President's Message

By Joseph M. Maraia, Pierce Atwood LLP

The Boston Patent Law Association continues to prove itself as one of the strongest intellectual property law associations in the country. Since our annual meeting last December, the BPLA's membership has grown to over 950 members, provided its members with over 16 seminars, honored the Federal Judiciary at the BPLA's Annual Judges Dinner, and has raised over $9000 for our Pro Bono Initiative. All of this would not be possible without the dedication of your Board of Governors, Committee Chairs, and our members. Thank you.

On June 14th, over 250 members and guests attended the BPLA's Annual Dinner in honor of the Federal Judiciary at the Fairmont Copley Plaza. I had the honor of presenting this year’s public service award to the Honorable Mark L. Wolf. Our keynote speaker, Boston Bruins Legend and NHL Hall of Famer Raymond Bourque talked about his career, living in Boston, and how patents are an essential part of his charity being able to donate over 13 million dollars for worthy causes. Through the efforts of our Pro Bono Committee, led by co-chairs Chelsea Loughran and Rex Huang, and the generosity of Ray Bourque, the BPLA raised $9000 for our Patent Pro Bono program that we look forward to launching later this year. I believe all those in attendance will talk about their own special moment from the evening, but the moment for me was witnessing Ray Bourque hoisting and kissing our Patriot Plate, akin to the players after winning the Stanley Cup.

The BPLA will host its annual PCT Seminar on November 4th and 5th.

Continues on Page 3
The BPLA Pro-Bono Committee continues to make significant progress towards the establishment of a Patent Pro Bono Program here in Boston. In late 2012, we circulated a survey to assess the interest in starting a pro bono patent program in Boston, and the results showed tremendous support for the idea in the patent law community. This show of support kicked off a resolute effort on the part of the BPLA Pro Bono Committee and Volunteer Lawyers for the Arts, a program of the Arts & Business Council of Greater Boston, to determine how best to operationalize a Boston-based Patent Pro Bono Program.

Today we are poised to establish such a program if we can raise adequate funds to support its operationalization at Volunteer Lawyers for the Arts and ensure its sustainability over the coming years. To launch this program by year’s end, we are seeking to raise first-round funding in the amount of $35,000.00. A significant step towards this funding goal was achieved at the BPLA Annual Dinner in Honor of the Federal Judiciary on June 14, 2013, where the Pro-Bono Committee hosted a silent and live auction with proceeds to benefit the formation of the Patent Pro Bono Program. Through generous donations made by keynote speaker Raymond Bourque and a variety of local businesses and law firms, and through lively bidding on the part of the BPLA membership, we were able to raise over a quarter of our funding target.

Now we need your help.

The time has come to establish a Patent Pro Bono Program in the Boston area, a region rightly considered one of the nation’s hubs for cutting edge research, development, innovation and entrepreneurship. We recognize that useful inventions come from all walks of life, including from those who do not have the means to pay the high attorney fees typically required to secure patent rights: for example, an artist designing an app that helps blind artists manage their workflow in creative and efficient ways, or a medical student devising a cure for a rare disease suffered by a tiny portion of our population. The Patent Pro Bono Program is intended to help these creative but under-funded individuals and businesses through counseling and, possibly, the securing of patent rights to further promote their useful inventions to the benefit of the larger community.

Such programs have already been launched and are operational in Minnesota, California, and Colorado. Federal Circuit Chief Judge Randall Rader is a member of the America Invents Act Pro Bono Task Force and is encouraging the formation of local programs across the country.

We sincerely hope you will join us in our efforts to promote creative entrepreneurship in the greater Boston area. Please take the time to consider an individual or corporate sponsorship donation and help us to make Boston the next location for a Patent Pro Bono Program.

If you would like to make a donation, please contact either of the Pro Bono Committee Co-Chairs (Chelsea Loughran at cloughran@wolfgreenfield.com or Rex Huang at Huang@fr.com) for more information. And, as always, if you were not able to participate in the survey mentioned above but would be interested in participating in the Patent Pro Bono Program, please feel free to e-mail the Pro Bono Committee Co-Chairs.

Stephan Williams has retired after 40 years of IP practice. Steve began his career as an examiner with the US Patent and Trademark Office in 1973, then held successive positions at Foster Grant Co. (American Hoechst), American Optical Corp., the Dike, Bronstein firm, Ares-Serono Inc., The Gillette Company (Procter & Gamble), and W.R. Grace & Co.
Once again, this year’s conference will be led by two speakers from WIPO: Matthias Reischle, Deputy Director, PCT Legal Division, Innovation and Technology Sector, and Carol Bidwell, PCT Consultant. Information for registration will soon be available on the BPLA website.

Co-chairs, Vic Polk and Lawrence Stanley of the Copyright Committee held a “Design Patent/Copyright Conundrum” roundtable on January 24, 2013. The panel discussed the importance design patents, highlighting the Apple v. Samsung patent litigation that resulted in a jury verdict in excess of $1 billion. In particular, the panel raised the issues concerning the differences between design patents and copyrights, which included the nature and scope of protection afforded by design patents and copyrights, the overlap in protection between the two, standards for infringement and remedies available for infringement of design patents and copyrights, and real world examples from recent cases where the design patent/copyright conundrum has played a role.

The Ethics Committee, led by co-chairs, Steven Henry and John Stickevers held an “Ethics Tales, Issues and New Rules” seminar on February 12, 2013. Deputy Director of the USTPO Office of Enrollment and Discipline (OED), William Griffin, discussed how the OED polices the patent bar, what its case load looks like, what its priorities are and what messages it wants us to hear, what it is trying to accomplish with the rule changes and what we as practitioners need to understand about them, as well as some very interesting stories about some ethics violations.

Co-chairs, Emily Whelan and Nicole Palmer, of the Patent Practice Committee held a roundtable discussion prior to the implementation of the new law that took effect on March 16, 2013. This roundtable focused on whether you should file before the AIA first-to-file effective date and whether and how to take advantage of our last chance at first-to-invent.

Co-chairs, Jeremy Bond and James Flaherty of the Medical Device Committee held a seminar on “Where Does US Patent Law Currently Stand On “Joint Infringement” on April 24, 2013. The seminar focused on the recent en-banc Federal Circuit decision in Akamai and McKesson. As discussed, this decision has dramatically changed what is needed to prove “joint infringement” under US patent law.

The Biotechnology Committee, led by co-chairs Leslie Meyer-Leon, Konstantin Linnik, Bo Han, and Jennifer Sieczkiewicz held a seminar on “Protecting Intellectual Property: Finding and Executing Best Strategies Under Cost-Cutting Pressure” on May 2, 2013. A panel of experienced counsel and IP managers discussed their views and experiences on how to effectively and efficiently provide legal services.
Characterizing Prior Art to Limit the Broadest “Reasonable” Claim Interpretation

*In Re Abbott Diabetes Care Inc.*

By Matthew B. Pinckney, Hoffman Warnick LLC

As patent practitioners in a post-KSR world, many of us have limited our descriptions and characterizations of prior art in patent applications, in fear of our words being used against our clients in obviousness-based rejections during prosecution. This conservative approach toward describing prior art likely helps applicants avoid certain rejections on obviousness grounds. However, in some cases, discussion of a significant shortcoming of the prior art can benefit the applicant during claim interpretation, particularly in view of the US Patent and Trademark Office (USPTO) standard of giving claim terms their broadest reasonable interpretation. The recent decision of the US Court of Appeals for the Federal Circuit (Fed Circuit) in *In Re Abbott Diabetes Care Inc.*, is an example of how a disparaging description of the prior art can benefit the applicant during claim interpretation, particularly in view of the US Patent and Trademark Office (USPTO) standard of giving claim terms their broadest reasonable interpretation. The recent decision of the US Court of Appeals for the Federal Circuit (Fed Circuit) in *In Re Abbott Diabetes Care Inc.* is an example of how a disparaging description of the prior art can benefit the applicant during claim interpretation, particularly in view of the US Patent and Trademark Office (USPTO) standard of giving claim terms their broadest reasonable interpretation. The recent decision of the US Court of Appeals for the Federal Circuit (Fed Circuit) in *In Re Abbott Diabetes Care Inc.* is an example of how a disparaging description of the prior art can benefit the applicant during claim interpretation, particularly in view of the US Patent and Trademark Office (USPTO) standard of giving claim terms their broadest reasonable interpretation. The recent decision of the US Court of Appeals for the Federal Circuit (Fed Circuit) in *In Re Abbott Diabetes Care Inc.* is an example of how a disparaging description of the prior art can benefit the applicant during claim interpretation, particularly in view of the US Patent and Trademark Office (USPTO) standard of giving claim terms their broadest reasonable interpretation.

In this decision, the Fed Circuit handed down a precedential ruling on an appeal from the Patent Trial and Appeals Board (PTAB) regarding reexamination of patents directed toward devices and methods of monitoring glucose levels for diabetics. During reexamination of the patents, the patent examiner finally rejected all of the claims as being indefinite, anticipated or obvious over several combinations of prior art references. (*In Re Abbott Diabetes Care Inc.*, Fed. Cir. 2011-1516, p. 7).

In particular, the examiner interpreted claim terms to an “electrochemical sensor” as including external cables and wires which connected the sensor to a control unit. The “electrochemical sensor” was claimed as having “contact pads” that are “couple[d]” to “conductive contacts”, or a “transcutaneous electrochemical sensor” that is “receive[ed]” by the sensor control unit. (*Id.* at p. 13, US Pat. No. 6,175,752, and US Pat. No. 6,565,509, respectively). The examiner’s claim interpretation allowed him to argue that a piece of prior art taught the features of the “electrochemical sensor” because that prior art taught external cables and wires which connected a sensor to a control unit. (*Id.*).

Abbott disclosed an electrochemical sensor that did not include external cables and wires, and highlighted the fact that its inventive diabetes monitoring device was less cumbersome than previously designed devices. The Fed Circuit noted that, “…the specification contains only disparaging remarks with respect to the external cables and wires of the prior-art sensors…” (*Id.* at p. 13). Even further, the Court noted, “…every embodiment disclosed in the specification shows an electrochemical sensor without external cables or wires. Indeed, the only mention of a sensor with external cables or wires in Abbott’s patents is a single statement addressing the primary deficiency of the prior art.” (*Id.*).

