



BOSTON PATENT LAW ASSOCIATION NEWSLETTER

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EDUCATION, SERVICE, COMMUNITY

Volume 36, Issue 3

PRESIDENT'S MESSAGE



Doreen M. Hogle

I hope that everyone has had an enjoyable summer, with some time off for much-needed rest and relaxation. All of us probably agree that September has arrived much too quickly.

The Annual Judges Dinner was held May 13 at the World Trade Center Boston. Over 200 members and guests attended including many judges from around the Commonwealth. Peter Gammons, now a Hall of Fame Sportswriter, was the guest speaker and treated us to some great sports stories based on "insider" knowledge. The evening ended with a live auction (complementing the silent auction held during the cocktail reception). Activities Chair, Joe Maraia, and Pro Bono Committee Chair and Board member, Lisa (a/k/a "Vanna White") Michaud, did a great job encouraging bids for the donated items. The highlight of the auction was an autographed Curt Schilling Red Sox jersey getting top dollar. We all had a great time and raised over \$5,500 for local charities. I'd

like to thank everyone who worked so hard to give us a fun-filled, memorable evening.

We've had two very informative and well-attended seminars this summer: "Post-Grant Opposition" and "Key IP Decisions of the Past Year". We also had a great turn-out for the Summer Outing at Fenway Park to see the Red Sox beat the Tampa Bay Devil Rays on a very humid July evening.

We have some great seminars planned for the fall/winter season, including an "IP Primer" on October 14th by the Young Lawyers Committee; "Trademark Year in Review" on October 19th by the Trademark Committee; the third seminar in our series on "Interference Practice" (date to be announced); and the "Advanced PCT Practice Seminar" on October 31-November 1. Please see the Upcoming Events in this Newsletter, or the BPLA website, for more details. And "save the date" for the Annual Meeting on December 7, 2005.

We are also pleased that on November 18 the BPLA will be co-sponsoring a seminar with Suffolk University Law School "Resolving Uncertainty in

Biotechnology Patent Law: Safe Harbor/ Experimental Use, Invention and Utility". Distinguished speakers, including John Whelan and Stephen Walsh from the Office of the Solicitor for the USPTO, Kenneth Burchfiel from Sughrue Mion, and John Duffy from George Washington University Law School, as well as a number of attorneys from private and corporate practice in the Boston area, will provide insights on biotechnology practice in light of recent court decisions.

Finally, I'd like to ask that all members take some time to read the article that appears in this Newsletter detailing the proposed new policy for the appointment of committee chairs and term limits for committee chairs. The Board also plans to add an additional committee to cover "Contested Matters". The Board believes that adding committees and initiating these new policies will permit more members to become actively involved with the BPLA. Please feel free to send your comments on the new policy to the Board for our consideration.

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PROPOSED BYLAW CHANGE FOR STANDING COMMITTEES

By Grant Houston, Esq.
Houston Eliseeva LLP

To improve the BPLA's committee structure, the Board is proposing changes in the bylaws to specify the tenure of committee chairpersons.

The Board believes that there are a number of potential advantages, including: 1) increase in planned activities; 2) broader involvement for active members, even in the context of current chairs who move to new committees (success in previous committees can be used as a metric for assigning them as chairs of new committees); and 3) an expansion of involvement of new members in the operation of the BPLA.

Also, the new bylaw provides for a "8. Committee on Contested Matters before USPTO" to cover interference practice and potentially post-grant opposition, as distinct from litigation.

Please direct any comments or suggestions to the Board.

The following bylaw will be presented for a vote at the annual meeting:

ARTICLE X: Standing Committees

The Chairpersons of the standing committees of the Association shall be appointed by the President-Elect subject to approval of the Board of Governors no later than the meeting of the Board immediately preceding the Annual Meeting. Each standing committee shall have one or more Chairpersons. Appointments of the Chairpersons will be announced at the Annual Meeting, at which time their terms shall commence. The Chairpersons shall serve (1) for not more than three years or (2) until their successors shall have been appointed by the President.

The standing committees of the Association shall be as follows:

1. Committee on Activities and Public Relations
2. Committee on AIPLA Moot Court
3. Committee on Amicus Briefs
4. Committee on Antitrust
5. Committee on Biotechnology

6. Committee on Chemical Patent Practice
7. Committee on Computer Law
8. Committee on Contested Matters before USPTO
9. Committee on Copyright Law
10. Committee on Corporate Practice
11. Committee on Ethics and Grievances
12. Committee on International and Foreign Practice
13. Committee on Licensing
14. Committee on Litigation
15. Committee on Patent Law
16. Committee on Patent Office Practice
17. Committee on Pro Bono
18. Committee on Trademark and Unfair Competition
19. Committee on Trade Secrets Law
20. Committee on Young Lawyers and Law Students

Special committees may be appointed from time to time by the President.

BPLA PRESENTS AWARD AT MASSACHUSETTS STATE SCIENCE FAIR

By Ingrid A. Beattie, Esq.
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo P.C.

On May 7, 2005, the BPLA participated in the 56th year of celebrating student achievement and innovation in science and technology at the Presentation of Awards for participants in the Massachusetts State Science Fair (MSSF). Nearly \$350,000 worth of prizes were awarded, including the BPLA award of \$1,350 to first place winner Anupama Khan.



Massachusetts Science Fair Winner Anupama Khan

The MSSF program is open to high school students and middle school students from all public, private and home environments in the Commonwealth. The event in which the BPLA participated was held at Johnson Athletic Center at MIT for allow Senior High School

students. These students presented their research in a public forum in a poster session format on par with the most prestigious professional societies in the world. 340 students participated in the

fair and over 60 schools were represented. 274 projects were entered into the competition. Entries are made as individuals or as a team. This year 214 individual and 60 team entries were submitted.

