

NYIPLA®

February/March 2010

Bulletin

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The
88th
Annual Dinner
IN HONOR OF THE
Federal
Judiciary
March
26,
2010

The Joint Patent Practice Seminar – 26 Years of Excellence

By Allen Bloom

This year's Annual Joint Patent Practice Seminar on April 29th at the Hilton Hotel will be the Twenty-Sixth.

The First Annual Joint Patent Seminar took place at the New York Penta Hotel on May 7, 1985 and it has been held every year thereafter. Inserting "Annual" in the name indicated that the organizers had high hopes that the seminars would continue. It was Ed Filardi's idea to organize a regional, one-day seminar that would provide the practitioner with an update of patent law and practice. The focus was on the practical and the current so that there have been virtually no topics related to pending legislation, proposed regulations or harmonization proposals.

The original seminar topic was chemical patent practice in recognition that the Connecticut - Philadelphia corridor was rich in chemical, pharmaceutical and biotechnology companies. In order to convey as much information as possible, the talks were short – originally five minutes and expanded to ten minutes after the first year. Each speaker provided a six-page paper in advance which was bound and distributed to the attendees. The seminar was supported by four local associations: Connecticut Patent Law Association, New Jersey Patent Law Association, New York Patent, Trademark & Copyright Law Association, and Philadelphia Patent Law Association. Subsequently, the associations' titles became the more inclusive in-

tellectual property law associations. The goal was to have equal speaker participation from each association divided evenly between industry and law firms.

There was no formal structure.

cont. on page 3



2009 program in session in the Grand Ballroom of the Hilton New York

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PRESIDENT'S CORNER

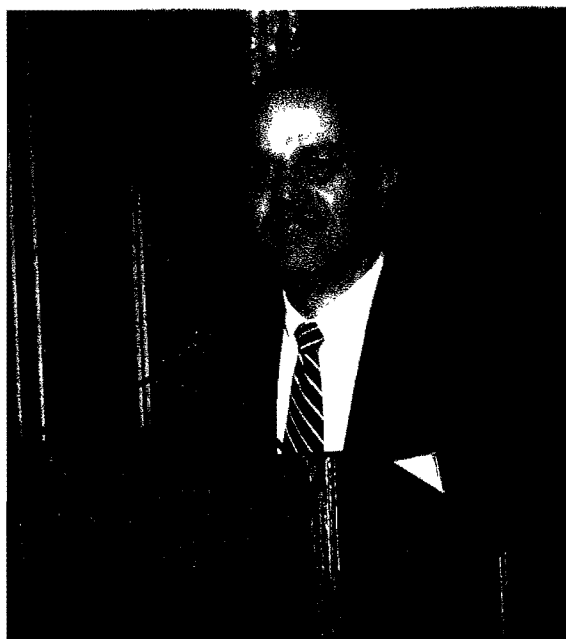
Dear Fellow Members,

In my last message, I commented on the activity of the Association's various committees during the first portion of the year. I am delighted to report that the successful work of our committees is continuing.

Our February monthly luncheon meeting featured David Kappos, the Director of the United States Patent and Trademark Office. Dave spoke to a sellout crowd of over 125 people. He described a number of initiatives underway at the PTO to improve the quality and efficiency of examination which are described in more detail in an article in this Bulletin. There also was a lively question and answer period at the end of Dave's prepared remarks. I would like to extend my gratitude to Rich Erwine and Rich Martinelli, the co-chairs of the Meeting and Forums Committee which oversees the luncheon meetings, for their management of this program and to past-president Chris Hughes for helping to bring Dave to New York.

The 88th Annual Dinner in Honor of the Federal Judiciary, which will be held on March 26, 2010, is upon us. As mentioned in the previous Bulletin, the Honorable Richard Linn of the U.S. Court of Appeals for the Federal Circuit will receive the NYIPLA Outstanding Public Service Award and our keynote speaker will be Governor Mario Cuomo. Judge Linn has proven to be a leader of the patent bar through his selfless dedication to the development of intellectual property law. Governor Cuomo, of course, is an intellectual, passionate and challenging force for social responsibility and diversity. He is also a dynamic speaker, so expect to be entertained and informed by his remarks. Registrations for the dinner are pouring in and we expect another year of terrific attendance.

