Nineteen Hundred and Twenty-two

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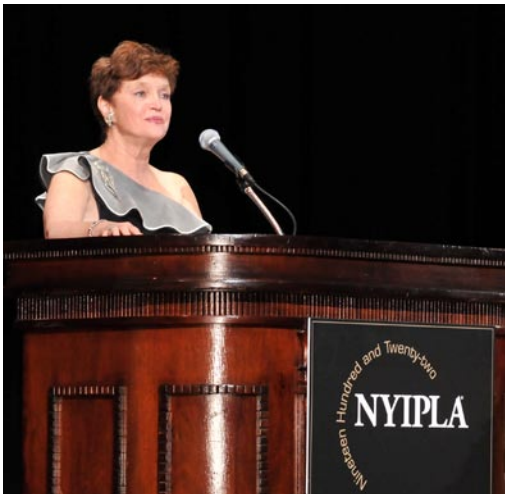
Judge Colleen McMahon's Keynote Address at the 2012 Judges Dinner

Thank you, Terri, for that kind and generous introduction. And thanks to all of you for your gracious hospitality this evening.

It is an honor to be asked to address this esteemed assembly. But you should know that every judge dreads having this particular honor conferred on him or her, because this is without a doubt the toughest speaking gig of the year – if only because the audience has just enjoyed the world's longest cocktail hour.

I understand that I was recommended for this year's address by my former friend, Joanna Seybert of the Eastern District of New York, and I do want to send her a very special shout out . . . and suggest that you might wish to ask her to speak next year.



There are many fascinating topics relating to Intellectual Property that one could address in a speech before such a knowledgeable audience. As you can see, I started to work up PowerPoint presentations on several of them before I was specifically warned not to give a lecture about some important new development or trend in the law. Instead, I was told that you were expecting me to be funny.

Indeed, I was told that that was why I had been selected as your speaker this evening.

Among my Second Circuit colleagues, I enjoy an entirely undeserved reputation for being able to deliver a funny speech. This tells me how very low the bar for humor is set in the legal profession . . . almost as low as the bar for pulchritude, which

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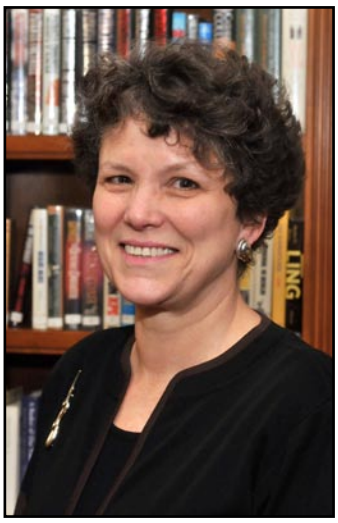
PRESIDENT'S CORNER

As I complete my term as President of the NYIPLA, I want to thank those who have contributed to a successful Association year.

First, a thank you to Judge McMahon for a totally entertaining keynote address at the 90th Annual Judges Dinner. Based on the feedback after the dinner, her speech qualifies as one of the best in memory. Thank you also to Judge Lourie for his thoughtful comments as this year's Public Service Awardee. The dinner was overall an enormous success, with attendance and revenues continuing their upward trend.

It has been an active year for the committees. Most substantive committees have shared responsibility for at least one meeting or CLE event. This collaboration between our substantive committees and those on the Meetings and Forums or CLE Committees produced a series of programs of superior quality. It also provided expanded opportunities for networking across committees. And it relieved the Meetings and Forums and CLE Committees of some of the disproportionate burden that has historically fallen on them.

Our Publications Committee has produced timely and informative Bulletins, while the Amicus Committee has continued to actively monitor cases for which amicus input from the Association would be beneficial. The Corporate, Young Lawyers and Women in IP Committees continued to sponsor networking opportunities for their members. Inventor of the Year and Conner Writing Competition Awardees to be honored at the Annual Meeting are the product of those committees' diligent efforts. I thank all of the committee chairs, the Board liaisons and the committee members for their contributions. As I did at the beginning of my term, I encourage all members to become active committee members.



A special thank you to Robin Rolfe Resources for its very able and more than competent administration of the Association. Whether dealing with small events, like board meetings, or massive undertakings, such as the Judges Dinner, I could always rest easy in the knowledge that the event would run smoothly. Because of RRR, I have been able to balance what has been an incredibly active year professionally with my responsibilities as president. A special thank you to Feikje van Rein and Lisa Lu, who were always ready to give that extra bit of assistance that made my job easier.

Because of RRR, the website has become a vital source of information for the Association. Thanks to the Website and Records Committees for their continued efforts to compile a complete set of the Association records and data, much of which is available on the website. (If any of you have historic records of the Association, the committee chairs would be pleased to receive copies to complete the records of the Association.)

Thank you to the membership for your continued support of the NYIPLA. In the coming year, there will be an effort to increase membership. Please support the future Association leadership, the Membership Committee and RRR in this effort by encouraging colleagues to become members.

Finally, thank you for entrusting the leadership of the Association to me for the past year.

With kind regards,
Terri Gillis

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my clerks tell me I cleared some years ago, when I was selected as a "judicial hottie" by the contributors to the website Underneath Their Robes.

And intellectual property may be even less funny than I am. Unable to think of a single amusing anecdote about patents, I went online and found a website called IP Attorney Jokes. It had exactly four entries, and two of them had the same punch line. I also Googled "copyright jokes," but it seems there are none . . . or at least, none that I can tell without being sued. There are, however, quite a few articles about how to copyright your jokes . . . which I will read with care if I manage to get any laughs tonight.

My task tonight was made even more difficult by the success of my predecessor at this podium, Judge John Gleeson. John, as those of you who attended last year's dinner know, is a gifted and graceful after-dinner speaker. Now John apparently did not get the memo about what it is that you folks do for a living – not that it would have made any sense to him, since the Eastern District of New York lacks subject matter jurisdiction over intellectual property actions. So John did not worry about the fact that intellectual property law is not intrinsically funny. Instead, he regaled you with wonderful stories about his days as an Assistant United States Attorney, where he earned his reputation as a fearless scourge of mobsters. I, as you have heard, spent my formative years toiling in a large New York City law firm. The stories of my pre-judicial legal career present far less fertile ground for humor.

One of my problems in crafting this speech is that I didn't have a lot of time to work on it. Those of you who live in and around New York City know that I have been extremely busy recently, presiding over a very long and complex trial that involves issues that are not part of a standard IP practice: official corruption, bribes, power politics, scandal and sex. I've also had to clean up after my clerks and interns, who, while I've been otherwise engaged, have made something of a mess out of my civil docket.

So, knowing that John's speech entertained you immensely last year – and intuiting that at least some of you have no memory of it whatsoever – I gave serious thought to just reading it. Sadly, my law clerks told me that I would likely run afoul of the copyright laws if I did so.

So I trolled the Internet, in the hope of finding some issue that would be of professional interest to you ladies and gentlemen, yet lend itself to a wry and gentle touch. I came across a lot of articles about the so-called "patent wars" in the smartphone industry, which I gather are keeping a number of you very busy. Since I do not have a dog in that fight, I asked my clerks to explain what was going on. They found an extremely easy-to-understand chart, which seems to indicate that every cellphone and droid device manufacturer in the world is suing or being sued by cellphone software providers in courts on six continents trying to figure out who owns the rights to various "computer-implemented methods" and "portable multifunction devices." Meanwhile, Google and Apple are engaged in a fight to the death over every aspect of smartphone technology – a fight that Steve Jobs told his biographer had all the hallmarks of "thermonuclear war."

I am sure there are the makings of a great speech in this little dust-up. But I'll bet that there isn't a single lawyer in this room who couldn't explain the whole thing to her children in a 10-minute bedtime story . . . and I wouldn't want to put you all to sleep.

Then I stumbled across the other big headline in your line of work: The America Invents Act. *That's* when I had my "Eureka!" moment. I decided I would tell you about my invention.

I know how important innovation is to our national interest. And I was distressed to learn that only 10% of new patents issue to women. So I decided I should become an American Inventor. But I know that, when the new rules go into effect, I have to be the first to file, not just the first to invent; I need to be ready for the race to the PTO. Unfortunately, because Federal judges are so notoriously underpaid, I couldn't afford to hire any of *you* to help me draft my patent application. So I turned to one of the country's most prestigious patent development firms for help, figuring that I could get some last minute advice and corrections from you, my captive audience of experts – pro bono, of course.

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So, without further ado, ladies and gentleman, I present to you: the e-Clerk.

The e-Clerk is an app that allows a Federal judge to download a multifunctional assistant onto a smartphone. Or, as I put it in the specification:

> The present invention relates to assistance and increased utilization for Federal judicial decision rendering persons bearing the title "Justice" or "Judge" – District, Circuit, Magistrate, and Bankruptcy inclusive. More specifically, the present invention relates to a computer-implemented method for use in a portable multifunction device, that comprises an assistant with legal active ontologies.

There is a crying need for the e-Clerk. Draconian budget cuts are decimating the Government's ability to provide all sorts of services to the public. And Congress' tendency to federalize every state crime in the hope of winning votes, coupled with law after law that confers the right to sue in Federal Court for every little grievance, have caused court dockets to skyrocket. As a result, Federal judges are facing unprecedented case loads.

But there has been no commensurate increase in the amount of assistance judges need in order to handle the increased workload. We need more law clerks: to perform research, write bench memoranda and draft opinions, assist at conferences, manage trials, and intelligently manage the docket, by communicating with attorneys, encouraging settlements, and closing inactive cases. Because we lack enough law clerk assistance, the American public is being effectively deprived of access to the judicial system – and the crushing overload of work is taking a tremendous toll on Federal judicial employees.

Now, electronic assistants have long been known in the art. They are used extensively by persons who have insufficient human help to accomplish their work. Recently, Apple introduced SIRI, a voice activated interactive research assistant, who answers questions – at least, *some* questions – in a soothing, slightly suggestive voice. [*video:* "Call me Siri"]

Electronic research skills are also familiar to those skilled in the art. Indeed, even the human clerk – long past patent protection, and sometimes referred to herein as "Clerk 1.0" – has Westlaw/Lexis compatible functionality, albeit at varying degrees of proficiency.

But the prior art does not disclose an electronic assistant capable of performing the sort of tasks a Federal judge requires to lighten his or her workload: legal research and opinion writing. It is an object of the present invention to fill that void.

It is yet another object of the present invention to free up time so that Clerks 1.0 can assist the judge in the myriad ways that human law clerks have since time immemorial – picking up lunch, delivering case files at odd hours of the night, editing preschool applications for the judge's grandchildren – none of which can be adequately accomplished without arms and legs.

The attached figures show the e-Clerk application as it appears on a smartphone screen. It displays several of the advantages afforded by the invention.

Figure 2 shows the e-Clerk's legal research functionality. Simply speak or type your natural language query into the fields 4 and 1 respectively; type or speak the relevant jurisdiction into field 2; in addition, or in the alternative, identify the subject matter or area of law in field 3. Then press "DONE" and e-Clerk gives you your answer.

To demonstrate how the invention represents a significant improvement over the prior art, I asked e-Clerk whether I might face liability under the Lanham Act for using the trademark "e-Clerk" for my invention. Seconds later, this is what I was told [*video*]:

> The question whether your use of "e-Clerk" to identify me would render you liable for infringement under Section 43 of the Lanham Act depends on whether someone else has developed a related protectable mark and, if so, whether your use of the mark creates a likelihood of confusion.
>
> Because "e-Clerk" would likely be considered a "descriptive" mark under the Second Circuit's *Abercrombie* continuum, whether an unregistered user is entitled to

protection depends on whether its use has developed a "secondary meaning." Additional facts are necessary to make that determination.

Also, I don't quite know how to tell you this, but Ben was sleeping under his desk this morning, while Scott spent 30 minutes emailing with his wife. Finally, you look wonderful today. How do you do it?!

If you look at the prior art, you will immediately recognize what a substantial improvement the e-Clerk represents. Let's see how "Clerk 1.0" handles a question about the famous *Polaroid* factors [video]:

Judge: Scott, I'm interested in the "likelihood of confusion" prong for violations of Section 43 of the Lanham Act. What are the *Polaroid* factors, and what is their relationship to the strength of a mark under *Abercrombie*?

Throughout question, Scott nonchalantly looks through drawers, on shelves, under papers, finally gets a yellow pad, sets to write as she finishes.

Scott: What? Confusion?

I also asked SIRI the same question about the *Polaroid* factors, and this is what she said [*video*]:

SIRI: I found a number of camera stores. 24 of them are fairly close to you.

The research function is great for giving answers to questions that are needed on the spot: mid-hearing rulings on evidentiary issues, for example. But for some matters nothing is more helpful than a thorough bench memorandum, addressed to the facts and the law, with recommendations; or even a draft opinion from which to work. e-Clerk can do that too.

In the first component 1, upload PDF files of the pleadings from the web or directly from e-Clerk's local storage. In the second component 2, upload factual submissions, such as declarations, affidavits, and exhibits. And in the third component 3, upload briefs, letters from counsel, and hearing and conference transcripts. Finally, set the ideolog-o-meter, component 4, to the desired point between Brennan on the left and Rehnquist on the right. Now press "DONE" . . . Wait thirty minutes, maybe go out for coffee. . . and voilà. The e-Opinion.

Now, the e-Opinion is just a draft. We haven't developed a "bench-slapping" or "tongue-lashing" function yet, and I would not want to render myself obsolete – it's bad enough that my clerks have taken to calling my signature stamp "e-Judge." So each e-Opinion requires attention from a real live judicial officer prior to publication. But in terms of speed and thoroughness of research, the e-Opinion far exceeds the capabilities of Clerk 1.0.

As you might imagine, one of the challenges I faced in putting this invention down on paper has been choosing claim language that is broad enough to forestall competitors from entering the field. I would rather avoid fighting a "thermonuclear war" over my invention with Bill Gates and the Ghost of Steve Jobs. But one can easily imagine some unscrupulous open source inventor coming up with something called the g-Clerk, or, worse, a much slicker and more ergonomic application called the "i-Clerk." I am still working on language broad enough to give me some wiggle room at a *Markman* hearing.

Sadly, the commercial value of the e-Clerk App is limited. After all, there are only about 800 Federal judges in the country, and Congress limits the number of clerks we can hire. Even if each judge purchased as many apps as we are entitled clerks – two for district judges, who do the heavy lifting; three for Court of Appeals judges, who work in groups; and four for Supreme Court justices, each one of whom will draft three or four meaningful opinions a year – the annual earnings potential for the e-Clerk app is low.

I have tried to come up with ways to maximize my revenue. For example, we intend to offer an upgrade for the e-Clerk – specially programmed at Harvard, Stanford, or Yale – which we call the e-Clerk Pro. e-Clerk Pro will use words like "apposite" rather than "on point," and will discuss foreign films and contemporary literature over lunch, rather than

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Jersey Shore and last week's *Maxim* magazine. We also hope to provide the e-Clerk Pro with an adjustable "independent thought" function to counter the basic model's tendency to excessive deference.

Our other business strategy is to generate the kind of mass hysteria that accompanies the yearly iPhone upgrade release – or, if we're *very* lucky, the frenzy evoked by the Federal Clerkship hiring plan – in order to charge a "prestige" premium for even the basic model e-Clerk.

Nonetheless, like many other app makers, I will be offering a "Lite," or unpaid version, called the "eNtern." The eNtern will have the same functions as the paid version, but it will only be accessible 5-10 hours a week – and even then will run only about 50% as efficiently as the basic e-Clerk model.

But the real commercial potential of this invention lies in extending its basic principle to related fields that offer a greater prospect for making money. Thus, I have included in my patent application dependent claim language on which I intend to rely when I am ready to introduce a derivative product, which I will call the "e-Associate." The e-Associate does everything the e-Clerk can do and more: you can work with it while it is recharging, and we've disabled sleep mode, so it is available 24-7-365.

e-Associate, however, is still in the early stages of development, and we need to work out several kinks.

First, if you don't pay for its annual bonus upgrade, e-Associate has a tendency to emit a high-pitched whine.

Second, e-Associate always seems to evade our efforts to prohibit its access to social media.

But worst of all, I cannot seem to get the cost of the e-Associate app below $160,000 a year.

Before I sit down, I must acknowledge the primary objects of my ribbing: my wonderfully human, e-for-excellent, i-for-inventive and g-for-great, Law Clerks: Scott Danner and Ben Alden. Law clerks really are like smartphones: I simply can't live without them, but they typically do need to be replaced about once every year.

In all seriousness; while it is true that the growth in the caseload has not been matched by growth in the budget, my clerks and interns – current and former, many of whom join me here tonight – have always risen to the challenge, while enhancing the quality of life in my chambers. Thanks to all of them.

And a special shout out to Annette Danner, Scott's wife, who prepared many of our PowerPoint diagrams and illustrations.

I also must thank the New York IP Law Association for inviting me to speak at this wonderful event. Practicing your trade, even in jest, was sufficiently challenging to give me a whole new appreciation for the technical fluency and exacting precision so many of you make look so easy. I should add my apologies to those of you who work in trademark and copyright, for focusing so heavily on patent issues. Although, truly, my presentation's liberal use of your clients' protected images is a case study in fair use . . . or at least I hope it is.

Finally, this event honors the Federal Judiciary, and I would be remiss not to acknowledge all my colleagues on the bench – District Court Judges, Magistrates, Bankruptcy Judges, Judges of the Courts of Appeal, and Justices of the Supreme Court – for all their hard work for the public good. Tonight I want to single out one of them, and take this rare opportunity to thank one hard-working judge who has been, at various times over the last thirty-seven years, my boss, my partner, my colleague, my mentor, my tormentor, my example, my helper, my big brother and my dear friend. Lew Kaplan exemplifies the best of both lawyer and judge, and I cannot possibly quantify what he has meant to my career. I can only choose him as my representative of the hard-working Federal Judiciary and say thank you for everything.

Enjoy the rest of the evening.

Maintaining Surprise in a Patent Case

By Kevin Murphy[1]

"All war is deception," advised Sun Tzu in his *Art of War,* by which he meant of course that one must strike the enemy when and where he is unprepared.[2] Sun Tzu's time-tested words should apply with equal force to litigation before the U.S. courts, which, as litigators can attest, often amounts to a no-holds-barred contest between corporations. However, the Federal Rules of Civil Procedure generally prohibit parties from surprising one another, thereby giving the parties every opportunity to settle the matter before picking a jury.

Is there yet a role for surprise in U.S. litigation? Certainly. The experienced attorney never forgets the joy, while rare, of tripping up a key witness unprepared to answer a question on either cross examination or re-cross. The attorney will likely highlight to the fact-finder on summation that witness's hesitation and uncertainty while testifying. While issues vulnerable to summary judgment must certainly be thoroughly explored in interrogatories, requests for admissions and depositions, that does not mean everything in an attorney's arsenal should be placed on the table for an adversary to see (and prepare for).

Patent litigation provides opportunities to potentially catch an adversary unprepared. In a patent case, a litigant may find she has pushed too hard on one issue, only to trip up elsewhere. Like Napoleon, good litigators never interrupt an enemy while she is making a mistake. It is black-letter law, for example, that the claims of a patent define the invention.[3] When a court is called upon to construe the claims for infringement or invalidity, the natural inclination of the patentee is to read the claims as broadly as possible so as to cover all potential competing products. But read them too broadly so as to cover prior art, and the patent is invalid as obvious under 35 U.S.C. § 103. According to the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*,[4] "[W]hat matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103." Much the same principle holds true under 35 U.S.C. § 102, where a broad claim construction could cover all of a particular piece of prior art, rendering the claim invalid as anticipated.