Entries are judged on the following criteria: 1. Scientific Approach to the Problem; 2. Original Project Journal/Scientific Notebook/Log; 3. Thoroughness; 4. Ingenuity and Creativity; and 5. Exhibitor's Advancement in Science. The field was impressive and highly competitive, and the entrants were passionate experts in their chosen area of work.

PATENTEES BEWARE: PURDUE'S REINFORCEMENT OF INEQUITABLE CONDUCT AS A DEFENSE TO INFRINGEMENT

*By Rebecca L. Hanovice, Esq.
Bromberg & Sunstein LLP*

Over the past few decades, the inequitable conduct defense has become increasingly popular in patent infringement lawsuits. Defendants accused of infringement routinely counterclaim that the asserted patent is unenforceable because the patentee withheld or misrepresented material information to the PTO. The Federal Circuit has condemned overuse of the inequitable conduct defense, noting its adverse effect on both attorney collegiality and the rights of patentees. *Molins PLC v. Textron, Inc.*, 33 U.S.P.Q. 2d 1823, 1829 (Fed. Cir. 1995) ("unjustified accusations of inequitable conduct are offensive and unprofessional. ... They have been called a 'plague' on the patent system. ... Unjustified accusations may deprive patentees of their earned property rights and impugn fellow professionals. They should be condemned.").

In response to pressure from industry and professional organizations, on June 8, 2005, the House of Representatives introduced HR 2795, an amendment to 35 U.S.C. that contemplates severe restrictions on the inequitable conduct defense. This amendment would preclude a defendant from basing an unenforceability defense "in whole or in part upon a violation of the duty of candor and good faith." HR 2795 § 136 (c)(3). Instead, a court would refer the inequitable conduct claim to a special office appointed by the Director of the Patent and Trademark Office to determine whether misconduct occurred and, more importantly, whether the Office actually relied on the misconduct

in its decision to allow the patent. If there is no clear and convincing evidence of reliance by the Office on a patentee's fraudulent behavior, any misconduct would not render the patent unenforceable.

Despite the push towards limiting the use of inequitable conduct in patent infringement suits, the recent Federal Circuit decision in *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.* demonstrates that inequitable conduct is an increasingly powerful defense. In this case, Purdue Pharma sued Endo, a generic drug maker, for infringing its patents for controlled release oxycodone medication. Endo counterclaimed that the patents were unenforceable due to Purdue's inequitable conduct before the PTO. The Southern District of New York found that Endo's proposed generic drugs would infringe Purdue's patents, but agreed with Endo that Purdue engaged in inequitable conduct. The Court enjoined Purdue from enforcing its patents, and Purdue appealed. *Purdue Pharma LP v. Endo Pharmaceuticals Inc.*, 70 U.S.P.Q. 2d 1185 (S.D.N.Y. 1004).

In affirming the District Court's decision, the Federal Circuit emphasized the patentee's "duty to disclose information known to the applicants to be material to patentability." *Purdue Pharma LP v. Endo Pharmaceuticals Inc.*, 410 F.3d 690, 695 (Fed. Cir. 2005). Here, Purdue repeatedly stated that it had "discovered" an improved controlled release formulation. *Id.* at 696. In fact, this improvement was based on one inventor's "insight," not scientific data, as

Purdue did not have clinical evidence supporting its improvement. The Federal Circuit acknowledged that "Purdue never expressly stated that the discovery of the four-fold dosage range was based on the results of clinical studies," but held that "that conclusion was clearly to be inferred from the language used by Purdue in both the patents and the prosecution history." *Id.* at 698 (emphasis added). The Court found that this implicit misrepresentation was material because it was a "key argument" that was made "consistently and repeatedly during prosecution to overcome prior art cited by the examiner in an obviousness rejection." *Id.* at 699. From this determination of materiality, and Purdue's failure to disclose that its innovation was based on the inventor's "insight", and not on scientific data, the Federal Circuit found that Purdue intended to mislead the PTO.

The *Purdue* decision explicitly shows deference to the work of the District Court, but it effectively equates a "misrepresentation" by implication, i.e., assertion of a scientific improvement based on insight unsupported by data, with explicit misstatements to the PTO. Therefore, despite public pressure to limit the applicability of inequitable conduct and the proposed amendment to patent law, *Purdue* makes it even easier for defendants to assert the defense. Given this ruling, patentees should avoid overly aggressive statements during prosecution concerning the evidentiary basis for the invention, and should ensure that all statements to the PTO are well grounded in fact.

C. YARDLEY CHITTICK HONORED

*By Lee Carl Bromberg
Bromberg & Sunstein LLP*

BPLA Life Member C. Yardley Chittick, at 104 years old the nation's oldest patent lawyer, was awarded an honorary degree by Franklin Pierce Law Center in May 2005. Mr. Chittick once interviewed with Thomas Edison for a job, but turned down Edison's offer to work for a golf club manufacturer. He became a patent attorney during the Great Depression.

Mr. Chittick is retired and lives in New Hampshire, and is a regular attendee at the BPLA Annual Meeting.

*The Honorable Carol
Conboy, Yardley Chittick
and Douglas Wood*

*Photo by John Beaudin, The Image Generation,
Manchester, NH; courtesy of Franklin Pierce Law Center*



2005 JUDGES DINNER

By Joseph M. Maraia, Esq.
Hamilton, Brook, Smith & Reynolds, P.C.