As in the past, we will have a CLE program on the day of the dinner which will include participation by many of the attending judges. Program Chair Ira Levy has put together an exciting program which will feature mock expert witness testimony in a patent damage case followed by a panel discussion and critique of the direct and



cross-examination. The participants in the program include: U.S. District Court judges Barbara S. Jones of the Southern District of New York and William G. Young of the District of Massachusetts, USPTO Deputy Director Sharon Barner, John R. Lane, Richard L. Rainey, Robert G. Krupka, Edward E. Vassallo and Annemarie Hassett.

As we look past the Judges' Dinner, work on the Inventor of the Year and Conner Writing Competition Awards are in full swing. We have received a number of very qualified nominations for the Inventor of the Year and expect to be able to announce the Inventor of the Year at the Judges' Dinner. The Conner Writing Competition has developed quite a following among law students at schools in the Northeast and papers are submitted at the end of the law school term. As in the past, these awards will be bestowed at our Annual Meeting and Dinner in May.

The Greenbook will be published shortly. Special thanks again to Stephen Quigley, Publications Committee Chair, for compiling the Greenbook and for putting together this Bulletin.

Thank you for your continued support of the Association. I look forward to seeing you at the Judges' Dinner.

Sincerely,
 Mark J. Abate
 President, New York Intellectual
 Property Law Association



2009 Panel on Ethical Issues in Patent Law. Seated (l. to r.) Panel Leader Ronald A. Clayton, Scott A. Lyndon, Peter A. Sullivan, Lou Budzyn, Andrea L. D'Ambra, Anthony P. Gangemi, Walter E. Hanley. Standing at the Podium, S. Peter Ludwig



JPPCLE Committee Members with 2009 Keynote Speaker Chief Judge Paul R. Michel, U.S. Court of Appeals for the Federal Circuit. Left to Right: Thomas J. Meloro, John S. Child, Jr., Nanette S. Thomas, Judge Michel, Anthony Giaccio, Francis E. Morris, Allen Bloom

Each year responsibility for taking the lead in running the program would pass from one association to the next. The Program Committee was made up of at least one representative of each association with the chair coming from the host association. The first seminar was headed by Ed Filardi representing New York.

The first year seminar was titled, "Chemical Patent Practice" and the panels were: New Legislation Affecting Patent Rights; New Developments Impacting upon Patent Litigation Strategy; United States Patent and Trademark Practice; Foreign Patent Practice; Biotechnology; and Recent Decisions of the CAFC. USPTO practice, biotechnology (and pharmaceutical) practice and patent litigation have been panel topics at every seminar since.

The second annual seminar was hosted by New Jersey, but was again held at the Penta Hotel for convenience. I was the Program Committee Chair. The seminar was titled "Patent Practice Update" with a broadened focus not limited to chemical patent practice. In addition to the three repeating panels from the

first seminar, there were panels on licensing and on interference practice.

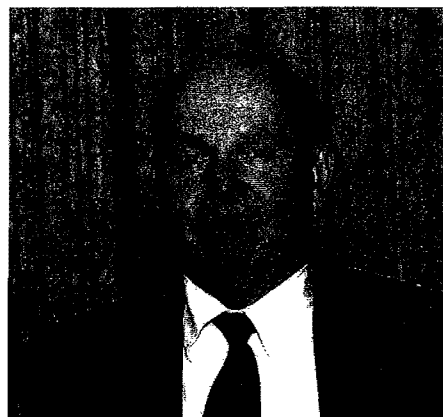
The third annual seminar titled "Patent Practice Update" was hosted by the Philadelphia Patent Law Association and was held at the Union League in Philadelphia. The Program Coordinating Committee was chaired by John Child, who is also the chair of this year's seminar.

The fourth seminar returned to the New York Penta and was hosted by Connecticut. Ron Clayton was the Program Committee Chair. Sponsorship of the seminars has continued to rotate among the four associations.

In subsequent years the Program Coordinating Committee has expanded. Since 2001, the seminar has been under the auspices of Joint Patent Practice Continuing Legal Education, Inc. with a more formalized structure and a luncheon speaker, but the same format. See the excellent website at www.jppcle.org. The Program Coordinating Committee has continued to work to provide a meaningful, cost-effective program.