A few years ago, Liebel Flarsheim Company ("Liebel") confronted just that situation when it sued its competitor Medrad, Inc. over a patent that covered syringes used in patients getting contrast dye injected before undergoing x-ray testing. In order to sweep competitor Medrad's syringes under its infringement theory, Liebel pushed for a broad interpretation of its claims. The district court held that the claims as construed "are of a far greater scope than [Liebel's] specification of what it invented or possessed when it filed its application."[5] The Federal Circuit agreed and upheld the district's court invalidation of the patents, noting that Liebel's broad construction had succeeded, but suffered "a Pyrrhic victory."[6]

Similar tensions exist between the patent law concepts of enablement and nonobviousness. Patents cannot issue, of course, unless the subject matter they cover is nonobvious to persons of ordinary skill in the art.[7] That encourages the prospective inventor to emphasize before the Patent Office and at trial the inability of persons of ordinary skill to reach the invention. But the inventor must also provide an enabling disclosure with the patent application. This disclosure must sufficiently enable persons ordinarily skilled in the art to make and use the invention without undue experimentation.[8] The disclosure must be as broad as the claims themselves.[9]

But inventors generally do not want to enable their competitors to make or use anything in their patent application, and thus generally disclose only the minimum required. The result is the typical comment in a patent application that a particular technique or process "would be readily understood by the person of ordinary skill in the art." Of course, any such comment defining the understanding of the person of ordinary skill can ultimately undermine an inventor's position that the invention is inventive, and therefore nonobvious. And the patentee's inclination to reach for the broadest claim possible forces just as broad a disclosure about how the invention's embodiments are to be made. Failure to do so risks a ruling of invalidity for non-enablement.

A patent challenger can take advantage of these tensions in litigation either by asserting outright

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alternative positions in the pleadings, or reserving the opportunity to assert alternative positions at a later time before the close of discovery. Obviousness under 35 U.S.C. § 103 and nonenablement under 35 U.S.C. § 112 are typical invalidity defenses to any claim of patent infringement, and must appear affirmatively in any Answer to a Complaint.[10] But to the extent inconsistent with each other, a challenger can set out these defenses "alternatively or hypothetically, either in a single count or defense or in separate ones."[11] While this can be common practice in a patent litigation, it naturally alerts the patentee that she is subject to both such attacks. Patentee's counsel will likely spend a great deal of time preparing the inventors and other fact and expert witnesses so that the resulting testimony demonstrates that the patent specification was enabling and the invention nonobvious over the prior art. In these days of the presumptive limitation of seven hours of questioning in a deposition, there is very little time to secure strong admissions supporting these complicated defenses.[12]

The better practice is generally to wait and see. The strongest defense should naturally be pled in the Answer. But there are several downsides to pleading in the alternative beyond that. First, and arguably most important, alternative pleading advertises the discovery plan to the other side. Second, pleading alternative defenses without sufficient backup can invite a motion to dismiss. Even if not granted, while the motion is pending, substantive discovery can be placed on hold. And the other side can use the opportunity to make its story the first one the court hears. If the court is deciding discovery motions itself and not delegating those motions to a magistrate judge, you want to make sure to get the first word in. Finally, a litigant will retain the advantage of catching the other side flat-footed in depositions, the only time an adversary is generally barred from directly interceding in discovery. If you secure useful admissions on the defense or defenses in reserve, you can always move the court to amend the answer. Courts are admonished under the Rules to "freely give" such leave.[13]

Here's an example from the author's practice. A number of years ago, the client, a generic pharmaceutical company, challenged a formulation patent which the patentee had purchased from a major foreign corporation. The patentee had since successfully marketed the product the patent covered in the United States. The patent was vulnerable to an obviousness attack, and our client spelled out that defense in its Answer and accompanying notice pleading. But the patent's claims were also excessively broad, covering essentially every potential pharmaceutical ingredient imaginable. Instead of a broad disclosure, the patent specification provided only two working examples, both with the same active pharmaceutical ingredient at issue in our case. There was no explanation as to how the formulation might work with any other active pharmaceutical ingredient, particularly those which were only effective at concentrations higher than that listed in the specification's examples. There was thus reasonable basis at the outset for an expert to opine that the specification did not enable the broad scope of the claims. But the client did not plead a defense of nonenablement at the outset.

Fortunately, the inventors still worked at the corporation which was the original patentee, and were available to testify under the Hague Convention. After the typical cumbersome wait for a deposition in a foreign country, the author got the chance to take their depositions. Each inventor was thoroughly prepared on the issue of obviousness, at times seeming to mouth back disagreements with the client's positions as outlined in the notice pleading. Each witness admitted that their attorneys had prepared them for questioning over the course of two days each. Yet, when the subject turned to factual issues of nonenablement, neither apparently had any idea of the concept. As one inventor explained, the purpose of the specification was to list ***any possible uses*** of the formulation. No attempt was ever made to verify through experiments that the patented formulation would work with any of the potential active ingredients apart from the working examples. Yet both witnesses had previously emphasized in their testimony – in an attempt to maintain the nonobviousness issue on which they were prepared – that nothing but actual experimental formulation data would be useful given that formulation was so unpredictable. This and other useful admissions appeared in an expert report served soon thereafter on the new issue of nonenablement. The following month, the case settled, on terms favorable to the client. Although the author attempted to settle the case previously at mediation and otherwise encour-

aged settlement discussions, the patentee had been summarily rejecting offers. Of course, there is no way to know what tipped the scale in favor of settlement: obviousness, nonenablement, or both. But certainly the inventors were either: 1) unprepared on the critical issue, 2) forgot their attorneys' advice, or 3) simply did not care anymore. But not putting the issue front and center in the pleadings in this instance actually helped secure the testimony that encouraged the patentee to settle.

In general, the surest way to secure useful admissions is to make full use of the adversary system. A litigant should keep her cards close to the vest, never disclosing more of the case or legal theories than is absolutely necessary. If the case has the potential to settle short of trial, use undisclosed information in the late stage of settlement negotiations. Otherwise, save it for a later-term motion to amend or, better yet, for cross-examination and the jury.

(Endnotes)

[1] Kevin Murphy is a partner with the law firm of Frommer Lawrence and Haug LLP, specializing in intellectual property litigation. The views expressed in this article are solely those of the author and are not to be attributed to Frommer Lawrence and Haug LLP or any of its clients.

[2] *Art of War, I.18.*

[3] *Phillips v. AWH Corp*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). In *Phillips*, the Federal Circuit stressed the concept as a "bedrock principle of patent law." *Id.* at 1312.

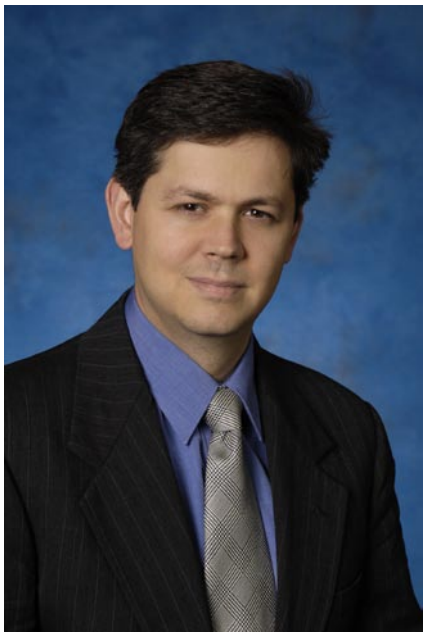
[4] 550 U.S. 398, 419 (2007).

[5] *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1376 (Fed. Cir. 2007).

[6] *Id.* at 1383.

[7] *See* 35 U.S.C. § 103.

[8] 35 U.S.C. § 112; *In re Wands*, 858



F.2d 731, 737 (Fed. Cir. 1988).

[9] *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991).

[10] Fed. R. Civ. P. 8(c) & (d).

[11] Fed. R. Civ. P. 8(d)(2).

[12] Fed. R. Civ. P. 30(d)(1).

[13] Fed. R. Civ. P. 15(a)(2).

Moving UP ▲ & Moving ON ➤➤➤

- Tony Pezzano and Michael Dougherty, formerly of Cadwalader, Wickersham & Taft LLP, have joined the Intellectual Property Practice of King and Spalding as partners.

- Leora Ben-Ami, Thomas Fleming, Patricia Carson and Christopher Jagoe, formerly of Kaye Scholer LLP, have joined the Intellectual Property Practice Group of Kirkland and Ellis as partners.

- Dominic Cerrito and Eric Stops, formerly of Jones Day, have joined the Intellectual Property Litigation Practice of Quinn Emanuel Urquhart & Sullivan LLP as partners. Evangeline Shih, also formerly of Jones Day, has joined Quinn Emanuel as Of Counsel.

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@cantorcolburn.com) or Robert Greenfeld (rgreenfeld@mayerbrown.com).

What *Kappos v. Hyatt* Means To The Endangered Right Of De Novo Judicial Review Of PTO Decisions Under The America Invents Act

Charles E. Miller[1]

On April 18, 2012, the U.S. Supreme Court in *Kappos v. Hyatt*[2] unanimously affirmed the Federal Circuit's November 8, 2010 *en banc* decision,[3] which held that there are no restrictions on the ability of a party – in this case a patent applicant *qua* plaintiff – to introduce new evidence relevant to a disputed issue of fact in a 35 U.S.C. § 145 civil action against the U.S. Patent and Trademark Office ("PTO" or "Agency") beyond those imposed by the Federal Rules of Evidence and the Federal Rules of Civil Procedure. In such cases the district court must make its own de novo (non-deferential) factfindings taking into account as a whole said evidence together with the evidence in the PTO administrative record, regardless of whether or not the new evidence in and of itself shows that the PTO's findings were erroneous.

So what does *Hyatt* tell us about administrative patent law in relation to the courts in a general sense? The Supreme Court's decision has provided the inventive community with a positive milestone in opposition to the insulation of PTO's decisional factfindings from de novo judicial review[4] of *all* relevant, non-cumulative evidence. The result advocated by the PTO, namely, the exclusion of such evidence which could have been presented during the administrative stage, but for whatever reason was not, would have diminished and devalued, and further curtailed the use of, the important right to challenge by civil action the PTO's decisions in administrative proceedings including in this case the denial of claims in patent applications.

This article examines *Hyatt* from the perspectives of (I) the operative statutes and judicial rules; (II) the Supreme Court's holdings on the questions presented; (III) the background facts, the PTO prosecution record, and the lower-court decisions; (IV) the proceedings in the Court; and (V) reasons why the case signals a principle of paramount importance to the continued well-being of the U.S. patent system.

I. INTRODUCTION; STATUTES AND RULES

The following statutes and rules, or their antecedents, governed the sequence of events in *Hyatt*, beginning in the PTO and culminating at the Supreme Court.

A. Statutes

Since time immemorial, adverse decisions of the PTO's Board of Patent Appeals and Interferences[5] and its predecessors, on broadly interpreted claims in applications for original and reissue patents have been subject to judicial oversight pursuant to the Patent Act of 1952 (Title 35, U.S.C.) and its antecedents[6] – and continuing under the Leahy-Smith America Invents Act ("AIA") – within the general ambit of Sections 702-706 of the Administrative Procedure Act (Title 5, U.S.C.) ("APA"). In particular, patent applicants dissatisfied with Board decisions in administrative appeals under 35 U.S.C. § 134(a) have two, mutually exclusive options for seeking judicial recourse. One option is to appeal directly to the Federal Circuit under 35 U.S.C. § 141(a)[7] for review of the Board's conclusions of law based on requisite substantial evidence fixed at the administrative level as prescribed by 35 U.S.C. § 144. *See also* 28 U.S.C. § 1295(a)(4)(A)[8] giving the Federal Circuit appellate jurisdiction of Board decisions.

Alternatively, and apropos of the controversy in *Hyatt*, a dissatisfied applicant may seek de novo judicial review of the Board's decision by *suing the PTO* in the person of the Director in a *civil action* in federal district court for an adjudication based on the administrative record *and* additional evidence submitted by *either party*. This is consistent with 5 U.S.C. § 706(2)(F) and is explicitly enabled by 35 U.S.C. § 145[9] which, as amended by the AIA, states as follows:

> § 145. Civil action to obtain patent.
>
> An applicant dissatisfied with the decision of the ~~Board of Patent Appeals and Interferences~~ >Patent Trial and Appeal Board< in an appeal under section 134(a) of this title may, unless appeal has been taken to the United States Court of Appeals for the Federal Circuit, have remedy by civil action against the Director in the United States District Court for the ~~District of Columbia~~ >Eastern District of Virginia< if commenced within such time after such decision, not less than sixty days, as the Director appoints. The court may adjudge that such applicant is entitled to receive a patent for his invention, as specified in any of his

claims involved in the decision of the ~~Board of Patent Appeals and Interferences~~ >Patent Trial and Appeal Board<, as the facts in the case may appear and such adjudication shall authorize the Director to issue such patent on compliance with the requirements of law. All the expenses of the proceedings shall be paid by the applicant. (Emphasis added.)[10]

By its terms, 35 U.S.C. § 145 operates as a statutory waiver of the Federal Government's sovereign immunity from suit against a specific Cabinet (Commerce Department) agency (the PTO), in a specific type of case (rejected patent applications), and in a specific forum (E.D. Va.) within a specific jurisdiction (the U.S. district court). As such, the provisions of Section 145 are an implicit subset within the general waiver statute, 5 U.S.C. § 702 of the APA. *See also* 28 U.S.C. § 1338(a) confirming the district court's original civil action/bench trial jurisdiction of Board decisions.

District court judgments in civil actions under 35 U.S.C. § 145 and 28 U.S.C. § 1338(a) are in turn reviewable by the Federal Circuit under 28 U.S.C. § 1295(a)(1) and § 1295(a)(4)(C).

Finally, the Federal Circuit's decisions in (i) 35 U.S.C. § 141 / 28 U.S.C. § 1295(a)(4)(A) appeals from the Board and (ii) 28 U.S.C. § 1295(a)(1) / (a)(4)(C) appeals from the district court are reviewable upon grant of certiorari by the U.S. Supreme Court under 28 U.S.C. § 1254(1).

B. Rules

As is typical of suits in federal district court, the adjective law governing the proceedings and the discovery and treatment of evidence in a Section 145 action is found in the Federal Rules of Civil Procedure and the Federal Rules of Evidence.

1. Federal Rules of Civil Procedure

Fed. R. Civ. P. 1 ("Scope and Purpose") states as follows: "These rules govern the procedure in all civil actions and proceedings in the United States district courts . . . . They should be construed and administered to secure the just, speedy, and inexpensive determination of every action and proceeding."

Fed. R. Civ. P. 4(i)(2) ("Agency; . . . Officer or Employee Sued in an Official Capacity") connects civil actions to suits against federal agencies by stating as follows: "To serve a United States agency . . . or a United States officer or employee sued only in an official capacity, a party must serve the United States and also send a copy of the summons and of the complaint by registered or certified mail to the agency, . . . officer, or employee."

2. Federal Rules of Evidence

Fed. R. Evid. 101 ("Scope; Definitions") states as follows: "(a) Scope. These rules apply to proceedings in United States courts. The specific courts and proceedings to which the rules apply . . . are set out in Rule 1101."

Fed. R. Evid. 1101 ("Applicability of the Rules") states as follows: "(a) To Courts and Judges. These rules apply to proceedings before: United States district courts; . . . . (b) To Cases and Proceedings. These rules apply in: civil cases and proceedings, ... (e) Other Statutes and Rules. A federal statute or a rule prescribed by the Supreme Court may provide for admitting or *excluding* evidence independently from these rules." (Emphasis added.)

The relevance, admissibility, and excludability of evidence in civil actions in federal district court in the present context are governed by Fed. R. Evid. 401, 402, and 403, respectively:

Fed. R. Evid. 401 ("Test for Relevant Evidence") states that: "Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action."

Fed. R. Evid. 402 ("General Admissibility of Relevant Evidence") states as follows: "Relevant evidence is admissible unless any of the following provides otherwise: . . . a federal statute; these rules; or other rules prescribed by the Supreme Court. Irrelevant evidence is not admissible."

Fed. R. Evid. 403 ("Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons") states as follows: "The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: *unfair prejudice, confusing the issues, . . . undue delay, wasting time, or needlessly presenting cumulative evidence*." (Emphasis added.)

Consequently, if additional evidence proffered in a Section 145 action – whether discovered, produced, or adduced by a party or compelled from third parties[11] – is relevant, Fed. R. Evid. 401, then it is admissible, Fed. R. Evid. 402. Whether it should be excluded must be adjudged under Fed. R. Evid. 403, and there is no pertinent statute or other pertinent rule alluded to above in Fed. R. Evid. 1101(e).

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II. THE SUPREME COURT'S HOLDING ON THE QUESTIONS PRESENTED

A. Issues and Contentions

Stated broadly, the main issue of contention in *Hyatt* was whether – in a civil action under a sui generis statute in federal district court seeking recourse from a government agency decision – relevant, non-cumulative evidence that ***for whatever reason*** *was not presented (but could have been presented) during the administrative proceeding* must be considered by the court in a de novo judicial review of the administrative decision. The Department of Justice, representing the defendant PTO, contended that the "evidence"[12] newly presented by the plaintiff, Mr. Hyatt, albeit relevant and hence admissible, was properly *excluded at the court's discretion* because Hyatt's failure to present it at the administrative stage was either *willful or negligent*. Hyatt argued what later became the Federal Circuit's en banc holding that 35 U.S.C. § 145 imposes no special, heightened standard of admissibility that would justify such exclusion; rather, Section 145 as worded, (i) allows the proffer of additional (new) evidence in district court actions and (ii) imposes no limitations on the admission of such evidence beyond the provisions of the Federal Rules of Evidence as applied to civil actions under the Federal Rules of Civil Procedure.

The specific issues certified for decision by the Court were informed by two questions set forth in the PTO's petition for certiorari as follows:

> **QUESTIONS PRESENTED**
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> When the United States Patent and Trademark Office (PTO) denies an application for a patent, the applicant may seek judicial review of the agency's final action through either of two avenues. The applicant may obtain direct review of the agency's determination in the Federal Circuit under 35 U.S.C. 141. Alternatively, the applicant may commence a civil action against the Director of the PTO in federal district court under 35 U.S.C. 145. In a Section 145 action, the applicant may in certain circumstances introduce evidence of patentability that was not presented to the agency. The questions presented are as follows:
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> *1. Whether the plaintiff in a Section 145 action may introduce new evidence that could have been presented to the agency in the first instance.*
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> *2. Whether, when new evidence is introduced under Section 145, the district court may decide de novo the factual questions to which the evidence pertains, without giving deference to the prior decision of the PTO.*

Petition for a Writ of Certiorari, 2011 WL 1336431 (emphasis added).