The Boston Patent Law Association held its Annual Dinner for the Federal Judiciary on Friday, May 13, 2005 at the World Trade Center, Boston, MA. There were 215 members and guests in attendance, including the Honorable Justices Joyce London Alexander, Marianne Bowler, Nathaniel Gorton, John Greaney, J. Garvan Murtha, Kenneth Neiman, George O'Toole, Patti Saris, Richard Stearns, Mark Wolf, and Rya Zobel.

The keynote speaker was Peter Gammons of ESPN's Baseball Tonight. Mr. Gammons talked about and answered numerous questions related to Major League Baseball, including the Boston Red Sox Championship Season and Major League Baseball's steroid issue.

The evening began with a cocktail hour that featured a silent auction organized by Lisa Michaud, Lisa Winsor, and the rest of the silent auction volunteers. Special thanks goes to them for a job

extremely well done. The evening ended with a live memorabilia auction to benefit local area charities, including Curt's Pitch for ALS and the Jimmy Fund. Among the items that were auctioned off as part of the live auction were an autographed Curt Schilling jersey, a World Series autographed picture of Trot Nixon, and a World Series autographed baseball by Trot Nixon and Mark Bellhorn.

The evening was a tremendous success. We thank all who attended and look forward to seeing you again next year.



Richard Wise and
BPLA President
Doreen Hogle



Hon. Mark L. Wolf,
BPLA Secretary Mark
B. Solomon, Patti
Stearns, and Hon.
Patti B. Saris



Kathleen
Campbell, Hon.
John M. Greaney
and Dan Gleason



Keynote
Speaker Peter
Gammons of
ESPN's Base-
ball Tonight



BPLA Amicus
Committee Co-Chair
Erik Paul Belt and
David Marder



BPLA
International
and Foreign
Practice
Committee Co-
Chair Diedre
Sanders, Adam
Wise, Christine
Doe and Michael
Yamauchi

BPLA SILENT AUCTION A SUCCESS!

*By Lisa J. Michaud, Esq.
Nutter McClennen & Fish, LLP*

The BPLA's second Silent Auction held during the Annual Judges Dinner on May 13, 2005 proved to be a success once again. Items to choose from included personal training sessions at Bodyscapes, spa packages for Elizabeth Grady and Giacomo & Rondi, a gold package for Butter Brook Golf Club, accommodations at the Boston Harbor Hotel with dinner at Andale Mexican Grill, season tickets to the Boston Philharmonic's Weeknight Discover Series, tickets to Jimmy Buffet,

accommodations at The Coonamessett Inn for the 4th of July, a Boston Helicopter Tour for Two, a cooking gift basket from Stapletons Florist, Red Sox tickets, a Wachusett Weekend with the kids, a night on the town including a limo, dinner at Fire & Ice, and tickets to The Phantom of the Opera, a fishing charter for eight, and other great times. This year, a live auction was also held to raise money for ALS. The live auction items included an authentic Red Sox jersey signed by Curt Schilling, a world

series photograph of and signed by Trot Nixon, a world series baseball signed by Mark Bellhorn and Trot Nixon, and a Patriots Football signed by Troy Brown.

Overall, the auction raised over \$5,600 to benefit the Jimmy Fund, The ALS Association, Project Bread, The Volunteer Lawyers for the Arts of Massachusetts, and The Huntington Theater. A special thanks to all of the winners and the volunteers for making the first BPLA Silent Auction a success!



BPLA Vice President Lee Carl Bromberg and Pam Bromberg



BPLA Board Member Lisa Michaud, Hon. George A. O'Toole, Jr. and Patti Stearns



BPLA Secretary Mark B. Solomon and Keynote Speaker Peter Gammons



Hon. Nathaniel M. Gorton and Hon. Richard G. Stearns



Hon. Rya W. Zobel, Hon. J. Garvan Murtha and Nicole Murtha



BPLA Board Member Neil P. Ferraro and Renee Ferraro

U.S. POST-GRANT OPPOSITION IS COMING: A COMPARATIVE PERSPECTIVE

by Christine M. Doe, Esq.
Hamilton, Brook, Smith & Reynolds, P.C.

On June 7, 2005, The International and Foreign Practice Committee and the Patent Office Practice Committee of The Boston Patent Law Association held an informative seminar entitled: "U.S. Post-Grant Opposition is Coming: A Comparative Perspective." The guest speakers were William E. Cohen, Esq., Assistant General Counsel for Policy Studies at the Federal Trade Commission; Bert Oosting, partner at Lovells, one of the largest law firms in Europe; and Mary E. Porter, Esq, intellectual property counsel for Saint-Gobain Corporation.

Mr. Cohen led off the discussion by noting that The Federal Trade Commission (hereinafter the "FTC"), a competition agency, is offering opinions of patent policy for the purposes of increasing the significance of the patent system and raising the awareness of dynamic efficiency in competition policy. In a report by the FTC entitled "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy," issued October 2003 (see www.ftc.gov/opp/intellect/index.htm), the FTC agrees with the PTO recommendations to enact legislation to create a new administrative procedure to allow post-grant review of, and opposition to, U.S. patents. Mr. Cohen noted that both patents and competition can promote innovation. However, invalid or overbroad patents can hinder innovation and competition, which may raise prices or interfere with follow-on innovation. Therefore, competition and patent policy must work together to provide better methods for challenging questionable patents. Mr. Cohen stated that the current examination system at The United States Patent and Trademark Office has limitations, such as limitations on available time and available information for Examiners to devote to

examining patent applications. Further, Mr. Cohen noted that the current reexamination procedure has limitations, such as limits on subject matter and tactical considerations. In addition, he noted that litigation has limitations in terms of cost, timing and standing. Mr.



