**From:** Douglas K Norman
**Sent:** Friday, October 05, 2012 1:45 PM
**To:** fitf_guidance
**Cc:** Till, Mary; Douglas K Norman; Robert Allen Armitage; Steven P Caltrider; Amy E Hamilton
**Subject:** Comments of Eli Lilly and Company concerning the Proposed Examination Guidelines

Dear Director Kappos and Ms. Till,

Attached please find the Comments of Eli Lilly and Company concerning the Proposed Examination Guidelines.

Sincerely,

Douglas K. Norman
Vice President - General Patent Counsel
Eli Lilly and Company

Robert A. Armitage
Sr. Vice President - General Counsel

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
Phone 317-433-5499
Fax 317- 433-3000

E-mail: armitage_robert_a@lilly.com

October 5, 2012

***Via Electronic Mail***
**fitf_guidance@uspto.gov**
**cc: mary.till@uspto.gov**

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Mail Stop Comments – Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn.: Mary C. Till, Senior Legal Advisor, Office of Patent Legal Administration,
Office of the Deputy Commissioner for Patent Examination Policy

**RE: Eli Lilly and Company (Lilly) Comments to the United States Patent and Trademark Office (Office) Notice of Proposed Examination Guidelines Entitled: Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act**

Dear Under Secretary Kappos:

Lilly appreciates the opportunity to submit comments in response to the United States Patent and Trademark Office's ("USPTO" or "Office") Request for Comments on the Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act that appeared at 77 Fed. Reg. 43759-43773 (July 26, 2012). Lilly has expressed its views in congressional testimony on certain aspects of the AIA implementation and appends that testimony to this letter in response in part to the USPTO's request for comments.

Lilly believes that absolute clarity is required in how the First-Inventor-to-File provisions are interpreted by the Office. Lilly is particularly concerned that the construction given to the phrase "or otherwise available to the public" in §102(a)(1) recognize that – *on the face of the statute itself* – an overarching requirement for public accessibility was imposed by Congress. Lilly associates itself fully with the comments made by Pharmaceutical Research and Manu-

facturers of America ("PhRMA"), which Lilly believes to be compelling on the issue of statutory construction.

In addition to fostering greater international patent harmonization by following the explicit statutory limitation on the scope and content of what might constitute prior art, the Office should implement the AIA in a manner provides that the greatest possible consonance with the requirements of TRIPS. Article 27 of TRIPS was designed to limit the bases on which patents might be denied. One such permitted basis for denying patentability under TRIPS is a requirement that a claimed invention be new or novel.

No member country of TRIPS should be allowed, consistent with TRIPS, to implement a novelty requirement based entirely upon secret activities, in which no non-confidential divulgation of the claimed invention has taken place, and in which, absent direct involvement of the patent applicant in the activities in question, the novelty of the invention is unaffected.

Such a requirement, rather testing a claimed invention for novelty, instead imposes a separate and distinct ground of invalidity. If the activities in question leave the novelty of the invention unaffected, except and unless the person making an offer for sale were to apply for a patent, it defines a personal forfeiture test – a non-novelty test.

In contrast, a TRIPS-consonant patent law would allow any claimed invention divulged to the public in any way, by any means, to be deemed to lack novelty and thereby fail this TRIPS-sanctioned test for patentability. As noted above, on its face, this is what the AIA accomplished in §102(a)(1).

Imposing, however, an "on sale" patentability bar that would extend to an invention never actually constructed, not available for purchase, and never divulged to anyone except in confidence, and that was only patent-barring if the patent applicant or a privy were involved in the patentability-defeating conduct, falls within none of the Article 27.1 grounds TRIPS permits, *i.e.*, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step [are non-obvious] and are capable of industrial application [are useful]".

Hence, while TRIPS broadly sanctions a novelty test, it affords no leeway for a distinct and inconsistent personal forfeiture test, *i.e.*, a test applied in a manner in which a claimed invention would remain "novel" if the activity in question were undertaken by an unrelated party, but would destroy novelty only the secret, non-public activity if undertaken by a patent applicant or privy.

Thus, at all costs, the USPTO should avoid construing the AIA provisions on patentability in any manner that would suggest the United States viewed a particular TRIPS limitation as inap-

plicable so long as the patentability test being imposed could be categorized, however artificially, as one of the TRIPS-sanctioned limitations on the availability of patent protection.

The concern of Lilly in this respect is not an academic one. In recent years, some jurisdictions have – under the rubric of a "utility" requirement for patentability – been imposing an extra-TRIPS requirement under which the patent disclosure itself must contain an unequivocal verification of utility, *i.e.*, a "sound prediction" requirement for patentability as applied to the "promise of the invention." Imposing such a non-utility utility requirement to a claimed invention that is not only useful in fact, but in circumstances where the patent specification unassailably enables the utility to be carried into practice, is a flagrant violation of treaty obligations.

Hence, in any guidance on the implementation of the AIA, the United States should not give like credence to the possible evasion of TRIPS requirements by implementing the AIA in a manner that would impose a parallel pseudo-novelty requirement for patenting.

Again, Lilly much appreciates the opportunity to provide its views on this topic.

Sincerely,

Robert A. Armitage

Robert A. Armitage
Sr. Vice President – General Counsel

Attachment: May 16, 2012 Testimony of Robert A. Armitage before the United States House of Representatives Committee on the Judiciary

Answers That Matter.