B. The Holding

The Court decided both questions in the affirmative. As a predicate for doing so, the Court noted its preference for the precedent in *Butterworth v. United States ex rel. Hoe*, 112 U.S. 50 (1884), involving a patent application, over that of *Morgan v. Daniels*, 153 U.S. 120 (1894), involving a patent interference, *Hyatt*, 132 S. Ct. at 1698-1700, and then held that:

a. Further to the statement in *Dickinson v. Zurko*, 527 U.S. 150, 164 (1999), that a patent applicant may present new evidence to the district court that was not presented to the PTO, "there are no evidentiary restrictions [on a patent applicant's ability to introduce new evidence in a Section 145 district court civil action] beyond those already imposed by the Federal Rules of Evidence and the Federal Rules of Civil Procedure." *Hyatt*, 132 S. Ct. at 1694.

b. Regarding "what standard of review the district court should apply when considering new evidence… the district court must make a *de novo* finding when new evidence is presented on a disputed question of fact," because "it makes little sense for the district court to apply a deferential standard of review to PTO factual findings that are contradicted by the new evidence. The PTO, no matter how great its authority or expertise, cannot account for evidence that it has never seen. Consequently, the district court must make its own findings *de novo* and does not act as the 'reviewing court' envisioned by the APA. See 5 U.S.C. § 706." *Id.* at 1694, 1696. "Though the PTO has special expertise in evaluating patent applications, the district court cannot meaningfully defer to the PTO's factual findings if the PTO considered a different set of facts. *Supra*, at 1697; cf. *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. —, —, 131 S. Ct. 2238, 2251 (2011) (noting that 'if the PTO did not have all material facts before it, its considered judgment may lose significant force'). For this reason, we conclude that the proper means for the district court to accord respect to decisions of the PTO is through the court's broad discretion over the weight to be given to evidence newly adduced in the § 145 proceedings." *Hyatt*, 132 S. Ct. at 1700.

c. "In deciding what *weight* to afford that evidence, the district court may, however, consider whether the applicant had an opportunity to present the evidence to the PTO." *Id*. at 1694 (emphasis added).

d. "[T]he principles of administrative exhaustion do not apply in a § 145 proceeding. [The PTO's rationale based on] 'the avoidance of premature interruption of the administrative process' . . . does not apply here because, by the time a § 145 proceeding occurs, the PTO's process is complete . . . [and] Section 145, moreover, does not provide for remand to the PTO to consider new evidence, and there is no pressing need for [remand] because a district court, unlike a court of appeals, has the ability and the competence to receive new evidence and to act as a factfinder." *Id*. at 1696-97 (citing *McKart v. United States*, 395 U.S. 185, 193-94 (1969)).

III. BACKGROUND FACTS AND PROCEEDINGS

A. Proceedings in the PTO

On June 6, 1995, on the eve of the effective date of the 20-year-from-filing patent term provisions of the Uruguay Round Agreements Act pursuant to the GATT Treaty,[13] an electrical engineer, businessman, and registered patent agent named Gilbert P. Hyatt, applied for a U.S. patent as the sole designated inventor of a computer system for processing and displaying visual image information.

1. Before the Examiner

The patent application, No. 08/471,702, entitled "Improved Memory Architecture Having a Multiple Buffer Output Arrangement," has antecedents under 35 U.S.C. § 120 going at least as far back as 1984. It included a 238-page specification with 15 claims (eventually increased during prosecution to 117 claims occupying 79 pages) and 40 sheets of drawings.

The PTO examiner rejected most of the claims for failing to describe the claimed invention in the specification as required by 35 U.S.C. § 112, ¶ 1. The rejection listed 13 multi-word limitations in 79 of the 117 claims as purportedly having no supportive basis in the specification. Hyatt, prosecuting his application pro se, replied to the rejection by submitting a tabulation of the individual words in the claim limitations together with representative pages and line numbers of the specification where those words appear – but without pointing out the substance of the limitations themselves.

Hyatt's reply failed to persuade the examiner to withdraw the rejection, whereupon Hyatt appealed to the Board in September 1998 pursuant to 35 U.S.C. § 134.

2. At the Board

In an unpublished, non-precedential decision issued July 30, 2002 in Appeal No. 2000-2049, the Board ruled that Hyatt's traversal of the Section 112 rejection was insufficient, characterizing it as being unhelpful, in part misleading, and merely akin to citing pages in a dictionary where particular words can be found in order to explain the meaning of passages in a book containing combinations of those words.

In his post-appeal brief filed September 30, 2002 in support of a request for rehearing, Hyatt offered new, claim-by-claim arguments in support of his traversal of the rejection. On January 23, 2003, the Board denied the request since, under the PTO's rules, Hyatt had waived his right to present them because they could and should have been made to the examiner and in Hyatt's initial, administrative appeal brief.

B. Proceedings in the District Court

Hyatt v. Dudas (D.D.C. 2005)

On April 16, 2003, Hyatt, now represented by counsel, sued PTO Director Rogan in the U.S. District Court for the District of Columbia under 35 U.S.C. § 145 / 28 U.S.C. § 1338(a) seeking adjudication of the Board's decision. Hyatt's election to pursue a civil action in district court – a proceeding that he knew he had to pay for in its entirety out of his own pocket, *see* 35 U.S.C. § 145, last sentence – rather than appeal directly to the Federal Circuit, was presumably motivated by the overriding need to buttress his case with the additional information which the Board had refused to consider. This would not have been possible in a direct appeal to the Federal Circuit under 35 U.S.C. § 141 since the factual predicates of that court's decision would have been limited by Section 144 to the contents of the administrative record in the Agency. Nor was the filing of a continuing application indicated in order to adduce the required additional evidence since doing so would have forfeited Hyatt's right to a patent term of 17 years from issuance in the event his application were ultimately granted.[14]

Without waiting for the case to proceed beyond the joinder of issue, the defendant PTO moved for summary judgment under Fed. R. Civ. P. 56 grounded on the Agency's assertion that the Board's decision affirming the examiner's written-description rejection, already supported by the requisite "substantial evidence" in the administrative record, sufficed to justify the court's deference to and hence affirmance of the PTO's factfindings under *Mazzari v. Rogan*, 323 F.3d 1000, 66 U.S.P.Q.2d 1049 (Fed. Cir. 2003). *Hyatt replied on January 28, 2004 by arguing the existence of "genuine issues of material fact" and submitting a written declaration setting forth*

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information establishing the requisite bases for the claims in the specification "as purported evidence supporting his opposition" to the PTO's summary judgment motion.

The district court (Henry H. Kennedy, Jr., J.) in an unpublished memorandum opinion dated September 30, 2005, 2005 WL 5569663, granted summary judgment after sustaining the PTO's objection to Hyatt's evidentiary declaration on the grounds, inter alia, that the declaration or its contents were tantamount to the presentation of new factual issues with no reason for failing to present them to the PTO at the administrative stage. *Under its interpretation of Section 145, the court excluded the declaration from evidence as being inexcusably late because it was available and could have been presented during the prosecution of the application, and Hyatt's failure to explain why he did not do so was deemed indicative of his* ***negligence*** *which justified the exclusion.*[15]

C. Proceedings in the Federal Circuit

Following the district court's September 30, 2005 denial of his motion for reconsideration, Hyatt appealed to the Federal Circuit under 28 U.S.C. § 1295(a)(1) / (a)(4)(C), Appeal No. 2007-1066.

1. Panel Decision: *Hyatt v. Doll* (Fed. Cir. 2009)

The appeal was argued on April 7, 2008. Over a year later, on August 11, 2009, in a split decision by a three-judge panel (Judges Michel, Dyk, and Moore), the Federal Circuit affirmed the district court's summary judgment, 576 F.3d 1246.

a. Majority Opinion

The majority opinion held that (i) the district court did not abuse its discretion in excluding Hyatt's declaration evidence because it was deemed *willfully* withheld from the PTO, 576 F.3d at 1275 (as opposed to *negligently* withheld as the district court had found) and (ii) the evidence of record in the PTO was in and of itself substantial and therefore enough to justify summary judgment as a matter of law. *Id.* at 1247-79.

The opinion acknowledged that although "this court has never squarely addressed the issue of exactly what standard governs district courts in ruling on the admissibility of evidence withheld during examination in the PTO," *id.* at 1253, "in some circumstances new evidence may be submitted. But merely because new evidence *may* be submitted does not necessarily mean this right is unfettered; there still may be situations in which new evidence *may* be excluded." *Id.* at 1261 (footnote omitted). "[I]t has been the general practice of federal courts for over eighty years in certain circumstances to exclude evidence which a party could and should have introduced before the Patent Office but did not despite an obligation to do so." *Id.* at 1266. To counter the argument in the dissent (see below) that a trial de novo is required when non-cumulative relevant new evidence beyond the administrative record on a dispositive issue is presented to the trial court, the panel majority reviewed how earlier courts handled the evidentiary standard and, in doing so, attached considerable importance to the holding in *Barrett Co. v. Koppers Co.*, 22 F.2d 395 (3d Cir. 1927), that "'the plaintiffs in this action under section 4915, R.S., are *estopped to offer evidence which was wholly within their possession and control at the interference proceeding* and which they withheld from that proceeding.'" 576 F.3d at 1262-63 (quoting *Barrett*, 22 F.2d at 397).

In addressing the APA, which the district court did not do, the opinion acknowledged that "[t]he usual rule . . . that judicial review of agency action should be on the agency record, regardless of whether the action is in the court of appeals or in district court," *id.* at 1267, could be overridden if the statute explicitly provides for adjudication and trial de novo. The opinion concluded that Section 145 does not do this, noting that "[t]he ambiguous silence of § 145 on the admissibility of evidence does not meet the high bar the Supreme Court has set for implying trial de novo." *Id.* at 1269 n.22.

As to when new evidence may be introduced, the opinion referred to *Citizens to Preserve Overton Park Inc. v. Volpe*, 401 U.S. 402 (1971):

> As the Supreme Court stated in *Overton Park*, where "agency factfinding procedures are inadequate," the APA allows a district court to take additional evidence. For example, the PTO does not take oral testimony in an examination of a patent application. In some cases credibility determinations will be very important to the resolution of the case, for example, where there is a question about the date of reduction to practice which will determine what is, or is not, prior art. In such circumstances, it makes sense to permit the district court to hear live testimony under *Overton Park* to resolve credibility issues because the PTO procedures are inadequate.

576 F.3d at 1270 (emphasis added).

The opinion then pointed out the circumstances of the instant case, noting that "none of the cited Congressional testimony specifically addresses situations where an applicant sought to overcome *the consequences of his own refusal to adhere to the rules of prosecuting a patent application*." *Id.* at 1272. The court then opined that Hyatt "was obligated to respond to the examiner's

written description rejection by *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996)." *Id*. at 1274. Criticizing Hyatt's offer of "Table 1" in response to the examiner's rejection, the panel majority ruled that such failure to reply adequately was not negligence, as the lower court had found, but a willful refusal to cooperate, "even though [Hyatt] necessarily possessed the information the examiner sought by the time he filed his application." *Id*. at 1274-75. Continuing, the court said:

> *On these facts*, the district court's exclusion of Hyatt's new evidence must be affirmed. . . . [I]t is clear from the record that Hyatt willfully refused to provide evidence in his possession in response to a valid action by the examiner. Such a refusal to provide evidence which one possessed was grounds in *Barrett* to exclude the withheld evidence. Similarly, we hold that in light of Hyatt's willful non-cooperation here, the district court did not abuse its discretion by excluding the Hyatt declaration.
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> * * *
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> There is, under *Alton*, only one acceptable response to a written description rejection: showing the examiner where by column and line number in the specification he may find written description support for each disputed claim limitation.

Id. at 1275, 1278 (underlining added) (footnotes omitted). After rejecting Hyatt's counter-arguments as offering "no acceptable excuse for his failure to properly present his declaration to the PTO," *id*. at 1277, the panel majority concluded that the district court did not abuse its discretion by excluding the declaration from evidence in the PTO's summary judgment motion.

b. Dissenting Opinion

In dissent, Judge Kimberly Moore criticized the panel majority for engaging in appellate factfinding that Hyatt "willfully" failed to present his best case to the PTO, 576 F.3d at 1279-90. She noted that neither the district court judge nor the PTO made any findings of "willful withholding or intentional suppression." *Id*. at 1279. Consequently, "[e]ither the majority is engaging in appellate fact finding or it is determining that breach of its newly created affirmative duty is willful withholding as a matter of law. . . . Ultimately, the majority's sweeping exclusionary rule is far broader than anything argued by the parties." *Id*.

Judge Moore then characterized the majority holding as the judicial promulgation of a "sweeping exclusionary rule" that imposes "an affirmative duty" or "obligation" on patent applicants to submit all available evidence to the PTO, effectively preventing the unfettered proffer of new evidence in district court and thereby "takes away this patent applicant's fundamental right" to a civil action under Section 145. *Id*. She reasoned that the majority opinion "mak[es] this [Section 145] proceeding more of an appeal than the new civil action contemplated and enacted by Congress," as "part of the [proceeding in the] application for the patent." *Id*. at 1279-80 (internal quotation marks omitted).

Further, Judge Moore questioned the majority's reliance on *In re Alton*, noting that while the case stood for shifting the burden of production after an examiner's written-description rejection, the burden shifts for any rejection. If such burden shifting creates "an affirmative duty," she wrote, then the result is a "per se rule that an applicant is deemed to have willfully withheld anything he possessed during prosecution that was responsive to a rejection regardless of the applicant's actual intent. Willfulness always requires intent and is simply not compatible with the majority's strict liability approach." *Id*. at 1287.

Judge Moore concluded by observing that "the majority blurs the line between an appeal pursuant to § 141 and the civil action of § 145. The admissibility of new evidence is exactly what distinguishes § 145 from § 141." *Id*. at 1289.

2. En Banc Rehearing and Decision: *Hyatt v. Kappos* (Fed. Cir. 2010)

Following Respondent's "Combined Petition for Panel Rehearing or Rehearing En Banc" filed November 30, 2009, the Federal Circuit issued an order on February 17, 2010, vacating the panel decision and reinstating Respondent's appeal from the district court's summary judgment for the purpose of rehearing it en banc. 366 F. App'x 170, 93 U.S.P.Q.2d 1871.

On November 8, 2010, following oral argument on July 8, the Federal Circuit issued a 7-2 decision vacating the summary judgment and remanding the case to the district court. 625 F.3d 1320.

a. Majority Opinion

The majority opinion, 625 F.3d at 1322-38, authored by Judge Moore, who had dissented from the panel decision, ruled that the district court erred by exceeding its authority in applying the wrong standard for admitting evidence in a Section 145 action, and in so doing abused its discretion in determining that Hyatt's "negligence affected admissibility." *Id*. at 1338. In doing so, the majority held that Section 145 permits the entry of any relevant (competent) evidence otherwise admissible under the Federal Rules of Evidence and the Federal Rules of Civil Procedure without inquiry as to why it was not presented during the administrative stage of the

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proceedings. The court went on to note that its holding is consistent with dicta in *Dickinson v. Zurko*, 527 U.S. 150 (1999), and the holding in *Mazzari v. Rogan*, 323 F.3d 1000 (Fed. Cir. 2003), that "[i]f the parties to a § 145 action do not introduce any new evidence before the district court, the court reviews the case on the same record presented to the agency and the reviewing court must apply the APA's substantial evidence standard to Patent Office fact findings." 625 F.3d at 1336. It further noted that the substantial evidence standard does not apply when new evidence is introduced. "'The presence of such new or different evidence makes a factfinder of the district judge,'" *id*. at 1333 (quoting *Zurko*, 527 U.S. at 164), and "the district court . . . must make de novo fact findings with respect to factual issues to which the new evidence relates," *id*. at 1336.

b. Partial Concurring/Dissenting Opinion

Judge Pauline Newman concurred with the majority decision, but went further by asserting in partial dissent, 625 F.3d at 1338-41, that the "statutory plan" of Section 145 does not contemplate district court deference to the PTO's factfindings even in the absence of new evidence. Judge Newman's position was inconsistent with the Supreme Court's dicta in *Zurko* and would have effectively overruled her own court's holding in *Mazzari*. Probably for that reason, her position was never advanced by Hyatt, although, curiously, some of the Supreme Court Justices during oral argument solicited counsels' views regarding Judge Newman's proposition but without probing their answers.

c. Dissenting Opinion

Citing *Citizens to Preserve Overton Park*, 401 U.S. at 414-20, Judge Dyk, in a dissenting opinion joined in by Judge Gajarsa, 625 F.3d at 1341-58, opined that Section 145 actions should not depart from what the judges regarded as settled administrative law under 5 U.S.C. § 706, namely, that new evidence may not be admitted in district court if it could have been introduced and considered during the proceedings before the PTO but for the fact, for example, that the Agency's procedures are inadequate to receive and entertain such evidence (e.g., direct and cross examination of live witnesses). They were concerned that the majority opinion would somehow encourage the deliberate withholding of evidence from the PTO by patent applicants seeking "a more hospitable forum" in the district court where non-expert judges would be more likely to accept it on face value. To buttress its reasoning, the dissent relied on what it considered to be the superior technical and patent law expertise of the PTO Corps of Examiners and the Board's administrative patent judges compared to that of district court judges. 625 F.3d at 1342-44.

IV. PROCEEDINGS IN THE U.S. SUPREME COURT

In reaction to the Federal Circuit's en banc decision, the Government petitioned for certiorari on April 7, 2011 on behalf of PTO Director Kappos, Case No. 10-1219. Hyatt opposed the petition on May 27. The parties' supplemental briefings on June 14 and 17 factored in the June 9 holding in *Microsoft Corp. v. i4i Limited Partnership*, 564 U.S. —, 131 S. Ct. 2238 (2011), confirming the clear-and-convincing evidence standard for challenging patent validity under 35 U.S.C. § 282 in adversarial court-litigation. The Supreme Court granted certiorari on June 27, 2011. 2011 WL 1343566.

The parties' merits briefs were filed during the period August through November 2011. Briefs nominally "in support of neither party" were filed in September 2011 by six amici curiae, including the New York Intellectual Property Law Association whose briefs in the Supreme Court and in the Federal Circuit were written and filed by the present author. The NYIPLA's arguments were entirely consistent with what ultimately became the Supreme Court's rulings.

Oral arguments were heard on January 9, 2012 and the Court's merits decision was handed down on April 18, 2012. *See supra* Part II.B.

V. WHY *HYATT* IS IMPORTANT

The business, scientific, and engineering communities should applaud the Supreme Circuit's reasons for affirming the Federal Circuit's en banc holding in *Hyatt*. Any inventor, assignee, or licensee could find itself in the position of having to proffer additional relevant evidence in a civil action in district court seeking plenary judicial recourse from an adverse decision of the PTO. The admissibility – and excludability – of such evidence should be governed only by the Federal Rules of Evidence, including Fed. R. Evid. 401-403, applicable to all civil actions generally under the Federal Rules of Civil Procedure. The Court's consideration of (aside from the weight given to) such evidence should not be affected by the fact that it could have been presented at the administrative stage, regardless of why it was not. There are sound reasons for this:

- The filing of continuing applications or RCEs in lieu of seeking de novo judicial review in district court in order to introduce additional evidence places applicants at an unfair disadvantage when the evidence required, e.g., oral (lay or expert) testimony, cannot be enter-

tained or considered by the PTO, or can only be compelled from third parties for which subpoenas are not available in non-contested cases.[16]

- The unavailability of patent term adjustments in continuing applications and RCEs unfairly penalizes patent applicants who need time to obtain and process additional evidence traversing examiners' rejections.
- IP portfolio managers can now make decisions affecting the timing, cost, and extent of producing evidence required to demonstrate patentability of inventions and allowability of patent applications.