Panelists William E. Cohen, Mary E. Porter and Bert Oosting

Cohen stated that the purpose of the post-grant review is to provide something that offers greater value than other procedures, something faster and less costly than litigation and something that safeguards against harassment. Mr. Cohen closed his presentation by discussing the elements of the proposed post-grant system, such as subject matter, timing, standing, evidence, the threshold, identification of the real party in interest, discovery, the hearing, claim amendments, the decision maker, the evidentiary standard, the time limits, the appeal process, estoppel, settlement agreements and the relationship to reexamination.

Mr. Oosting discussed the opposition procedure before the European Patent Office, including rules providing who can lodge an opposition, when to lodge an opposition, discovery, evidence and depositions. Mr. Oosting also discussed the strengths and weaknesses of the European opposition system. Mr.

Oosting noted that the strengths include the fact that the system is inexpensive and that once the European patent is revoked, it revokes patents for all designated European Contracting States. Further, he noted that the weaknesses include the fact that oppositions take a very long time and that the European Patent Office is not the right venue for evidence taking and for revocation of patents based on prior use. Mr. Oosting also discussed the effects on co-pending litigation, including the possibility of suspension of co-pending litigation pending resolution of the opposition. According to Mr. Oosting, opposition decisions are not binding on national courts, but are highly persuasive in The Netherlands and Germany. He noted that the opposition system generally does not consider evidence obtained during co-pending litigation.

Ms. Porter closed the seminar by presenting the corporate counsel perspective on the proposed U.S. post-grant opposition. Ms. Porter began by summarizing the current U.S. post-grant challenge procedures including Federal Court litigation, Ex Parte Reexamination and Inter Partes Reexamination. Ms. Porter then discussed the benefits and deficiencies of such procedures and the reason for the call to reform. Ms. Porter discussed her personal experiences with post-examination patent challenges in other jurisdictions, such as Japan and Europe. She then compared the AIPLA proposed U.S. post-grant system and the European system and closed her presentation by providing her personal suggestions for U.S. post-grant system.

Copies of slides for these presentations are available at www.bpla.org under the "events" heading.

FINAL REMINDER REGARDING
BPLA DUES

All BPLA membership dues should have been paid. If your dues have not been paid you risk possible suspension from the BPLA. To check whether your dues

are paid, please go to the BPLA website, www.bpla.org. Click on Members. And login. Click on the first letter of your last name. An asterisk beside your names indicates that your dues have not been paid. Please forward your dues, and the \$25.00 late fee to:

Leslie-Meyer-Leon
BPLA Treasurer
c/o IP Legal Strategies Group, PC
1480 Falmouth Road
P.O. Box 1210
Centerville, MA 02632-1210.

SUPREME COURT BROADENS RESEARCH EXEMPTION

By Meredith L. Ainbinder, Esq.
Bromberg & Sunstein LLP

On June 13, 2005, the United States Supreme Court ruled unanimously in *Merck KGaA v. Integra Lifesciences I, Ltd.*, giving a broad construction to the research exemption provided by 35 U.S.C. § 271(e)(1), and overturning the Federal Circuit Court of Appeals' narrower interpretation of the language. § 271(e)(1) reads, "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

At issue in *Merck* was the company's funding of cancer research which involved experimentation on RGD peptides as angiogenesis inhibitors. These RGD peptides are the subject of patents owned by Integra Lifesciences I, Ltd., and the Burnham Institute. In particular, the Court examined the issue of whether preclinical research that identifies the best drug candidate for future FDA testing is covered by § 271(e)(1) or constitutes patent infringement. The Court held that the "exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA."

The Court disregarded Integra's arguments that patented compounds could only be used to submit preclinical data related to the safety of a drug in

humans, that testing on patented compounds must comply with the FDA's good laboratory practice regulations, that the research exemption does not reach experimentation on drugs that are not submitted to the FDA, and that experiments that are not later included in a submission of information are infringing. Recognizing that drug development is a complex, multistage process, and that the language of § 271(e)(1) calls for exemption for "reasonably related" uses rather than solely successful uses, the Court was unwilling to limit the applicability of the research exemption based on the stage where the patented compound is used. The Court explained, "At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is 'reasonably related' to the 'development and submission of information under . . . Federal law.'" The Federal Circuit, by contrast, had given a strict interpretation to the statutory language, encouraging the application of the exemption to research submitted directly to the FDA, and focusing on the use of the exemption to allow for expedited approval of generic drugs rather than to apply to experimentation at all stages of new drug development. In light of the Supreme Court's remand, the Federal Circuit has called for further briefing in *Merck*, "with particular attention paid to the Supreme Court decision."

Notably absent from the Court's opinion was a decision on the application of the research exemption to patented research tools. In a footnote, the Court explained that the Federal Circuit's treatment of the research tool issue was unnecessary and declined to rule, "Respondents have never argued the RGD peptides were used at Scripps as research tools, and it is apparent from the record that they were not We therefore need not—and do not—express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of 'research tools' in the development of information for the regulatory process." This portion of the opinion provided some relief to patent holders and academic institutions. For example, life sciences company Invitrogen Corporation, which had taken part in an amicus brief arguing against the application of § 271(e)(1) to patented research tools, issued a statement that the ruling "will not have a material effect on Invitrogen's business."

For large pharmaceutical companies, however, this ruling is a clear victory, providing some breathing room in their research and testing procedures and insulation from accusations of patent infringement. While drug manufacturers and scientists are still prohibited from using patented compounds in general research that bears no relationship to FDA submissions, the Supreme Court has carved out the ability for researchers to use patented compounds earlier in the drug development process

UPCOMING EVENTS

Friday, October 14, 2005
2:00 p.m. - 5:00 p.m. Young Lawyers IP Primer

Wednesday, October 19, 2005
8:30 a.m. - 12:00 p.m. Trademark Year in Review

Monday & Tuesday, October 31 - November 1, 2005
Advanced PCT Practice Seminar

Friday, November 18, 2005
8:30 a.m. - 4:30 p.m. Suffolk University Law School Symposium on Biotechnology Patent Law

Wednesday, December 7, 2005
Annual Meeting

NOTICE TO COMMITTEE CHAIRS

The newsletter would like to know of any upcoming events, whether clear or brown bag lunches, that the committees are planning. We are happy to promote your events in our newsletter listings and we welcome descriptions of your planned events for publication.

