevin Ecker (by telephone)
Alexandra Urban (by telephone)
Leora Ben-Ami (by telephone)

Absent and excused from the Board: Dorothy Auth and Charles Hoffmann. Feikje Van Rein was in attendance from the Association's executive office.

Terri Gillis called the meeting to order.

The Minutes of the June Board meeting were approved.

As relates to the financial situation, Jeffrey Butler reported the 2010-2011 draft Financial Statement as presented by John Lisa, NYIPLA's accountant. He requested approval from the Board to move the Judges Dinner expenses into the current year which means 2011-2012 will take a double year but in years coming the revenue and expenses will be reported in the same fiscal year. In his new role as treasurer, Jeffrey has reviewed current financial procedures and requested approval from the Board to streamline deposits and upgrade QuickBooks and online bill payment. The Board passed a motion to allow the Treasurer to pay bills online up to an amount of \$10,000. All invoices over \$10,000 require approval from the President or President-Elect except the monthly RRR invoice. Jeffrey will circulate a resolution for approval by the Board. Terri Gillis reinforced that the NYIPLA needs an independent accountant who can perform an annual audit not necessarily in the capacity of the current accountant who serves more like a controller. The Treasurer needs to remain in full control over the accounts receivables as well as payables.

Jeffrey will discuss with Citibank NYIPLA's investments in various CDs. The Board passed a motion to move the funds into non-risk interest-bearing accounts dependant on FDIC insurance. Another item still in need of follow up is the Certificate of Incorporation due to the entity name change in the 501(c)(6) letter from IRS and NY state filings. These changes will need to be coordinated with the Secretary, Dorothy Auth.

Jeffrey Butler, as Treasurer, read the name of one new NYIPLA member. The new member was approved by the Board.

Ira Levy, as Board Liaison of the Meetings and Forums committee reported on the status of the CLE Luncheon planning. Each luncheon will be managed in

conjunction with one of the other committees. He presented an Editorial Calendar for the upcoming year.

Sue Progoff, as Board Liaison of the Trademark Committee, reported a successful Trademark program in June with a profit of \$2,500. The Board agreed that July might be a better month for the Trademark event in the future.

An overall discussion was initiated on the Committee Preference Selection and the overall reply rate of volunteers. The Board exchanged ideas to attract more and new members to be involved in the activities of the Association.

Kevin Ecker, as Board Liaison for the Inventor Of The Year Award committee, reported that his committee is looking for ways to increase the number of submissions by contacting other associations. The committee may publicize its request for submissions by early October and to move the submission deadline to mid December.

Anne Hassett, as Board Liaison for the Young Lawyers committee, reported on the upcoming program at the Princeton Club. The program is going to be based on hypotheticals moderated by Dan Reagan from Goodwin Procter. Current attendance is at 75 people.

Bruce Haas, as Board Liaison for the Membership Committee, reported on the status of the membership renewal process which is far ahead in timing of last year. The Board discussed various marketing ideas, and the possibility of an overall marketing plan, which includes the possibilities of joint programming. Bruce Haas will collect input from Board members which can be used to communicate with potential members regarding NYIPLA membership.

Tom Meloro, as Board Liaison for the Amicus Committee, communicated the committee's request to prepare a brief in *Kappos v. Hyatt*| in the Supreme Court in support of the Hyatt position. A motion was passed, with no recusals. Regarding the Mayo v. Prometheus case, the Board was asked by the committee to file a brief in support of neither party. The Board requested a more detailed outline of the position, to be followed by a Board conference call. Subsequently, a conference call was conducted on July 18, 2011 at 4pm, and a motion to authorize preparing the brief was passed. Terri Gillis, Jeffrey Butler and Susan Progoff were recused.

Terri Gillis reported that NYIPLA had been asked to provide input into Local Patent Rules being considered in the Eastern and Southern Districts of New York courts. Input will be solicited from various firms and individuals, with the intention of communicating suggestions to the Rules Committee of those courts.

The meeting was adjourned by Terri Gillis at 2:10pm.

MINUTES OF SEPTEMBER 13, 2011

MEETING OF THE BOARD OF DIRECTORS OF THE NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION

The meeting of the Board of Directors was called to order at The Princeton Club, 15 West 43rd Street, New York, New York at 7:30 P.M. by President Terri Gillis.

In attendance from the Board:

Theresa Gillis
Thomas Meloro
Charles Hoffmann
Dorothy Auth
Jeffrey Butler
John Moehringer

Sue Progoff
Walter Hanley
Bruce C. Haas
Dale Carlson
Ira Levy
Kevin Ecker
Annemarie Hassett

Alexandra Urban and Leora Ben-Ami participated by telephone. Absent and excused from the Board was Anthony Lo Cicero. Robin Rolfe and Feikje Van Rein attended from the Association's executive office.

Terri Gillis called the meeting to order.

The Board approved The Minutes of the July Board meeting.