Fortunately for the patent community, the PTO in *Hyatt* failed to persuade the Court to saddle the district court with the task of having to decide whether to exclude relevant (and hence admissible) evidence that was not, but could have been, presented at the Agency level – rather than admitting it into evidence and then weighing it in arriving at the court's conclusions of fact and law. The result sought by the PTO and rejected by the Supreme Court in *Hyatt* would have hamstrung the business community's ability to rely on the judicial process by foreclosing the unfettered right to proffer evidence beyond the administrative record when necessary in order to have a fair opportunity to refute the factual bases for adverse decisions of the Agency in circumstances where it might not have been feasible to introduce the requisite evidence at the administrative stage. These include the presentation of live testimony, survey and statistical evidence, and the obtaining of experimental test results needed to address alleged inherent disclosures in prior art references.

In non-contested (*ex parte*) administrative proceedings, the PTO has long been averse to allowing parties appearing before it and who are aggrieved by its actions to have recourse by civil action in district court. That aversion was manifested nine years ago in PTO rulemaking aimed at eliminating district-court jurisdiction of the Agency's decisions in *ex parte* patent reexaminations requested post-November 28, 1999.[17] That rule, 37 C.F.R. § 1.303(d), was challenged in recent litigation against the Agency[18] as having been prescribed by the PTO without statutory authority and hence was invalid as being ultra vires *ab initio*. The Agency's aversion unfortunately has now resurfaced, this time in the AIA. In particular, SEC. 6(h)(2)(A) and SEC. 7(c)(1) of the AIA amend 35 U.S.C. § 141 and § 306 to bestow *nunc pro tunc* immunity from suit upon the PTO in patent reexaminations in Chapter 30 of title 35, U.S.C., irrespective of when the request for reexamination was filed, thereby stripping patent owners of their long-standing, fundamental, statutory right to challenge adverse decisions of the Agency in those cases by civil action in federal district court.[19]

Likewise, with respect to contested (*inter partes*) administrative proceedings, the AIA established two new post-patent-grant revocation (claim invalidation) procedures, namely, "*inter partes* review" under SEC. 6(a) (revising Chapter 31 of title 35, U.S.C.) and "post-grant review" under SEC. 6(d) (adding new Chapter 32 of title 35, U.S.C.). Revised Section 319 in Chapter 31 and Section 329 in new Chapter 32, together with 35 U.S.C. § 141 as revised by SEC. 7(c)(1), preclude district-court jurisdiction of PTO decisions in these cases.[20]

Also troubling is the possibility of future problems arising out of the concurring opinion of Justice Sotomayor (joined by Justice Breyer), which reads in pertinent part as follows:

> Consistent with ordinary equity practice and procedure, there may be situations in which a litigant's conduct before the PTO calls into question the propriety of admitting evidence presented for the first time in a § 145 proceeding before a district court. The most well-known example was presented in *Barrett Co. v. Koppers Co.*, 22 F.2d 395, 396 (C.A. 3 1927), a case in which the Barrett Company, during proceedings before the Patent Office, "expressly refused to disclose and to allow their witnesses to answer questions" essential to establishing the priority of its invention. After the Patent Office ruled against it, the Barrett Company attempted to present in a subsequent R. S. 4915 [the predecessor of 35 U.S.C. § 145] proceeding "the very subject-matter concerning which . . . witnesses for the [patent] application were asked questions and the Barrett Company forbade them to answer." *Id.*, at 396. The Third Circuit understandably found the Barrett Company estopped from introducing evidence that it had "purposely" withheld from prior factfinders, lest the company be allowed "to profit by [its] own . . . wrong doing." *Id.*, at 397.
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> ***
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> Because there is no suggestion here that [Hyatt's] failure to present the evidence in question to the PTO was anything other than the product of negligence or a lack of foresight, I agree that [Hyatt] was entitled to present his additional evidence to the District Court. <u>But I do not understand today's decision to foreclose a district court's authority, consistent with "'the ordinary course of equity practice and procedure,'" *ante*, at 1700 (quoting *Butterworth*, 112 U.S., at 61,</u>

cont. on page 18

cont. from page 17

> 5 S. Ct. 25), to exclude evidence "deliberately suppressed" from the PTO or otherwise withheld in bad faith. For the reasons set out by the Court, see *ante*, at 1700-1701, an applicant has little to gain by such tactics; such cases will therefore be rare. In keeping with longstanding historical practice, however, I understand courts to retain their ordinary authority to exclude evidence from a § 145 proceeding when its admission would be inconsistent with regular equity practice and procedure.

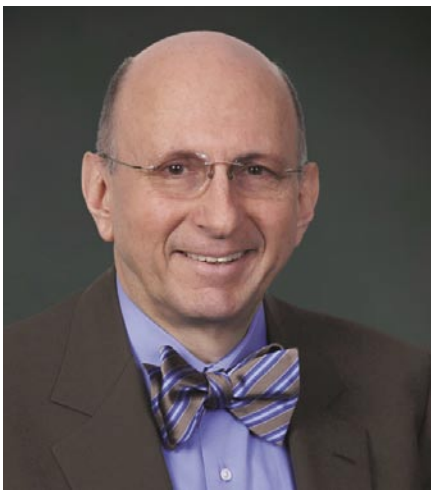
Hyatt, 132 S. Ct. at 1701-02 (Sotomayor , J., concurring) (alterations in first paragraph in original) (underlining added).

It would not be an unreasonable stretch of the imagination to suppose that the PTO will seek to take advantage of the above-quoted dicta by inquiring of patent applicants during the prosecution stage whether all of the evidence available to the applicant that supports the traversal of a rejection has been submitted. Could the failure to respond or to identify any such evidence which was available at the time be used by the PTO to estop the applicant in subsequent prosecution, or to support an inference in the event of a subsequent Section 145 action that evidence newly presented which could have been obtained (albeit more likely than not at considerable expense, e.g., by retaining experts to conduct tests and submit affidavits) during the examination stage had been "deliberately suppressed" or "otherwise withheld from the PTO in bad faith?" That an applicant would, for no good reason, engage in "deliberate suppression" of, or "withhold in bad faith" existing or procurable evidence supportive of patentability in the administrative proceeding as contemplated by the concurrence in *Hyatt* is too counterintuitive, illogical, unrealistic, and improbable of occurrence to warrant serious concern.

Nevertheless, despite the virtual impossibility of such a speculative and specious scenario, one might view it as creating a tension between the PTO's interest in limiting the basis for maintaining a Section 145 civil action, and the exercise of sound professional judgment on the part of patent practitioners in foregoing an "evidentiary data dump" that would lard their clients' patent application records in the PTO with evidence of patentability[21] beyond what is necessary to make the point and to avoid supplying fodder for possible estoppel theories in future litigation. In such circumstances, one would be well advised to respond to the PTO's inquiry by stating to the effect that, in the professional opinion and judgment of the applicant's representative, the evidence presented is considered sufficient to address the rejection, and that moreover, the applicant reserves the right to present additional evidence as may be appropriate in the event a subsequent de novo judicial review proceeding becomes necessary. It remains to be seen whether the PTO, prompted by a certain degree of indifference within the patent bar,[22] could thwart the prophylactic benefit of such a response through rulemaking statutorily authorized by a future "technical" amendment of the AIA, or by persuading Congress to statutorily limit the evidentiary scope of 35 U.S.C. § 145, or eliminate the section entirely, thereby achieving a milestone in what appears to be the PTO's campaign to abolish the right of de novo judicial review of all its decisions once and for all.

VI. CONCLUSION

In sum, the result advocated by the PTO in *Hyatt* – and which may yet loom over the inventive community through legislation and rulemaking would create harmful economic policy antithetical to the interests of the business community by frustrating the constitutional purpose of the patent system "to promote the Progress of the . . . useful Arts," U.S. Const. art. I, § 8, cl. 8. Patent applicants and their assignees and licensees would be precluded from fully exercising, if and when the need arose, their historic statutory right to a square deal in seeking plenary, district-court adjudication of the PTO's refusal to grant legal protection for patentable inventions. In the long run, it would create uncertainty for inventors and entrepreneurs who rely on settled business expectations based on a stable patent system that justifies and encourages the investment of risk capital in developing and fostering the creation , legitimate protection , and enjoyment of quiet title to technological innovations.



(Endnotes)

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[2] 566 U.S. —, 132 S. Ct. 1690 (2012) (Thomas, J.) (concurring opinion by Sotomayor, J., joined by Breyer, J.).

[3] *Hyatt v. Kappos*, 625 F.3d 1320 (Fed. Cir. 2010) (en banc).

[4] "De novo judicial review" – as opposed to appellate judicial review – is defined in Black's Law Dictionary, 9th ed. p. 924 (West Group 2009) as "[a] court's nondeferential review of an administrative decision, usually through a review of the administrative record plus any additional evidence the parties present." The de novo judicial review sought in *Hyatt* was thus aimed at an adjudication in district court in contrast to a direct appeal to the Federal Circuit which would have had to defer to the Agency's factfindings on a record fixed at the administrative stage.

[5] Under SEC. 7(a) of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (Sep. 16, 2011), the Board of Patent Appeals and Interferences will become the Patent Trial and Appeal Board ("PTAB") on September 16, 2012. Both of these administrative tribunals are referred to herein as the "Board." This date coincides with the effective date of the AIA provisions enabling *inter partes* review (SEC. 6(c)(2)(A)) and post-grant review (SEC. 6(e)), and conferring jurisdiction on the PTAB.

[6] *Hyatt*, 132 S. Ct. at 1697-98.

[7] *See* SEC. 7(c)(1) of the AIA.

[8] Amended by SEC. 7(c)(2) of the AIA.

[9] The Court made plain that its concern is "only with § 145 proceedings in which new evidence has been presented to the District Court," *Hyatt* , 132 S. Ct. at 1699, and that "[n]either party contends that the [AIA] has any effect on the questions before us," *id*. at 1694 n.1. However, there appears to be no reason why the Court's holding would not apply equally to civil actions under Section 145's Lanham Act counterpart in 15 U.S.C. § 1071(b). Also, with regard to the Court's latter observation, *see infra* Part V.

[10] *See supra* note 5. Also, under SEC. 9(a) of the AIA, venue in all civil actions against the PTO has been relocated from the District of Columbia to the Eastern District of Virginia. Because the latter forum is noted for its uniformly robust "rocket docket" handling of cases, one can expect trial of such actions within time frames comparable to if not shorter than the PTO's handling of continuing applications or requests for continued examination ("RCEs").

[11] *See Dome Patent, L.P. v. Doll*, No. 07-1695 (PLF), slip op. at 6 n.5 (D.D.C. Mar. 30, 2009) ("the availability of discovery under the Federal Rules of Civil Procedure is a significant incentive for parties challenging PTO action to file suit in United States district courts rather than in the Federal Circuit") (available on PACER).

[12] *See infra* note 15.

[13] Pub. L. No. 103-465, Dec. 8, 1994, amending 35 U.S.C. §§ 104, 111, 154, and 271.

[14] *Id*.

[15] Hyatt's declaration was treated by the district court essentially as a document whose contents constituted additional evidence. On the other hand, one could say that the actual purpose of the declaration was to point out where the evidence required under Section 112 to support the rejected claims existed in the specification of the patent application which was already part of the administrative record before the PTO and hence was not new evidence at all. Viewed as such, the declaration was more in the nature of an argument that Hyatt (or his attorney had he had one at the time) could have presented in the "Remarks" section of his response to the examiner's rejection rather than in a subsequent declaration, or even in an appeal brief in the Federal Circuit had he chosen that route. This point was not discussed to any significant extent during the appellate review of the district court's granting of summary judgment in the wake of the exclusion of Hyatt's declaration.

[16] *See supra* note 11.

[17] 37 C.F.R. § 1.303(d) (2003) ("For an ex parte reexamination proceeding filed on or after November 29, 1999 . . . no remedy by civil action under 35 U.S.C. § 145 is available."). The rules when prescribed was (in the present author's opinion) ultra vires and hence invalid. *See* Charles E. Miller & Daniel P. Archibald, *Interpretive Agency-Rulemaking vs. Statutory District Court Review-Jurisdiction In Ex Parte Patent Reexaminations*, 92 J. Pat. & Trademark Off. Soc'y 498, 502 n.7 (2010). In a current case of first impression, *Teles AG v. Kappos*, No. 11-cv-00476, 2012 WL 695610 (D.D.C. Mar. 5, 2012) (Howell, J.), the district court addressed the question as to whether 35 U.S.C. § 306 confers pre-AIA district-court jurisdiction under 35 U.S.C. § 145 of PTO decisions in post-November 28, 1999 *ex parte* reexaminations (thereby providing discovery mechanisms under the Federal Rules of Civil Procedure that are not available in direct appellate review in the Federal Circuit). *See supra* note 11. The court upheld the validity of 37 C.F.R. § 1.303(d) which flies in the face of the express language of 35 U.S.C. § 306 in effect at the time ("The patent owner involved in a[n *ex parte*] reexamination proceeding . . . may seek court review under the provisions of sections 141 to 145 of this title, with respect to any decision [of the Board] adverse to the patentability of any . . . claim of the patent."). *Teles*, 2012 WL 695610, at*2 (emphasis added). An appeal of the district court's ruling was filed in the Federal Circuit on April 3, 2012.

[18] *Id*.

[19] A more detailed treatment of this aspect of the AIA is contained in a soon-to-be-published article by Charles E. Miller & Daniel P. Archibald, tentatively titled *Beware the Suppression of District-Court Jurisdiction of Administrative Patent-Validity Determinations Under the America Invents Act: A Critical Analysis of a Legislative Black Swan in an Age of Preconceived Notions and Special-Interest Lobbying*. Preprints are available from the present author upon request.

[20] *Id*.

[21] Such an attitude would not be inconsistent with the ratio decidendi of the holding in *Therasense, Inc. v. Becton, Dickinson & Co*., 649 F.3d 1276 (Fed. Cir. 2011) (*en banc*). A patent applicant's behavior in withholding evidence *supportive* of patentability in order to avoid unduly burdening the application record would be of no relevance to the duty of disclosure under 37 C.F.R. § 1.56 because it could not be a basis for imputing to the applicant the requisite state of mind for inequitable conduct.

[22] To say that the filing of some 200 civil actions under Section 145 since the 1952 Patent Act came into effect, and of numerous other suits under the predecessor statute, evinces a degree of desuetude relative to direct appeals to the Federal Circuit such that de novo judicial review no longer serves its purpose thereby warranting the abolition of Section 145 (not to mention the trademark (Lanham Act) counterpart, 15 U.S.C. § 1071(b)) gives one pause, to say the least. On that basis, why not abolish the sections of other titles of the United States Code that are supposedly underutilized?

Comics and Copyrights and a Super Legal Battle

James W. Gould[1]

Superman Is Created

It was a hot summer night in 1934 in Glenville, Ohio when the teenaged Jerry Siegel conceived of Superman as an alien with super powers hiding in plain sight as Clark Kent. The next morning he rushed over to Joe Shuster, his high school friend and the artistic half of the pair. Together, they developed the characters. Shuster drew Superman and Clark, in their now familiar garb, and Lois Lane from a real-life teenager named Laura, who aspired to be a model. Ultimately, Jerry married his "Lois Lane" for life.

Jerry and Joe tried for years to interest publishers in a Superman comic strip, since in the 1930s there was more money for artists in syndicating a comic strip than in the nascent comic book industry. In late 1937, they signed a contract with Detective Comics (D.C. to comic fans) for some non-Superman work, with a sixty-day option to publish new features. Shortly thereafter, D.C. decided to launch a new comic book titled Action Comics. D.C. put out a request for new material, leading the McClure Newspaper Syndicate to submit the Superman comic strips it had earlier rejected. D.C. decided that their first issue, Action Comics No. 1, would be Superman. (An original copy of Action Comics No. 1 recently sold at auction for $1.2 million.) In comic industry parlance, No. 1 was the "origin story" of Superman.

Jerry and Joe changed the Superman strips into comic book format. Before it was printed, D.C. sent Siegel a check for $130 (which was the going rate for the thirteen-page Action Comics No. 1; that equals about $2000 in today's dollars.) Also enclosed was the fateful assignment to D.C. of "all [the] good will attached . . . and exclusive right[s]" to Superman "to have and to hold forever." Siegel and Shuster cashed the check and signed and returned the assignment. A few months later, in September of 1938, D.C.'s worldwide ownership rights to Superman were confirmed in an employment agreement. Other agreements followed.

A quick primer on copyrights: in relevant part, under 17 U.S.C. § 106 the owner of the copyright in a cartoon has the exclusive right to:

- Reproduce;
- Prepare derivative works;
- Distribute copies by sale, rental, lease or lending; and
- Display the work publicly.

Derivative works for cartoons include movies, television shows, action figures, clothing and other accessories with the copyrighted image. While a derivative work can have its own copyright on new material, it will still need rights to the original copyright to avoid infringement. Further, the rights in a copyright may be assigned or licensed in whole or in part.

The simple clauses in the agreements between D.C. and Superman's creators would lead to a legal struggle over these various rights that has lasted over 60 years. Today a case is still pending on appeal in the Ninth Circuit. For most of that period, Siegel and Shuster repeatedly lost in court until finally in 2008 Siegel's heirs won a partial victory relating to the copyright renewal term for Superman. This legal saga illustrates many legal issues concerning copyright protection for cartoons. We will get to all of that, but first, as they say, back to the story.

Action Comics No. 1 Creates An Industry

Action Comics No. 1 was published on April 18, 1938. 1938 was otherwise not a good year. The Depression was still going on and Hitler annexed Austria and part of Czechoslovakia. The response to Superman was, to use a popular word from the 1930s, "astounding." The first run sold out immediately. In three months, D.C.'s monthly sales went from 30,000 comic books to 1.3 million, all due to Superman. It is not an exaggeration to say Superman created the superhero comic industry. The timing of a Superman who used his powers for good, in stark contrast to the Nazi concept that Übermen are entitled to dominate others, may also have played a part.

Siegel and Shuster continued to work out of their studio in Cleveland under contract. Other aspects of and related to Superman evolved, including his ability to fly, X-ray vision, super hearing, heat vision, his weakness to kryptonite and the characters of Jimmy Olsen and Lex Luthor. When each of those aspects and supporting characters were developed and whether they were created as a work made for hire ultimately became issues for both liability and damages apportionment. But I digress.

D.C. cashed in on Superman through radio, novels, movies, TV and merchandising. D.C. trademarked key Superman symbols, notably the "S in a Shield," and "Look up in the sky! . . . It's a bird! . . . It's a plane! .

. . It's Superman." Of course we lawyers love "Truth, Justice and the American Way." Maybe some firm should license the trademark.