We are especially proud of the 2010 seminar which will update all IP practitioners with the most recent developments in patent law and practice. This year's program will feature the Hon. Pauline Newman, Circuit Judge, U.S. Court of Appeals for the Federal Circuit, as our Keynote Speaker. The Twenty-Sixth Annual Joint Patent Practice Seminar provides a unique opportunity for IP practitioners to stay on top of the latest developments in their profession.

Allen Bloom has been working as an independent consultant since he retired from Dechert LLP after serving as a partner and Co-Chair of the Intellectual Property Group. He can be contacted at allenbloom@comcast.net.



26th Annual Joint Patent Practice Seminar

Thursday, April 29, 2010 - Hilton New York

PROGRAM PREVIEW – EVERYTHING NEW IN ONE DAY !!!

8:40 - 8:45 AM Welcome Remarks

Panel I - Litigation

- | | |
|--------------|---|
| 8:45 - 8:55 | Gemtron Corp. v. Saint-Gobain Corp., 91 USPQ 2d 1409 (Fed. Cir. 2009) - Infringing product manufactured outside of the United States. |
| 8:55 - 9:05 | The Forest Group Inc. v. Bon Tool Co. et al., 2009-1044 (Fed. Cir. Dec. 28, 2009) False marking case - per article penalties - recognition of the qui tam aspect of the statute. |
| 9:05 - 9:15 | Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc., 2008-1269, 1270 (Fed. Cir. 2009) - Plaintiff bore the burden of proving ownership of the patents pursuant to a contractual agreement and failed to do so. |
| 9:15 - 9:25 | Cardiac Pacemakers, Inc. et al. v. St. Jude Medical, Inc. and Pacesetter, Inc., 2007-1296, 1347 (Fed. Cir. 2009) |
| 9:25 - 9:35 | Lucent Technologies, Inc. v. Gateway, Inc., 92 USPQ 2d 1555 (Fed. Cir. 2009) [Microsoft v. Alcatel-Lucent]; and Cornell University v. Hewlett-Packard Co. 89 USPQ 2d 1575 (N. D. N.Y.) - Royalty calculations |
| 9:35 - 9:45 | In re Lister, 2009-1060 (Fed. Cir. 2009) - Prior Accessibility of Prior Art: PTO Must Provide Evidence of Indexing Date |
| 9:45 - 9:55 | Titan Tire Corp. et al. v. Case New Holland, Inc. et al., 566 F.3d 1392 (Fed. Cir. 2009) - Legal standard and burden of proof for preliminary injunction in a patent case |
| 9:55 - 10:05 | Q & A - 10 minutes |

Panel II – Pharmaceuticals/Life Sciences

- | | |
|---------------|---|
| 10:05 - 10:15 | Bayer Schering Pharma AG v. Barr Laboratories, Inc., 91 USPQ 2d 1569 (Fed. Cir. 2009) - Patent invalid because the formulation was obvious. |
| 10:15 - 10:25 | Ischemia Research and Education Foundation v. Pfizer, 1-04-CV-026653 (Santa Clara County Superior Court 2009) - Trade secrets dispute |
| 10:25 - 10:35 | Ariad Pharmaceuticals, Inc. et al. v. Eli Lilly and Company, 560 F.3d 1366 (Fed. Cir. 2009) Written disclosure requirement |

10:35 - 10:45	Amgen Inc. v. F. Hoffmann-La Roche Ltd., No. 2009-1020 (Fed. Cir. Sept. 15, 2009) - Material change under 271(g)
10:45 - 10:55	Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282 (Fed. Cir. 2009) (en banc) - Infringement of product-by-process claims
10:55 - 11:05	University of Pittsburgh et al. v. Hedrick et al., 573 F.3d 1290 (Fed. Cir. 2009) - Inventorship and co-invention in biotech setting.
11:05 - 11:15	Q & A - 10 minutes
11:15 - 11:30	Break