ROBERT A. ARMITAGE
SENIOR VICE PRESIDENT AND GENERAL COUNSEL - ELI LILLY AND COMPANY
MAY 16, 2012

The Leahy-Smith America Invents Act holds enormous promise for the U.S. patent system. The realization of that promise is, in the near term, tied to the work of the United States Patent and Trademark Office in designing regulations to implement the new law and patent examination guidelines that will implement its first-inventor-to-file provisions. This hearing presents the opportunity to offer a "mid-implementation" scorecard on the Office's efforts. In brief, it has earned high grades on the process it has followed, but has important work remaining to optimize the implementing regulations:

- ***Process***. The USPTO gets high grades for the transparency of the rulemaking process and its efforts to secure input on implementation issues from the diverse constituencies who will be impacted by the new provisions of the AIA. The candor, transparency and completeness of USPTO communications with the user community have helped users to provide informed input into the Office's rulemaking process.
- ***Fee Setting***. Again, the work of the Office deserves high grades. The USPTO faces serious and longstanding issues from chronic underinvestment in human and technology resources. The agency's backlogs in patent examination and patent appeals reflect poorly on the U.S. patent system. Affording the Office access to its expected fee revenue of $2.93 billion for FY 2013 will allow major strides forward on the hiring of essential personnel, building needed IT infrastructure, and tackling its backlog. In general, the Office's actions in implementing its fee-setting authority reflect a balanced understanding of the policy-making implications of fee-setting that Congress has entrusted to the USTPO and vindicate the decision to afford the Office this new authority.
- ***Supplemental Examination***. The USPTO's proposed limitations on use of this new procedure, including its fee-setting proposal, indicate that the Office has not yet embraced its full potential to improve the quality of patent examination and the reliability of issued patents. Final regulations should reflect a fuller embrace of the potential for supplemental examination to improve the quality of issued patents.
- ***Assignee Filing and Formalities***. The USPTO's proposed rules failed to take advantage of the leverage Congress provided to simplify – and globally harmonize – the formalities associated with seeking patents. Dialogue with the Office suggests that these concerns may be addressed in the final rules.
- ***Post-Grant Review***. The USPTO's proposed rules to implement the new inter partes review (IPR) and post-grant review (PGR) require significant improvement. For these procedures to function in a fair, balanced, and efficient manner, it is critical that IPR/PGR petitioners, at the time of the petition filing, provide all evidence on which their patent invalidity allegations are based, as well as initial disclosures of information otherwise relevant to their invalidity arguments. The available discovery of right for both petitioners and patent owners – and the limitations on such discovery – should be set out clearly in the rules themselves. Clear rules, both mandating and limiting what must be filed and what can be discovered, are needed to assure these proceedings can operate with minimal oversight from administrative patent judges and with minimal procedural burdens on the participants.


Robert A. Armitage
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

Robert A. Armitage became senior vice president and general counsel for Eli Lilly and Company in January 2003, and is a member of the company's executive committee. He joined the company as vice president and general patent counsel in October 1999. Armitage was born in Port Huron, Michigan, and received a bachelor of arts degree in physics and mathematics in 1970 from Albion College. He received a master's degree in physics from the University of Michigan in 1971 and a juris doctor from the University of Michigan Law School in 1973. Prior to joining Lilly, Armitage was chief intellectual property counsel for The Upjohn Company from 1983 to 1993. He also was a partner in the Washington, D.C. office of Vinson & Elkins LLP from 1993 to 1999. Armitage is a past president of the American Intellectual Property Law Association (AIPLA) and the Association of Corporate Patent Counsel (ACPC). He is also a past chair of the National Council of Intellectual Property Law Associations (NCIPLA), the intellectual property committee of the National Association of Manufacturers (NAM), the Fellows of the American Intellectual Property Law Association, the patent committee of the Pharmaceutical Research and Manufacturers of America (PhRMA), and the Intellectual Property Law Section of the State Bar of Michigan. Mr. Armitage currently serves as chair of the Intellectual Property Law Section of the American Bar Association (ABA IPL Section). He has served as an adjunct professor of law at George Washington University, a member of the board of directors of Human Genome Sciences, Inc., and president of the board of directors of the Hospice of Southwest Michigan, Inc. He has also served as a member of the board of directors of both Intellectual Property Owners (IPO) and the National Inventors Hall of Fame Foundation (NIHFF). Mr. Armitage currently serves as a member of the U.S. Department of State's Advisory Committee on International Economic Policy and is a trustee on the Albion College Board of Trustees, which recognized him with its Distinguished Alumnus Award in 2006. In 2004, the American Intellectual Property Law Association awarded Armitage its highest recognition for lifetime achievement in intellectual property, the AIPLA Excellence Award. In 2008, the New Jersey Intellectual Property Law Association awarded Armitage its Jefferson Medal, an award recognizing exceptional contributions to the field of intellectual property. More recently, Armitage was inducted into the IP Hall of Fame in recognition of his decades-long advocacy of legislation to modernize the U.S. patent system. He played a major role in the successful efforts to enact the America Invents Act, which made the most sweeping changes to U.S. patent law in the past 175 years.


Answers That Matter.

Statement of
Robert A. Armitage
Senior Vice President and General Counsel
Eli Lilly and Company, Indianapolis, Indiana

Before

The United States House of Representatives

Committee on the Judiciary

On

"Implementation of the Leahy-Smith America Invents Act"

Wednesday
May 16, 2012

Answers That Matter.

Chairman Smith, Ranking Member Conyers, and Members of the Committee:

Mr. Chairman and Ranking Member Smith, my name is Robert Armitage. I am pleased to have this opportunity to testify on the implementation of the Leahy-Smith America Invents Act.

The patent community owes an enormous debt of gratitude to this Committee, and its Subcommittee on Intellectual Property, Competition, and the Internet, for the work in crafting H.R. 1249, and the legislative efforts – beginning with H.R. 2795 in the 109th Congress – that preceded it and that ultimately resulted in this new law being signed by the President on September 16, 2011. For me, personally, seeing the AIA come to fruition represents the last stride in a 30-year marathon. [1] Like many in the patent profession who worked with Congress to bring the AIA into being, getting to the finish line was worth the effort. Today, the United States has resumed in its rightful role as the leader in the global patent community, with what has been hailed as the world's first 21st century patent law – one with an unprecedented inventor friendliness and a clear recognition of the role that collaborations play in the discovery and development of new technologies.