Siegel and Shuster began to feel they deserved a portion of all this cash flow. World War II put a hiatus on seeking a money resolution for the duration. Joe was rejected from service because of his poor eyesight. He continued to work for D.C., eventually managing a stable of artists for cartoons including Superman. Siegel enlisted in the Army in Cleveland on June 28, 1943, listing his profession as "Category 006 – Authors, Editors and Reporters." He was discharged in 1946. Unfortunately, all other Army records regarding Siegel and millions of others were lost in a 1973 fire. Through contacts with Siegel's daughter the author has learned that Siegel was stationed mostly in Hawaii, working on the Mid-Pacifican section of Stars and Stripes, the newspaper funded now by Congress to give independent news to those serving.[2]

During the war, Superman comics continued, but Superman appeared only a few times in stories fighting the Axis powers. It appears that it was difficult to reconcile his super powers with the war effort – why not just fly to Berlin and nab Hitler? Besides, if Superman really did that, what would they put in the next issue? Nonetheless, Superman's appearances were enough for Hitler's propaganda machine to denounce Superman.

The First Lawsuit

After the war, Siegel and Shuster acted on their unhappiness by filing suit in 1947 against D.C., seeking *inter alia*, to annul and rescind their assignment for lack of mutuality and consideration. After a trial in Westchester County, New York, the "official referee" found the 1938 assignment valid and affirmed D.C. as the exclusive owner of all rights to Superman. Eventually the case was settled with D.C. paying $94,000 to Siegel and Shuster ("S&S" for short) and S&S affirming D.C.'s full ownership of Superman.

The Second Lawsuit

The settlement would seem to have ended the legal battle, but this was not to be a one-act play. In 1969, S&S filed a declaratory judgment action in United States District Court for the Southern District of New York seeking the copyright renewal rights to Superman under the then extant 1909 Copyright Act. Under that Act, there were two 28-year terms, the initial and the renewal. The concept of renewal terms in part was that an author might reap some reward later in life if his work became successful. S&S lost on summary judgment, so a jury never heard their story.[3] Unfortunately for S&S, the Supreme Court had held that an assignment of "all rights" applied to the renewal term, even though it had not yet vested.[4]

The summary judgment also applied *res judicata* to the 1947 State Court judgment of assignment of copyright. While a defeat, the Federal Court decision did have one aspect that would later prove useful. Specifically, the Second Circuit found that "Superman had been spawned by the plaintiffs four years before the relationship between his authors and the defendants existed. . . . We do not consider this sufficient to create the presumption that the strip was a work made for hire."[5] More on work made for hire later.

By 1975 Siegel and Shuster were 61 years old and nearly destitute. Their legal challenges to D.C. had led to them being essentially blackballed by the industry; they found it hard to get work in their field. Shuster at one point worked as a messenger and as an illustrator of underground comics. Siegel was reduced to working as a clerk. Luckily for them, a fellow cartoonist, Neal Adams, took up their cause. Neal explained his tactics, which any litigator should admire, to the author.

Neal Adams has had a long and illustrious career as an artist, including commercial art. But his first love has always been cartoons, approached as art. Neal was one of the first to "break the frame" of the traditional comic book format of six equal size panels per page. During the time he was involved with drawing Batman for D.C. during the later 1960s to early 1970s, he returned the character to his original Dark Knight roots/persona. In so doing, he steered Batman away from the campy, costumed comic character that mirrored the then-popular 1960s live action "Batman" TV series.

Neal's artistic portrayal of Batman still provides inspiration for the artists who draw Batman to this day. Neal's Batman has even inspired the recent version of the Dark Knight, (as played by Oscar® winner Christian Bale), which has been the focus of filmmaker Christopher Nolan's Batman films.

Neal also admired the early comic artists, especially the creators of Superman. Neal saw that Siegel and Shuster were foundering in their legal battle and contacted them. Siegel and Shuster agreed to have Neal represent them as an attorney-in-fact. Neal approached Jay Liebowitz, son of Jack Liebowitz (of D.C.) who had signed the original contracts relating to Superman. Jay had been given D.C.'s ancillary and licensing rights, including the movie rights to Superman. Jay refused to give anything to S&S, on the ground that comics lost money.

Neal responded, "That's B.S. You have made millions on all the licensing spinoffs."

Jay backed off, but still refused to make an offer. Not being a lawyer, Neal knew he could not go to the

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courts, which in any event had not been hospitable. But he could, and did, take the issue to the Court of Public Opinion. Neal first went to newspapers and talk shows, but this did not move the money needle. Neal made a plea at a National Cartoonists Society ("NCS") meeting, giving an impassioned speech laced with many gerunds beginning with the letter between e and g. The NCS agreed it would consider the issue and maybe send a letter.

After the NCS meeting, outside the coat room, a man said to Neal, "Quite a speech. Do you know what building you are in?"

"Allied Chemical?"

"No. The National Press Club. Do you know who I am?"

"No. Should I?"

"I am the President of the Press Club. [Likely William Broom, President for 1975.] If you want, I can call a press conference for tomorrow morning for you to tell your story."

Neal eagerly agreed, then went back upstairs to tell the NCS that it could either come to the press conference tomorrow or prove it was irrelevant to cartoonists' rights.

The next morning the NCS and many reporters came to the press conference. An uproar followed; Jay was now willing to talk. This led to an offer of a pension of $20,000. Shuster, desperate for financial help, authorized the deal. Neal pushed some more and got the number to $25,000.

A lawyer for the NCS then became involved and negotiated medical benefits for life for S&S and Siegel's wife. Then Neal asked for S&S to be given credit as the creators of Superman. Jay refused, likely concerned that any admission about attribution might affect title to the Superman copyrights.

By now the newspapers had begun following the story. Neal told reporters that everything was good, "just about." That was an irresistible hook for reporters to ask follow-up questions as to what was missing. Neal told them about the credit issue. Shortly after this, Neal had to leave town for a comics convention in Florida. He asked Jerry Robinson, then President of the NCS (Robinson was a revered and respected comic artist who created the most famous superhero sidekick of all-time – Robin, the Boy Wonder – and the most iconic/popular comic villain of all time – The Joker) to handle the negotiations. Neal told Jerry he was confident that Jay Liebowitz would call in the morning.

Jay, predictably, was harried by many reporters. Jay could not reach Neal (who was deliberately incommunicado), so Jay called Jerry, asking for help on the credit issue. Jerry responded he was the "worst person in the world to talk with about that. In comics, having your name on the work is very important."

Ultimately, the public pressure proved too much and Jay folded. Warner Communications, which had bought D.C. largely for the movie rights to the cartoon superheroes in D.C.'s stable, owned up to a "moral obligation" and settled. The 1975 settlement stated that the pensions would end if either Siegel or Shuster sued for any rights to the copyright in Superman. But their moral victory in the settlement of being given credit as the creators of Superman was also very important. Artists, indeed all creators, want credit for their work.

Neal's victory on the attribution issue presaged a change to the Copyright Law. On December 1, 1990, Congress passed § 106A of the Copyright Act, "Rights of certain authors to attribution and integrity."[6] Section 106A(a)(1)(A) gives the author of a work of visual art the right to claim authorship of that work. Section 106A(a)(2) gives the author the right to prevent the use of his or her name as the author of a work he or she did not create. Only the author has these rights, whether or not the author is the copyright owner.

Thus today, Neal's fight to get S&S attribution would have been far easier. Corporations should also not fear giving attribution today because the statute draws a clear distinction between an author and a copyright owner. On a more practical note, while under the statute artists may waive their attribution rights to a specific work, it is usually in a corporation's interest to give attribution to an artist to help cement their working relationship with artists.

Well, by now in this story you might think that S&S's legal saga is over, after all of the settlements and affirmations of copyright ownership. But then from stage right entered Congress, barely after the curtain fell on the 1975 settlement. The Copyright Act of 1976 in Section 304(c) allows an author to terminate an assignment of "all rights" with respect to the renewal term of a copyright. But (doesn't there always seem to be a "but"?) not if the copyright was in a "work made for hire."

A simple example of "work made for hire" is an artist employed by Disney to draw cels for an animated film. Since he is an employee and his specific job is to create the work, the work made for hire doctrine makes an express assignment unnecessary. This is important to employers, because it eliminates the need for an assignment of each new work. The 1976 Act specifically defined "work prepared by an employee within the range of his or her employment" as a work made for hire.[7]

In contrast, when authors were independent contractors, the presumption in early law was that the author retained the copyright to her work. Until the 1960s, the work made for hire doctrine was generally applied to

only the employer-employee relationship. About then, courts began applying the work made for hire doctrine to independent contractors depending on the degree of control or supervision of the artist's work.[8] This was codified in the 1976 Act, which stated that if an author (in copyright parlance, an artist is an author) is "specially ordered or commissioned" to create a contribution to a "collective work" and "expressly agree[s] in a written instrument signed by them that the work shall be considered a work made for hire," then legally it is.[9] This created a potential trap for artists unaware of the legal meaning of the phrase.

While the work made for hire doctrine generally is still alive today, the renewal termination provisions of § 304(c) of the 1976 Act applied only to copyrights in existence as of January 1, 1978 and only to assignments executed before that same date. The Copyright Act later changed things by moving to a single term of life of an author plus 50 years, for a minimum of 75 years, which eliminated the renewal termination issue for new copyrights.[10] (The 1998 Sonny Bono Copyright Extension Act[11] increased the term for copyrights in their renewal term to 95 years from the date the copyright was initially secured.[12] For copyrights in their initial term, the renewal term was lengthened to 67 years.) Thus, disputes over "work made for hire" relating to renewal term rights will eventually end since there are no "renewals" of copyrighted work created after 1978. But, since so many superhero characters were created before 1978, there was the potential for many suits.

For Superman, it was this termination right that Siegel's widow, Joanne (his Lois Lane), and Siegel's daughter, Laura Siegel Larson, sought in a new case in 2004 against D.C. and Warner Brothers (which had purchased D.C.) in the United States District Court for the Central District of California. The Siegels had to navigate the tricky statutory requirements of giving notice within the statutory window for each Superman copyrighted work to terminate the 1938 assignment, the 1948 stipulation and the 1975 agreement outlined above. Shuster's estate gave similar termination notices.

Eventually, the Siegel claim was teed up for trial on *inter alia*, the issues of: (1) whether the termination notices were effective; and (2) if so, what aspects of the copyright in Superman were subject to termination and which were subject to the work made for hire exception. In other words, the key issue was what work belonged to Warner Brothers and D.C. because it was done under the employment work made for hire agreement and what belonged to the Siegels because it predated the work made for hire agreement.

Remember that in 1937 S&S signed a two-year employment agreement with D.C. This agreement stated that all work done by them "during said period of employment, shall be and become the sole and exclusive property of the Employer, and the Employer shall be deemed the sole creator thereof. . . ."[13] This language illustrates a work made for hire, although that term is not used.

The 1938 agreement between D.C. and S&S illustrates an assignment of copyright:

> This release sold and transferred to Detective such work and strip [Superman], all good will attached thereto and exclusive rights to the use of the characters and the story, continuity and title of strip contained therein, to you [Detective] and your assigns to have and to hold forever and to be your exclusive property… . The intent hereof is to give you exclusive right to use and acknowledge that you own said characters or story and the use thereof exclusively. . . ."[14]

The decision from which much of this history was taken came down on March 26, 2008.[15] While the lengthy and entertaining opinion addresses many subsidiary issues, the key holding was that:

> After seventy years, Jerome Siegel's heirs regain what he granted so long ago – the copyright in the Superman material that was published in *Action Comics*, Vol. 1.[16]

To oversimplify, the holding is based on Siegel and Shuster creating much of the content of Action Comics No. 1 before there was an employment agreement for a work made for hire. For this content, there was only an assignment, and the assignment of the renewal term was null and void under the statute because of the termination notices.

Various post-trial motions failed, leaving this holding intact. The damages phase was stayed while Warner Brothers appealed to the 9th Circuit, where the case was still pending as of the final manuscript date. If the decision is affirmed, there will be a trial to apportion profits between what was in No. 1 and what was created as a work made for hire. There will also be a trial over "whether to include the profits generated by D.C. Comics' corporate sibling's exploitation [think Superman movies] of the Superman copyright."[17]

In movie terms, we might call this "The Never Ending Story." In literary/legal terms, it conjures images of Dickens' literary tale of the multi-generation lawsuit *Jarndyce v. Jarndyce*. Or maybe just that Truth, Justice and the American Way seem finally poised to prevail, provided there is no work made for hire.

Art v. Copyright

Besides assignment and work made for hire, cartoonists have also struggled with another issue: the own-

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ership of their original art as its value has soared. It is important to distinguish between legal ownership of the physical work of art (*e.g.*, a painting or a drawing) and the intangible copyright protecting it. Mere sale of the physical work does not convey copyright any more than the sale of a copyrighted book or DVD. For cartoonists, their original art was kept by the publishing house or simply destroyed. But who owned the original art? Into this fray once more rode the bold Neal Adams.

Neal saw his own work being shredded after plates were made for a press run. Neal told the worker not to destroy his art, getting a desultory response, "Yeah."

Neal said, "Let me put it this way. If you don't save them, I will come back and punch you hard in the face." That worked.

Starting in 1981, Neal fought for six years to resolve ownership while the art languished in storage. Some artists did not wait and just took their work. During the fight, D.C. tried a test auction of an original piece of comic art for $200. Two hundred dollars was bid, but D.C. withdrew the piece, likely for fear of a suit for selling art it might not own. Eventually, in 1987 D.C. decided to return the original art to the artists. Marvel followed. This single step doubled the income of artists that year.

But issues surrounding the ownership of original art are not dead. Jack Kirby[18] got much of his art back from Marvel, after Neal Adams' successful fight. Later, Kirby's heirs sued Marvel to enforce an agreement to return the rest of his original art. Kirby's heirs lost because the statute of limitations had expired.[19] They also lost on their efforts to terminate assignment of the renewal term because the comics were created under a work made for hire agreement.

The messages to cartoonists from the Kirby case are to (1) act quickly and aggressively to retrieve their original art and (2) avoid a work made for hire clause and only license their work, if possible.

EPILOGUE

Comics have changed with the digital age – 80% of comics are now created digitally and most lettering is done by machine rather than by hand. The line between cartoons, video games and CGI (Computer Generated Images) movies continues to blur while movies based on cartoon characters continue to be made. The economics are still not good for most comic artists, yet some companies, on occasion, have agreed to continuing royalties rather than just a fixed amount. But many of the same legal issues still apply. Because of the Superman legal battle, more artists are aware of the pitfall of "work made for hire" language as well as words of assignment in their contracts.[20] They should also be aware that in 1989 the Supreme Court established a list of factors to determine whether a work is one made for hire, even if the author/artist does not sign an express agreement stating that it is:

- The hiring party's right to control the manner and means by which the product is accomplished;
- The skill required;
- The source of the instrumentalities and tools:
- The location of the work;
- The duration of the relationship between the parties;
- Whether the hiring party has the right to assign additional projects to the hired party;
- The extent of the hired party's discretion over when and how long to work;
- The method of payment;
- The hired party's role in hiring and paying assistants;
- Whether the work is part of the regular business of the hiring party;
- Whether the hiring party is in business; the provision of employee benefits; and
- The tax treatment of the hired party. [21]

Cartoon artists should consider these factors in deciding such things as who provides the supplies and studio space.

They should also remember that their physical art is distinct from copyright in that art. But even with all this, young comic book artists, like struggling artists everywhere, are often more concerned about getting their work out there than the related legalities.

One might also think that more creators of older comics would have sought to terminate the copyright renewal term, but it seems few have done so.[22]

The world of cartoon artists is also in blog overdrive over a recent decision in a case brought by a cartoonist, Gary Friedrich, against Marvel Comics over the rights to Ghost Rider. The December 8, 2011 decision from the United States District Court for the Southern District of New York[23] illustrates the difficulty of an artist challenging assignment, even if an agreement was just a short statement of endorsement on the back of free-lancer checks[24] and even if the consideration for another agreement was a promise of future work which never materialized, because an exchange of promises was deemed consideration. But (again the but), the Southern District of New York also noted that "following execution of the 1978 Agreement, [Kirby] essentially disappeared for a year – he was an alcoholic and was riding in a truck with a friend for a period of time."[25] Thus, the artist's own actions may have prevented Marvel from giving him any work.

The decision is somewhat confusing for stating that if the Ghost Rider character was not created as a work made for hire, Friedrich would get the renewal rights, yet also holding that the contracts of assignment conveyed renewal rights. If there was no work

made for hire, and if the artist in fact had provided termination notice for the renewal term, then, according to *Siegel v. Warner Brothers*, as explained above, the contracts of assignment could have been terminated for the renewal term. However, the decision does not discuss this issue.

The same decision has also spawned a blogging frenzy over whether this decision means Marvel will now go after artists who make sketches of their own creations at comic conventions and sell them on the spot. Marvel has publicly tried to allay this fear; the author agrees with this stance that artists should be free to sketch their creations at comic conventions.

First, the decision indicated that Friedrich "conceived and wrote the text" of the first comic issue of Ghost Rider. [26] While text is important, Friedrich did not draw any art. Thus, Friedrich was selling prints and books of art he did not create, a different situation from artists reprising their own work at conventions.

Second, a judgment on February 6, 2012 enjoined Friedrich only from "using or appropriating the work."[27] Although artists recreating sketches of their own prior work may technically be copyright infringement, it seems to the author that an agreement affirming the corporate ownership of copyright with a limited license for cartoonists to make and sell original sketches would protect both parties. It would be a wise step to avoid the ire of both artists and fans.

Another reason such an agreement would be wise for corporations is that there may arguably be an underlying issue as to whether such sketches by the artists fall under the Fair Use Exception of 17 U.S.C. § 107. The statutory factors to be considered in a fair use dispute include, in relevant part:

1. Whether it is for commercial use (yes – the sketches are sold);
2. The nature of the copyrighted work (a comic strip, a comic book, a movie, etc.);
3. The amount and substantiality of the portion used in relation to the copyrighted work as a whole (a sketch of one character vs. a full comic book or movie); and
4. The effect of the use upon the potential market for or value of the copyrighted work (such sketches should enhance the value of the copyrighted comic books by increasing fan reader loyalty, as can be seen by visiting a comic book convention).

This defense does not appear to have been raised in the *Marvel* case, but it might profitably be raised in a future case.

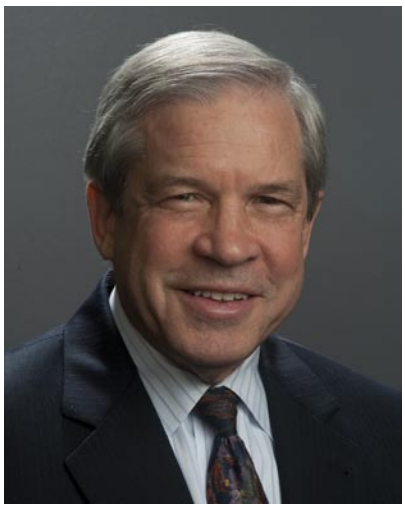
The blogs also seem fearful that the Court's decisions will block Friedrich from representing himself as the creator of Ghost Rider. In fact, the decisions contain no such express language. If they had, that might present a conflict with the attribution rights under 17 U.S.C. § 106(a)(1)(A), as explained above. Despite all of these decisions and statutory changes, it seems likely that copyright in cartoons will continue to be a fertile field for litigation.

And D.C. Comics? After Warner Brothers bought it, it moved D.C.'s headquarters from New York to Los Angeles. Warner Brothers brought in a CEO with no publishing or comic book experience, but who had done spinoff licensing for Harry Potter. Superman is on track to be on much more than T-shirts, boys' pajamas, and Halloween costumes. Ultimately, Superman may be as ubiquitous as Hello Kitty. But expect a spirited legal fight over apportioning profits if the Ninth Circuit affirms the reversion of the renewal term, as explained above.