The Fed Circuit writes, “[i]t is true that the specification does not contain an explicit statement disclaiming electrochemical sensors with external cables or wires. But this is not an instance where the specification would necessarily have to disavow an embodiment that would otherwise be covered by the plain language of the claims – rather, claim terms like “couple[d]” and “receive[ed]” are entirely consistent with and even support the specification’s exclusive depiction of an electrochemical sensor without external cables or wires. (*Id.* at pages 13-14). The Court ruled that this was not an instance where an explicit disclaimer was necessary in the specification because, “nothing suggests or even hints that the claimed electrochemical sensor can include external cables or wires.” (*Id.* at p. 15).

Continues on Page 5
Naturally Occurring DNA Not Patentable, Man-Made cDNA is: What’s Next for Other Biologicals?

By Yu Lu, Partner, MCarter & English LLP

"Are human genes patentable?" On June 13, 2013, in a highly anticipated decision in Ass’n for Molecular Pathology vs. Myriad Genetics, Inc. (“AMP v. Myriad”), the U.S. Supreme Court drew a sharp distinction between naturally occurring DNA and made-made cDNA, and held unanimously that the former (and its encoded information) is not patent eligible even if isolated, while the latter is, provided that the cDNA is not so short and may be indistinguishable from natural DNA. The Court, however, took pains to narrow the decision by expressly declining to opine on the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. The Court also hinted that methods of making and/or using the otherwise unpatentable DNA may be patent eligible.

This decision continues a decade-long trend of limiting patent eligible subject matter by the Court in laws of nature (e.g., as applied to diagnostic methods in Mayo v. Prometheus, 132 S.Ct. 1289 (2012)), natural phenomena, and abstract ideas (e.g., as applied to certain business methods in Bilski v. Kappos, 130 S.Ct. 3218 (2010)). Although the decision had little guidance to the patent eligibility of other biological materials such as RNA, protein, antibody, small molecule, stem cell, etc., a careful analysis of the Court’s rationale may shed some light on this topic.

In reaching its holding, the Court focused on the fact that Myriad’s DNA claims are not expressed in terms of chemical composition, or rely in any way on the chemical changes that result from its isolation, but are defined by the genetic information encoded in the claimed BRCA1 and BRCA2 genes. In contrast, the lab-created cDNA molecule altered the informational component of the natural DNA by removing the non-coding intron portion of the genomic DNA sequence. This informational content change is apparently sufficient to render the cDNA “not naturally occurring” and thus patent eligible.

Thus, it seems that the Court has adopted an information-centric view of the DNA based on the claims. It remains to be seen whether claims directed to other biological materials, such as isolated or purified proteins, chemical molecules, or stem cells, defined by what they are (e.g., structure) rather than what they do (e.g., function), sufficiently distinguish these biological materials from the natural products from which they are isolated or purified. It may also be important to see whether the process used to obtain the biological materials created something new or “markedly different” compared to the naturally existing material, or merely reproduced the naturally existing material. Regardless, it becomes more important than ever to include well drafted method claims directed to the make or use of biological products that could become patent ineligible under this decision.

In all, the AMP v. Myriad decision potentially has a far reaching impact in the biotechnology and pharmaceutical industry, especially in companies or organizations.

Continues on Page 6

* - Matthew B. Pinckney is a registered patent attorney with Hoffman Warnick LLC, and manages the firm’s Boston Office.

In Re Abbott Diabetes Care Inc. Continues from Page 4

In view of this decision, applicants may feel slightly more comfortable in characterizing the shortcomings of the prior art in their patent applications. In select cases, it may be beneficial to characterize the known deficiencies of prior art in order to prevent an undesirably broad interpretation of a claim element during examination before the USPTO. As the Federal Circuit illustrated in In Re Abbott Diabetes Care, these sorts of statements, when not contradicted by the applicant’s disclosed embodiments, can help to limit the extent of the broadest “reasonable” interpretation of claim terms.
Summer 2013  
BPLA NEWSLETTER  
Volume 44, Issue 2

President's Message  
Continues from Page 3

Co-chairs, David Miranda and William DeVaul of the in-house Committee held a seminar on “Technology and processes to support in-house prosecution practice” on June 12, 2013. Senior IP counsel discussed their views and experiences on technology, applications, and processes to effectively and efficiently provide in-house legal services.

The Contested Matters Committee, led by co-chairs Susan Glovsky and Ian Liu, held a seminar on “Fighting it Out in the Patent Office” on June 19, 2013. The seminar focused on Inter Partes Review, a new trial proceeding conducted at the Patent Trial and Appeal Board to review the patentability of one or more claims in a patent only on a ground that could be raised in §§ 102 or 103, and only on the basis of prior art consisting of patent or printed publications.

I would like to thank our Biotechnology Committee who continues to hold its monthly “Case Law Club” meetings to discuss current case law pertaining to protecting and exploiting IP in the life sciences. Please visit the BPLA website for a schedule of upcoming meetings.

I encourage each of you to remain actively involved with the BPLA, and to reach out to the Board of Governors, the Committee Chairs, or myself with any comments or suggestions. Please feel free to contact me at (617) 488-8117 or by e-mail to jma-raia@pierceatwood.com.

Natural DNA Not Patentable  
Continues from Page 5

engaging in research and development of natural products or related biological materials. Indeed, the USPTO has already published its preliminary guidance relating to nucleic acid-related technology, as a memo to the Patent Examining Corps, instructing the Examiners to “reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. § 101.” The memo also cautions that “other claims, including method claims, that involve naturally occurring nucleic acids may give rise to patent eligibility issues.” Patent owners are well advised to review their patent portfolios and determine whether reissue patents should be applied for in order to protect the present patent-eligible subject matter.

Writing Competition

Sponsored by the Boston Patent Law Association

1st Prize: $1000 • 2nd Prize: $500

The BPLA is once again holding its annual Writing Competition. Law students are encouraged to submit papers on a subject relating to intellectual property law. The requirements for eligibility are outlined below.

Judges will consider the merits of the article as a contribution to the knowledge respecting intellectual property law and the extent to which it displays original and creative thought or information not previously published or available.

Contest Rules:

- Papers must have been written or published between September 1, 2012 and September 2, 2013.
- Papers must be submitted to the Boston Patent Law Association on or before September 30, 2013.

Please send articles to:

Deirdre E. Sanders, Esq.  
Boston Patent Law Association  
c/o Hamilton, Brook, Smith & Reynolds, P.C.  
530 Virginia Road  
P.O. Box 9133  
Concord, MA 01742  
Phone: (978) 341-0036  
Fax: (978) 341-0136  
Email: Deirdre.Sanders@hbsr.com
Pre-Issuance Submissions to the US Patent and Trademark Office

By Matthew B. Pinckney, Hoffman Warnick LLC, Garrett K. Quillia, Hypertherm, Inc.

This past September, the US Patent and Trademark Office (USPTO) instituted changes to procedures for allowing third parties to submit references for consideration by the Office during examination of applications. These changes are one of the many new provisions included in the America Invents Act (AIA)*.

Under the new pre-issuance submissions (also called third-party submissions) procedure, any member of the public (excluding the applicant or the applicant’s representative) may submit patents, published patent applications or other printed publications of potential relevance to the examiner of a patent application. These third-party submissions are provided to the patent examiner for consideration during examination. The submission need only identify the submitting party (e.g., patent agent or patent attorney), thereby allowing the interested party to submit anonymously if so desired. However, in order to remain anonymous after submission, it may be advisable to have a newly affiliated patent attorney serve as the submitting party. This may help prevent an interested party from identifying the third party based upon a known relationship with the submitting patent attorney.

There are two timelines to keep in mind when considering a third-party submission. In accordance with the AIA, a timely submission must be made before the earlier of:

a) The date the Notice of Allowance is issued to the applicant; or

b) The later of: (i) Six months from the publication date of the application, or (ii) The date of the first rejection of any claim during examination.

Due to the large number of patent applications currently awaiting examination at the USPTO, it is more likely that the date of publication will act as the triggering event for considering a third party submission. Therefore, it may be an effective strategy to monitor the publication of applications in technical areas of interest on a regular basis.

In making a third-party submission, it is necessary to identify portions of the patents and/or publications which the submitter believes to be particularly relevant to the claim(s) of the pending application. It is also necessary to include a concise description of the asserted relevance of each item included in the submission. However, the concise description must not propose rejection of the claims. Instead, the description should include a factual explanation of the relevance of the document to the pending application. It is impermissible to submit arguments against patentability or set forth conclusions regarding whether one or more claims are patentable. Despite these restrictions, it is permissible to submit the concise explanation in the form of a claim chart or a narrative, so long as the explanation does not form a conclusion regarding the patentability of claims or their features. The USPTO recommends submitting the concise description of the references in separate documents or entries for each reference.

If the publication date of a reference (e.g., a printed publication) is unknown, the third party may still submit that printed publication in a third-party submission. However, the submitting party must provide information regarding the date

Continues on Page 8
“Fighting It Out in the Patent Office”
Contested Matters Committee Organized a Breakfast Seminar on Inter Partes Review

By Ian Liu, Ph.D., Finnegan LLP
Susan G.L. Glovsky, Hamilton, Brook, Smith, Reynolds,

The America Invents Act (AIA) provides patent owners and patent challengers new battlegrounds in the Patent Office. Starting last September, a patent challenger can fight out the validity of a patent with the patent owner in new post-grant review proceedings before the Patent Trial and Appeal Board (PTAB). These proceedings include Inter Partes Review (IPR), Post-Grant Review (PGR), transitional Post-Grant Review of Covered Business Method Patents (CBM), and derivation proceedings. IPRs account for more than ninety percent of new PTAB filings to date.