The enactment of the AIA, from my perspective at least, will stand as one of the seminal accomplishments of the 112th Congress. The new law contains sweeping reforms of the U.S. patent system. Its provisions constitute the first comprehensive patent system reform that Congress has made since 1836.

A case can be made that it is the most important set of changes that have been made to U.S. patent laws since the original 1790 Patent Act, enacted by the First Congress. During my last testimony before this subcommittee in February, I noted that:

> The Leahy-Smith America Invents Act, the world's first truly twenty-first century patent act, contains all the elements needed for a patent system to operate effectively, efficiently, economically, and equitably. If the decade ahead yields greater international patent cooperation and harmonization among patent systems around the world, the starting point for that effort should lie in the incorporation of its provisions into patent laws across the globe."[2]

---

[1] See generally, Robert A. Armitage, *Reform of the Law on Interference: A New Role for an Ancient Institution in the Context of a First-to-File System*, 64 J. PAT. OFF. SOC'Y 663 (1982), making the case for creating a comprehensive and coordinated set of reforms to U.S. patent law, centered on adoption of the first-inventor-to-file principle, mandatory publication of patent applications at 18 months from initial filing, and a patent term that provided patents would expire 20 years from the initial patent filing.

[2] Robert A. Armitage, "LEAHY-SMITH AMERICA INVENTS ACT: WILL IT BE NATION'S MOST SIGNIFICANT PATENT ACT SINCE 1790?", Washington Legal Foundation Legal Backgrounder, Vol. 26, No. 21 (September 23, 2011), available at: http://www.wlf.org/Upload/legalstudies/legalbackgrounder/09-23-11Armitage_LegalBackgrounder.pdf.

More recently, I have had the opportunity to reflect on the new patent law in the American Intellectual Property Law Association Quarterly Journal:

> The America Invents Act has made many significant changes to the patenting landscape in the United States. It is a giant step toward a more transparent patent system, where a person skilled in the technology of a particular patent and knowledgeable in patent law can review a patent, reference only publicly accessible sources of information, and make a complete and accurate assessment of the validity of the patent. At its core, the AIA seeks a more objective patent law, where subjective issues like an inventor's contemplations or a patent applicant's intent bear no relevance to any issue of validity or enforceability of the patent. It is a patent law that, in many situations, may require no discovery of the inventor to determine if a claimed invention is patentable.
>
> Congress took bold steps to reach these goals. The "loss of right to patent" provisions were all repealed. The "best mode" requirement was made a functional dead letter. All references to "deceptive intention" were stripped from the patent law. A new "supplemental examination" procedure was instituted to address any error or omission in the original examination of a patent and bar the defense of patent unenforceability once the procedure has run to completion. Finally and most dramatically, it concisely limited "prior art" on which the novelty and non-obviousness of a claimed invention was to be assessed. Nothing can qualify as prior art absent representing a prior public disclosure or an earlier patent filing naming another inventor that subsequently became publicly accessible—casting aside 175 years of a more complicated, subjective, and uncertain standard for patenting.
>
> Thus, without question, *transparent*, *objective*, *predictable* and *simple* are four words that should come to describe the hallmarks of the new patent law arising from this historic legislative achievement. Those four words suggest a fifth that appears to be equally apt. *Remarkable*.[3]

As just one example of the promise of the new patent law, Congress has now streamlined and refined patentability criteria in ways that make them simple and

[3] Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, AIPLA Q.J. 40:1, 133 (2012).

straightforward to express, and – for both patent professionals and the inventors and investors that they advise – far more understandable:

> Congress has managed to boil patentability law down to four requirements for a claimed invention in a patent to be valid:
>
> • *Sufficient differentiation* from the prior art. "Prior art" is defined in a simple and transparent manner as subject matter that, at the time of an inventor's patent filing, was already available to the public, or available from a previously-filed U.S. patent or published U.S. application for patent, subject to the inventor-friendly and collaboration-friendly "grace period" and "self-collision protection" provisions that have long been part of U.S. patent law.
>
> • *Sufficient disclosure* in the inventor's patent filing to identify the embodiments of the claimed invention and enable them to be put to a specific, practical, and substantial use.
>
> • *Sufficient definiteness* in the inventor's patent claims, to reasonably identify the subject matter being claimed from that not being claimed.
>
> • *Sufficient concreteness* in the subject matter claimed, such that the process or product being claimed is not excessively conceptual or otherwise abstract.[4]

There are important consequences to this new patent law for the rest of the world:

> The Act's simple, clear, and objective patentability law—although over 220 years in the making—may prove to have been well worth the wait and, as global patent harmonization discussions recommence, the mold and model for the rest of the world to now emulate.[5]

As the U.S. patent community looks to the implementation of the AIA, part of its assessment of whether the *practice* under the AIA matches the *promise* of the AIA will reside in whether the USPTO can establish new rules and procedures that U.S. interests would wish to see used as the mold and model elsewhere. Can the USPTO implement the AIA so that U.S.-based innovators realize the full benefits of more efficient, streamlined, and effective patenting mechanisms domestically that serve as the model for patenting processes internationally?

One hope across the U.S. patent community is that the AIA has positioned the United States to urge foreign patenting systems to now follow the U.S. lead, not only in

[4] Robert A. Armitage, *Perspective*, ABA IPL Section Landslide 4:1 (August-September 2011) at p. 1.
[5] Robert A. Armitage, *Perspective*, *supra*, at p. 1.

crafting transparent, objective, predictable and simple substantive standards for patentability, but in marrying those provisions with more inventor- and collaboration-friendly features. For the United State to lead, however, U.S. negotiators must be positioned to urge foreign governments to "do as we do," rather than simply "do as we say." Thus, I would like to explain in detail what I believe the United States, particularly the USPTO, must now *do* in implementation of the AIA in order to realize and reinforce a U.S. leadership role.