Comics *per se*? They are not dead, just being redefined as graphic novels and underground and digital comics. A new generation of artists will start a new cycle in the evolution of superheroes, usually with each character having a dramatic weakness or flaw. But whatever new superheroes are born, whatever the legal fights, it is safe to say that Superman will survive through it all.

(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. The author would like to thank John Barrett, a long-term comic fan, for inspiring this article by arranging a meeting with Neal Adams and for providing background about comic artists.



[2] Recent cuts to the military budget have led to a proposal to move Stars and Stripes from Washington, D.C. to Fort Meade, a military base in Maryland. This has led to protests and possible Congressional action, citing concerns over reportorial independence. *See, e.g.*, April 25, 2012 article by Ernie Gates at www.stripes.com/blogs/ombudsman.

[3] *See Siegel v. Nat'l Periodical Publ'ns, Inc.*, 364 F. Supp. 1032 (S.D.N.Y. 1973), *aff'd*, 508 F.2d 909 (2d Cir. 1974).

[4] *See Fred Fisher Music Co. v. M. Witmark & Sons*, 318 U.S. 643, 656-59 (1943). *Fred Fisher* also gives a concise history of the origin of America's two-term copyright beginning in 1709 with the English Statute of 8 Anne, c. 19. *Id.* at 647-53.

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[5] *Siegel,* 508 F.2d at 914.

[6] Codified at 17 U.S.C. § 106A.

[7] 17 U.S.C. § 101.

[8] *Twentieth Century Fox Film Corp. v. Entm't Distributing*, 429 F.3d 869, 877 (9th Cir. 2005) ("in the last decade that the [1909] Act was effective, courts expanded the concept to include less traditional relationships, as long as the hiring party had the right to control or supervise the artist's work") (citations omitted).

[9] 17 U.S.C. § 101.

[10] Interestingly, this change parallels a change in English Copyright Law. *See Fred Fisher*, 318 U.S. at 648.

[11] The Sonny Bono Act is sometimes referred to as the Mickey Mouse Extension Act, as Disney's concern about the expiration of Mickey's copyright was one of the main drivers of the act.

[12] 17 U.S.C. § 304(b).

[13] *Siegel*, 508 F.2d at 911.

[14] *Id.*

[15] *Siegel v. Warner Bros. Entm't Inc.*, 542 F. Supp. 2d 1098 (C.D. Cal. 2008).

[16] *Id.* at 1145.

[17] *Id.*

[18] Jack Kirby is the author or co-author of The Incredible Hulk, Iron Man, X-Men, The Fantastic Four and Spiderman. There has been a long simmering dispute as to the relative contributions of Kirby and Stan Lee to these characters.

[19] *Marvel Worldwide, Inc. v. Kirby*, 756 F. Supp. 2d 461 (S.D.N.Y. 2010).

[20] The work for hire issue is also alive in other areas like music. The children of Ray Charles are seeking to rescind their waivers of any claim to copyright on Ray's songs, using the Section 304 recapture doctrine described above. The Ray Charles Foundation recently sued to enforce the waivers with a backstop argument of work for hire.

[21] The factors were laid out by the Supreme Court in *Community for Creative Non-Violence v. Reid*, 490 U.S. 730, 751-52 (1989).

[22] *See, e.g., Siegel v. Warner Bros. Entm't, Inc.*, 690 F. Supp. 2d 1048 (C.D. Calif. 2009).

[23] *Gary Friedrich Enters., LLC v. Marvel Enters., Inc.*, No. 08 Civ. 1533(KBF)(JCF), 2011 WL 6817709 (S.D.N.Y. Dec. 28, 2011).

[24] *Id.* at *5 (citing *Archie Comic Pubs., Inc. v. DeCarlo*, 258 F. Supp. 2d 315, 331 (S.D.N.Y. 2003)).

[25] *Gary Friedrich Enters.*, 2011 WL 6817709, at *4.

[26] *Id.* at *2.

[27] *Gary Friedrich Enters., LLC v. Marvel Enters., Inc.*, No. 08 Civ. 1533(KBF)(JCF) (S.D.N.Y. Feb. 6, 2012).

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Reactions To The FDA's Draft Guidance Documents On Biosimilars Express Concerns About The Intellectual Property Rights Of Reference Product Sponsors

by Joseph Mahoney and Andrea Hutchison[1]

On February 15, 2012, the U.S. Food and Drug Administration (FDA) issued three draft guidance documents on biosimilars (also known as "follow-on biologics" or "biogenerics"). In response, numerous pharmaceutical manufacturers, industry organizations, government entities and healthcare providers have submitted comments and other petitions reflecting concerns about the abbreviated pathway for approving biosimilars.

The guidance documents reflect the agency's attempt to assist applicants who seek approval of a proposed biologic product under the abbreviated approval pathway set forth in the statute known as the *Biologics Price Competition and Innovation Act* ("BPCI Act").[2] The BPCI Act amends the Public Health Service Act ("PHS Act") and was enacted on March 23, 2010, as part of the Patient Protection and Affordable Care Act ("Affordable Care Act"). The legislation creates an abbreviated pathway for biological products that are demonstrated to be "highly similar" or interchangeable with a reference biological product (*e.g.*, antibodies, blood and blood components, proteins, vaccines) that has already been approved or "licensed" by the FDA.

The BPCI Act provides a successful biosimilar applicant with 12 years of data exclusivity. However, the Act provides less certainty for biosimilar applicants compared to generic applicants in the Hatch-Waxman regime. No Orange Book exists, increasing the number of potentially relevant patents and parties. Some estimate that a biosimilar will cost $80 to $100 million to develop compared to about $5 million for a generic in the Hatch-Waxman construct. Thus, biosimilar applicants will be well advised to conduct extensive patent due diligence before filing an application with the FDA.

The FDA Draft Guidance Documents

The FDA's three guidance documents describe key scientific and regulatory factors involved in submitting applications for biosimilar products for agency approval ("351(k) applications"). Following the enactment of the BPCI Act, members of the pharmaceutical and biotechnology industries have anxiously awaited guidance from the FDA. The guidance documents do not establish any legally enforceable duties on the FDA or sponsors because the FDA has yet to issue corresponding regulations. Juxtaposed against the manufacturers of conventional small molecule drugs, biosimilar manufacturers face greater technical barriers to entry, more complicated manufacturing processes, and, without an analog to the "Orange Book," significant uncertainty about the number of patents that may cover the reference biologic product. Consequently, the FDA's guidance has been heralded both as a set of rules for filing new applications and as the agency's attempt to implement a plan that strikes a balance between the competing goals of innovation, competition, affordable healthcare, and patient safety.

The first guidance document, entitled "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product,"[3] focuses on therapeutic protein products and describes the FDA's risk-based approach in evaluating 351(k) applications. At the outset, the FDA's approach requires an evaluation of the "totality-of-the-evidence." Not surprisingly, the scale and content of the evidence that will pass muster will be determined on a product-specific basis. The FDA further discusses a "stepwise approach" to demonstrating biosimilarity. Among other things, the FDA provides guidelines pertaining to the analysis of (1) structure, (2) function, (3) animal data (*e.g.*, toxicity, pharmacokinetics ("PK") and pharmacodynamic ("PD") measures, and immunogenicity), and (4) human data (*e.g.*, PK, PD, clinical immunogenicity, clinical safety and effectiveness, clinical study design and the extrapolation of human data across indications). The FDA further mentions the significance of post-marketing monitoring and consultation with the agency throughout the development process.

In addition, the FDA sets forth a listing of terminology. Among the list of terms are the agency's definitions for "protein" and "chemically synthesized polypeptide" as used in the BPCI Act to amend the definition of "biological product" set forth in section 351(i) of the PHS Act (42 U.S.C. § 262(i)). According to the FDA's guidance:

- "*Protein*" means any alpha amino acid polymer with a specific defined sequence that is greater than 40 amino acids in size; and
- "*Chemically synthesized polypeptide*" means any alpha amino acid polymer that is a) made entirely by chemical synthesis, and b) less than 100 amino acids in size.

While the FDA notes that, in general, a sponsor must provide information to demonstrate biosimilarity based on data directly comparing the proposed product with the reference product (*e.g.*, analytical studies and at least one human PK and/or PD study intended to support a demonstration of biosimilarity must include an adequate comparison to the reference product licensed

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under section 351(a)), the agency makes clear that, under certain circumstances, a sponsor may seek to use data comparing a proposed product with a non-U.S.-licensed product. For example, data derived from animal or clinical studies of a non-U.S.-licensed product might be used to address, in part, the requirements under section 351(k)(2)(A). To do so, the sponsor must further provide evidence establishing an acceptable bridge to the U.S.-licensed reference product.

The second guidance document, entitled "Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product,"[4] is a discussion of analytical factors relevant to the determination of whether a proposed product is "highly similar," *i.e.*, biosimilar, to the innovator product. The factors to consider include: (1) the expression systems used, (2) manufacturing processes, (3) physiochemical properties, (4) functional activity, receptor binding and immunochemical properties, (5) impurities, (6) stability, (7) finished product characterization, and, not insignificantly, (8) a physicochemical and biological assessment of the reference product and reference standards, including "a thorough analytical comparison between the proposed biosimilar product and the reference product."

Again, while the FDA generally requires a direct comparison of the proposed protein product with the reference product, under certain circumstances, a sponsor may seek to use data derived from animal or clinical studies comparing a proposed protein product with a non-U.S.-licensed product to address, in part, the requirements under section 351(k)(2)(A) of the PHS Act. The sponsor must further provide evidence establishing an acceptable bridge to the U.S.-licensed reference product.

The third guidance document, entitled "Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009,"[5] attempts to answer questions from 351(k) applicants. The questions are grouped into the following categories: (1) biosimilarity or interchangeability; (2) requirements for submitting a Biologics License Application ("BLA") for a "biological product"; and (3) exclusivity.

The first section addresses practical questions when seeking to obtain licensure for a biosimilar product. By way of example, representative questions include:

- Can a proposed biosimilar product have a different formulation than the reference product?
- Can an applicant obtain licensure of a proposed biosimilar product for fewer than all routes of administration for which an injectable reference product is licensed?
- Can an applicant obtain licensure of a proposed biosimilar product for fewer than all presentations (*e.g.*, strengths or delivery device or container closure systems) for which a reference product is licensed?
- Can an applicant obtain licensure of a proposed biosimilar product for fewer than all conditions of use for which the reference product is licensed?
- Can a sponsor use comparative animal or clinical data with a non-U.S.-licensed product to support a demonstration that the proposed product is biosimilar to the reference product?
- Can an applicant extrapolate clinical data intended to support a demonstration of biosimilarity in one condition of use to support licensure of the proposed biosimilar product in one or more additional conditions of use for which the reference product is licensed?

The proposed answers to all of the preceding questions is "yes," *albeit* with further qualifications and cautions from the FDA specific to each question. There are many other questions in this first section, each of which has a different answer and explanation.

In the second section, the FDA provides, among other things, insight into how it interprets terms such as the category of "protein (except any chemically synthesized polypeptide)" in the amended definition of "biological product" in section 351(i)(1) of the PHS Act and how it defines "product class" for purposes of determining whether an application for a biological product may be submitted under section 505 of the Food, Drug, and Cosmetic Act. Finally, the third section of this draft guidance discusses whether an applicant can include in its section 351(a) BLA submission a request for reference product exclusivity under section 351(k)(7) of the PHS Act and how to determine whether there is an unexpired orphan exclusivity for an indication.

Because "interchangeability" as defined by the BPCI Act will be difficult for a biosimilar applicant to achieve, the FDA is open to minor modifications. Composition of matter patents may thus be avoided and a premium will be placed on additional patent strategies covering formulations, combinations (*e.g.,* companion diagnostics), post-translational modifications, and comparative assays. For instance, the Hatch-Waxman case, *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, Civ. Action No.11-11681-NMG, 2011 WL 5114475 (D. Mass. Oct. 28, 2011), illustrates the use of such strategies. In that case, Momenta and Sandoz Inc. filed an Abbreviated New Drug Application ("ANDA") seeking approval for a generic equivalent to Sanofi's Lovenox® (enoxaparin), an anticoagulant comprising low molecular weight heparin. The drug is biochemically complex and it was therefore difficult to show "active ingredient sameness" as required for an ANDA. Recognizing this difficulty, Sanofi filed a Citizen Petition with the FDA arguing that no generic be approved until Lovenox was further characterized. The FDA denied Sanofi's request but set forth criteria for

establishing "active ingredient sameness." Momenta then developed an acceptable manufacturing control process, patented it, and then sued the later generic applicant Amphastar for patent infringement. The court granted Momenta's request for preliminary injunction. In the context of biosimilars, such strategies to enforce patents are expected to be more prevalent.

Comments On The FDA's Guidance

Since the issuance of the FDA's guidance documents, several companies have expressed concerns relating to the IP rights of reference product sponsors. Of particular interest, in part because of a Citizen Petition filed by Abbott Laboratories ("Abbott") on April 2, 2012, Doc. No. FDA-2012-P-0317-0001 (Apr. 2, 2012), is whether the FDA can properly protect trade secret information contained in the reference product sponsor's BLA when approving a biosimilar application. *See, e.g.*, Pharmaceutical Research and Manufacturers of America (PhRMA), Comment, Doc. No. FDA-2011-D-0611-0039 at 4-5 (Apr. 16, 2012); Abbott Laboratories, Comment, Doc. No. FDA-2011-D-0611-0024 (Apr. 16, 2012); Genentech, Inc., Comment, Doc. No. FDA-2011-D-0611-0005 at 3-6 (Apr. 10, 2012); Amgen Inc., Comment, Doc. No. FDA-2011-D-0611-0033 at 8 (Apr 16, 2012). [6]

Abbott's Citizen Petition urged that the FDA "not accept for filing, file, approve, or discuss with any company, or otherwise take any action indicating that the agency will consider, any application or investigational new drug application (IND) for a biosimilar" that cites as its reference product any product for which the BLA was submitted to the FDA prior to March 23, 2010, the date on which the BPCI Act was enacted. Abbott focused on the trade secret rights of the reference product sponsor, noting that the information in the BLA is a trade secret under state and federal law. Citing pre-enactment sponsors' expectations at the time they filed their BLA and statements made on prior occasions by FDA representatives indicating that the FDA lacks legal authority to approve biosimilar applications, Abbott urged that it had a reasonable expectation that its trade secrets would remain "inviolate" and not be used to benefit a competitor. The company cited the lengthy BLA application as replete with details constituting proprietary trade secret information. More broadly, Abbott contended that the safety and efficacy data of the reference product is necessarily relied upon by the biosimilar applicant, and that this information, even if public, is dependent upon the reference product's confidential underlying data, including clinical trial data. In other words, the FDA cannot separate the "public finding" from the underlying data, and relying upon the finding of safety necessarily constitutes use of the trade secrets. According to the Petition, the use of the sponsor's trade secrets would constitute a taking of private property in violation of the Fifth Amendment to the U.S. Constitution. The concern about trade secrets of the reference product sponsor has been echoed in several other comments already submitted to the FDA. *See, e.g.*, PhRMA, Comment, Doc. No. FDA-2011-D-0611-0039 at 4-5 (Apr. 16, 2012); Abbott Laboratories, Comment, Doc. No. FDA-2011-D-0611-0024 (Apr. 16, 2012); Genentech, Inc., Comment, Doc. No. FDA-2011-D-0611-0005 at 3-6 (Apr. 10, 2012); Amgen Inc., Comment, Doc. No. FDA-2011-D-0611-0033 at 8, 35-36 (Apr 16, 2012).

Another topic that is disputed as potentially discouraging innovation is the FDA's treatment of the 12-year exclusivity period. Several comments disagree with the FDA's approach requiring that the 12-year exclusivity period be justified, rather than granted as of right. *See, e.g.*, PhRMA, Comment, Doc. No. FDA-2011-D-0611-0039 at 7-8 (Apr. 16, 2012); Amgen Inc., Comment, Doc. No. FDA-2011-D-0611-0033 at 8, 39-41 (Apr 16, 2012); Bayer Healthcare LLC, Comment, Doc. No. FDA-2011-D-0611-0029 at 2, 5-6 (Apr. 16, 2012); Bristol-Myers Squibb Co., Comment, Doc. No. FDA-2011-D-0611-0041 at 2 (Apr. 12, 2012); Hon. Anna Eshoo, Comment, Doc. No. FDA-2011-D-0611-0043 at 2 (Apr. 16, 2012). The entities opposing this process contend that sections 351(k)(7)(A) and (B) are drafted so as to confer a presumption of exclusivity and for a clear time period. By contrast, the FDA's Question and Answer Guidance Document suggests that the applicant is presumed ineligible for exclusivity unless proven otherwise. The opponents of the FDA's proposal emphasize the disincentive innovator companies would have in bringing their product to market without some guarantee of exclusivity. Consequently, the FDA has been requested to change its position and to also avoid potential ambiguity by publishing its exclusivity determinations.

Relating to the BPCI Act's premarket litigation provisions, some comments have requested that the FDA require a "certification" by the biosimilar applicant that includes a broad disclosure of manufacturing information sufficient to allow the reference product sponsor to conduct a premarket litigation assessment. *See, e.g.*, Abbott Laboratories, Comment, Doc. No. FDA-2011-D-0611-0024 at 6-8 (Apr. 16, 2012); PhRMA, Comment, Doc. No. FDA-2011-D-0611-0039 at 12-13 (Apr. 16, 2012).

These entities have suggested that a certification requirement would not impose much burden on the agency but would allow reference product sponsors to take "immediate patent infringement action," which was purportedly the Congressional intent in creating section 351(l). Comments such as these suggest that reference product sponsors seek to have the litigation provisions more closely follow the procedures in Hatch-Waxman Act cases.

In addition, numerous entities have suggested that the biosimilar products should have distinguishable

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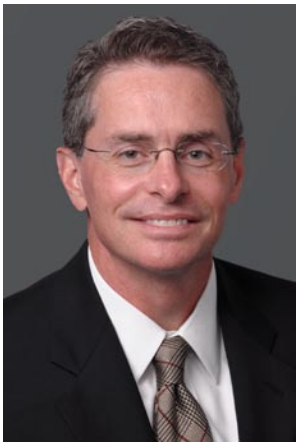
non-proprietary names in order to prevent inadvertent substitution and help track adverse events. *See, e.g.*, Allergan, Inc., Comment, Doc. No. FDA-2011-D-0605-0043 at 7-8 (Apr. 16, 2012); MedImmune, Comment, Doc. No. FDA-2011-D-0605-0048 at 2 (Apr. 16, 2012); Amgen Inc., Comment, Doc. No. FDA-2011-D-0611-0033 at 30 (Apr 16, 2012); PhRMA, Comment, Doc. No. FDA-2011-D-0611-0039 at 10 (Apr. 16, 2012); Novo Nordisk, Comment, Doc. No. FDA-2011-D-0611-0004 at 16-17 (Apr. 5, 2012); Biotechnology Industry Organization (BIO), Comment, Doc. No. FDA-2011-D-0605-0049 at 11 (Apr. 16, 2012); Hon. Anna Eshoo, Comment, Doc. No. FDA-2011-D-0611-0043 at 2 (Apr. 16, 2012). Reference product sponsors appear to believe that distinguishing the nomenclature and the package labeling may help differentiate the innovator product from the follow-on biologic. Taken together, these issues suggest that there may be disputes concerning the labels used by biosimilar products, which naturally leads to questions about advertising, trademarks and trade dress.