Panel III - Ethics

11:30 - 11:40	In re Bose Corp., 2008-1448 (Fed. Cir. 2009) - Reversal of decision to cancel trademark registration due to fraud
11:40 - 11:50	Is Civility Dead?
11:50 - 12:00	Ethical issues relating to Mergers/Acquisitions
12:00 - 12:10	Exergen Corp. v. Wal-Mart Stores, Inc., 91 USPQ2d 1656 (Fed. Cir. 2009) - Pleading inequitable conduct
12:10 - 12:20	Board of Trustees of the Leland Stanford Junior University et al. v. Roche Molecular Systems, Inc. et al., 2008-1509, 1510 (Fed. Cir. 2009) - How technology transfer activities of universities and research institutes may affect ownership, interest, license and shop rights to patents
12:20 - 12:30	NY - State Rules Revised: Attorney as a Witness
12:30 - 12:40	Q & A - 10 minutes

Keynote Speaker

Hon. Pauline Newman, Circuit Judge
United States Court of Appeals for the Federal Circuit

12:40 - 1:55 Lunch and Keynote Speaker

Panel IV - Licensing/Foreign Practice/ITC

1:55 - 2:05	Epistar v. International Trade Commission and Philips Lumileds Lighting, 91 USPQ 2d 1180 (Fed. Cir. 2009) - Impact of Merger/Buyout on Prior Agreement to Not Challenge Patent Validity
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- 2:05 - 2:15 AsymmetRx, Inc. v. Biocare Med. LLC, 92 USPQ 2d 1113 (Fed. Cir. 2009) - In maintaining the right to sue, as part of a license, although certain restrictions alone might not be destructive of the transfer of that right to the licensee/assignee, their totality may be sufficient to do so.
- 2:15 - 2:25 Euclid Chemical Co. v. Vector Corrosion Technologies, Inc. et al., 90 USPQ 2d 1220 (Fed. Cir. 2009) - Patent assignment language assigning all continuation applications was found ambiguous as to previously issued patents not specifically identified in the assignment.
- 2:25 - 2:35 Current status of Princo Corporation et al. v. International Trade Commission and U.S. Philips Corp., 90 USPQ 2d 1673 (Fed. Cir. 2009) - Legal standards for patent misuse in licensing
- 2:35 - 2:45 Synthes v. G.M. Dos Reis Jr. Ind. Com. De Equip. Medico, 90 USPQ 2d 1609 (Fed. Cir. 2009) - Attending US trade shows can subject a foreign company to the jurisdiction of the US Court at that location.
- 2:45 - 2:55 Inventor Remuneration - UK, France, Germany and Japan - Is the Inventor King?
- 2:55 - 3:05 License Drafting - Trademarks and Patents
- 3:05 - 3:15 Corebrace v. Star Seismatic, 566 F.3d 1069 (Fed Cir 2009) - Implicit license to "have made" by a third party arises in a general make, use and sell license unless expressly disclaimed
- 3:15 - 3:25 The International Trade Commission and Design Patents
- 3:25 - 3:35 Q & A - 10 minutes
- 3:35 - 3:50 Break

Panel V - USPTO

- 3:50 - 4:00 USPTO - Enrollment and Discipline presentation
- 4:00 - 4:10 Current status of In re Bilski, 88 USPQ 2d 1385 (Fed. Cir. 2008) - Patentable subject matter
- 4:10 - 4:20 Hindsight Bias
- 4:20 - 4:30 Larson Mfg Co. of South Dakota, Inc. v. Aluminart Products Ltd., 90 USPQ2d 1257 (Fed. Cir. 2009) - Office Actions in copending applications
- 4:30 - 4:40 Best Practices on Inventorship - What is a contributor and how to evaluate
- 4:40 - 4:50 Wyeth et al. v. Kappos, 2009-1120 (Fed. Cir. Jan. 2010) - Patent Term Extension
- 4:50 - 5:00 Q & A - 10 minutes
- Program Concludes at 5:00 PM

This program is sponsored by Joint Patent Practice Continuing Legal Education, Inc. and co-sponsored by: Connecticut Intellectual Property Law Association, New Jersey Intellectual Property Law Association, New York Intellectual Property Law Association and Philadelphia Intellectual Property Law Association.
The Preliminary Program Preview reflects topics planned as of February 1, 2010.
www.jppcle.org

"As Time Goes By -

'A Richly Rewarding Association: The NYIPLA as His Spring-Board'*

by Dale Carlson

The late Federal Circuit Court of Appeals Judge Giles Sutherland Rich's dad, G. Willard, was well aware of the New York Patent Law Association (as our association was previously known) before his son may have even dreamed of following in his father's footsteps by becoming a patent lawyer. In fact, G. Willard Giles was one of 258 attendees at the NYIPLA's first annual dinner in honor of the federal judiciary at the Waldorf=Astoria on December 6, 1922. That dinner marked the beginning of a long and hallowed tradition of honoring federal judges each year at an NYIPLA dinner - a tradition that continues to this day.