KEY I.P. DECISIONS OF THE PAST YEAR AND THEIR IMPLICATIONS FOR IN-HOUSE COUNSEL

Robert T. Conway, Esq.,
Hamilton, Brook, Smith & Reynolds, P.C.

The Corporate Practice Committee of the BPLA held a luncheon seminar on August 17, 2005 entitled "Key I.P. Decisions of the Past Year and Their Implications for In-House Counsel." The event, which was held at the Ritz-Carlton Hotel in downtown Boston, was attended by about 64 corporate I.P. attorneys and their firm-side counterparts. The panel speakers included Thomas M. Sullivan, Esq., of Lowrie, Lando, & Anastasi, LLP (Cambridge, Mass.), John L. Welch, Esq., of Foley Hoag LLP (Boston, Mass.), and Cynthia D. Vreeland, Esq., of Wilmer, Cutler, Pickering, Hale, & Dorr, LLP (Boston, Mass.). Mr. Sullivan reviewed and discussed key decisions in the area of patent law, while Mr. Welch and Ms. Vreeland reviewed and discussed key decisions in the areas of trademark law and trade secret law, respectively.

The seminar, which was hosted by Co-Chairs James G. Cullem, Esq. (Cell Signaling Technology, Inc.), Walter Dawson, Esq. (Pearson & Pearson, LLP), and Faith Driscoll, Esq., is part of an ongoing initiative by the Corporate Practice Committee to host educational events relevant to I.P. practice within the corporate setting.

Mr. Welch discussed a number of recent U.S. Supreme Court cases directed to trademarks and trade dress. In *Wal-Mart Stores Inc. v. Samara Brothers Inc.*, 54 U.S.P.Q.2d 1065 (U.S. S.Ct. 2000), Wal-Mart contracted with a supplier to manufacture outfits based on photographs of Samara. After discovering the selling of the knockoffs, Samara brought an action for infringement of unregistered trade dress under Section 43(a) of the Lanham Act. The Court found that unregistered product designs can never be inherently distinctive, but they must have secondary meaning to be protectable. Unlike with words or packaging, consumers are not predisposed to see product shapes as source indicators.

Mr. Welch then discussed *Traffix Devices Inc. vs. Market Displays Inc.*, 58 U.S.P.Q.2d 1001 (U.S. S.Ct. 2001). Market Devices claimed that its sign stands were recognizable to buyers and users because the expired patent and

utility design was visible near the sign stands base and was entitled to trade dress protection. There is a "well-established rule" that trade dress protection is unavailable for product features that are functional. The Trademark Act in 1999 was amended to state that one who asserts trade dress protection has the burden of proving nonfunctionality. A utility patent is strong evidence that the features therein claimed are functional. Thus, the design was found functional and not entitled to trade dress protection.

In *Moseley v. Victor Secret Catalogue Inc.*, 65 U.S.P.Q.2d 1801 (U.S. S.Ct. 2003), the owner of the VICTORIAS SECRET trademark sued for dilution under Section 43(a) of Lanham Act, which uses the phrase "causes dilution." The Court found that the text "unambiguously requires a showing of actual dilution, rather than a likelihood of dilution. Legislation has been proposed to amend the law to require only "likelihood of dilution."

In *Dastar Corp. v. Twentieth Century Fox Film Corp.*, 66 U.S.P.Q.2d 1641 (U.S. S.Ct. 2003), Fox produced a television series for which it never renewed the copyright leaving the series in the public domain. Dastar released a video set made from tapes of the original version of television series at a price substantially less than for a Fox licensed version. Fox brought a "reverse passing off" action under Section 43(a) of the Lanham Act. The court held that Section 43(a) does not have boundless application as a remedy for unfair trade practices. Although it prevents "false designations of origin," it does not prevent unaccredited copying of work in the public domain. "Origin" refers to the producer of tangible goods, not to the author of ideas.

In *KP Permanent Make-Up, Inc. v. Lasting Impressions I, Inc.*, 72 U.S.P.Q.2d 1833 (U.S. S.Ct. 2004), all the parties used the term "micro color" in marketing permanent cosmetic makeup. The issue was whether a defendant raising the statutory affirmative defense of fair use has the burden to negate any likelihood of confusion. Section 33 of the

Lanham Act states that use of a term that is descriptive of, and used fairly and in good faith to describe a party's goods is not an infringement. The Court stated that likelihood of confusion is relevant to the fair use defense, but the accused infringer does not have the burden to show no likelihood of confusion.

In a Trademark Trial and Appeal Board case, *Medinol Ltd. v. Neuro Vasx Inc.*, 67 U.S.P.Q.2d 1205 (T.T.A.B. 2003), a trademark was registered for stents and catheters. The mark was not used on stents. Registrant claimed the word "stents" had been overlooked when its verified Statement of Use form was completed and said it did not intend to commit fraud. The Board found that "the appropriate inquiry . . . is not into the registrant's subjective intent, but rather into objective manifestation of that intent." Mr. Welch advised that a verified statement as to use of a mark had better be true. Lack of legal advice, misunderstanding of the statutory requirements or language difficulties or combination thereof will not provide a defense to a charge of fraud. The assertion of lack of fraudulent intent will not help. The consequences can be severe according to Mr. Welch. The application or registration is rendered void in its entirety. The constructive first use date is lost that would have applied to the goods on which the mark has been used. His advice if you find out that your client's registration is overly broad is to amend the registration now rather than wait for a challenge.