The audience had the opportunity to hear from Jennifer Bailey of Hovey Williams LLP in Kansas, who represents Garmin in Garmin Int’l Inc. v. Cuozzo Speed Technologies LLC, the first IPR filed in the PTAB, and the prevailing party in the first discovery motion brought in an IPR. Jennifer provided insight on appearing before the PTAB. David Cavanaugh and Peter Dichiara, both

Continues on Page 25

Submissions to the US Patent Office
Continues from Page 7

when the document was retrieved or available as a publication, as well as evidence that establishes the document as a publication. Evidence establishing the document as a publication can include affidavits, declarations or other pertinent evidence.

The third-party submission must include an English language translation of any non-English language document; and machine translations are permissible. The third party may submit up to three (3) documents along with a concise description without paying a fee. This fee exemption is applicable for the first and only submission made by the third party. Submitting between four (4) and ten (10) documents costs $180, and every group of ten documents or fewer above the first ten documents costs an additional $180. For example, submitting four (4) documents costs $180, while submitting twelve (12) documents costs $360.

After a third-party submission is accepted by the USPTO, the applicant is notified of the submission through the USPTO electronic-Office Action program. The contents of the third-party submission are made available to the applicant and the public through the application’s Image File Wrapper. Submitting references and comments as a third party can be an effective mechanism for influencing the prosecution of a competitor’s patent application without incurring significant costs. Further, the procedure for making third-party submissions allows the interested party a chance to remain anonymous. These considerations may make third-party submissions an attractive option when viewing patent applications filed by competitors or other parties of interest.

** -This article was written using information available from the USPTO, which can be found at the “AIA Frequently Asked Questions” page, sub-titled, “Preissuance Submissions”, available at http://www.uspto.gov/aia_implementation/faqs-preissuance-submissions.jsp.
The 2013 Invented Here! selection process is complete! The Honorees will be recognized at the Invented Here! recognition event at the Museum of Science on Thursday, September 19, 2013, beginning at 6:30 p.m. If you would like to attend the Invented Here! recognition event to meet the Honorees, hear their stories, and network with other members of our innovation community, please register via a link at http://www.mos.org/invented-here.

So, how does one select Honorees from among the diverse science and engineering categories of New England’s innovations? That was the exciting question that the Boston Patent Law Association (BPLA) and Museum of Science Selection Committees were tasked with answering this summer, and they rose to the challenge.

On July 16, 2013, the BPLA Selection Committee presented thirteen Honorees, from among the many nominations received in the Issued Patents category, to the Museum of Science’s Selection Committee. The BPLA Selection Committee, which mostly consisted of patent attorneys from the BPLA’s New Lawyers and Law Students Committee, evaluated the nominations based on a variety of criteria, which included the scope of claim coverage afforded by the nominated patents, the invention’s significance and characteristics, and its presentability. On August 13, 2013, the Museum’s Selection Committee selected three of the thirteen Honorees to be featured at the closing recognition event. The Museum Selection Committee, which consisted of a number of widely respected individuals from the innovation and entrepreneurship community, evaluated the honorees based on the invention’s technological impact, “wow” factor, and the suitability for the Museum’s audience.

Thank you to all who nominated patents and published applications. The diverse fields represented include, in no particular order, clean energy, medical devices, optics, biotechnology, chemistry, pharmaceuticals, mechanical engineering, and many others. The nominators, many of whom are BPLA members, did a phenomenal job again this year.

This year’s three Featured Honorees in the Issued Patents category will be showcased throughout the year at the Museum, and all 13 Honorees will be listed on the BPLA website. The three selected Fan Favorite Honorees in the Published Applications category, as well as one Featured Honoree, will also receive recognition. To see past Honorees, go to the BPLA’s Events page at http://tinyurl.com/InventedHere.

The Co-Chairs for this year’s Invented Here! BPLA Planning Committee are Mark Solomon, Rory Pheiffer, and Aaron Connor. The Co-Chairs for this year’s BPLA Selection Committee are Reza Sadr and Michael Carbonello. BPLA members serving on the BPLA Selection Committee include (in alphabetical order): James Acheson; Christopher K. Albert; Joshua M. Brandt; Elias Domingo; Derek Lam; Rebecca A. Menapace; Andrea Daley Merin; Seth Milman; Matthew Pinckney; Dipti Ramnarain; Brian E. Reese; Dave Rocco; John W. Rooney; Robert N. Sahr; Andrew Schultz; Mary Rose Scozzafava; William Shaw; Janet Smart; Christopher J. Stow; Robin Weatherhead; Michael M. Yamauchi; and Andrina Zink.

To learn how to join our current Event Partners, Microsoft and MassChallenge, or Participating

By Don Steinberg, Vic Souto, and Greg Lantier, WilmerHale

On May 10, 2013, the Federal Circuit issued its decision in CLS Bank International et al. v. Alice Corporation Pty., Ltd., (2011-1301), which it decided en banc in order to address two questions:

a. What test should the court adopt to determine whether a computer-implemented invention is a patent ineligible “abstract idea”; and when, if ever, does the presence of a computer in a claim lend patent eligibility to an otherwise patent-ineligible idea?

b. In assessing patent eligibility under 35 U.S.C. § 101 of a computer-implemented invention, should it matter whether the invention is claimed as a method, system, or storage medium; and should such claims at times be considered equivalent for § 101 purposes?


In a short per curiam opinion, the court held:

[u]pon consideration en banc, a majority of the court affirms the district court’s holding that the asserted method and computer-readable media claims are not directed to eligible subject matter under 35 U.S.C. § 101. An equally divided court affirms the district court’s holding that the asserted system claims are not directed to eligible subject matter under that statute.

The court then issued six additional opinions, none of which was joined by a majority of the court.

Judge Lourie (in an opinion joined by Judges Dyk, Prost, Reyna and Wallach), restated the two-part test for determining patent-eligible subject matter:

We must first ask whether the claimed invention is a process, machine, manufacture, or composition of matter. If not, the claim is ineligible under § 101. If the invention falls within one of the statutory categories, we must then determine whether any of the three judicial exceptions nonetheless bars such a claim—is the claim drawn to a patent ineligible law of nature, natural phenomenon, or abstract idea? If so, the claim is not patent eligible. Only claims that pass both inquiries satisfy § 101. Lourie Op. at 8-9.

Judge Lourie stated that this test has proved difficult to apply, which he suggested was due to the inability to consistently and predictably differentiate between claims that would tie up laws of nature, natural phenomena, or abstract ideas and claims that merely "embody, use, reflect, rest upon, or apply" those fundamental tools. Lourie Op. at 9 (citing Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012).)

Judge Lourie then identified three guideposts to a § 101 analysis based on US Supreme Court precedent:

1. patents should not be allowed to preempt the fundamental tools of discovery—those must remain “free to all . . . and reserved exclusively to none”;

2. courts should avoid overly formalistic approaches to subject-matter eligibility that invite manipulation by patent applicants; and

3. courts should apply a flexible, claim-by-claim approach to

Continues on Page 11
subject-matter eligibility that avoids rigid line drawing.

Lourie Op. at 15-17.

Addressing the asserted claims of the Alice patents, Judge Lourie identified the abstract idea and then looked to see whether the rest of the claim adds "significantly more." Lourie Op. at 26. Finding that these claims did not, Judge Lourie found the asserted claims not directed to patent-eligible subject matter. Lourie Op. at 28 ("But for the implied requirement for computer implementation, the broad, non-technical method claims presented here closely resemble those in *Bilski*, which also explained a 'basic concept of . . . protecting against risk.'" (citations omitted.).)

In a concurring-in-part and dissenting-in-part opinion, **Chief Judge Rader** (joined by Judges Linn, Moore and O'Malley), began his analysis with Alice's asserted system claims, stating that a computer-implemented invention is eligible for patenting under § 101 because computers are "machines." Rader Op. at 27. Thus, the issue was whether the system claims were barred from patent eligibility because they claimed an abstract idea. *Id.* at 28. Chief Judge Rader would have found that Alice's system claims are patent eligible because "[the system] claims do not claim only an abstract concept without limitations that tie it to a practical application." *Id.* at 35. He stated that an escrow arrangement can be used in many applications without computer systems, and even with computers but in ways that do not infringe the claims. Next, Chief Judge Rader tested the additional elements beyond the abstract idea of an escrow present in the claim and found that the recited steps are not inherent in the process of using an escrow. In addition, Chief Judge Rader found that these limitations are not stated at a high level of generality. "Because of the number and specificity of the structural limitations, these claims have narrow, if any, relevant pre-emptive effect." Rader Op. at 37.

When reviewing Alice's asserted method and media claims, Chief Judge Rader agreed that these claims are not eligible for patenting under § 101, finding that they were abstract: "each step individually recites merely a general step inherent within the concept of an escrow." *Id.* at 41. He explained that an escrow is an abstract concept and "the attempt to limit the escrow concept to a particular field is not sufficient" to make it patent-eligible. *Id.* at 42.

Dissenting-in-part, **Judge Moore** (joined by Chief Judge Rader and Judges Linn and O'Malley), wrote to express her concern "that the current interpretation of § 101, and in particular the abstract idea exception, is causing a free fall in the patent system." Moore Op. at 1-2. Specifically, Judge Moore wrote that "[h]olding that all of these claims are directed to no more than an abstract idea gives staggering breadth to what is meant to be a narrow judicial exception. And let's be clear: if all of these claims, including the system claims, are not patent-eligible, this case is the death of hundreds of thousands of patents, including all business method, financial system, and software patents as well as many computer implemented and telecommunications patents." *Id.* at 2. Noting that many of the recent Supreme Court § 101 cases found no patent eligible subject matter, Judge Moore indicated that this case presents an opportunity for the Supreme Court to distinguish between claims that are and are not directed to patentable subject matter.

In a concurring-in-part opinion, **Judge Newman** stated that she believed the court missed an opportunity to provide clarity to § 101 jurisprudence and proposed that "the court resolve the present impasse by returning to the time-tested principles of patent law":


2. The court should hold that the form of the claim does not determine § 101 eligibility. Newman Op. at 4.

3. The court should confirm that experimental use of patented information is not barred. *Id.*

Continues on Page 12
Supreme Court Affirms Support for WilmerHale Client in Bowman v. Monsanto Ruling

By Monica Grewal, Wilmer Hale

WilmerHale secured a victory for client Monsanto Co. in a significant patent law case decided today by the United States Supreme Court. The Court unanimously held in Bowman v. Monsanto Co. that producing new crops of soybeans containing Monsanto’s patented Roundup Ready® trait without Monsanto’s permission constitutes patent infringement. It rejected farmer Vernon Bowman’s defense that he had the right to make new copies of Monsanto’s invention under the “patent exhaustion” doctrine.