At the first NYIPLA dinner, G. Willard was in good company. The guest list included luminaries from the federal bench, including Augustus and Learned Hand. It also included Archibald Cox, a member of the NYIPLA's Board of Governors and father of Archibald Cox, Jr., special prosecutor for the Watergate scandal. Perhaps not without irony, Archibald, Jr. began his legal career as a law clerk for Judge Learned Hand.

The first NYIPLA annual dinner must have been a spectacle to behold, replete with a menu in the form of a patent to co-inventors "Cook" and "Chef". The patent contained drawings of the menu items, including one depicting a cocktail glass containing an undisclosed beverage. By way of further description, the specification was short on details, noting only that the beverage "if not made by a 'secret process' is certainly made by a process in secret." Needless to say, the Prohibition in effect at the time did not put a damper on the festivities, nor the good humor of the participants.

We may wonder what effect the spectacle of that "judges dinner" may have had on G. Willard's psyche, and whether the effect was conveyed to his son, who at the time was just starting college at Harvard. In any event, by the time Giles had completed his law studies at Columbia, and was ready to join his dad's law firm, the roaring 20s had ended and the stock market was in the process of crashing.

Early on, Giles wrote with the logical mind of someone destined to one day become a judge.



In a 1933 article entitled "The Wrong Clue, Sherlock", appearing in the Journal of the Patent Office Society, he critiqued another author's

Dale Carlson, a partner at Wiggin & Dana, serves as the NYIPLA Historian, and as President-Elect.

statements concerning the Constitutional mandate relating to inventions. The other author had commented that "an invention must promote progress in order to be patentable."

In dissecting Article 1, Section 8, Clause 8 of the Constitution, Giles concluded that the Constitutional restrictions are but two, namely that the exclusive right is for the benefit of the inventors, and the right applies only to their discoveries. He concluded that "we see no condition precedent to the granting of a patent requiring that the invention patented shall promote anything. Congress has the power to make laws which shall promote progress. The laws are to do the promoting..."

Less than two decades later, Giles was on the ladder toward becoming the NYIPLA's President. As NYIPLA Vice-President in 1948 and 1949, Giles was responsible for explaining to Congressional committees several bills that the NYIPLA had introduced in Congress to legislatively overrule the Supreme Court's *Mercoird* cases that effectively abolished the doctrine of contributory patent infringement.

During 1950 and 1951, Giles served as the NYIPLA President. He also worked on a two-person drafting committee, together with Paul Rose, to prepare what later became the Patent Act of 1952. Needless to say, he was in the national limelight for patent matters.

When Giles expressed an interest in becoming a federal judge, the NYIPLA stood ready to help. In an internal NYIPLA memo dated January 16, 1956, Virgil C. Kline, a past member of the NYIPLA's Board of Governors, wrote:

Mr. Floyd Crews [the NYIPLA's President, 1956-57] called me about a week ago and said that he was interested in securing some help for Giles Rich's attempt to become appointed a Judge of the CCPA....

Mr. Judson Morehouse, Chairman of the Republican State Committee, has his office in the National Republican Club. Perhaps I can approach him....

All they hope to have is for Mr. Morehouse to pass on the word that as far as the State Committee is concerned, Mr. Giles Rich would be satisfactory for the appointment....

On May 17, 1956, President Eisenhower nominated Giles to be an Associate Judge of the CCPA. Would this have happened without the NYIPLA's active support for the nomination? Perhaps, but not without the long Rich association with the NYIPLA that thrust him into the national limelight in the first instance.

*Reprinted with permission from the Journal of The Federal Circuit Historical Society, Volume 3, pages 101-102 (2009). See www.federalcircuithistoricalsociety.org.