Mr. Welch further touched on extra-territorial reach of the Lanham Act, pop-up advertisements and keywords, and gripe sites.

Ms. Vreeland in her discussion on trade secret law stated that it has recently remained relatively stable. She noted that five developments are worth being aware of 1) strict enforcement of the requirement that a plaintiff specify its trade secrets with reasonable particularity, 2) confirmation that the Massachusetts courts will exercise independence in evaluating trade secret claims under Section 93A, 3)

(Continued on page 9)

Key I.P. Decisions (con't)

(Continued from page 8)

confirmation that failure to “mark” material confidential under a non-disclosure agreement will not necessarily preclude a trade secret claim, 4) the explicit recognition of software design trade secrets, and 5) the re-introduction of legislation in Massachusetts of the Uniform Trade Secrets Act (U.T.S.A.).

Massachusetts courts traditionally have required the plaintiff to specify its trade secrets with particularity. In *Cambridge Internet Solutions, Inc. v. Avicon Group*, 1999 WL 959673 (Sept. 1999), defendants filed motion to dismiss on ground that the plaintiff had not identified the trade secrets in issue with sufficient particularity. The court agreed that “[a] plaintiff has no cognizable trade secret claim until it has adequately identified the specific trade secrets that are in issue.” The plaintiff was ordered to provide a more definite statement of its claims, “identifying with greater particularity the specific customer material and/or trade secrets it alleges to have been misappropriated.”

According to Ms. Vreeland, the courts are taking an independent look at Chapter 93A claims. In *Softscape, Inc. v. Cambria Consulting, Inc.*, Case. No. 03-2848 (Mass. Super. Jan. 2004), the plaintiff filed various claims relating to defendant’s competing software product, developed after failed merger talks between the parties. The jury found for plaintiff on the trade secret claim. The judge found for the defendant on Chapter 93A claim based on same facts, and set aside the bulk of the jury’s damages award on the trade secret claim. Each side presented expert witnesses that took opposite positions on the issue. The judge found that the jury could have, as it seems to have, believed the plaintiff’s experts, while the court could have, as it did, believed the defendant’s experts.

The failure to mark material confidential as required in a non-disclosure agreement (NDA) was highlighted in view of *TouchPoint Solutions, Inc. v. Eastman Kodak Co.*, 345 F.Supp.2d 23 (D. Mass. 2004). Prior to discussions, the parties had entered into a NDA that required confidential information to be “clearly labeled as confidential.” The judge found

that the plaintiff was likely to prevail on its trade secret claim – even though it had provided relevant information to the defendant without marking it confidential. He stated that “Unquestionably, the better practice would have been for [the plaintiff] to remain utterly faithful to the written protection provision. But the standard is reasonableness, not perfection.” The court found sufficient protection of the trade secrets because the information was disclosed within a confidential relationship, the NDA was not integrated, and the plaintiff had taken other measures to protect the trade secrets.

In the same case, explicit recognition of software design trade secrets was found. The judge recognized that, in software cases, “trade secret protection is not limited to the source code.” He granted the injunction (in part) – without any comparison of source code - after concluding that the plaintiff was likely to prevail on its claim that Kodak had misappropriated the “overall design” for its “client-side” oriented, distributed computing software.

Ms. Vreeland noted that legislation has been re-introduced in Massachusetts for the U.T.S.A. Massachusetts is only one of six states not to have adopted some version of the U.T.S.A. Ms. Vreeland said that the likelihood of passage in the current legislative sessions is unclear.

If passed, the Massachusetts U.T.S.A. would make explicit the requirement that a plaintiff identify its trade secrets with particularity. The Massachusetts U.T.S.A. would change the definition of “trade secrets” to “specified or specifiable” information that at the time of the alleged misappropriation, derived economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, others who might obtain economic value from its acquisition, disclosure, or use, and (ii) has at all times been the subject of efforts that are reasonable under the circumstances to give notice that it should not be and to ensure that it is not acquired, disclosed or used without the consent of the person asserting ownership thereof, or such person’s predecessor in interest. By this definition, trade secrets would include information of actual or potential competitive value.

The Massachusetts U.T.S.A. would explicitly recognize the “head start” rule. The legislation U.T.S.A. provides: “Upon application to the court, an injunction shall be terminated when the trade secret has ceased to exist, but the injunction may be continued for an additional reasonable period of time in order to eliminate commercial advantage that otherwise would be derived from misappropriation.”

The Massachusetts U.T.S.A. would change the rules concerning multiple damages. The Massachusetts trade secret statute authorizes the court, in its discretion, to increase damages “up to double the amount found.” Chapter 93A authorizes double or treble damages if the court finds the defendant’s conduct was “willful or knowing.” The U.T.S.A. authorizes exemplary damages, not exceeding twice the amount found, “if willful and malicious misappropriation exists.” The Massachusetts U.T.S.A. would also change the rules concerning multiple damages. Damages for trade secret misappropriation include the plaintiff’s lost profits, and the defendant’s illicit gains. The SJC has held that Chapter 93, § 42 authorizes double damages only when damages are measured by the plaintiff’s lost profits. The U.T.S.A. authorizes exemplary damages whether damages are measured by the plaintiff’s lost profits or the defendant’s gains.

The Massachusetts U.T.S.A. could provide support for recognition of the “inevitable disclosure” doctrine. This doctrine, if recognized, would authorize a court to issue an injunction, even absent a non-compete agreement, if it appeared “inevitable” that a former employee, leaving to work for a competitor, would use or disclose the plaintiff’s trade secrets at his new job.