For decades, efforts at U.S. leadership on creating more globally harmonized patent laws have been stymied because the majority of the U.S. patent community had no interest in seeing our patentability standards and criteria exported globally. When U.S. interests defined the "best practices" internationally for crafting a patent law and patent system, those practices were in key respects absent in our laws. The AIA has ended that era of followership for the United States. The supporters of the AIA look at its provisions as the epitome of best patenting practices.

Thus, a critical filter through which Lilly – and other U.S.-based innovators – look at AIA implementation is whether the congressional promise of using the AIA as a tool for global leadership on patent system matters is being realized. How completely can our new law fulfill this enormous domestic promise and international potential for good for U.S.-created innovation?

With this enormous promise for the new patent law, now eight months old, what is the current state of its implementation? To answer this question requires a look first at the upcoming work the Office will undertake to implement the first-inventor-to-file provisions of the AIA and then to follow that look with an analysis of how USPTO proposed rules in the areas of supplemental examination procedures, assignee filing/inventor's statement requirements, and post-grant review procedures either do or do not serve to advance both domestic concerns of the U.S. patent user community and the broader international leadership role that the United States needs to play to advance U.S.-based interests globally.

***First-Inventor-to-File Provisions – Implementing Congressional Intent***

If there be one aspect of the AIA that Congress would have wished to be seen as crystal clear, it would be the new rules that Congress laid out on the most fundamental aspect of patent law: *What acts preceding the filing of a patent application can bar the ability of an inventor to secure a valid patent on an invention? Most specifically, what can qualify as "prior art" against which an invention is assessed for novelty and non-obviousness?* The answer to these questions can be simply restated: What pre-filing acts or actions can the USPTO cite to bar the issuance of U.S. patent as failing to meet the requirements under new §102 of the patent statute?

With its drafting of new §102, Congress itself believed its new statutory language met the tests of clarity and non-ambiguity. This is clear from the encyclopedic, chapter-and-verse analysis of the AIA's new provisions in the legislative history. Congress was,

on its face at least, clear and unambiguous with respect to what constitutes "prior art" and what, contrary to the pre-AIA law, no longer serves as a bar to patenting.

There is a cogent confirmation that the congressional crafting of these key components of the AIA was completely clear. Recently published is a complete analysis of "what got done when and why." It can be found in Joe Matal, *A Guide to the Legislative History of the America Invents Act, Part I of II*, Federal Circuit Bar Journal 21:435 (2011). Mr. Matal worked on the AIA for leading congressional sponsors of patent reform, Senators Kyl and Sessions.

At pp. 466-475 of the Matal analysis, the entirety of the legislative development of new §102 is set out. On the "prior art" provision of the new patent law, at p. 468, Mr. Matal notes:

> The final Committee Report for the America Invents Act [H.R. Rep. No. 112-98] was issued on June 1, 2011, and the full House began debate on June 22, 2011. On that first day of debate, Representative Lamar Smith, the Chairman of the House Judiciary Committee and lead sponsor of the bill, engaged in a colloquy with Representative Charles Bass of New Hampshire regarding the AIA's new definition of "prior art" and its grace period. The Smith-Bass colloquy was similar in substance to the Leahy-Hatch colloquy[6] of March 9, 2011. [157 Cong. Rec. S1496-97] It concluded by noting that, "*contrary to current precedent, in order to trigger the bar in the new 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date*." [157 Cong. Rec. H4429; emphasis supplied.]

The "available to the public" standard was employed in part, according to this analysis, to overrule old "loss of right to patent" provisions,[7] most notable among which

---

[6] Matal quotes two passages from the Leahy-Hatch colloquy in order to explain how the new "prior art" definition in §102 will operate:
"[T]he important point is that if an inventor's disclosure triggers the 102(a) bar with respect to an invention, which can only be done by a disclosure that is both made available to the public and enabled, then he or she has thereby also triggered the grace period under 102(b). *If a disclosure* resulting from the inventor's actions is not one that is enabled, or *is not made available to the public*, then such a disclosure *would not constitute patent-defeating prior art under 102(a) in the first place*."
"One of the implications of the point we are making is that subsection 102(a) *was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art*. That will no longer be the case. In effect, the new paragraph 102(a)(1) imposes an *overarching requirement for availability to the public*, that is a public disclosure, which will limit paragraph 102(a)(1) prior art to subject matter meeting the *public accessibility standard that is well-settled in current law, especially case law of the Federal Circuit*." [Emphasis supplied.]

[7] The pre-AIA heading for §102 was titled "Conditions for patentability, novelty and loss of right to patent," and in the AIA the repeal of these "loss of right" provisions was in part evidenced by the new title

were the "forfeiture provisions" in pre-AIA §102(b) in which an inventor's secret offer for sale or secret use of an invention, once deemed "ready for patenting," would bar the inventor from seeking a valid patent for the invention unless the patent was sought within the one-year period from the date of such a secret undertaking.

The new legal standard under §102, under which the "loss of right to patent" provisions were to be repealed, *i.e.*, by requiring that any patent bar under §102 should require some act, action or activity that rendered subject matter "available to the public," was a consensus position of the U.S. patent user community. It was identified as an essential "best practice" in devising the standards for whether or not a valid patent might be issued for an invention. Thus, one of the primary objectives of the supporters of H.R 1249 was to assure that secret, private, confidential or otherwise non-public acts of the inventor would no longer constitute a "forfeiture" of the inventor's right to secure a patent on the invention.