U.S. Patent and Trademark Office Strategic Objectives

By Peter Thurlow and Abhishek Bapna

David Kappos, Director of the U.S. Patent and Trademark Office, presented "What's in Store From the USPTO" at the NYIPLA CLE program on February 5, 2010.

The presentation focused on the USPTO's strategic objectives for improving patent quality and reducing patent pendency and backlog, as well as the initiatives being implemented to achieve these objectives. This article discusses a number of these initiatives: 1) Small Entity Application Acceleration; 2) Green Technology Pilot Program; 3) First Action Interview Pilot Program; 4) Patent Quality Improvement; and 5) Increased Work-sharing between Patent Offices.

Small Entity Application Acceleration: This procedure allows an application to be advanced out of turn (accorded special status) for examination if the applicant files: 1) a petition to make special and 2) a letter in which the applicant expressly abandons another co-pending unexamined application (see 74 F.R. 62285). This provides small entity applicants with multiple pending applications greater control over the priority with which their applications are examined while also reducing the backlog of unexamined applications. Both the application for which special status is sought and the application being abandoned must have actual filing dates earlier than October 1, 2009. This program commenced on November 27, 2009, and is scheduled to end on June 30, 2010.

Green Technology Pilot Program: An application will be accorded special status and examined earlier if the subject matter pertains to green technologies, including environmental quality, energy conservation, development of renewable energy resources, or greenhouse gas

emission reduction. This is expected to reduce the time it takes to patent these technologies by an average of one year. The benefits of this program include accelerating the development and deployment of green technology, creating jobs, and promoting U.S. competitiveness in the Green Tech field. The USPTO will accept only the first 3,000 petitions to make special under this program, provided that the petitions meet the program requirements (see 74 F.R. 64666), including that the application was filed before December 8, 2009. As of the end of January, the USPTO had already received several hundred requests for expedited review under this program. The program is open to applicants until December 8, 2010.

Enhanced First Action Interview Pilot Program: Under the original program, applicants were permitted to conduct an interview with the USPTO Examiner after reviewing a Pre-Interview Communication ("PIC") providing the results of a prior art search conducted by the Examiner. Benefits of the original program included: 1) the ability to advance prosecution of an application; 2) enhanced interaction between applicant and the examiner; 3) the opportunity to resolve patentability issues one-on-one with the examiner at the beginning of the prosecution process; and 4) the opportunity to facilitate possible early allowance. The USPTO has since added the following enhancements to the program: 1) the program was expanded to include more USPTO group art units; 2) after receiving the PIC, applicants now have greater flexibility in choosing whether they would like to use the full pilot procedure, waive the interview, waive both the interview and first action, or waive only the first action (previously, participants had to utilize the full pilot procedure); 3) the time period to reply set forth in the PIC was made extendable by one month (previously, the time period for reply was non-extendable); 4) failure to timely reply to the PIC or to timely conduct the interview will not result in abandonment of the application – instead, a first action will be provided, similar to waiving the interview; 5) the time period to conduct the interview was changed to two months from the date of filing the interview request form (previously, the two-month time period started on the date of the PIC).

Patent Quality Improvement: The USPTO is re-engineering its quality management program to focus on improving the process for obtaining the best prior art, and for improving the quality of the initial application and the entire application and prosecution process. Public com-



Richard Erwine, Richard Martinelli, David Kappos, Mark Abate

ment is being sought with respect to methods that may be employed by applicants and the USPTO to enhance the quality of issued patents, to identify appropriate indicia of quality, and to establish metrics for the measurement of the indicia (see 74 F.R. 235). In addition, the USPTO is considering monitoring quality at each stage in the application, prosecution, and examination processes with the goals of reducing duplication of work and increasing examination efficiency and quality, thereby reducing pendency. In particular, the USPTO has identified five areas of concern: 1) prior art; 2) comprehensive initial application; 3) comprehensive first office action on merits, with clear explanation of all issues; 4) comprehensive and clear response to office action on the merits; and 5) proper use of interviews.