“It’s a huge victory for innovation. The Court made clear that strong patent protection is critical to preserving the incentives for innovation that Congress intended. The clarity—and unanimity—of the decision should put to rest any questions about the role of the patent system in protecting technologies like Monsanto’s,” said WilmerHale Partner Seth Waxman.

The Supreme Court’s decision affirms Monsanto’s victory in the U.S. Court of Appeals for the Federal Circuit, which in turn affirmed a judgment for Monsanto in the U.S. District Court for the Southern District of Indiana.

CLS Affirmed
Continues from Page 11

In a dissenting opinion, Judge Linn (joined by Judge O’Malley) expressed his view that the Alice asserted method, media, and system claims must rise and fall together—either they are all patent eligible or they are not. He stated that the analyses of the method claims conducted by Chief Judge Rader’s opinion and Judge Lourie’s opinion are divorced from the record, including stipulations by which CLS agreed to be bound. Judge Linn would apply the same analysis Chief Judge Rader applied to the system claims to find the method, media and system claims patent eligible.

In additional reflections, Chief Judge Rader counseled that courts should focus on the language of the patent statute. Chief Judge Rader noted that the statute offers patents to both inventions and discoveries, including simply an improvement on a known process or product, so long as they meet the conditions of patentability set forth in § 102 and 103 of the Patent Act. He stated that § 101 is not a condition of patentability and that the statute does not list § 101 among invalidity defenses to infringement.
AIA and IP Due Diligence

Stacy Lewis, Donna Meuth, Tom Irving

I. Introduction

An intellectual property ("IP") due diligence investigation involves a complex and challenging process of examining patents and other IP, typically under demanding time constraints. IP due diligence can arise in a variety of transactional contexts, such as an investor evaluation, a merger or acquisition, litigation, or negotiation of a licensing agreement. If the situation is one where the strength of the IP can significantly impact the terms and value of the transaction, or even whether the transaction is to be completed, a company’s goal, when it is the suitor, is to thoroughly evaluate the IP of the target at issue prior to “signing on the dotted line.”

Whatever the business reason for due diligence, the result of inadequate IP due diligence can range from simply wasted resources to catastrophic consequences of being precluded from marketing and/or protecting the acquired technology. Inadequate IP due diligence can result in expenditure of millions of dollars on a deal only to find out when it is too late that the underlying IP is fundamentally flawed and virtually worthless when it comes to being able to afford protection.

Perhaps there was a failure of the target company to acquire title or exclusive title to the IP. Or a failure to recognize that the transaction would impose unwarranted IP obligations on the purchaser, both with respect to IP procurement and IP enforcement. Or a failure to realize that the suitor was purchasing an IP lawsuit, which, if unsuccessful, could eliminate the opportunity to market the acquired technology.

And of course, as we move further and further into the American Invents Act ("AIA”), the suitor will need to evaluate additional issues now associated with an IP due diligence. The various effective date provisions of the AIA, and the possibilities for addressing any problems discovered, will have to be considered in relation to the patents involved in the IP due diligence. Practitioners will have to be alert to whether pre-AIA law or AIA applies to the claims in the patents/patent applications under investigation. Along with the existence of the new AIA law, pre-AIA law will be in play until at least 2034! For the foreseeable future, however, practitioners will be making many AIA determinations at least somewhat in the dark, since there is no guidance yet on how the courts will ultimately interpret the AIA.6

The biggest impact of the AIA on IP due diligence may be a practical one: attorneys may need more time, if AIA applies in whole or in part, to thoroughly conduct the IP due diligence. This may be challenging since there is often severe time pressure in conducting an IP due diligence. In addition, more time or even the same amount of time but more issues may mean companies need to budget more resources for IP due diligence investigations.

Practitioners may need to educate clients on the variety of additional considerations in light of AIA, and agree up front on what will and will not be part of the due diligence investigation.

This article will discuss new AIA considerations as they might apply to the three conventional prongs of an IP due diligence: inventorship/ownership, freedom to operate ("FTO"), and validity/enforceability.

II. Inventorship/Ownership

As each patent and application of the target is analyzed in an IP due diligence, one of the first questions is: who invented the patent? Inventorship determines ownership in the U.S.; the proper and correct naming of the inventor permits the legal chain of title to be established from the inventor to the assignee-applicant for patent. Under AIA, for patent applications filed after September 15, 2012, inventors are still required to be named,6 even if a patent application may now be filed by a third party (assignee).7

Of course inventorship is important

Continues on Page 14
AIA and IP Due Diligence
Continues from Page 13

for pre-AIA patents and applications because pre-AIA first-to-invent patent laws apply. In addition to the ownership issue noted above, inventorship remains important under AIA because in the U.S., for patents and applications subject to AIA (i.e., at least one claim with an effective filing date after March 15, 2013), proof of inventorship could be necessary lest any derivation proceeding arise and for removing prior art under the new prior art statutory exceptions found in AIA’s 35 U.S.C. §§102(b)(1) and (b)(2).8

And, for patents and applications including at least one claim with an effective filing date before March 16, 2013, and at least one claim with an effective filing date after March 15, 2013, which we will refer to herein as “Jedi Master Mixer” or “JMM” applications, AIA considerations of derivation and removing prior art will remain relevant AND prior inventorship under pre-AIA 35 U.S.C. §102(g), as well as interference proceedings under pre-AIA 35 U.S.C. §§ 135 and 291 will also apply!9

A challenge for a practitioner involved in an IP due diligence will be determining whether pre-AIA law or AIA law was applied and whether that choice of law was correct. In terms of inventorship/ownership, this will be a key factor because the pre-AIA and AIA grace periods are different.10 The answer to the question of what law should apply may determine whether threatening prior art can be removed or was even considered!

If pre-AIA law applies, than the applicable grace period is one-year prior to the filing date of the US application and applies to patents and printed publications anywhere and public uses and sales in the U.S.11

If at least one claim has an effective filing date after March 15, 2013, the applicable grace period is still one year, but it only applies to global prior public disclosures made by the inventor or one who obtained the subject matter disclosed from the inventor or if someone else unrelated to the inventor disclosed within the year, the inventor or one learning from the inventor, would have had to previously disclose within that grace period year.12

The difference in the timing of the grace periods can be illustrated by an example:

- Pre-AIA patent/application (all claims have an effective filing date before March 16, 2013) is filed in the U.S. on January 1, 2007. The one-year grace period reaches back to January 1, 2006.

- AIA patent/application (all claims have an effective filing date after March 15, 2013) or JMM patent/application (at least one claim with an effective filing date before March 16, 2013, and at least one claim with an effective filing date after March 15, 2013) is filed in the U.S. on January 1, 2015, claiming priority to a foreign-filed application filed on January 1, 2014. The one-year grace period reaches back one year to January 1, 2013, because the one-year calculation is based on the effective filing date. This date is 2 years earlier than the U.S. filing date.

Furthermore, under the AIA definitions of prior art, if, for example, there was a public use anywhere in the world, within one year of the effective filing date of the claimed invention, the grace period exception will only apply if there was a disclosure by (or from) the inventor.13 Determining which should law apply, therefore, can dramatically impact the application of the grace period and what prior art is subject to it.

Continues on Page 15
AIA and IP Due Diligence
Continues from Page 14

And, subject to differing future judicial interpretation, the grace period apparently removes qualifying prior art ONLY for the same subject matter earlier disclosed; “related” subject matter could still be used against the patentee under §103 and MIGHT even preclude the claimed invention from being patentable at all because of §103!!! In terms of prior art under new 35 U.S.C. §102(a)(2) (prior-filed U.S. patents and applications naming another inventor), there are exceptions, but there is no grace period.

Another time when choice of law will determine the options for removing potentially problematic prior art will arise when analyzing a possible common ownership situation. If pre-AIA law applies, the CREATE act only protects subject matter commonly owned “at the time the invention was made” and only that which is obvious; it does not protect subject matter which is not novel.

In contrast, the AIA expanded common ownership/joint research agreement (“JRA”) provisions protect both obvious and non-novel claimed subject matter against a challenge under 35 U.S.C. §102(a)(2) as long as the common ownership/JRA situation arose before the effective filing date of the claim under consideration.14

So for claims with at least one effective filing date after March 15, 2013, an acquiring company may be able to proactively take care of a potential §§102(a)(2)/103 problem uncovered during an IP due diligence.

An example utilizing 35 U.S.C. §102(b)(2)(C) might help illustrate:

Company X files a narrow patent application on new compounds A and B and all the claims therein have an effective filing date after March 15, 2013.

Company Y is about to file a broad patent on a genus of compounds encompassing compounds A and B.

If, before Company Y files for a patent, it concludes a JRA that has within its scope the discovery, synthesis, and testing of compounds within the broad genus, then the JRA applies to Company Y’s subsequent patent filing and the anticipatory patent filing of Company X under 35 U.S.C. §102(a)(2) is removed as prior art under 35 U.S.C. §102(b)(2)(C).

One final note is that AIA removed “without deceptive intent” from all of 35 U.S.C., including the correction of inventorship provisions.16 Practitioners will not necessarily have to include analyzing the reason for correcting inventorship in the IP due diligence.17

Inventorship/Ownership Summary

- Were patents examined under the correct law?
- Are current applications being examined under the correct law?
- Are the current applications correctly filed in the name of the applicant or should they be filed in the name of the inventors because it is under the pre-AIA 35 U.S.C. § 120/119(e)?
- Was the proper inventor’s oath used?
- Was appropriate ADS submitted at time of filing?

III. Freedom-to-Operate (“FTO”)

A client’s potential freedom to operate (“FTO”) will likely be one of the most significant aspects of the IP due diligence investigation. In light of potential exposure associated with infringing third-party patents, FTO can be a deal maker or breaker.