Furthermore, several companies have disputed the proposed definitions of "protein" and "chemically synthesized polypeptide" as scientifically substantiated. *See, e.g.*, Merck & Co., Inc., Comment, Doc. No. FDA-2011-D-0611-0032 at 5-6 (Apr. 16, 2012); Bayer Healthcare LLC, Comment, Doc. No. FDA-2011-D-0611-0029 at 2, 7 (Apr. 16, 2012); Novo Nordisk, Comment, Doc. No. FDA-2011-D-0611-0004 at 1-6 (Apr. 5, 2012); Biogen Idec, Comment, Doc. No. FDA-2011-D-0602-0037 at 3-4 (Apr. 16, 2012). Specifically, incorporating a size cutoff into the definition of these terms proposed by the FDA has been criticized as arbitrary. Instead, it appears that referenced product sponsors are urging the FDA to allow more flexibility or to broaden the definition to include products manufactured biologically.

Although these comments are just illustrative of some of the intellectual property-related concerns that industry members have expressed in light of the BPCI Act and the FDA's Draft Guidance Documents, they indicate that many new issues regarding the protection, enforcement and procurement of intellectual property for reference product sponsors and biosimilar applicants alike will naturally arise as biosimilar applications are filed and premarket litigation options investigated. With some estimating biologics comprising more than half of the top-ten selling drugs by 2014, the FDA's proposed scheme is far-reaching and will undoubtedly lead to further concerns and questions by industry.



(Endnotes)

[1] Joseph Mahoney is a Partner in the Chicago office of Mayer Brown LLP, specializing in patent matters relating to pharmaceuticals, medical devices, biotechnology and chemicals. Andrea Hutchison is an associate in the Chicago office of Mayer Brown LLP, specializing in patent litigation, procurement and counseling with particular emphasis on pharmaceutical patent litigation. The views expressed in this article are solely those of the authors and are not to be attributed to Mayer Brown LLP or any of its clients.

[2] Sections 7001-7003 (Biologics Price Competition and Innovation Act of 2009) of the Patient Protection and Affordable Care Act (Public Law No. 111-148). The relevant text of the BPCI Act can be found at the FDA's website at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM216146.pdf.

[3] Found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf.

[4] Found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291134.pdf.

[5] Found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM273001.pdf.

[6] The Citizen Petition and Comments may be accessed at http://www.regulations.gov by typing the document number into the Search bar.

ATTN: 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 1.914.286.2813.

HISTORIAN'S CORNER

As Time Goes By – Judges Dinner Keynotes of Note - Re-dux

Canadian David Mulligan played golf at the Country Club of Montreal back in the 1920s. One day after hitting a poor tee shot, he is said to have re-teed and hit again, calling it a "correction shot." His friends named the shot after him. Coincidentally, he later became manager at the Waldorf=Astoria.

Another Mulligan was also associated with the Waldorf; this one as keynote speaker at our Association's Judges Dinner – not once, not twice, but thrice. However, the second and third keynotes were not "correction shots," since Judge William Mulligan of the U.S. Court of Appeals for the Second Circuit never laid an egg when it came to public speaking.

Judge Mulligan's first address before our Association resulted from a dilemma concerning the Judges Dinner that Past President William Conner (later Judge Conner) faced when he took the helm of the Association's ship-of-state in 1972. His concern was that, because in prior years so few judges were in attendance, the name "Judges Dinner" might need to be changed if the trend continued.

President Conner concluded that the key to success was choosing a keynote speaker from the judiciary who was highly respected among peers and a superb speaker to boot. Judge Mulligan fit the bill to a tee.

When he took the podium at the 1973 Judges Dinner, Judge Mulligan talked about judicial opinions and their underlying authority. He pointed out that "[s]ometimes, indeed, also there is no authority at all and one must resort to reason, a somewhat tricky and dangerous alternative."[1]

He then discussed a case posing what he called "an intriguing and novel fact pattern arising in the sophisticated and busy Second Circuit."[2] The case related to a *pro se* plaintiff alleging that the-then Secretary of Defense, Melvin Laird, had in some way unknown to the plaintiff succeeded in putting his (Laird's) head into the plaintiff's mouth. The alleged result was serious injury to plaintiff's teeth and gums.

In a Watergate allusion, Judge Mulligan observed:

> Although the Nixon Cabinet has since been accused of many trespasses, this was the first occasion as far as my law clerks could discover that any cabinet member had been accused of putting his head into the mouth of any ordinary citizen. The pleadings did not indicate whether the plaintiff was a Democrat or a Republican, which might have been helpful if intent were to be an element of this tort. We had all heard of unofficial reports of cabinet members of various administrations putting their foot in their mouths, but, after a conference, we found the cases quite distinguishable. We also found cases of animal trainers or visitors to the zoo who had playfully put their heads into the mouths of lions or tigers but, oddly enough, no case of a suit brought by a lion or even his guardian for injury to the molars. On the other hand, we did find suits by lion-tamers or, more properly, next-of-kin seeking damages against negligent or deliberate lion tort feasors. I only cite this as typical of the perplexing questions of first impression brought into our court. We affirmed the dismissal of the complaint here without an opinion. I wanted to write on this subject, but my colleagues persuaded me not to lest we encourage this disgusting practice which might spread even to lesser federal or even state officials.[3]

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

Judge Mulligan's 1973 keynote was a big hit, and attendance among the judges at the Judges Dinner was up. His second keynote appearance, at our 1978 Judges Dinner, at which he told amusing antecdotes about the various types of lawyers who paraded before the Second Circuit, was another big hit.

After his time of service on the bench, Judge Mulligan was back at the podium for our 1985 Judges Dinner. He opened thusly:

> It is indeed an honor and a privilege to once again be invited to address the Patent Law Bar Association [sic, NYIPLA] at your annual dinner. When I was on the bench, invitations to this dinner were always accepted with alacrity. Perhaps some of my colleagues came because of the opulent pre-prandial refreshments and vintage wines at a fine dinner. But I came only because it gave me the opportunity to discuss file wrapper estoppel, the latest advances in microbiology, and nuclear mathematics and physics with those of you who, like me, were scientifically trained and au courant with star wars and other fascinating developments. The only one I could discuss these problems with sensibly in the courthouse lunchroom was Judge Conner. I do admit that after several jars at this party some of my other colleagues displayed a remarkable eloquence in these esoteric matters.[4]

For those of you who've not had the opportunity to hear Judge Mulligan speak, suffice it to say that it was a memorable experience. A current-day likeness of that quality of speaking talent was found in Judge John Gleeson's address at the 2011 Judges Dinner.[5]

The role of judicial keynote speaker continued with a fine presentation at the 2012 Judges Dinner by Judge Colleen McMahon. May the trend long continue!

With kind regards,
Dale Carlson

(Endnotes)

[1] *Mulligan's Law: The Wit and Wisdom of William Hughes Mulligan* 69, 70 (William Hughes Mulligan, Jr. ed. 1997).
[2] *Id.* at 70.
[3] *Id.*
[4] *Id.* at 184.
[5] *See Judge John Gleeson's Keynote Address at the 2011 Judges Dinner*, NYIPLA *Bulletin*, April-May 2011, at 1, 3-9.

Report on U.S. Bar/EPO Liaison Council 2011 Meeting, Washington, D.C.

by Thomas E. Spath[1]

The U.S. Bar/EPO Liaison Council held its 27th annual meeting in Washington, D.C. on October 19, 2011. The meeting was hosted by the Intellectual Property Owners Organization at its offices. The location of the U.S. Bar/EPO Liaison Council meetings alternates between Munich and the United States; our meetings in recent years have been held in Washington, often in proximity to the AIPLA meeting.

Although the president of the European Patent Office, Benoit Battistelli, had indicated his intention of continuing the president's tradition of attending the annual Council meeting, other business prevented him from traveling to Washington. The three EPO attendees represented the office of legal counsel and two heads of examining divisions.

The U.S. contingent consisted of 17 delegates from various national and regional bar associations in the United States, as well as in-house corporate intellectual property counsel. (As a result of a special initiative begun in 2011, the membership of the U.S. Bar/EPO Liaison Council has added new representatives from a number of IP bar associations from around the country who will be encouraged to participate in our annual meeting with the EPO representatives.)

The NYIPLA representative at this council meeting was Thomas Spath from Abelman, Frayne & Schwab. Samson Helfgott, who has attended all of the 26 prior annual meetings of the Council, was precluded from attending as a result of the timing of the meeting, and we look forward to his continuing representation and the expertise that he brings on behalf of our Association.

EPO Developments

Among the wealth of information reported by the EPO, it was noted that 2010 saw an increase in filings of 11% from the prior year with 235,000 European application filings, that being the greatest number in the Office's 34 years of operation. U.S. filers represented the largest number from a single country at 26%, with the next closest being Japan at 18%; China and Korea were far behind, each with about 5%. Almost 40% of the EPO filings originate from the 38 member states of the European Patent Organization. It was also noted that filings through July 2011 showed an increase of approximately 8% over that same period in the prior year, so that the upward trend continues.

It was noted that the percentage of granted patents has continued at a generally consistent rate, having been 43% for 2010 and 42% in the prior year. Of the balance, 42% of the applications filed were abandoned after receipt of the search report and 35% were either rejected or withdrawn during the examination phase. Granted patents totaled 58,100, an increase of about 11%, which indicates that the Office is keeping up with the increase in the rate of new application filings.

The EPO also expressed general satisfaction with its pendency times, European searches being completed on average within 7.5 months of filing, which compares favorably with pendencies of the first office action of the IP5 partner offices. Where the EPO is the office of first filing (OFF), the pendency is well below 6 months, averaging 4.8 months, thereby allowing applicants a significant amount of time to determine appropriate international filing strategies within the priority year and well before the publication of their applications at 18 months. The average time from filing to grant in 2010 was 43.5 months. The accelerated examination program referred to as PACE was requested by only about 5% of applicants – a surprisingly low rate to most U.S. practitioners since there are no special petitions or fees payable when PACE is requested; the only requirement imposed upon the applicant is that responses be filed within a somewhat shortened reply period.

The European Patent Organization has comprised 38 member states and two extension states for some time. These 40 countries cover an overall market of some 600 million people. The EPO is continuing its interest in exporting the European model as a coherent and carefully defined legal framework to enable users to benefit from patent rights abroad that will enjoy a high presumption of validity at a low cost and validation through a straightforward procedure. It is the goal of the EPO to contribute in this way to the extension of the global integration of the patent system. As was reported last year, the EPO concluded a validation agreement with Morocco which still requires the necessary implementation legislation to be passed by the

Moroccan government. In May 2011, the EPO signed a memorandum of understanding with the Tunisian IP office, the objective being to conclude a similar validation agreement with that country by the end of 2012. It was reported to the Council that no further growth is contemplated.

In order to advance its goal of maintaining the standing of the EPO as one of the leading patent authorities in the world, additional efforts are being directed to increasing efficiency while maintaining or even improving patent quality in a financially sustainable manner. An independent study commissioned by the EU and published in March 2011 reported that the companies polled assigned the European patent system the highest overall rating; also of interest was the finding that users considered compliance with legal requirements far more important than other criteria, including timeliness.

When President Battistelli took office in July 2010, he commissioned two external audits: one related to finance and the other to the IT systems of the EPO, the former topic having been of expressed concern by his predecessor. It was reported that the EPO is currently in sound financial health, with mid- and long-term concern regarding paying the pensions of its aging staff.

Based upon the results of the audit, the current fee structure will be maintained for the foreseeable future, with a 5% increase. (This is good news for applicants since the EPO's former president had predicted the need for substantial front end loading of the application fee structure in order to meet projected requirements.)

On the IT front, it was candidly admitted that the EPO is going to face challenges, again due to its aging systems. Five so-called "Road Maps" were described. These are: (1) Human Resources, (2) Quality, (3) Cooperation, (4) Buildings, and (5) IT. Specific examples provided are the construction of a new office in The Hague, with the termination of leases on four buildings in Munich and The Hague. It was also noted that the EPO has adopted the same policy as the USPTO with respect to encouraging its examiners to work from home 3 or 4 days a week in order to permit an increase in the number of examiners while avoiding the necessity of providing additional office space. On the IT side, efficiency improvements in the key areas of search tools and information management, and in the patent granting process are under study.

Translations

Translation costs are one of the principal concerns of the EPO, as well as its users, due to the requirement imposed by many national IP laws for the filing of a translation of the complete application in order to secure validation in that country. These translation requirements are of utmost relevance since there are 28 languages used in the 38 member countries, and political as well as economic interests must be considered. Member nations have expressed strong interest in preserving their respective cultural and linguistic heritages.

Another concern that the EPO is addressing is that expressed by its members and the larger patent community regarding the unavailability of translations until the end of the grant process. There is clearly a great interest by the public in early translations to permit review of the application as it is published. The EPO itself has long been concerned about the inclusion of Asian documents in its searching.

In order to address the concerns and interests, the EPO and Google entered into a long-term agreement in 2011 to collaborate on machine translation of patents into all 28 European languages, as well as into Chinese, Japanese, Korean and Russian. The availability of the translations will be phased, with expected completion of the entire project by the end of 2014. So-called "on the fly" real-time translations will be available in the three official languages of the EPO and from and into the other 32 languages through both the EPO and Google websites. Most importantly, the service will be **free** to all users.

EPO Practice and Procedures

The EPO wishes applicants and their representatives to take note of the new practice of issuing a second written opinion prior to officially issuing a negative IPER under Rule 66.4 PCT, where the EPO has acted as the ISA and the applicant has filed amendments or arguments relevant to the international preliminary examination. This is to avoid the issuance of a negative IPER and advance the prosecution.

Modification of PCT practices also appear to have improved the overall application processing. For example, examiners are allowed to invite applicants to clarify their application before search and to require applicants to indicate the basis of any amendments. A further change favoring applicants is the reinstatement of the pre-2002 practice of affording the examiners greater latitude in making reasoned useful suggestions on their own initiative for modifying the text of the application communicated under Rule 71(3) EPC.

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Concerns expressed by applicants with the time limit for filing divisional applications have been ameliorated with the adoption of a cover sheet on which the examiner enters the time limit set for filing such voluntary divisional application under Rule 36(1)(a) EPC. Another concern of applicants that has been addressed in Rule 70(a) EPC is the extending of the time from one to six months for filing the required response to a negative written opinion, IPER or supplementary international search report.

Based upon an analysis of the procedure a mandating a response to a negative search opinion, there has been a major increase in amendments filed prior to the beginning of examination which has resulted in greater procedural economy and celerity.

One specific aspect of EPO practice that was addressed by a number of the U.S. Council members was the stringently applied requirements under Rule 123(2) and 123(3) for the requirement that claim amendments find verbatim support in the specification. It was suggested the EPO examiners provide a clear statement of why claim amendments were accepted during the examination stage in order to alleviate what is perceived by applicants to be an abuse by opposers of Rule 123(2). On this point, a decision by the Enlarged Board of Appeal in Case G2/10 was discussed which modified the permissibility of disclaimers that carve out subject matter disclosed in the application. The Board indicated that such disclaimers were permissible if "the remaining subject matter can be considered to have been originally disclosed in the application as filed." This decision is an apparent conflict with the broad statement in the earlier G1/03. The current policy set forth in the practice Guidelines will have to be revised and new internal instructions provided to the examiners. In view of the new Board ruling, each case will have to be taken on its own merits.

The EPO has decided that it is important to allow time for analysis of the results of the recent "Raising the Bar" initiative in order to assess its effects, and there is be a moratorium on significant changes to the Implementing Regulations, at least for the time being. Once the impact of the recent rule and practice changes has been assessed, adjustments, if any, will be considered.

In order to enhance the transparency of the legislative process within the European Patent Organization in the future, a web-based system will be implemented to gather feedback from interested parties regarding proposed substantive amendments to the Implementing Regulations as well as changes in the fee structure, and modifications to examination practice. These consultations will not extend to minor amendments of an editorial nature or regular updates, such as biennial fee increases. The present goal is to collate and summarize such comments and make them publicly available on the website in order to allow users from around the world to provide the EPO with input on substantive issues early in the legislative process. In the interest of improving the quality of issued patents, the EPO has set up a web-based tool for the filing of third-party observations under Article 115 EPC.

The Unitary EU Patent

As was reported last year, the stalemate in the adoption of regulations for the so-called Unitary European patent that would be enforceable in all member states without individual national validations and translations was overcome by a group of 25 of the European Patent Organization members, leaving only Spain and Italy in opposition. The proposed maintenance fees for the Unitary patent will be equivalent to current fees for about 6 or 7 countries. Representatives of the U.S. delegation indicated that this cost factor would be a major issue for U.S. corporations, particularly where the corporate patent owner may need to reduce the maintenance fee expenses as the patent matures and can stop paying in selected countries under the current system.

The decision to proceed with the "unitary effect" of a European patent application is made by the applicant after the decision to grant is issued by the EPO, all other procedures for search and examination remaining unchanged.

As adopted by the European Commission, there will be no revision to the EPC and all proceedings will be as usual in the EPO. The EPO will be responsible for record keeping and collecting the annual maintenance fees, which will be shared equally with all member states.

If the application were prosecuted in French or German, it would have to be translated into English; if prosecuted in English, the patent would not have to be translated.

In view of the rejection of the proposed European Union Patent Court having jurisdiction over all member states for disputes involving a Community patent, it is anticipated that a diplomatic conference will be convened among the twenty-five supporting members to create a separate treaty that is not under the purview of the Commission.

International Cooperation

In October 2010, the EPO and the USPTO entered into an agreement to create a joint classification system referred to as the Cooperative Patent Classification (CPC) for patents and patent literature. The EPO reports that the CPC implementation group has been making steady progress with the CPC expected to come into effect in January 2013. The JPO is currently studying the possibility of merging its FI classification system with the CPC, which is based upon the European classification and incorporates the best practices of the USPTO.

Another initiative reached resulted in an agreement between the EPO and the USPTO that is concerned with work-sharing goals. It was noted that the priority given by the EPO as the OFF results in searches being reported within the first half of the priority year; however, where the EPO is an office of second filing (OSF), it finds that the other IP5 offices generally have no search results available. In a pilot project, the USPTO will prioritize approximately 100 USPTO first filings in which second filings with the EPO are identified, thereby enabling the EPO to obtain the results of the USPTO's searches. This form of prioritization is seen by the EPO as ensuring the requisite timeliness for a work-sharing program to be mutually beneficial.

An agreement has also been reached for a Common Documentation Policy to create, maintain and enhance a common documentation data set for a given patent or patent family that will be consulted by IP5 offices when drawing up searches.

Under Rule 141, EPO applicants are obliged to submit the results from OFF searches as soon as they became available; the U.S., Japan, and certain other countries were excluded from this requirement.