Tom Meloro reported that the Amicus Committee proposed the preparation of an Amicus Brief for the case entitled *Cybersource Corp v. Retail Decisions, Inc.*, wherein the brief would be due on September 29, 2011. Tom also indicated that an author is available to prepare the brief. After some Board discussion, solicitation of comments and a vote was scheduled to be requested on Sept. 16th.

Jeffrey Butler, as Treasurer, reported that the Association is on solid footing. Jeffrey also noted that an audited financial statement will need to be prepared.

The new members list was reviewed and discussed by the Board. Walter Hanley noted that Elizabeth Mansfield was listed as a new member but was not an attorney. Discussion regarding how the list of new members is generated ensued, and the executive administrators agreed to review the forms for new membership.

Terri Gillis discussed ways to stimulate early member registration and renewal, i.e., before the Judge's dinner. In addition, Terri considered ways to make the NYIPLA more relevant to its current members. A suggestion was made to conduct a survey of current members asking why they are members. Other suggestions included sending timely notices or announcement of news, such as enactment of new laws in IP to the membership, by email blast or website posts. Dale Carlson suggested that such email blasts may be too much of an intrusion and create an information overload on our members. Annemarie Hassett suggested we circulate Wikis, which are short summaries of important information to our members. Kevin Ecker suggested that instead of additional written materials, the NYIPLA prepare and circulate short videoclips that talk about the relevant news. Other Board members endorsed the videoclips idea. Terri concluded this topic discussion by requesting that the Publications and Website & Records committees investigate ways of implementing the videoclips and other ideas. Walter Hanley, as Board Liaison to the Publications Committee, and Dale Carlson, as Board Liaison to the Website & Records Committee, will discuss with their committees.

Terri Gillis discussed the Patent Pilot program and the preparation and review of proposed local rules regarding patent cases in the SDNY and EDNY. These draft rules are intended to address the need for flexibility in patent litigations. They also address recent legislative and precedential changes in patent law. The EDNY and SDNY rules committees are reviewing the draft rules to bring them into conformity with EDNY and SDNY practice. The rules will be subject to further review and comment.

Terri Gillis discussed Judge Seybert's efforts to obtain sponsorship for the International Association of Judges. Eight law firms have already committed to sponsor in the amount of \$3,000 - \$5,000 each.

Terri Gillis discussed the request by the AIPPI-US to advertise their event through the NYIPLA. The AIPPI requested the NYIPLA's mailing list so that it could circulate the announcement for the AIPPI's annual meeting. After some Board discussion, the Board resolved to not release the member list, but rather offer to post a passive web-post of the AIPPI meeting announcement on the events page of the NYIPLA website.

Annemarie Hassett reported on the most recent event organized by the Young Lawyers Committee, which occurred in July 2011. The program was well attended and provided an excellent opportunity for the law students to practice their networking skills. Another event centered around preparing to take the Patent Bar exam will be scheduled for January 2012.

Dorothy Auth reported on the preparations undergoing for the November 2011 One-Day Patent Law event. Dorothy reported that although almost all of the speakers are confirmed, the CLE Committee is still searching for a keynote speaker. Suggestions were made by Board members regarding several potential candidates.

Kevin Ecker reported on the Inventor of the Year project. Kevin suggested moving the due date for identifying candidates. The Board discussed this proposal as well as other parameters of the Inventor of the Year honor. It was concluded that the identification of an Inventor of the Year must be considered on a case-by-case basis and that bright-line rules relating to geographical or extent of honor are inappropriate.

Charles Hoffmann reported on the progress for preparations of the Judge's Dinner. Charles reported that the Honored Guest list will be reviewed by Terri Gillis, Tom Meloro and himself.

The Board also discussed whether the NYIPLA's Annual Dinner should be expanded to include committee meetings. Feikje suggested that the event could start with a lunch, then Committee meetings could be held, followed by the dinner event. Terri decided that the Board would postpone making a decision on this event until Anthony Lo Cicero was present.

Tom Meloro proposed that the NYIPLA pay respect to a long-time and devoted member, Ron Clayton, who recently passed away. Tom suggested that the NYIPLA make some monetary donation or sponsor an event in Ron's honor. Bruce Haas provided the information regarding a charity organization requested by Ron's family, as follows:

Mercy Learning Center 637 Park Avenue Bridgeport, CT 06604

The meeting was then adjourned by Terri Gillis at 9 pm.

MINUTES OF OCTOBER 11, 2011

MEETING OF THE BOARD OF DIRECTORS OF THE NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION

The meeting of the Board of Directors was called to order at the offices of Mayer Brown, LLP, 1675 Broadway, New York, New York at 5 P.M. by President Terri Gillis.

In attendance from the Board:

Annemarie Hassett

Theresa Gillis
Charles Hoffmann
Anthony Lo Cicero
Dorothy Auth
John Moehringer

Walter Hanley
Sue Progoff
Kevin Ecker
Leora Ben-Ami

Jeffrey Butler and Dale Carlson participated by telephone conference. Absent and excused from the Board were Thomas Meloro, Ira Levy, Bruce C. Haas and Alexandra Urban. Feikje Van Rein attended from the Association's executive office.