Regarding FTO, it can be important to consider whether a current com-
petitor or likely competitor occupies a substantial amount of patent "space" that might be relevant now or in the future. What is the current relationship with that competitive entity? How might the relationship with the competitor change after the deal is completed? If the target appears to have licenses that would affect FTO, will there be a full transfer of any obligations and rights under the target company’s existing IP licenses?

The FTO search can start with the large amount of publicly available information within the United States and worldwide. IP counsel is called upon to determine whether any valid and enforceable claims of issued third-party patents are infringed if the target’s technology is practiced. Such “blocking patents” could affect, if not curtail, the ability to freely exploit the target’s technology.

The AIA creates different time-frame considerations for IP counsel, both for analyzing the target’s patent portfolio and for analyzing third-party patents, applications, and other potential prior art. For example, patents containing only claims with effective filing dates before March 16, 2013, will be under pre-AIA patent law, while patents having at least one claim with an effective filing date after March 15, 2013, will be subject to the provisions of the AIA. There could be JMM patents and applications containing both: at least one claim with an effective filing date before March 16, 2013, and at least one claim with an effective filing date after March 15, 2013. As noted above, such patents will be subject to the full prior art provisions of the AIA and pre-AIA, 35 U.S.C. §102(g), 135, and 291.18

Regarding the scope and content of the prior art, the AIA greatly expanded the scope of the investigation by removing language and geographic barriers that existed in the definition of prior art pre-AIA. As of March 16, 2013, the prior art against patents/applications containing at least one claim with an effective filing date after March 15, 2013, includes prior disclosures anywhere in the world in any language.19

Language in the new prior art definition has stirred debate over whether secret sales are included in the AIA definition of prior art.

New §102(a)(1) reads:

§102 Conditions for patentability (a) NOVELTY; PRIOR ART.

A person shall be entitled to a patent unless—

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention;

"Use" is clearly indicated as “public,” but "on sale" does not have any qualifier attached. This has led some to speculate that secret sales could be prior art. The enacters of AIA argue that the final phrase, “or otherwise available to the public” provides a catch-all indicating Congress’ objective that an overarching requirement for “availability to the public” be the standard by which prior art is judged.20

The USPTO issued Examination Guidelines stating that, at least until the courts decide differently, examiners would assume the “otherwise available to the public” phrase indicates that “secret” sales or uses do not qualify as prior art.21 This position will mean "that the AIA grace period can extend to all of the documents and activities enumerated in AIA 35 U.S.C. 102(a)(1) that would otherwise defeat patentability."22

Also, for the present, in determining whether a disclosure is sufficiently public, examiners will rely on the pre-AIA standard of public availability: whether one “ordinarily skilled in the subject matter or art[,] exercising reasonable diligence, can locate it.”23

Congress could have said “publicly on sale” if it intended to make the law clear that no “secret sale” is prior art. Watch for this issue to be litigated.

Even if AIA §102(a)(1) does not include secret sales or offers for sale, evidence of a public use or offer to sell anywhere in the world may be VERY difficult for the applicant to find out about prior to discovery in litigation. While a due diligence investigation may increase the odds of finding out about the potential prior...
AIA and IP Due Diligence
Continues from Page 16

art, any time and budget constraints may mean the prior art remains undiscovered.

In an effort to recommend options to mitigate each FTO risk presented by third-party patents and applications, IP counsel might want to consider design-around options, administrative cancellation challenges, or a declaratory judgment action (if jurisdiction requirements can be met). Alternatively, there might be a possibility of licensing any potentially blocking patent or, if applicable, exploring the broadened common ownership/joint research agreement provisions under the AIA.

After these issues are raised, IP counsel can begin to assess whether the client will have FTO with the target’s technology after the transaction is complete.

FTO Summary

- Is the target company involved in any current IP litigation?
- What is the threat of future IP litigation? Administrative cancellation challenges?
- Are the patents/applications at issue subject to pre-AIA patent law or AIA patent law or both?
- Are there options that would move a pre-AIA patent to AIA, if that would resolve any prior art issue(s)?

IV. Validity, Infringement, And Enforceability Of IP Important To Transaction

The existence of a patent does not automatically mean the patent is valid, enforceable, or covers, from a point of view of infringement, what the target asserts it does. Scope, validity and enforceability of a patent are potential points of attack by a competitor. An IP due diligence review will analyze how well the patents at issue might withstand those attacks. It will determine whether the acquired patents are of sufficient scope to cover the key products and processes, as well as at least foreseeable variations of such products and processes. For any patent at issue, this will involve construing the claims after analyzing the claim language, the specification, the prosecution history, any related application(s), and any foreign counterpart patents or applications. The prosecution history may reveal that the claim scope is not as broad as the claim language indicates. Counsel will have to determine whether pre-AIA or AIA law applies and whether the correct law was applied during prosecution.

There will also be an examination of any and all relevant prior art, which again raises the question of whether the pre-AIA, AIA, or both definitions of prior art apply, investigations of public use and/or disclosure, and importantly, any publications or presentations by inventor(s) named on the patent(s) at issue. IP counsel will want to compare the publication/disclosure/effective filing dates with the priority dates of the patent applications, as well as compare the list of inventors to the list of authors of the publication(s). If the inventors and authors are not the same, this may be an issue to investigate further.

All of the patents at issue will be analyzed for compliance with 35 U.S.C. § 101 (patent eligible subject matter, and if eligible, practical utility) and 35 U.S.C. §112 requirements (written description, enablement, and best mode ). Additionally, file histories must be reviewed for potential enforceability issues. According to 37 C.F.R. § 1.56,

[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability . . . .

Patents are unenforceable if Rule 56 and/or the duty of candor is breached. The duty of disclosure encompasses more than prior art. Federal Circuit case law describes numerous bases on which a patent may be held unenforceable. Some examples are: selective disclosure of test results, failure to disclose inventors’ publication contradicting the patent claims, inability to support assertions of advantages or properties obtained, examples written in the past tense even though they were never performed, and failure to
**AIA and IP Due Diligence**  
Continues from Page 17

disclose proceedings in a co-pending application.

In the United States, a finding of inequitable conduct is devastating. It will render all claims of an otherwise valid and infringed patent completely unenforceable. Unlike validity, which courts adjudicate on a claim-by-claim basis, inequitable conduct will render all claims in a patent unenforceable even if the conduct pertained only to one claim. Identifying an enforceability issue during the due-diligence process, therefore, can have a significant impact on the overall. IP counsel should flag any potential inequitable conduct issues for further consideration and evaluation when access to documents and key witnesses becomes available.  

**A. Prior Art**

The prior art may reveal issues related to, for example, novelty and obviousness, or it may raise questions of compliance with 35 U.S.C. §112 (written description, enablement, and best mode).

The prior art considered should include that cited during prosecution. However, an independent prior art search should also be performed, particularly as AIA has expanded, at least to some extent, the scope and content of the prior art. If the patent at issue resulted from a continuation application, IP counsel should examine the prosecution history and any restriction requirements in the ancestor applications to identify any relevant issues.

In addition, IP counsel should determine the date of offers for sale and any public uses of the technology at issue. A review of the conditions of any use and/or offer for sale prior to the patent application filing date should also be done.

For prior art against claims with an effective filing date before March 16, 2013, nonobviousness is judged “at the time the invention was made.” AIA changed 35 U.S.C. §103 for patents/applications with at least one claim having an effective filing date after March 15, 2013. For such claims, nonobviousness is judged as of “the effective filing date of the claimed invention[.]” Usually, the effective filing date is later in time than the time the invention was made, so there may be significantly more prior art to review when analyzing obviousness when AIA applies.

For patents/applications with at least one claim having an effective filing date after March 15, 2013, the Hilmer doctrine no longer exists; a foreign priority date can be used offensively as prior art under AIA’s 35 U.S.C. §102(a)(2), as long as the subject matter was at least described in a foreign priority document which was “effectively filed” relative to the relevant subject matter and eventually publishes in a U.S. patent, U.S. patent application publication, or WIPO published application.

For applications containing only claims with effective filing dates before March 16, 2013, the possibility exists of deliberately creating a JMM, by filing a continuation application and adding at least one claim with an effective filing date after March 15, 2013. By doing so, the entire application moves from pre-AIA to AIA, except for the continued application of 35 U.S.C. §§102(g), 135, and 251. Statutory bars in pre-AIA 35 U.S.C. §102(a)-(f) may disappear.

**B. Administrative Options**

If IP counsel identifies patents or other publications raising questions about the validity of third-party patents raising FTO issues, counsel might consider administrative options to recommend to the client if a deal is done. The USPTO canceling the problematic claims could resolve the potential problem. The

Continues on Page 19
AIA and IP Due Diligence
Continues from Page 18

AIA expanded the options available to a third party beyond ex parte reexamination to include third party pre-issuance submissions, inter partes review (“IPR”33) and post-grant review (“PGR”34). The AIA also created a supplemental examination petition for patent owners for possibly removing a potential inequitable conduct issue. Each proceeding has its own requirements and consequences to consider.35

Ex parte reexamination and IPR are limited to determining the patentability of patent claims based on patents and printed publications.36 IPR may only be requested on grounds of anticipation or obviousness.37 So, for example, inequitable conduct, which goes to enforceability, is not a proper issue for ex parte reexamination or IPR. Nor is any issue under 35 U.S.C. §§ 101 and 112, with the exception of raising §112 issues to dislodge a patentee from priority/benefit and thus open up the scope of the prior art.