Increased Worksharing Among Patent Offices: The USPTO has implemented a Patent Prosecution Highway ("PPH") program with other major patent offices worldwide. In the PPH program, after an office of first filing determines that an application is patentable, the applicant may request that the second office fast-track examination of its corresponding application. The USPTO is now working cooperatively with other offices and users to dramatically increase use of the PPH pro-

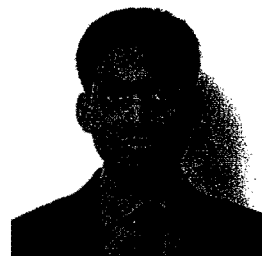
gram in order to maximize its benefits. The USPTO is also planning the implementation of the concept known as Strategic Handling of Applications for Rapid Examination ("SHARE"). SHARE enables the prioritization of examination work at the office of first filing (first filings are taken up first for examination), so that the office of second filing has a much greater likelihood of finding available search and examination results when it takes up the corresponding case for action.

Additional details regarding each of these initiatives may be found on the USPTO website.



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Peter Thurlow is a Chairperson of the USPTO Oversight Committee and Senior Associate at Jones Day. He can be contacted at pgthurlow@jonesday.com.



NYIPLA Calendar

88th Annual Dinner in Honor of the Federal Judiciary

* March 26, 2010 *

Waldorf=Astoria Hotel • 301 Park Avenue, New York

CLE PROGRAMS

NYIPLA CLE Day of Dinner Program

* Friday, March 26, 2010 *

Earn 2.0 NYS CLE Credits

The Starlight Roof at the Waldorf=Astoria Hotel • 301 Park Avenue, New York

Twenty-Sixth Annual Joint Patent Practice Seminar

* Thursday, April 29, 2010 *

Hilton New York • 1335 Avenue of the Americas, New York

Keynote Speaker: Hon. Pauline Newman, Circuit Judge

United States Court of Appeals for the Federal Circuit

More programs to come!

For Additional Information See: WWW.NYIPLA.ORG

Delaying Generic Drugs: The Legal Landscape Surrounding Reverse Payment Agreements to Protect Patent Holders

by Safet Metjahic

Settlement agreements involving reverse payments by pharmaceutical patent holders to delay the introduction of generic equivalents are receiving increased attention from all three branches of the federal government.

Due in part to persistent judicial and legislative challenges to such agreements by the Federal Trade Commission (FTC), the legality of reverse payment settlements in ANDA-based patent infringement cases remains uncertain. The legal landscape surrounding these agreements ranges from being presumptively unlawful to being legal restrictions within the exclusionary scope of patents.

In the context of the Hatch-Waxman Act, reverse payments are typically payments made by a drug company holding a patent on a brand name drug to a generic drug company to delay, or entirely forego marketing its generic version of the drug during the term of the patent. The Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act of 1984) was enacted by Congress in an effort to accelerate the approval process for lower price generic versions of already approved brand name drugs. The Act provides an expedited drug approval process under an Abbreviated New Drug Application (ANDA) procedure to generic drugs that are bioequivalents of drugs already approved by the Food and Drug Administration (FDA) for safety and effectiveness. The FDA maintains a list of such approved drugs in what is commonly known as the "Orange Book."

As an incentive for generic drug manufacturers to challenge weak patents, the Hatch-Waxman Act offers the first ANDA filer with a paragraph IV certification (that the patent in question is invalid or would not be infringed by the manufacture, use, or sale of the new drug) the opportunity to market its generic drug exclusively for 180 days. To this end, the FDA may not approve the ANDA of a subsequent filer until 180 days after the earlier of the date 1) the first ANDA filer commercially markets the generic drug, or 2) a court concludes that the patent in question is invalid or not infringed. [21 U.S.C. § 355(j)(5)(B)(iv)(I)-(II)] Many times, the patent holder and the ANDA filer will settle a patent infringement suit with an agreement that involves a reverse payment.

The FTC has been very vocal in its disapproval of reverse payment settlement agreements, keeping the issue in the forefront by repeatedly and aggressively challenging such agreements through court actions. Its position is that reverse payment agreements, which it calls "pay-

for-delay," are *per se* violations of the antitrust laws. The FTC argues that the agreements impermissibly delay less expensive generic drugs from reaching consumers until the end of the term of an underlying patent which is likely invalid. Many of the FTC's court challenges, however, have been unsuccessful.