Indeed, the development of this consensus among U.S. interests, *i.e.*, that there be a *public accessibility* requisite in new §102 in order for earlier-disclosed subject matter to serve as a bar to patenting, was recently detailed in a publication of the Intellectual Property Law Section of the American Bar Association:

> In a 2001 *Federal Register* notice, the USPTO sought views on no less than 17 harmonization-related issues, including: "As to priority of invention, the United States currently adheres to a first-to-invent system. The remainder of the world uses a first-to-file rule in determining the right to a patent. Please comment as to which standard is the 'best practice' for a harmonized, global patent system."
>
> Dozens of domestic entities and individuals responded to the 2001 notice, expressing views on the first-inventor-to-file principle and how best to implement it. Reading the responses, it becomes clear that a consensus emerged, not just on the principle of adopting a first-inventor-to-file rule, but on numerous details of its implementation.
>
> When Congress sought to write the new statute, it drew on the domestic consensus from 2001. It provided a globalized "prior art" standard, rejected Europe's novelty-only "prior art" rule for earlier patent filings, retired the *Hilmer* doctrine, *ended each of the §102 "patent forfeiture" doctrines*, and secured a strong "grace period"

---

for §102, "Conditions for patentability, novelty," *indicating without ambiguity that no such "loss of right to patent" provisions remain.*

> for inventors who publish before patenting.[8] [Emphasis supplied.]

The desire to see the demise of the "forfeiture" doctrine was fully documented because it was one of the 17 "best practice" issues on which the USPTO sought input from the patent user community in its 2001 notice.[9] The specific question posed by the USPTO in 2001 on "forfeiture" was the following one:

> United States law provides for loss of right provisions, as contained in 35 USC 102(c) and 102(d), that discourage delays in filing in the United States. Further, 35 USC §§102(a) bars the grant of a patent when the invention was "in public use or on sale" more than one year prior to filing in the United States. *Secret commercial use by the inventor is covered by the bar* in order to prevent the preservation of patent rights when there has been successful commercial exploitation of an invention by its inventor beyond one year before filing. *Most other patent systems do not have such provisions*. [Emphasis supplied.]

Among the organizations whose comments then indicated in very explicit terms that the forfeiture doctrine had no place in a modern patent law, based upon the aforementioned "best practices" capable of serving as a model for patent systems globally, were a litany of leading national organizations that would later become the leading supporters of the AIA, specifically:

- National Association of Manufacturers
- Biotechnology Industry Organization
- Intellectual Property Owners Association
- Intellectual Property Law Section of the American Bar Association
- American Intellectual Property Law Association

The comments of NAM were typical of the views on "best practices" for a 21st century patent system, one that needed to repeal a forfeiture doctrine so that it could be the foundation for a more globally harmonized set of "best practice" rules for patenting:

> A major component of any harmonization treaty should be the maintenance of the right to obtain patent protection so long as the acts of the inventor are not *publicly accessible* to persons of ordinary skill in the art. If the acts of the inventor or the inventor's agents cause a *disclosure of the invention that is reasonably and effectively accessible* to persons of ordinary skill in the art,

[8] Robert A. Armitage, *Perspective*, ABA IPL Section Landslide 4:4 (February-March 2012) at p.1.
[9] See 66 Fed. Reg. 15409-15411 (March 19, 2001).

> it should be *patent-defeating after one year*. If the invention is not so accessible, *there should no longer be a personal forfeiture*. This avoids the complexity and arbitrariness of the "ready for patenting" standard recently set forth in the United States.[10]

Given that Congress was clear on what would be required for securing a valid patent under new §102 – and given that the leading proponents for patent reform in the U.S. patent community had long ago gone on record as to the "best practices" they were seeking to have ensconced into new §102 – it is worth exploring how the new law's provisions on this key point are being discussed by the wide spectrum of commentators as to its import.

What has transpired since the enactment of the AIA among commentators who have dissected the new law?

One example worthy of note can be found in the conclusions drawn by two noted academicians whose lectures on the eve of enactment of the new law still reside on their website. They have come to the diametrically opposite conclusion relative to the aforementioned consensus "best practice" on whether the new patent law can trigger a "forfeiture" bar to patenting based upon subject matter that is confidential and, thus, unavailable to the public. Two slides from their website appear as follows:[11]

**New Act perpetuates current rule in distinguishing prior art events initiated by inventor and those of 3rd parties**

- ANY disclosure by inventor him or herself – including confidential on-sale activities and non-informing public uses – initiates a 1-year grace period
  - Inventor has 1 year within which to file after on-sale or public use event

**Under the statute**

- A's on-sale activity or non-informing public use creates a grace period FOR A but DOES NOT bar a patent for others such as B
  - Why not? Because it is prior art ONLY TO A under 102(a)(1), and *therefore* a "disclosure" under 102(b)(2) which qualifies for the 1 year grace period
- Also: As under current law, confidential third party on-sale and non-informing public use activities by third party B do NOT create prior art for patent applicant A

The views depicted in the slides above are, of course, simply incapable of reconciliation with the views of the House and Senate sponsors of the legislation and, on the House side, contrary to the clear understanding of the new law to be found in this Committee's report that preceded the floor debate on H.R. 1249. While it is difficult to understand how any holistic reading of the new definition of prior art under §102(a)

[10] See, for all comments received in response to the USPTO's Federal Register notice, United States Patent and Trademark Office, Comments Regarding the International Effort to Harmonize the Substantive Requirements of Patent Laws, USPTO.GOV, http://www.uspto.gov/web/offices/dcom/olia/harmonization/.
[11] Prof. Robert Merges and Prof. John Duffy, *Leahy-Smith America Invents Act: Overview (9.15.2011)*, http://www.law.berkeley.edu/files/bclt_Leahy-Smith_AIA_2011_Overview_Final.pdf, at slides 25-26, as viewed on May 8, 2012.

could lead to a conclusion that there is a different standard for what constitutes a bar to patenting in the case of the inventor, in contrast to someone other than the inventor, what is relevant is that – for whatever reason and on whatever basis – such contentions can be found.[12]

The mere existence of views other than those of the Committee on the intent and the meaning of the new statute makes it important for the implementation efforts relating to the new provisions in §102 to align fully with congressional intent. The USPTO, starting on March 16, 2013 – 10 months from today – will begin receiving patent applications in which the new §102 will apply. As that date approaches, inventors are entitled to certainty as to the Office's views of what the new law will demand and what standards the Office will use in examining inventors' claims for novelty and non-obviousness over the prior art.