For PGR, the challenge can be more broadly based, including “any ground” of invalidity.38 But PGR is only available as an option if filed within 9 months of a patent being issued. And PGR is only available for patent with claims having an effective filing date after March 15, 2013. It is doubtful that many patents have been filed and issued in the last three months, so no PRG proceeding has yet started up.39

For possible enforceability issues uncovered in the target’s portfolio, IP counsel may consider the new supplemental examination request, a procedure by which the patentee can request a supplemental examination to consider, reconsider, or correct information in the patent.40 Within 3 months of a supplemental examination request, the Director determines whether the information presented in the request raises a substantial new question of patentability.41 If so, the Director shall order reexamination of the patent.42 Anything considered in the supplemental reexamination shall not be the basis for a finding of unenforceability later.43

But there are perceived downsides in the supplemental examination procedure, such as antitrust violations, criminal proceedings, and even disciplinary proceedings for the practitioner.44 Perhaps for those reasons, the supplemental examination proceeding has been used sparingly so far.45

As is true during the original prosecution, claims during reexamination, or IPR, or PGR should, at least at present, be given their broadest reasonable interpretation consistent with the interpretation that those skilled in the art would reach based on the specification and the claim language. The “broadest reasonable” claim construction, combined with a preponderance of evidence standard of proof, and no presumption of validity mark three fundamental differences between administrative cancellation proceedings, such as reexamination, IPR, and PGR, and district court litigation.46 And those differences may be sufficient to motivate a third party to avail itself of the USPTO administrative cancellation proceedings.

Concerns about the validity of key patents, the narrow scope of important claims, or about possible inequitable conduct may result in a reduced valuation of the IP in the transaction. These issues may or may not be deal breakers, depending on their significance to the overall transaction objectives and their ability to be managed or addressed.

Validity/Enforceability/Scope of Claim/Infringement Summary

- Were patents examined under the correct law?
- Are current applications being examined under the correct law?
- Under the correct law, what prior art is applicable to target patents/applications?
- Under the correct law, what options are available for correcting issues? Removing issues?
- By moving pre-AIA claims to a JMM application can one or more statutory bars be avoided?
- If JMM patent/application is discovered in the due diligence investigation, was the proper ADS statement filed with the USPTO?47

Continues on Page 20
AIA and IP Due Diligence  
Continues from Page 19

V. Conclusion

This article briefly discusses AIA considerations that will now be cast into the mix of the three conventional prongs of an IP due diligence: inventorship/ownership, freedom to operate (“FTO”), and validity/enforceability/infringement. The goal of adequate and thorough IP due diligence is to assess risks, consider ways to resolve or manage those risks, and communicate those findings to the client. There are now new risks and tools to manage those risks under the AIA, significantly increasing the considerations involved in the IP due diligence. Practitioners should be alert to whether pre-AIA law or AIA applies to the IP under investigation and to how the courts ultimately construe many of these relevant principles.

Footnotes:

1 Stacy Lewis is an attorney-at-law serving as a law clerk with Finnegan, Donna Meuth is Associate General Counsel at Eisai, Inc., and Tom Irving is a partner with Finnegan.

2 These materials are public information and have been prepared solely for educational and entertainment purposes to contribute to the understanding of U.S. intellectual property law. These materials should not be taken as individualized legal advice and do not reflect the views of FINNEGAN or EISAI. It is understood that each case is fact-specific, and that the appropriate solution in any case will vary. Therefore, these materials may or may not be relevant to any particular situation. Thus, FINNEGAN or EISAI or the authors cannot be bound either philosophically or as representatives of their various present and future clients to the comments expressed in these materials. The presentation of these materials does not establish any form of attorney-client relationship with FINNEGAN, EISAI, or the authors. While every effort was made to ensure that these materials are accurate, errors or omissions may be contained therein, for which any liability is disclaimed.

3 Portions of this article are based on a full IP Due Diligence coursebook written by Finnegan attorneys Bryan Diner, Anthony Gutowski, and Andrew Holtman for Patent Resources Group.

4 America Invents Act, 125 STAT. 284, PUB. LAW 112–29 (Sept. 16, 2011).

5 The USPTO recognized this in the Examiner Guidelines, “The Office appreciates that the courts may ultimately address questions concerning the meaning of AIA 35 U.S.C. 102 and 103. However, as a practical matter, the Office needs to provide examination guidelines so that the public is aware of how the Office will apply AIA 35 U.S.C. 102 and 103. The Office considers its interpretation of AIA 35 U.S.C. 102 and 103 as set forth in these examination guidelines to be the correct interpretation of AIA 35 U.S.C. 102 and 103 based upon the statutory language of the AIA and its legislative history.” 78 Fed.Reg. 11,061 (Feb. 14, 2013).

6 AIA SEC. 4; 35 U.S.C. §115. Also, note that it is still best practice to identify inventors at the time of filing for Rule 56 reasons, and because the statutory requirement for disclosing best mode is alive and well in 35 U.S.C. §112(a).

7 AIA SEC. 4; 35 U.S.C. §118.


9 AIA SEC. (3)(n)(2) expressly brings into play 35 U.S.C. §§ 102(g), 135, and 291, where proof of first inventorship may be critical.


11 Pre-AIA 35 U.S.C. §102(b): A person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States;

12 35 U.S.C. §102 (b)(1)(A) and (B) EXCEPTIONS.

13 AIA SEC. 3; 35 U.S.C. §102(b)(1)(A) and (B).

14 AIA SEC. 3; 35 U.S.C. §102 (b)(2) EXCEPTIONS — …

15 Pre-AIA 35 U.S.C. §102(b): A person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States;


17 Pre-AIA 35 U.S.C. §102(b): A person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States;


19 AIA SEC. 3; 35 U.S.C. §102(c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.— Subject matter disclosed and claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying
the provisions of subsection (b)(2)(C) if—the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention; the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

15 Note that buying prior art works only under §102(a)(2) not §102(a)(1). See §102(b)(2)(C).

16 AIA SEC. 20; 35 U.S.C. §§116 and 256. Changes apply to “proceedings commenced on or after [Sept. 16, 2012].” Although intentional incorrect inventorship may still be grounds for inequitable conduct.

17 Similarly, for reissue applications and patents, this may be a case where there is less work involved post-AIA because it will not be necessary to investigate whether any “deceptive intent” was involved in the “error” on which the reissue under § 251 is based or whether any “deceptive intent” was involved in a claim being disclaimed under §253. Because Rule 56 remains, practitioners will still have to be vigilant for circumstances that suggest an intent to deceive the USPTO.

18 AIA SEC. 3(3)(2).

19 AIA SEC. 3; §102(a)(1).

20 See, e.g., Cong Rec. S1371 (March 8, 2011) and S9992 (Sept. 27, 2008).

21 78 Fed. Reg. 11,059, 11,063-64 (Feb. 14, 2013)(“the Office views the ‘or otherwise available to the public’ residual clause of the AIA’s 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art. These examination guidelines also indicate that an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if, for example, it is among individuals having an obligation of confidentiality to the inventor.”)

22 Id. at 11,062.

23 Id. at 11,063-64; Manual of Patent Examining Procedure (MPEP) §2128.

24 Discussed in Section IV, infra.

25 New 35 U.S.C. §102(b)(2)(c) and §102(c); discussed in Section II.

26 USPTO Examination Guidelines: "when subject matter is claimed in an application having priority to or the benefit of a prior-filed application (e.g., under 35 U.S.C. 120, 121, or 365(c)), care must be taken to accurately determine whether AIA or pre-AIA 35 U.S.C. 102 and 103 applies to the application.” 78 Fed. Reg. 11,084 (Feb. 14, 2013). And, of course, with new post grant cancellation proceedings in the USPTO, a question will be whether claims will, as examined in the USPTO, still be patentable under, at least for now, a broadest reasonable claim construction, no presumption of validity, and a preponderance of the evidence burden to establish unpatentability of a claim.

27 “Best mode” remains a requirement of 35 U.S.C. §112, but the AIA amended 35 U.S.C. §282 so that failure to disclose best mode can no longer be grounds “on which any claim of a patent may be canceled or held invalid or otherwise unenforceable.” See SEC. 15, 125 STAT. 328, effective Sept. 16, 2011. It also changed §119(e) and §120 to allow a priority claim even if the best mode is not supported in the priority document. Id.

28 The status of Rule 56 is unclear at present. The USPTO issued a proposed rule change on July 21, 2011 (76 Fed. Reg. 43,631 (July 21, 2011)), but finalizing the rule change was put on the back burner while all the rule-making associated with AIA took place. A practitioner can, at least for now, focus on the standards for materiality and intent set forth in the en banc Federal Circuit Therasense case: “but for” materiality (the PTO would not have allowed a claim had it been aware of the undisclosed prior art) and “single most reasonable inference” that one with a Rule 56 duty “knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” There is also an “affirmative egregious misconduct” exception for situations where there is no “but-for” materiality but it would otherwise be unjust to allow the patentee to enforce the patent. An example is filing of an unmistakably false affidavit. .

29 AIA did not directly address the U.S. court developed doctrine of inequitable conduct. However, changes in AIA involving the scope and content of the prior art, and if identified above, have a direct influence on what was the relevant prior art and whether the duty was discharged relating to that prior art.


31 AIA SEC. 3; 35 U.S.C. §102(a)(2) and §102(d).

32 Additional benefits may include the elimination of forfeiture (according to USPTO) and broader common ownership provisions in AIA 35 U.S.C. §102(c).

33 A request for IPR may be filed at least 9 months after grant, and the threshold is “more likely than not that one or more claims invalid.”

34 A request for PGR may be filed within 9 months of grant, and the threshold is a “reasonable likelihood would prevail.”

35 These new procedures have estoppel implications and statutory relationships with district court, US PTO, and ITC proceedings that must be very carefully considered. Also, in contrast to ex parte reexamination, IPR and PGR do not permit a challenger to be anonymous.

36 35 U.S.C. and §302 and §311(b).


39 However, post-grant review for covered business method patents did start on September 16, 2012. See AIA SEC. 18.


43 AIA SEC. 12; 35 U.S.C. § 257(c).

44 AIA SEC. 12; 35 U.S.C. § 257(e) and (f).

45 According to the USPTO, http://www.uspto.gov/aia_implementation/statistics.jsp, between the supplemental examination effective date of September 16, 2012, and April 30, 2013, 18 requests for supplemental examination have been filed.