Mr. Sullivan discussed in detail three important cases, *Knorr-Bremse, Phillips*, and *Merck. Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 72 U.S.P.Q.2d 1560 (Fed. Cir. 2004) was an appeal of a district court finding of willful infringement and award of attorney fees based in part on conclusion that opinion of counsel not produced was unfavorable.

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Key I.P. Decisions (con't)

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The court answered four questions regarding opinions and attorney-client privilege. First, when the attorney-client privilege and/or work-product privilege is invoked by a defendant in an infringement suit, is it appropriate for the trier of fact to draw an adverse inference with respect to willful infringement? Answer: No, there is no adverse inference from invocation of the attorney-client privilege and/or work product privilege.

Second, when the defendant has not obtained legal advice is it appropriate to draw an adverse inference with respect to willful infringement? Answer: No, the issue is not of privilege, but whether there is a legal duty upon a potential infringer to consult with counsel, such that failure to do so will provide an inference or evidentiary presumption that such opinion would have been negative.

Third, if the court concludes that the law should be changed, and the adverse inference withdrawn as applied to this case, what are the consequence for this case? Answer: Finding of willful infringement and award of attorney fees were vacated and remanded for further consideration.

Fourth, should the existence of a substantial defense to infringement be sufficient to defeat liability for willful infringement even if no legal advice is secured? Answer: No, but it may be a factor considered among others in a totality of circumstances analysis.

In the dissent, Judge Dyk stated that he would eliminate the "due care" requirement that exists upon notice of another's patent rights.

Implications and recommendations for in-house counsel from Mr. Sullivan are that the duty of due care is unchanged. Counsel should consider totality of circumstances (at least those in existence), likelihood of litigation and potential damages in determining need for opinion of counsel. A well-reasoned opinion of counsel is still best defense against willful infringement according to Mr. Sullivan.

The second case discussed by Mr. Sullivan was *Phillips v. AWH Corp.*, 75 U.S.P.Q.2d 1321 (Fed. Cir. 2005). The issue in the case was interpretation of "means disposed inside the shell for increasing its load bearing capacity comprising internal steel baffles extending inwardly from the steel walls."

The Federal Circuit found that an earlier case placed too much emphasis on dictionaries. Specification and prosecution history should be given the most weight. Since claim term was not ambiguous, the court did not have to address the doctrine of construing claims to preserve their validity.

Mr. Sullivan said that the lessons from *Phillips* include continue to avoid limitations of invention in specification, include multiple embodiments in specification with specific statements that invention is not limited to any particular embodiment, and include a variety of claims using different terms.

The third case discussed by Mr. Sullivan was *Merck v. Integra*, 74 U.S.P.Q.2d 1801 (U.S. S.Ct. 2005). The question before the court was whether the use of patented inventions in preclinical research, the results of which are not ultimately included in the submission to the Food and Drug Administration (FDA) are exempted from infringement.

The Supreme Court reversed the Federal Circuit and held that exemption does apply. Where a developer has a reasonable basis for believing that a patented compound may work . . . and uses the compound in research that if successful, it would be appropriate to include it in a submission to the FDA. The use is "reasonably related" to the development and submission of information under federal law. Leaving data out of submission does not make experiment less "reasonably related". The use of patented compounds in preclinical studies is protected under Section 271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce the types of information that are relevant to a submission.

Mr. Sullivan comments on the case include that developers should be careful to characterize their development work such that it would come within the exemption, patentees are lobbying to change/clarify ruling by statute (Patent Reform Act), and that it is unclear where this leave developers/patentees of research tools.

Also, Mr. Sullivan touched on a number of cases that dealt with extraterritorial (outside United States) activities and its effect on Section 271(f)(1). "Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part." In addition, Mr. Sullivan reviewed a number of cases on Section 102 activities and references.

SUPREME COURT OF JAPAN CONFIRMS PATENTEE'S RIGHT TO INJUNCTION NOTWITHSTANDING EXCLUSIVE LICENSE GRANT

*by John A. Tessensohn, Esq.
Shusaku Yamamoto*

In a significant pro-patentee decision, the Supreme Court in *Sumisho Computer Systems Corporation v. A & Institute of Medicinal Molecular Design, Inc.*, Case No. H16 (uke) 997 dated June 17, 2005, ruled to allow a patentee's right to seek an injunction against an infringer even

though the patentee had granted an exclusive license under the patent.

In the first instance hearing, the Tokyo District Court issued a decision, Case No. H13 (wa) 21278 dated Feb. 6, 2003, refusing the patentee's injunction request on the grounds that the patentee had

granted an exclusive license of the patented invention. On appeal, the Tokyo High Court, Case No. H13 (ne) 1223 dated Feb. 27, 2004, overruled the District Court and held that the patentee could obtain an injunction against the accused infringer. The accused infringer

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Supreme Court of Japan (con't)

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subsequently appealed to the Supreme Court of Japan. The Supreme Court granted leave to hear the appeal from the Tokyo High Court, and in a succinct three paragraph judgment, it maintained the Tokyo High Court's position. The translation of the Supreme Court's self-explanatory reasoning is as follows.

A patentee has a right to require a person who is infringing that patentee's patent right to discontinue or refrain from such infringement (Patent Law, Section 100(1)). Further, it is stipulated that a patentee who grants an exclusive license will lose a right to commercially work the patented

invention to the extent that the exclusive licensee exclusively possesses the right to work the patented invention (Patent Law, Section 68). Thus, in this case, it becomes a matter as to whether the patentee loses the right to demand an injunction based on the patent right.