What does this suggest is the next critical juncture in the AIA's implementation?

For many of the AIA's proponents, the most crucial "get it right" event in the AIA implementation will be the manner in which the new standard for "prior art" under §102 is described in the USPTO's examination guidelines. These guidelines will set out the expert agency's understanding of the text of the new law's provisions in order that patent examiners can know what to examine for and patent applicants can know when and under what circumstances they might be entitled to file for a patent.

The Office simply cannot be equivocal, have reservations, or express uncertainty about the manner in which it will be examining patent applications – and what requirements a patent applicant must meet under the new law in order for a patent to be legitimately sought and validly issued.

It should not be too much for Congress to ask of the USPTO that it commit to implementing the provisions of the new law in a manner that is both consistent with the plain wording of the new patent statute itself and the clear intent of its House and Senate legislative sponsors in enacting it.[13] This is particularly important given the relationship

---

[12] In the case of the slides displayed above, the authors elsewhere in their presentation concluded that "[p]rior art categories under 102(a)(1) incorporate existing [pre-AIA] law defining each category," a contention that stands in defiance of the modifier Congress placed in the new statute, "or otherwise available to the public," as well as in contradiction to the plain meaning of those statutory words (and reinforcement of that plain meaning in the House report on H.R. 1249). The authors did so on the slender reed that the "statute specifically distinguishes between 'disclosure' and 'PUBLIC disclosure'." This distinction, the authors concluded, means that subject matter other than a "public disclosure" must have been contemplated under §102(a)(1) as qualifying as prior art, thereby wholly ignoring that the use of the term "public disclosure" in both §102(b)(1)(B) and §102(b)(2)(B) was clearly intended to limit the availability of both these subparagraph (B) exceptions (from subject matter otherwise qualifying as prior art) to only subject matter the inventor disclosed in the manner described in §102(a)(1), that is, by making the subject matter available to the public, as opposed to subject matter disclosed in the manner described in §102(a)(2), namely a disclosure made in a patent filing that is not public – and may never become public.

[13] The Committee has made its expectations clear to the Office at different times in different ways over the past 60 years. In its consideration of the Patent Law Amendments Act of 1984, it directed the patent office to undertake a broadly based expansion of the "obviousness-type double patenting" doctrine as part of

between §102(a)'s prior art definition and clearly interrelated provisions in the AIA that depend upon a transparent and objective law on patentability.

The House's viewpoint on the interrelationship between §102's new provisions and the remaining reforms in the AIA was not just a view expressed there; it was a view clearly shared in the Senate. "Thus, new section 102(a)(1) imposes a public-availability standard on the definition of all prior art enumerated in the bill—an understanding on which the remainder of the bill is premised." Senator Kyl, 157 Cong. Rec. S1368-1371 (March 8, 2011).

Perhaps the most significant of those provisions of the AIA on which an implementation of new §102 that is faithful with congressional intent depends is the new post-grant review procedure. These PGR proceedings do no less than demand a transparent standard for what subject matter can qualify as prior art. Transparency in what is or is not a bar to patenting is essential – namely, it is critical to have a prior art definition that is keyed to *public accessibility* – so that the USPTO can confine its inquiry into the "scope and content of the prior art" to subject matter that had become publicly accessible before the patent was sought.

The rationale for the new PGR proceedings was to permit the USPTO to decide administratively in the Office any issue of patent invalidity that a court could consider in the context of a declaratory judgment of patent invalidity or an invalidity defense to a charge of patent infringement. The "forfeiture" doctrine is notorious for its discovery implications – requiring extensive fact-finding on what the inventor or those operating at the inventor's behest may or may not have undertaken in work with third parties, done in secret years before, and, simultaneously, attempting to ferret out facts as to whether the

---

statutory reforms that pulled back on the statutory grounds under which "obviousness" could exist: "The Committee expects that the Patent and Trademark Office will reinstitute in appropriate circumstances the practice of rejecting claims in commonly owned applications of different inventive entities on the ground of double patenting. This will be necessary in order to prevent an organization from obtaining two or more patents with different expiration dates covering nearly identical subject matter." See Analysis of H.R. 6286, Congressional Record (October 1, 1984) at H10525 to H10529, remarks by Representative Robert Kastenmier, Chairman of the Subcommittee on Courts, Civil Liberties and the Administration of Justice of the Committee on the Judiciary. Similarly, see the implicit direction to interpret §102(a) under the 1952 Patent Act, such that "known or used" would be limited by the patent office to mean "publicly known or publicly used" at S. Rep. No. 82-1979 at 17 (1952), reprinted in 1952 U.S.C.C.A.N. 2394, 2410. "The interpretation by the courts of paragraph (a) [of pre-AIA § 102] as being more restricted than the actual language would suggest (*for example, known has been held to mean publicly known*) is recognized but no change in the language is made at this time." [Emphasis added.] Finally, see H.R. Rep. No. 108-425, at 6, setting out congressional expectations for implementation of the CREATE (Cooperative Research and Technology Enhancement) Act of 2004: "Congress intends that parties who seek to benefit from this Act to waive the right to enforce any patent separately from any earlier patent that would otherwise have formed the basis for an obviousness-type double patenting rejection. Further, Congress intends that parties with an interest in a patent that is granted solely on the basis of the amendments made pursuant to this Act to waive requirements for multiple licenses. In other words, the requirements under current law for parties to terminally disclaim interests in patents that would otherwise be invalid on "obviousness-type" double patenting grounds are to apply, mutatis mutandis, to the patents that may be issued in circumstances made possible by this Act." The USPTO then proceeded to implement rules to accomplish this intent. See http://www.uspto.gov/web/offices/com/sol/og/2005/week45/patcrea.htm.

patented invention at such time met the hypothetical standard of being "ready for patenting."