46 See, e.g., In re Baxter Intern., Inc., 678 F.3d 1357, 1365 (Fed. Cir. 2012).

47 37 CFR §1.55(j).
Job Opportunities

NUTTER MCCLENNEN & FISH LLP
Boston, MA

Intellectual Property Associate
Nutter McClennen & Fish LLP seeks an intellectual property associate with 2-5 years of experience. The primary responsibilities for this position include preparing and filing patent applications in the U.S. Patent & Trademark Office and prosecution of foreign patent applications. Qualified candidate will also have experience in some or all of the following areas: patentability searches and opinions, conducting freedom to operation studies, and drafting infringement and invalidity opinions. Engineers, physics, or similar degree preferred. Registration to practice before the USPTO required.

Katherine Thatcher, Director of Legal Recruitment, Nutter McClennen & Fish LLP, Seaport West, 155 Seaport Boulevard, Boston, MA 02210, Email: kthatcher@nutter.com, Phone: 617.439.2471, www.nutter.com

O’SHEA GETZ PC
Springfield

Patent Attorney
O’Shea Getz PC, an intellectual property boutique firm located in Springfield, MA, is seeking an experienced patent attorney. Our target candidates have a BS or advanced degree in Electrical Engineering, Mechanical Engineering Physics, Chemistry or Bio-chemistry, excellent writing skills, and must have at least one (1) year of experience in patent preparation and prosecution. Candidates must be registered to practice before the USPTO. Admission to the MA or CT bar is preferred but not required for the right candidate.

We offer a very competitive compensation and benefits package, and the opportunity to work in a supportive environment. Please send resume, cover letter, and writing sample in confidence to boshea@osheagetz.com.

MORSE, BARNES-BROWN & PENDLETON, P.C.
Waltham

Biochemistry/Chemistry Patent Attorney
Respected business law firm in Waltham, MA is currently seeking a partner-level Biochemistry/Chemistry Patent Attorney with substantial experience in patent prosecution and client counseling to join successful and growing patent practice. Candidate should have strong qualifications in pharmaceuticals, organic chemistry, and polymer chemistry; advanced degree preferred. Excellent written and verbal communication skills are required, along with a reasonable amount of portable business. Sophisticated and challenging work in a genuinely pleasant environment.

Send resume to: Laurie Macdonald, Firm Administrator, Morse, Barnes-Brown & Pendleton, P.C., CityPoint, 230 Third Avenue, Waltham, MA 02451, Email: lmacdonald@mbbp.com, Fax: 781-622-5933
EOE. Principals only.

NEW ENGLAND BIOLABS, INC.

Patent Attorney - Part-Time
New England Biolabs, Inc. (NEB) is a privately held biotechnology company with a worldwide reputation for providing quality reagents for the molecular biology market. NEB’s customers range from small academic laboratories to major research institutions to large industrial corporations. NEB has a strong research focus, and relies on the cooperative interaction of a motivated workforce for its success. NEB is located in a beautiful estate setting, LEED certified building north of Boston.

Patent Attorney - Part-Time - Job Code 9142HS
New England Biolabs, Inc., a recognized leader in enzyme design and development, is seeking a part-time Patent Attorney who will be responsible for assisting the Intellectual Property Counsel with drafting and prosecuting patent applications.

Primary Responsibilities:
• Drafting and prosecuting patent applications.

Continues on Page 23
Job Opportunities
Continues from Page 22

- Filing and prosecuting oppositions in the US and overseas and FTO opinions.

Required Qualifications:
- Ph.D. in molecular biology or chemistry.
- Admission to the Massachusetts bar.
- Admission to the USPTO with at least 5 years preparation and prosecution of patents.
- Familiarity with the new AIA rules.

Preferred Qualifications:
- At least 3 years law firm experience.
- Experience as an Examiner at the USPTO is highly desirable.
- Familiarity with domestic and foreign filing requirements.

New England Biolabs, Inc. is an equal opportunity/affirmative action employer
Qualified candidates may apply online at www.neb.com or by accessing the following link: Career Opportunities: http://tbe.taleo.net/NA11/ats/careers/jobSearch.jsp?org=NEB&cws=1

WOLF GREENFIELD
Boston

Bio, Chem, EE, and Mech Associates

Wolf Greenfield is the largest New England-based law firm focused solely on intellectual property (IP) law. We have immediate openings for mid-level patent prosecution associates in the Biotechnology, Chemical & Materials Technologies, Electrical & Computer Technologies, and Mechanical Technologies groups.

Preferred candidates will have an advanced degree and/or industry experience, a strong academic background, and a minimum of 4-6 years of solid patent prosecution and opinion-related experience. The ideal candidate will have the ability to establish, develop, and maintain business relationships with clients and prospective clients.

Our associates enjoy an interesting variety of work on complex IP matters, increasing client management responsibilities, one-on-one mentoring, and regular professional development and educational opportunities. We offer a collegial and team-oriented work environment with competitive salaries and compensation packages which include medical, dental, life and disability insurance, a 401(k) plan with employer matching and a profit sharing contribution, back-up daycare, domestic partner benefits, and pre-tax medical, dependent care and transportation benefits. Wolf Greenfield is an equal opportunity employer.

Contact: Jo Parente, jparente@wolfgreenfield.com

MICROSTRATEGY INCORPORATED
Tysons Corner, Virginia (D.C. metro area)

Senior Counsel / Assistant General Counsel Strategic Commercial & Intellectual Property Transactions
What We Do:

Four disruptive technology trends -- Big Data, Mobile, Cloud and Social -- are reshaping companies, industries and economies around the world. MicroStrategy is a NASDAQ-listed technology company that is transforming the way organizations interact with data to harness these forces. The MicroStrategy Business Intelligence (BI) Platform™ enables leading organiza-

Continues on Page 24
Job Opportunities

Continues from Page 13

tions to analyze the vast amounts of data available to their enter-
prises to make better business decisions. Through MicroStrat-
edy Mobile™, we extend our BI platform to mobile devices and
also make mobile app development fast and easy. We have
embraced the flexibility and innovation of the cloud by offering
cloud-based access to our entire platform via MicroStrategy
Cloud™. Capitalizing on the growth in mobile computing and
social media, MicroStrategy has most recently unveiled new ap-
lications for mobile commerce (Alert), mobile identity (Usher™)
and market intelligence (Wisdom™). A global business with off-
ce in 25+ countries, MicroStrategy has been positioned by
Gartner, Inc. in the “Leaders” quadrant in the 2012 “Magic Quad-
rant for Business Intelligence Platforms” report. To learn more
about MicroStrategy (NASDAQ: MSTR), visit us on the web,
Facebook and Twitter.

Find out more about the members of our Corporate Legal Team
at Who Knew?

The Role:
You will join a top-flight legal team based at HQ in structur-
ing, drafting and negotiating complex commercial agreements
involving intellectual property that are both domestic and inter-
national in scope. You will work closely with senior business and
technology executives to develop proposals and processes for
executing on our strategic commercial initiatives. You are able
to move projects forward both skillfully and efficiently. Precision
drafting and a sharp analytical mind are critical for this role. You
have significant transactional experience that you would enjoy
applying to new and unfamiliar contexts, and you are also well-
versed in intellectual property agreements. You are a quick-study
with the ability to adapt to the needs of our evolving business,
and you enjoy collaborating on cross-departmental projects.

Responsibilities:
• Counsel on a wide range of US and international transac-
tional matters
• Develop transaction-support processes and procedures
  for the growing applications business
• Advise on commercial matters, including apps initiatives,
e-commerce, IP registration and licensing matters
• Draft policies to establish and enhance regulatory and
  business standards compliance
• Support corporate transactions such as acquisitions or di-
  vestitures and joint ventures

Requirements:
• J.D. from top tier law school with significant (more than 5
  years) experience at reputable law firm and/or in-house
department
• Significant experience drafting agreements and coun-
seling clients on domestic and international commercial
transactions involving intellectual property
• Superior interpersonal skills and judgment are paramount
• Ability to manage fast-paced workload and add value to
  multiple projects simultaneously
• Self-starter who shows project ownership and enjoys
  working across departments

MicroStrategy is an Equal Opportunity Employer
Contact: Tiffany Simmons, tsimmons@microstrategy.com

MICROSTRATEGY INCORPORATED
Tysons Corner, Virginia (D.C. metro area)

Corporate Counsel (Social Media &
Apps Business)

What We Do:
Four disruptive technology trends -- Big Data, Mobile, Cloud
and Social -- are reshaping companies, industries and econo-
 mies around the world. MicroStrategy is a NASDAQ-listed
technology company that is transforming the way organizations
interact with data to harness these forces. The MicroStrategy
Business Intelligence (BI) Platform™ enables leading organi-
zations to analyze the vast amounts of data available to their
enterprises to make better business decisions. Through Mi-
croStrategy Mobile™, we extend our BI platform to mobile de-
vices and also make mobile app development fast and easy. We
have embraced the flexibility and innovation of the cloud by of-
fering cloud-based access to our entire platform via MicroStrat-
ey Cloud™. Capitalizing on the growth in mobile computing
and social media, MicroStrategy has most recently unveiled
new applications for mobile commerce (Alert), mobile identity
(Usher™) and market intelligence (Wisdom™). A global busi-
ness with offices in 25+ countries, MicroStrategy has been po-
sitioned by Gartner, Inc. in the “Leaders” quadrant in the 2012
“Magic Quadrant for Business Intelligence Platforms” report. To

Continues on Page 25
Job Opportunities
Continues from Page 24

learn more about MicroStrategy (NASDAQ: MSTR), visit us on the web, Facebook and Twitter.

Find out more about the members of our Corporate Legal Team at Who Knew?

The Role:
You’ll join a top-flight legal team in supporting our mobile/internet applications business. You will help address IP licensing, social media, e-commerce and privacy issues that are cutting-edge and critical to our business vision and strategy. Based at the company’s HQ, you will contribute on both transactional and compliance/regulatory initiatives worldwide. Precise drafting, analytical thoroughness, creativity and collaboration are the hallmarks of this role. You enjoy a fast-paced environment but understand the importance of getting things right.