From the wording of Patent Law, Section 100(1), there is no basis for finding that the right of a patentee who has granted an exclusive license to demand an injunction is restricted.. Further, from a substantive point of view, where an exclusive license agreement stipulates that an amount of royalty is to be determined based on an amount of sales, there clearly exists a

practical benefit for the patentee to remove an infringing act in order to ensure its royalty income, or, to avoid a decrease thereof. In addition, if an act of infringement of the patent right is left unchecked, there is a risk that the patentee will suffer detriment where the exclusive license is annulled for some reason, and the patentee itself tries to work the patented invention. Thus, it should be understood that it is necessary to recognize the patentee's right to demand an injunction.

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CHALLENGE AN OFFENDING PATENT WITH INTERFERENCE

*By Michael T. Siekman, Esq.
Wolf, Greenfield & Sacks, P.C.*

It seems every company has at one time or another seen a competitor's issued U.S. patent and said, "How did they get that?" or "Everybody knew that." or "That doesn't work." All that may very well be true. A company might even obtain an opinion from its patent attorney stating that the offending patent is invalid on one of those grounds. But the USPTO issued the patent, and the patent is statutorily entitled to a presumption of validity in any U.S. court. If the offending patent covers the company's technology, every time the company seeks to raise funds, the value of its business will be discounted by the uncertainty the patent creates, even if 100 people agree the patent is invalid.

Unfortunately, the United States does not have an effective way of eliminating the uncertainty created by such an offending patent. Unless the patent owner actually sues, or sufficiently threatens to sue, the company, patent litigation is not available. Moreover, no company wants to invite a patent litigation, which is very expensive, invasive, and distracting.

Many other countries address the problem of such offending patents by providing a post-grant review process by which parties can oppose in the patent office the grant of a patent soon after its

issuance. If the opposer prevails, the patent office revokes the patent. While there are growing calls for such a post-grant opposition procedure in the US, none exists. Instead, the United States has experimented over the years with a hodge-podge of reexamination procedures where a company can request, or put political pressure on the patent office to decide on its own, that an offending patent be reexamined. Those reexamination procedures, however, continue to be unsatisfactory, largely because the deck is stacked in favor of the patent owner. Rather than request a likely unsuccessful reexamination (and forfeit certain rights in any subsequent litigation with the patent owner) most companies are well advised legally to do nothing. Of course, this does nothing to resolve the uncertainty.

Fortunately, many companies may have another alternative available to them for challenging an offending patent. To determine the first to invent among competing inventors, the patent office conducts "interference" proceedings. Since 1984, the patent office has also determined patentability issues in interferences. This provides a potential avenue for challenging the validity of an issued patent-one that is highly favorable

to a patent challenger. Few patent attorneys are comfortable with interferences, however, and few recognize their potential.

To have the patent office consider the patentability of an issued patent, a company needs to have a pending application claiming the same invention. If a company is developing a patent portfolio and the offending patent covers its technology, it will often have such an application pending before the patent office.

Moreover, the application need not presently claim the same invention. As long as a pending application supports claims to the "same patentable invention," the company can add claims to it ("copy claims from the patent") to provoke an interference. If no such application exists, a company might file for reissue of an issued patent and use the reissue application to provoke an interference. The claims must be present at some time before one year from the patent's issue date, and they must be allowable. Finally, the challenger must be able to show that it is at least possible that it could establish an earlier date of invention than the patent owner. If these conditions are met, the patent

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Challenge an Offending Patent with Interference (con't)

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office should declare an interference between the pending application and the issued patent.

The patent office has recently indicated a reluctance to declare any interference that is a mere "post-grant cancellation proceeding." Nonetheless, if a challenger meets those threshold requirements for provoking an interference, the patent office should consider the validity challenges to the offending patent.

Interferences have numerous advantages for challenging an offending patent. First, with essentially no discovery and no live testimony, interferences are much less expensive than district court litigation. Second, unlike reexaminations, interferences can consider all patentability issues. Third, patentability issues will be decided by administrative patent judges who, unlike judges and juries, regularly find inventions unpatentable and, being technically

trained, understand the inventions. Fourth, a patent is not entitled to the statutory presumption of validity in an interference proceeding, and the challenger's burden of proof is lower in an interference than in a district court litigation. Fifth, "interference estoppel," which prevents a losing party from obtaining in its patent portfolio claims that it could have pursued in the interference, potentially puts the patent owner's entire portfolio (as well as the challenger's) at risk, increasing the incentive to settle.

Before attempting to provoke an interference to challenge the validity of a patent, a company should consider whether traditional estoppel (collateral estoppel and issue preclusion) could prevent it from asserting in a subsequent litigation validity challenges that it previously lost in the interference. One old case that is binding precedent for all patent litigation, *Coakwell v. United States*, arguably supports the application of such an estoppel. *Coakwell's* scope is uncertain, in over 40 years it has never been applied in this way, and few patent

attorneys are aware of its existence. Nonetheless, it should be considered when deciding whether to provoke an interference to challenge the validity of an offending patent. Indeed, for patent challenges likely to depend upon discovery (such as invalidity due to a prior sale) or live testimony (such as inequitable conduct), a district court might offer a more favorable forum, and the risk of estoppel from an interference should be avoided entirely.

Interferences potentially provide a highly favorable and relatively inexpensive forum for challenging the validity of an issued patent. A company faced with a blocking patent it believes is unpatentable should consider the availability of an interference to challenge the offending patent.

Michael T. Siekman is counsel with the Biotechnology, Interference, and Pharmaceutical Practice Groups of Wolf Greenfield, a leading Boston IP law firm. He can be contacted at (617) 646.8336 or msiekman@wolfgreenfield.com.

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