Congress indicated that it sought to end this quagmire by injecting the term "available to the public" into section 102. Simultaneously, it extracted other subjective and secret elements that served to bar patents under pre-AIA. By doing so, the Congress limited the amount of fact-finding, much of which under pre-AIA law was highly discovery-intensive, that might be relevant to patent validity. Indeed, as noted above, in many situations, the restriction of patent validity to a set of transparent, objective, predictable and simple requirements means that no discovery from the inventor may be of potential relevance to the validity of many patents.

It was this cleanup of the patent law that made PGR feasible as a means for addressing all issues of validity of an issued U.S. patent—and fair to both patent owners and patent challengers to construct a procedure that would need significant limitations on discovery in order to meet the one-year statutory deadline for completion once instituted.

Consider the following hypothetical example of a post-grant review proceeding in which an attack is made on a patent as being invalid under a contention that §102's new provisions allow consideration of an inventor's forfeiture of the right to patent, *i.e.*, through a confidential, non-public, foreign-origin offer for sale:

> A competitor of Armonk Software Solutions, Istanbul Business Machines, files a petition for a post-grant review of a key patent on which Armonk has staked much of its future. The petition seeks invalidation of the Armonk patent under §102(a). The facts alleged in the petition are that, during a visit to Istanbul's headquarters in Ankara, a Turkish employee of Armonk who was at the time Armonk's general manager in Turkey, undertook discussions under a confidential disclosure agreement with Istanbul, indicating that the patented technology – although still under development by Armonk – was nonetheless available for sale to Istanbul, as part of Armonk's desire to collaborate more broadly with Istanbul.
>
> In support of its contention that §102(a)'s provisions had been violated because Armonk's claimed invention was secretly "on sale" in Turkey, Istanbul offered a document, purporting to be a transcript of the discussions with Armonk's Turkish employee. The document containing the transcript was dated one year and one day before the Armonk patent was initially sought. Thus, Istanbul contended, Armonk could not avail itself of the "grace period" exceptions under §102(b) to the novelty requirement under §102(a).

> Armonk could not deny that its Turkish employee had visited Istanbul, had signed a confidentiality agreement relating to the same field of technology covered by the patent, and had discussed the possibility of a number of business relationships with Istanbul, including the possibility of collaborating more broadly with Istanbul in the development of the type of technology present in its patented invention. *Armonk, however, denied authorizing its employee to make any offer for sale. The employee, however, had later resigned from his position with Armonk and now could not be found at the last address that Armonk had for the employee.*
>
> Istanbul, in addition to the document asserted to be a transcript of the encounter with its ex-employee, also included with its post-grant review petition declarations from two of Istanbul's participants in the discussions with Armonk. The declarants for Istanbul corroborated the content for the transcript.
>
> To decide the petition for post-grant review, the USPTO, as a threshold matter, would need to decide whether confidential discussions at Istanbul's home office, although not available to the public, could qualify as "prior art" under §102(a)'s "on sale" provision and, additionally, whether it was more likely than not that the petition established the invalidity of Armonk's patent.
>
> If the PGR proceeding is implemented, a mere preponderance of the evidence will determine if the Armonk patent will be canceled based on the alleged non-public activities that an ex-employee is alleged to have engaged in private, potentially placing Armonk's future viability at risk by opening up the U.S. market for its patented technology to Istanbul Business Machines, its most serious global rival.

The above hypothetical exemplifies precisely what most proponents of PGR have sought to avoid by assuring that only subject matter that had become available to the public could be the basis for barring a patent to an inventor under §102(a)(1).[14] It was the

[14] In fairness, it appears that not all the supporters of the AIA share this view. The USPTO is receiving an array of input on the implementation of the AIA, including on the issue of what and to what extent "uses" can bar a patent. One example of a contrary view can be found on the USPTO website from IBM. http://www.uspto.gov/patents/law/comments/x_aia-e_ibm_20110916.pdf. IBM has stated: "As the AIA limits prior art to that which is available to the public, we believe it is important to address the impact on

reason why both House and Senate consideration of H.R. 1249 was replete with legislative history citing to the overarching requirement for public accessibility in §102(a)'s definition for prior art.[15]

Congress acted to avoid having the USPTO face the difficult challenge of ferreting out the truth of the matter in deciding what happened in secret, behind closed doors, years earlier. In order to get at the truth of the matter in the above hypothetical situation – whether or not an oral offer for sale had been made in a distant foreign country in the course of a confidential discussion – in a fair manner, where a mere preponderance of the evidence is sufficient to destroy a patent of potentially immense commercial value, it is clear that significant discovery may be needed. Moreover, the