Responsibilities:
• Draft, review and negotiate customer, partner and vendor agreements as well as other technology related agreements regarding software, SaaS, mobile apps, social media and API licensing
• Provide solution-based counseling on e-commerce, including platform policies, digital transactions, authentication, permission-based activities, privacy, advertising and trademark matters
• Develop transaction-support processes and procedures for the growing applications business
• Draft policies to establish and enhance regulatory and business standards compliance
• Collaborate with the apps team to integrate legal strategies with business and technology strategies
• Plan and implement legal aspects of apps initiatives in the context of marketing strategies, corporate governance and international business expansion plans

Requirements:
• J.D. from top tier law school followed by 4-10 years of experience with reputable law firm and/or in-house department
• Ability to manage fast-paced workload and add value to multiple projects simultaneously
• Self-starter who shows project ownership and enjoys working across departments

MicroStrategy is an Equal Opportunity Employer
Contact: Tiffany Simmons, tsimmons@microstrategy.com

Fighting It Out in the Patent Office
Continues from Page 8

of WilmerHale, discussed their representation of EMC and VMware in six recent IPRs.

Susan and Ian introduced the program with a discussion of post-grant review proceedings available under the AIA, and specifically, IPRs. The audience and panelists engaged in a lively discussion of critical issues, including:

• The newly-constituted PTAB’s accelerated pace of proceedings and heavy focus on rules
• Selecting appropriate prior art for IPRs
• What to include in an effective IPR petition
• Whether the patent owner should file a preliminary statement
• Availability and scope of discovery
• Motion practice
• Claim construction
• Claim amendments
• The interplay between IPR and litigation
• The scope and consequences of estoppel, and differences among IPR, PGR, and CBM proceedings

This seminar, which offered valuable observations and insights from people who are deep in the trenches, fighting it out in the Patent Office, was warmly welcome by the audience.
Committees

ACTIVITIES & PUBLIC RELATIONS
activities@bpla.org
Nikhil Patel, Pierce Atwood LLP

AIPLA MOOT COURT
moocourt@bpla.org
Elizabeth Burkhard, Holland & Knight
Joshua M. Dalton, Bingham McCutchen, LLP

AMICUS
amicus@bpla.org
Erik Paul Belt, McCarter & English, LLP
Robert M. Abrahamsen, Wolf, Greenfield & Sacks, P.C.

ANTITRUST LAW
antitrust@bpla.org
Benjamin M. Stern, Proskauer Rose LLP
John W. Pint, Philips Intellectual Property

BIOENGINEERING
bioengineering@bpla.org
Katherine A. McKelvey, Hoff & Sollers LLP
William DeVaul, Cubist Pharmaceuticals Inc.

BUSINESS & MARKETPLACE
jeremybond@bpla.org
Jamie Kemler, Stryker Corporation

CHEMICAL PATENT PRACTICE
chemical@bpla.org
Lin J. Hymel, Ph.D., Weingarten, Schurgin, Gagnebin & Lebovici LLP
Dean Farmer, Cooley LLP
Rebecca M. McNeill, VIVICAR Law, PLLC

COMPUTER LAW
computer@bpla.org
Edmund J. Walsh, Wolf, Greenfield & Sacks, P.C.
Weber Hsiao, Pierce Atwood LLP

CONTESTED MATTERS
contestedmatters@bpla.org
Susan G.L. Glovsky, Hamilton, Brook, Smith & Reynolds, P.C.
Ian Liu, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

COPYRIGHT LAW
copyright@bpla.org
Nicole Rizzo Smith, Ropes & Gray LLP
Lawrence T. Stanley, Jr., Bingham McCutchen LLP

CORPORATE IN-HOUSE PRACTICE
inhouse@bpla.org
William DeVaul, Cubist Pharmaceuticals Inc.
David Miranda, Jr., Raytheon Company

ETHICS AND GRIEVANCES
ethics@bpla.org
Steven J. Henry, Ab Initio Software LLC
John J. Stieckwiers, Sunstein, Kann, Murphy & Timbers, LLP

INTERNATIONAL & FOREIGN PRACTICE
international@bpla.org
Elias Domingo, Covidiens
Sarah Gates, Lando & Anastasi, LLP

LICENSING
licensing@bpla.org
Will Worden, Pierce Atwood LLP
Jamison J. Barr, Jenzabar, Inc.

LITIGATION
litigation@bpla.org
Jacob K. Baron, Holland & Knight
Douglas C. Dosokicki, Goodwin Procter LLP

MEDICAL DEVICES PRACTICE
medicaldevices@bpla.org
Jim Flaherty, Foley Hoag
Jeremy Bond, Finnegan, Henderson, Farabow, Garrett, and Dunner, L.L.P.

NEW LAWYERS & LAW STUDENTS
newlawyers@bpla.org
Reza Sadr, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.

PATENT AGENTS & TECHNICAL SPECIALISTS
patagents_techspecs@bpla.org
Cristin Berkey, Choate, Hall & Stewart LLP
Natalie Grace, Choate, Hall & Stewart LLP

PATENT LAW
patents@bpla.org
Michael Bergman, Bergman & Song LLP
Justin J. Daniels, Proskauer Rose
Rajesh Vallabh, Foley Hoag LLP

PATENT OFFICE PRACTICE
patentinofficepractice@bpla.org
Emily Whelan, Wilmer Cutler Pickering Hale and Dorr LLP
Nicole Palmer, Lando & Anastasi, LLP

PRO BONO
probono@bpla.org
Chelsea Loughran, Wolf, Greenfield & Sacks, P.C.
Rex I. Huang, Fish & Richardson P.C

TRADE SECRETS LAW
tradesecrets@bpla.org
Russell Beck, Beck Reed Riden LLP
Michael Bunis, Hall, & Stewart LLP

TRADEMARKS & UNFAIR COMPETITION
trademarks@bpla.org
John L. Welch, Lando & Anastasi, LLP
Christina Licursi, Wolf, Greenfield & Sacks

The Boston Patent Law Association (BPLA) is an association of intellectual property professionals, providing educational programs and a forum for the interchange of ideas and information concerning patent, trademark, and copyright laws. Through a volunteer Board of Governors and committees, it organizes and hosts educational seminars, social events, and conventions, and comments on rules, legislation, and judicial decisions impacting the profession. Visit the BPLA at www.bpla.org.

The BPLA Newsletter is published four times a year by the Boston Patent Law Association. Articles appearing in the newsletter represent the views of the authors and do not necessarily carry the endorsement of the BPLA.

Editor-In-Chief:
Gregory J. Sieczkiewicz, Ph.D., J.D.

Contributors:
Susan Glovsky
Rex Huang
Tom Irving
Greg Lantier
Stacy Lewis
Ian Liu
Chelsea Loughran
Yu Lu
Joseph M. Maraia
Donna Meuth
Matthew B. Pinkney
Garrett K. Quillia
Vic Souto
Don Steinberg

Boston Patent Law Association
One Batterymarch Park, Suite 101
Quincy, MA 02169-7454

Letters to the editor, articles and job postings are encouraged. E-Mail all correspondence to: vice-president@bpla.org

©2013 Boston Patent Law Association. All rights reserved.
On June 12, 2013, the US Supreme Court issued its long-awaited decision in *Myriad Genetics*. The unanimous decision invalidated one of Myriad’s patents that claimed mutated BRCA-gene sequences associated with increased risk of breast cancer. Though widely referred to as “a gene patent,” Myriad’s patent, in fact, did not claim genes per se, but instead claimed the genomic sequences in their “isolated” form. Such claims—“isolated XYZ substance”—have long been widely accepted as a valid approach for claiming purified or isolated substances extracted from nature (e.g., insulin, antibiotics, blood coagulation factors, to name a few). However, the Supreme Court held in *Myriad* that for genomic DNA sequences, “isolation” does not go far enough in distinguishing them from the genomic DNA. According to the Court, naturally-occurring DNA sequences such as full-length genes and fragments thereof are unpatentable “products of nature” that are not rendered patent-eligible merely by their discovery and subsequent isolation from the human genome. The Court specifically noted that complementary DNA (“cDNA”, non-naturally occurring DNA molecules in which noncoding DNA is deleted) and other forms of non-naturally occurring DNA molecules remain patent-eligible.

In general, the *Myriad* decision appears to have little impact on bio/pharma companies centered around recombinant proteins and small molecules. Such companies usually focus their patent strategy first and foremost on the products themselves. Further, to the extent that the products are made via DNA sequences, the DNA sequences used in the production of such products are usually engineered in some fashion.

However, for companies focusing on diagnostics and personalized medicine, new patent strategies will be needed, particularly in view of last year’s Supreme Court decision in *Mayo v. Prometheus*, which held some diagnostic tests unpatentable on the basis of the “natural law” exception. Also potentially impacted are those companies focusing on natural products or nucleic acid-based therapeutics. Even though the *Myriad* decision was only concerned with genomic DNA—not with other biological sequences—it seems all too easy to extend the Court’s logic to claims directed to other naturally-found biologic molecules, such as “isolated” antisense DNA, microRNA, siRNA, bacterial and viral nucleic acids or even sequence fragments of naturally occurring proteins, natural antibiotics, hormones, isolated stem cells, etc. Has the Supreme Court singled out human gene sequences while other naturally occurring “isolated” compounds remain patentable? Future court decisions in the next several years will establish the exact breadth of *Myriad*, and the interplay between *Myriad* and *Prometheus*.

Worth highlighting to the patent bar in general is that lack of education in science and the nature of patent rights may be guiding such decisions, both on and off the bench. Justice Scalia in his concurrence, essentially admitted that he did not understand the science himself, and deferred to others’ expertise in forming his opinion. How many other justices are not being as forthright? Further, it seems apparent from the flurry of negative publicity surrounding the *Myriad* case and the involvement of the ACLU in this case that a good many in this country have a strong anti-patent sentiment that may well be based in ignorance of the scientific and legal facts. It would behoove us as members of the patent bar, who are trained in both law and science, to dedicate time to ensuring that the general public and bench are as well-informed of the facts and what patents can and cannot do as possible. Please join or renew your trade/bar association memberships, join pro bono efforts, volunteer in the schools or start writing articles today!

Co-Chairs of the Biotech Committee are
Konstantin M. Linnik
Leslie Meyer-Leon,
Bo Han,
Jennifer Zarutskie Siewczkiewicz