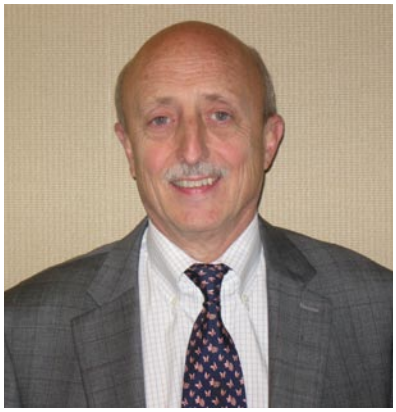
Another significant program announced was the launching of the Common Citation Document at the Tri-lateral conference in November 2011. This virtual document will combine all citation data relating to a family of patent applications being examined by the tri-lateral offices into a single data base that will be accessible by both patent offices and the general public. This is another step in the efforts to increase efficiency and reduce burdens on applicants by moving from the applicant-driven submission of search results (e.g., the US IDS) to an inter-office electronic exchange. Agreements have been reached between the EPO, USPTO, UK IPO and the JPO. The prior art cited under the common citation program will be posted in the EPO espacenet website.

A collaboration between the EPO, USPTO, and KIPO tested the feasibility of having examiners work together in one PCT application with the objective to establish a single, common, high-quality international search report and written opinion. No results of this project were available for reporting.

A comment was also made on behalf of the EPO that the "historical signing" of the America Invents Act (AIA) is seen as putting wind into the sails of harmonization from the U.S. perspective; this was taken as a favorable comment on the United States decision to move from a first-to-invent to a first-to-file system – a point of distinction that had long been argued by Europeans and nationals of other countries as an obstacle to further harmonization initiatives. This one change in our statutes may give the U.S. a stronger voice in future harmonization discussions.

US Bar Presentations

In accordance with generally established custom, U.S. representatives discussed recent decisional law deemed to be of special significance to those concerned with U.S. patent practice before the PTO, as well as litigation. A number of Supreme Court cases and decisions by the Federal Circuit Court of Appeals were outlined and their holdings discussed. Comments were also provided regarding the recent legislative history and congressional actions taken to secure passage of the AIA by those U.S. Council representatives that were closely involved with the effort on behalf of U.S. business and IP organizations. As is often the case with a substantial and detailed piece of legislation, it was predicted that a number of legislative corrections would be required in the coming year.



Endnote

[1] Thomas E. Spath is Of Counsel at Abelman, Frayne & Schwab and specializes in United States and International Patent, Trademark and Licensing Law, with a concentration in the Chemical Engineering Patent Arts.

March 23, 2012 Day of the Dinner CLE Program "The Practical Impact of the AIA on Patent Litigation"

by Mark Bloomberg

Approximately 125 judges and attorneys attended the 2012 Day of the Dinner CLE Program on the Practical Impact of the AIA on Patent Litigation. The Program also addressed the Patent Pilot Program and local patent rules.

The distinguished panel included the Honorable P. Kevin Castel of the United States District Court for the Southern District of New York, the Honorable Mark Falk of the United States District Court for the District of New Jersey, and Raymond Chen, Deputy General Counsel for Intellectual Property Law and Solicitor of the United States Patent and Trademark Office. NYIPLA President Terri Gillis of Mayer Brown LLP and Second Vice-President Anthony Lo Cicero of Amster, Rothstein & Ebenstein LLP moderated the panel and provided practitioners' views. The audience was engaged in the presentation, asking the panel a number of questions that showed deep interest in these timely topics.

The Program was organized by the Association's CLE Committee (Co-Chairs Mark Bloomberg and Richard Parke).

April 12, 2012 CLE Program "Hot News - Hot New Doctrine or Yesterday's News?"

by Maya Tarr

On April 12, 2012, the Meetings and Forums Committee and the Copyrights Committee co-hosted a Continuing Legal Education (CLE) luncheon at the Union League Club entitled "Hot News - Hot New Doctrine or Yesterday's News?" Professor Jeanne C. Fromer of Fordham Law School (visiting professor at New York University School of Law this year) moderated the discussion. The panelists included Andrew L. Deutsch of DLA Piper, Benjamin E. Marks of Weil, Gotshal & Manges LLP, and Glenn F. Ostrager of Ostrager Chong Flaherty & Broitman P.C.

Tom Kjellberg and Joel Karni Schmidt of Cowan, Liebowitz and Latman, P.C., who co-Chair the Copyrights Committee, introduced the panelists, who discussed *Barclays Capital Inc. v. Theflyonthewall.com*, 650 F.3d 876 (2d Cir. 2011), and the "hot news" doctrine in general. While the District Court had found Theflyonthewall.com ("Fly"), an online financial news subscription service that was publishing Barclays Capital's, Merrill Lynch's and Morgan Stanley's equity research, liable for "hot news" misappropriation, the Second Circuit reversed in part, finding that the plaintiffs' "hot news" misappropriation claims were preempted by copyright law because Fly was not "free-riding" on the plaintiffs' products and services.

Mr. Marks, who was part of the team at Weil that represented the plaintiffs, argued that the "hot news" claim should have survived on the basis that the extra elements required to survive copyright preemption were met – specifically, the plaintiffs generated information at a cost; the research they were compiling was time sensitive; Fly was free-riding on the plaintiffs' work; Fly and the plaintiffs were direct competitors; and Fly posed a substantial threat to the plaintiffs' products and services.

Mr. Ostrager, who represented Fly, argued against the plaintiffs' free-riding claim on the basis that Fly put substantial efforts into distributing information on its site and that it provided attribution, and asserted that Fly was not competing with the plaintiffs since it is not an investment bank. He also emphasized the importance of preserving information in the public domain and argued against the plaintiffs' time-sensitivity claim.

Mr. Deutsch, who wrote an amicus brief on behalf of various news companies, discussed the position that the "hot news" doctrine should be preserved without being preempted by the Copyright Act, and mentioned, among other things, his article in support of a federalized "hot news" doctrine.

Minutes of March 13, 2012
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 12:30 P.M. by President Terri Gillis.

In attendance from the Board:

Theresa Gillis	John Moehringer
Thomas Meloro	Alexandra Frisbee
Anthony Lo Cicero	Susan Progoff
Jeffrey Butler	Bruce C. Haas

Charles Hoffmann, Dorothy Auth, Walter Hanley and Kevin Ecker participated by telephone conference. Absent and excused from the Board meeting were Annemarie Hassett, Dale Carlson, Leora Ben-Ami, and Ira Levy. Feikje van Rein was in attendance and Robin Rolfe participated by telephone from the Association's executive office.

Terri Gillis called the meeting to order.

The Board approved the Minutes of the February 2012 Board meeting.

Jeffrey Butler provided the financial report, reporting that the association is in good standing. Jeffrey requested Board approval to give the Association's accounting firm limited Power of Attorney for the filing of certain IRS forms (Form 990). The Board approved this request.

Jeffrey read the new members' list and the Board approved these new members.

Terri Gillis and Feikje reported on the progress of collecting pledges for the upcoming International Association of Judges IP event. The Association has collected $23,000 and already sent $15,000 to the event organizers. The Association will receive 30 seats for the event, which will be scattered among the tables of attending judges. The Board approved sending up to $50,000 to cover the committed pledges.

Terri reported that the NY Local Patent Rules will be released soon. Terri predicts that many judges will not follow these rules.

Anthony Lo Cicero reported on the proposed alternate CLE format. In particular, Anthony proposed that the Association send members a questionnaire to determine what types of training are needed by practitioners. In the meantime, Anthony suggested the Board consider skills training sessions for young associates, such as a deposition skill training in a patent case.

Tom Meloro reported on the Amicus Committee, which is considering filing amicus briefs in four cases.

Charles Hoffmann reported the Judges Dinner preparations are close to final, with final approval of the Bulletin pending. Feikje reported that the number of guests attending the event is up from last year; 175 honored guests are confirmed.

Dorothy Auth reported that the Day-Of-Dinner CLE event is finalized. A final preparation session will be held on the morning of the event to coordinate the topics for discussion on the panel. Terri Gillis added that Ray Chen will present the USPTO perspective and discuss the new *Inter Partes* and Post-Grant Review proceedings and Judge Castel and Magistrate Judge Falk will give the judicial perspective. Feikje noted that currently 50 people are registered for the event, 20 of whom are judges.

Walter Hanley reported that the next Bulletin will be out in the coming weeks.

Kevin Ecker reported that the Inventor of the Year committee has decided that Dr. Radoslav Adzic will be the winner, and the formal announcement will appear in the next Bulletin. Dr. Adzic was a Locke Lord nomination.

John Moehringer reported that 39 entries have been received in the Conner Writing Competition. The Writing Competition Committee has split the entries into two categories for their initial review: (1) patent-related entries and (2) non-patent related entries. After a first review, each entry will be read again to determine the top three entries in each category. The final three entries will be submitted to the Board one week before the next Board meeting.

Bruce Haas indicated that there was nothing new to report from the Membership Committee. Terri suggested that the Association organize membership-building events. John Moehringer recommended that such events be held in the beginning of the year (i.e., in June), while Robin recommended such a campaign be held after the summer.

Anthony Lo Cicero reported that an outline for the CLE portion of the Annual Meeting was sent to the CLE Committee. Dorothy Auth suggested that the Committee convene next week to discuss the event. Anthony and Terri discussed the schedule for the Annual Meeting, proposing the following: Lunch CLE event from 12:30-2 pm, Committee Meetings from 2-4 pm, Business meeting from 4-5 pm, Reception and Board meeting from 5-6 pm and Dinner from 6-9 pm.

Charles Hoffmann reported that the Copyrights Committee has organized the next CLE luncheon event which will be held in April.

Alexandra Frisbee reported there are no new updates from the Corporate Committee, but she is working with the Committee Chairs to identify a speaker to discuss the joinder topic of the AIA.

Sue Progoff reported on the Privacy Committee's February CLE Luncheon. The program was good, but attendance was problematic. Anthony suggested that the Association consider targeting small firms that could benefit most in the future from the networking

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aspect of these events. John Moehringer suggested that instead of monthly luncheon events, the Association put on fewer half-day events.

Jeffrey Butler reported on the activities of the Patent Law Committee, which has received an inquiry as to whether the Association is interested in participating in the USPTO's pro bono program. No decision was reached by the Board.

Anthony Lo Cicero reported on the Patent Litigation Committee, which is considering e-Discovery guidelines for Federal Judges. In this regard, Anthony reported that the Committee plans to submit an article for publication in the Bulletin on this topic.

Sue Progoff reported that the Trademark Committee is busy preparing the Half-Day Trademark event and is finding speakers for the already-identified topics of interest.

Dale Carlson reported that the Website & Records Committee met with Feikje and reviewed many of the Association's old records. The Committee is in the process of converting relevant records into a loadable form for the website. The Board approved destruction of documents and things, if approved by the Website & Records Committee in consultation with Feikje and a Board member, and excluded from destruction any non-duplicative Bulletins and Greenbooks.

The meeting was adjourned by Terri Gillis at 2 pm.

Minutes of April 18, 2012
Meeting of The Board Of Directors Of
The New York Intellectual Property Law Association

The Board meeting was called to order at The Princeton Club, 15 West 43rd Street, New York at 7:50 pm by President Terri Gillis. The Board meeting was preceded by a meeting of the Board with Committee Chairs and Co-Chairs who gave reports of their committee's activities in 2012. In attendance at the Board meeting were:

Theresa Gillis	Ira Levy
Charles Hoffmann	John Moehringer
Anthony Lo Cicero	Susan Progoff
Dorothy Auth	Bruce C. Haas
Annemarie Hassett	Walter Hanley
Kevin Ecker	Leora Ben-Ami

Absent and excused from the Board meeting were Jeffrey Butler. Dale Carlson participated via telephone. Alexandra Frisbie also participated via telephone for approximately 30 minutes. Feikje van Rein and Robin Rolfe were in attendance from the Association's executive office. Also in attendance for the initial presentations at the Board meeting were Edward Bailey, Gary Butter and Pejman Sharifi.

Terri Gillis called the meeting to order.

Ed Bailey, as special Board appointee for the Diversity Scholarship, presented his findings regarding which law school he recommended to receive the NYIPLA's 2012 Diversity Scholarship. Ed recommended that St. John's University School of Law be this year's recipient of the Scholarship. The Board approved the recommendation.

The Co-Chairs of the Conner Writing Competition, Gary Butter and Pejman Sharifi, presented their recommended winners for the 2012 Conner Writing Competition. Two submissions were discussed, one by Karmel, the other by Miller. The Co-Chairs and the Board agreed that the Karmel submission was the winning submission, however a discussion regarding a posted copyright notification on the submission ensued. After some discussion, the Board approved the Co-Chairs' recommendation that Karmel be named the 2012 winner of the Conner Writing Competition, subject to confirmation that the Karmel article can be published by the NYIPLA.

The Board approved the Minutes of the March 2012 Board meeting.

In Jeffrey Butler's absence, Feikje provided the financial report, reporting that the Association is in good standing and is, in fact, in better financial standing than last year at this time.

Leora Ben-Ami read the new members' list and the Board approved these new members.

Terri Gillis explained that under the Association's By-Laws, the Notice of the Annual Meeting must be circulated to all NYIPLA members of the judiciary. The Board approved a waiver of this requirement. In addition, Terri discussed the need to make a substantive amendment to the Association's By-Laws, *i.e.*, to allow electronic mailings of the Notice of the Annual Meeting. After some discussion, the Board approved presenting this amendment to the Association's membership at the Annual Meeting.

Charles Hoffmann reported on the outcome of the Judges Dinner. With 95% of the invoices now paid, Charlie reported that this year's event was higher than last year's event. However, Feijke reported that the event had generated greater revenues than last year's event. In addition, Charlie reported that several judges approached him at and after the Dinner to complain that their hosts' hospitality was lacking. Further, Terri described an incident at the Dinner in which a server collapsed and died. The Board approved a $1000 donation to the person's family in memoriam.

Anthony Lo Cicero reported that the CLE program for the Annual Dinner event was progressing and that most of the speakers have been secured.

Annemarie Hassett and Anthony Lo Cicero reported together on the progress made in developing alternative CLE program formats. The two observed that because the 12-2 pm time frame is not convenient for many practitioners, evening programs may be a better format. Annemarie proposed the Association engage "host" law firms where the events can be held to keep costs down. Terri proposed a yet-lower price point for students, young associates and corporate attorneys. Kevin Ecker proposed that a flat fee be charged for a pre-determined number of participants in advance as yet another alternative fee structure.

The meeting was adjourned by Terri Gillis at 9 pm.

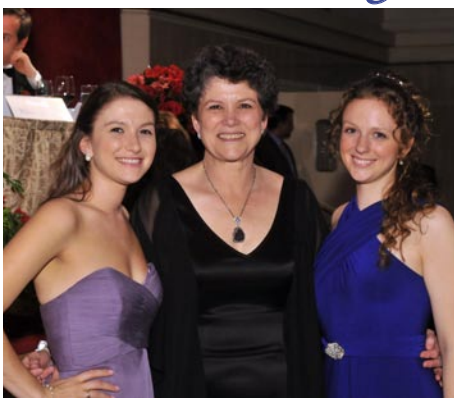
90th Annual Dinner in Honor of the Federal Judiciary

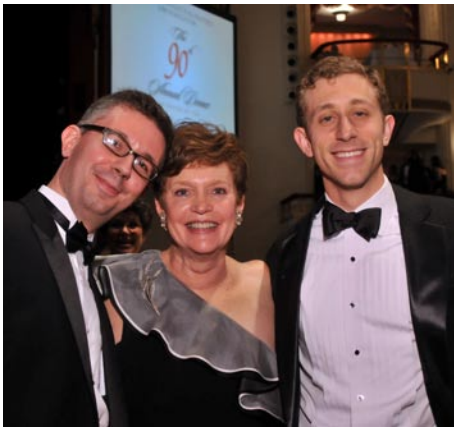
The New York Intellectual Property Association held its 90th Annual Dinner in Honor of the Federal Judiciary on March 23, 2012 at the Waldorf=Astoria.

President Terri Gillis welcomed the honored guests, members of the NYIPLA, and their guests. Joseph Bartning, Amy Buckley and Malena Dayen opened the evening's events with a magnificent rendition of the National Anthem.

The Association's Tenth Annual Outstanding Public Service Award was presented to the Honorable Alan D. Lourie of the United States Court of Appeals for the Federal Circuit.

The Keynote Speaker was the Honorable Colleen McMahon of the United States District Court for the Southern District of New York. Her remarks are printed in the entirety in this Bulletin.





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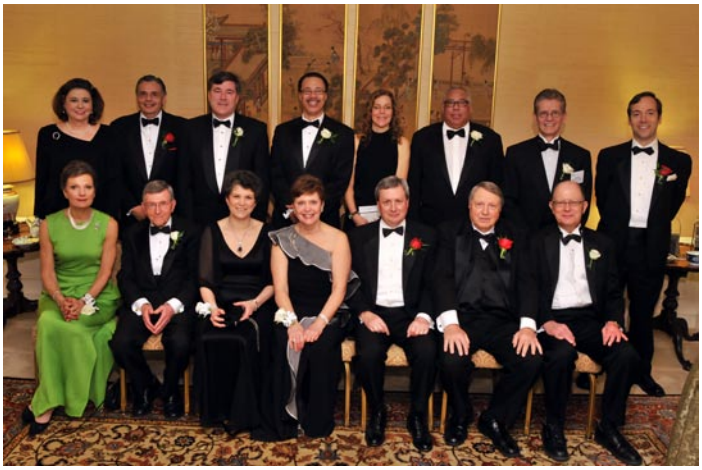

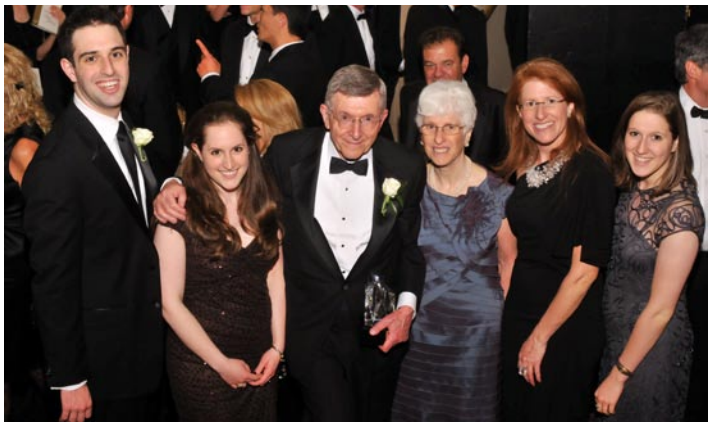

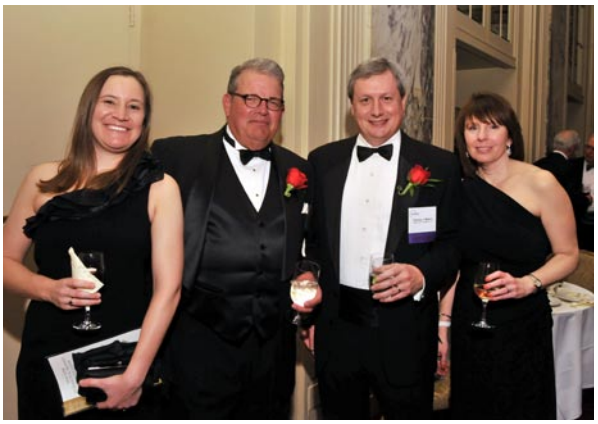

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