On the other hand, the Department of Justice (DOJ) recently reversed its prior stance and aligned itself with the FTC. In response to an invitation from the Second Circuit in *Arkansas Carpenters Health and Welfare Fund v. Bayer*, 05-2851-cv(L) (2009), the DOJ submitted a brief in which it recommended against the legality of reverse payment settlement agreements under the antitrust laws. In its brief, the DOJ proposed that an antitrust plaintiff should be able to establish a *prima facie* case of illegality under the antitrust laws by showing that 1) the generic manufacturer gave up its challenge to the branded patent's validity, 2) the patent holder provided consideration to the generic manufacturer, and 3) the consideration accompanied an agreement to withdraw the validity challenge. However, the DOJ proposed that the antitrust defendant should be given the opportunity to rebut that *prima facie* case through a rule of reason analysis showing that the reverse payment settlement did not unreasonably restrain competition.

The Circuit Courts are split. While the Sixth Circuit agrees with the FTC that reverse payment settlements are *per se* violations of the antitrust laws, *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), the more recent wave of decisions in the Second, Eleventh and Federal Circuit Courts of Appeals have held reverse payments to be acceptable restrictions within the exclusionary scope of patents. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *FTC v. Schering Plough Corp.*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1327 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009). In these more recent decisions, the general rule appears to be that a reverse payment agreement will not likely be found to be violative of the antitrust laws so long as the agreement is not found to have anti-competitive effects outside the exclusionary zone of the patent. That is, the underlying patent must not have been procured through fraud, the related patent infringement litigation must not have been objectively baseless, and the anti-

competitive effects of the agreements must not be outside of the exclusionary scope of the underlying patent.

To date, the Supreme Court has refused to consider the issue of reverse payment agreements, denying certiorari in the *Schering Plough* and *Ciprofloxacin* cases. In *Schering Plough*, the Court allowed the Eleventh Circuit's holding to stand that neither the rule of reason nor *per se* analysis was appropriate in the context of reverse payment agreements. In *Ciprofloxacin*, the Court allowed the Federal Circuit's holding to stand that reverse payment settlements do not violate antitrust laws, except where the underlying patent was procured through fraud, the related patent infringement litigation was objectively baseless, or the anti-competitive effects of the settlement agreement are outside of the exclusionary scope of the underlying patent.

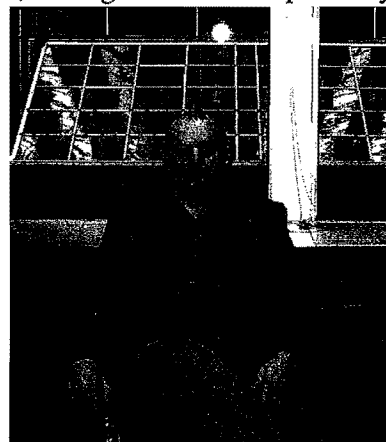
On February 3, 2009, Senator Herbert Kohl (D-WI) introduced S.369, the Preserve Access to Affordable Generics Act. The Act seeks to prohibit brand name drug companies from compensating generic drug companies to delay entry of a generic drug into the market. The Act would make unlawful any settlement of patent litigation which involves payments by a brand name drug maker to a generic drug maker in exchange for delay to market entry of a generic version. The bill was reported by the Senate Judiciary Committee to the Senate as a whole on October 15, 2009 and has been placed on a calendar of business.

In the House, on March 25, 2009, Representative Bobby Rush (D-IL) introduced a related bill, H.R. 1706, the Protecting Consumer Access to Generic

Drugs Act of 2009. Like its Senate counterpart, this Act seeks to eliminate reverse payment settlements in the context of the Hatch-Waxman Act. The bill has been referred to the Energy and Commerce Committee's Subcommittee on Commerce, Trade and Consumer Protection as well as the Judiciary Committee. The Subcommittee forwarded the bill to the Full Committee by a vote of 16 to 10.

In conclusion, the general thrust of judicial precedent, with certain exceptions, is that reverse payment agreements are likely legal, so long as the underlying patent was not procured through fraud, the related patent infringement litigation was not objectively baseless, and the anti-competitive effects of the agreements are not outside of the exclusionary scope of the underlying patent. However, the executive and legislative branches of the government appear to be aligned in seeking to eliminate, or severely restrict, such agreements. It is presently unclear whether the House and Senate bills will build up enough momentum to make it into law.

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