Terri Gillis called the meeting to order.

The Board approved The Minutes of the September Board meeting as amended to include Jeffrey Butler's amendment regarding the need for an audited financial statement.

Terri reported that there were no new Amicus Committee issues. However, Anthony added that there are many cases to watch.

Jeffrey reported that the Association is closely tracking this year's expenses as compared to last year's. However, Jeffrey noted that the Association's web expenses have increased. Terri remarked that the Association must remain mindful to continue to vigorously promote the Association's CLE events.

Leora remarked that she did not feel that the recent Women's Committee-sponsored lunch CLE event was very well promoted. Despite this, Annemarie reported that the Women's Committee-sponsored lunch CLE event was a worthwhile event and was well received. Some discussion followed regarding the upcoming Trademark Committee-sponsored CLE luncheon and the lack of early registrations for the event. Terri also remarked on the issue of whether the Association should be more attentive to inviting local speakers rather than out-of-towners in order to more appropriately encourage participation of local members/attorneys and keep costs under control.

Jeffrey read the new members list and the Board approved.

Anthony remarked that the new patent laws will bring litigators into the Patent Office in order to participate in the new Post-Grant Review and Inter Partes Review procedures. This change may prompt new interest in learning about patent office procedures and obtaining patent registration numbers.

Terri announced that the NYIPLA will donate \$1000 to the Ron Clayton Memorial Fund.

Terri discussed the Patent Pilot program and the prepara-

tion and review of proposed local rules regarding patent cases in the SDNY and EDNY. These draft rules are currently "in committee."

Terri announced that the SIPO is forming a US Bar Liaison Counsel. The Association is planning to send two delegates.

The Board briefly discussed technical issues surrounding recent email marketing efforts for the September and October CLE luncheon events. The email mailings did not come through and discussion ensued regarding how to ensure proper delivery of these emails.

Dorothy provided an overview of the ongoing preparations for the Fall One-Day Patent Law event.

With regard to the preparations for the Judges' Dinner, Terri remarked that electronic payment is not advisable and that only check or wire transfers will be accepted. Terri also announced that Judge McMahon will be the keynote speaker for the Judges Dinner for the upcoming event. Terri also asked that the Board consider whether the keynote speech should be delivered before or after dinner. Terri announced that she is considering various candidates for the public service award and asked that the Board also identify candidates who have made a difference in the patent community recently.

Anthony proposed that the Annual Meeting include a CLE program, meetings of the various Subcommittees and the annual meeting dinner. Anthony is considering May 22nd as the date for the event and he is currently seeking an appropriate keynote speaker.

Terri proposed that the topic for the Day of Dinner luncheon CLE should relate to how the new patent law will change U.S. patent litigation, for example, how the new laws will affect the question of stays and severance in pending cases.

The meeting was then adjourned by Terri Gillis at 6:05 pm.

Moving UP ▲ & Moving ON ➤➤>

The Bulletin has introduced a new feature 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: Wanli Wu (wwu@wiggin.com) or Robert Greenfeld (rgreenfeld@mayerbrown.com).

NYIPLA Calendar

www.nyipla.org

December CLE Luncheon

Thursday, December 15, 2011 FARN LO NYS/NJS CLE PROFESSIONAL CREDIT Speaker: Honorable Randall R. Rader.

Chief Judge for the United States Court of Appeals for the Federal Circuit The Union League Club • 38 East 37th Street, New York, NY

Day of Dinner CLE Program

Friday, March 23, 2012 The Waldorf=Astoria Hotel • 301 Park Avenue, New York, NY

90th Annual Dinner in Honor of the Federal Judiciary

Friday, March 23, 2012

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

NYIPLA Announcements

CALL FOR NOMINATIONS 2012 NYIPLA INVENTOR OF THE YEAR AWARD

Deadline: Thursday, December 15, 2011

We invite you to nominate an individual or group of individuals who, through their inventive talents, have made a worthwhile contribution to society by promoting the progress of Science and useful Arts. The **2012 Call for Nominations - Inventor of the Year** rules and instructions can be found at www.nyipla.org.

For more information contact: Jessica L. Copeland at 1.716.848.1461, jcopeland@hodgsonruss.com or Anna Erenburg at 1.212.504.6526, anna.erenburg@cwt.com

2012 NYIPLA HONORABLE WILLIAM C. CONNER INTELLECTUAL PROPERTY LAW WRITING COMPETITION

Deadline: Friday, March 9, 2012

The Winner will receive a cash award of \$1,500.00 The Runner-up will receive a cash award of \$1,000.00

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.

The **2012 Conner Writing Competition** submission requirements can be found at www.nyipla.org.

For more information contact: Peiman F. Sharifi at 1.212.294.2603 or psharifi@winston.com



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