---

patentability of secret commercial use by an inventor. IBM believes the change to the scope of prior art made by the AIA should not limit application of the rule that prevents an inventor from seeking patent protection after an extended period of secret commercialization." IBM's position, which in effect would require a return to the pre-AIA law where "in public use" or "on sale" would permit a patent to be barred under the scenario described above facing Istanbul Business Machines, is curious in several respects. First, the proposition of law that IBM suggests that the USPTO recognize post-AIA was never the law prior to the AIA. A foreign-based entity was always able to exploit an invention commercially outside the United States for an unlimited period before applying for a U.S. patent. The principle, somewhat bizarrely, only impacted a U.S.-based entity. Moreover, once this bar took hold, it had the negative impact of deterring making the invention public and forcing continued reliance on trade secret protection. The AIA, of course, turned the patent law upside down on the policy underpinnings for barring a commercial user's ability to seek a patent after commencing a secret commercial use. The first-inventor-to-file rule provides an incentive to seek patents promptly. Moreover, so long as the invention has not yet become public, that incentive continues. Finally, once any public disclosure of the invention has been made, the ability of someone other than the disclosing party to seek an after-the-fact patent vanishes. These factors, taken together, form a far superior public policy to the personal bar to patenting for a secret commercial user or for a secret offer for sale. They avoid the absurd result that the same patent filing on the same day claiming the same invention with the same claim to novelty and non-obviousness over all subject matter theretofore that had been publicly accessible is wholly valid if sought by one inventor, but wholly a nullity if sought by a second inventor, depending only on activities that were beyond public view. In such a case, both inventors advanced the state of public knowledge and both inventors did so under a first-inventor-to-file rule that encouraged promptly filing for a patent, a right that would be forfeited by any disclosure – even if only made a day before a patent filing – that sufficed to make the invention obvious in view of such disclosure.

[15] The non-transparency issue of the old pre-AIA forfeiture bar – and the difficulty to reconcile the bar with the simplicity and predictability essential for a modern patent law to operate in the public interest – can be appreciated from a short hypothetical. Consider that a patent issues that is entirely valid based on the tests for sufficient differentiation, disclosure, definiteness and concreteness described earlier, but assume further that the patent was issued to (1) a U.S.-based inventor who had made a secret offer for sale to a U.S.-based partner more than one year before seeking the patent, (2) a German-based inventor who had made a similar offer to a German-based partner, or (3) a Japanese-based inventor who asserts that its discussion with a Japanese partner at no time involved such an offer for sale. Under pre-AIA law, only the U.S.-based inventor could forfeit the right to patent the invention. Under IBM's view expressed to the USPTO, the AIA would require that both the U.S.-based and German-based inventors' patents would be invalid for forfeiture, but unless more evidence could be adduced to demonstrate that the Japanese inventor's conduct amounted to an offer for sale at a time the Japanese inventor's invention was "ready for patenting," there would be no forfeiture of the Japanese inventor's right to patent. *A U.S. patent law that treats the identical patent with the identical claims differently depending upon secret, non-public information – that is far easier to conceal the more distant the conduct is from the U.S. courthouse where the validity of the patent is being assessed – is neither a patent law that can serve U.S. competitive interests nor entice anyone outside the United States that it is a viable model for the rest of the world to follow.*

credibility of the witnesses to the events in question may be crucial to arriving at a fair result. Finally, the imperative that Congress placed on concluding the post-grant review period within a one-year statutory time limitation imposes yet a further strain on securing a fair and just result.

Hence, much is at stake as the USPTO moves to implement the new first-inventor-to-file prior art standard under the AIA's §102(a). Either a transparent, objective and simple implementation of the new law will impose an overarching requirement for public accessibility for any subject matter to qualify as a §102(a)(1) bar to patenting, or patent owners may be faced with a situation no one supporting the enactment of the AIA could have imagined or would have supported. Without the "public accessibility filter," private, secret, or otherwise confidential subject matter, inaccessible to the public anywhere in the world, could be dredged up from any location on the planet to invalidate a patent in a post-grant review or a patent enforcement action in the courts.

In conclusion, as Congress looks to exercise oversight over implementation of the AIA, it is critically important that the USPTO's actions on the first-inventor-to-file prior art guidelines for patent applicants are fully consistent with and fully recognize not just congressional intent, but the only reasonable construction the words of the new patent law could have. I must admit, it is perplexing that there are those who read the words, "in *public* use … or *otherwise available to the public*" as a clear signal from Congress that *non-public* activities can qualify under §102(a)(1) to bar an inventor from securing a valid U.S. patent."

However, I promise – this is not an issue that I simply manufactured out of thin air, to "cry wolf" before this Committee, much as that might appear. As the slide presentation cited above, authored by well-regarded patent academicians indicates, this is an implementation issue where Congress may wish to speak, and speak again, until no doubt exists as to the words it placed into the statute and the import and intent of those words.

***USPTO Financing Provisions – Assuring Fees Meet Policy Objectives Set by Congress***

**THE USPTO HAS JUSTIFIED ITS NEED FOR $3 BILLION IN 2013 FEES**

A second set of critical policy issues in connection with the implementation of the Leahy-Smith America Invents Act lie in its provisions relating to the financing of the operations of the United States Patent and Trademark Office. For the first time since the Office was created pursuant to the 1836 Patent Act, it now has an unprecedented opportunity, through its new fee-setting authority and the related AIA provisions assuring the Office will have access to the fees that it collects from users, to address longstanding structural issues.[16]

[16] All stakeholders in the U.S. patent system commend Congress for taking steps in the AIA to end, at once and all time, diversion of USPTO user fees. We commend the Judiciary Committees in the House and the Senate for working closely with the respective Appropriations Committees, the Majority and Minority

After decades of starts and stops in building needed capabilities, the Office at last has a financing model that permits sustained investments in building critical capabilities. It can increase its professional staff to the scale required by the level of new patent filings. It can build the new capabilities that the new responsibilities entrusted to it under the AIA will now demand. It can address what had become an unconscionable backlog of unexamined patent filings, and a similarly distressing backlog in deciding patent appeals. It can use its growing cadre of human resources to undertake and complete the examination of patent applications in an efficient, timely, and accurate manner – and to a degree heretofore unattainable.

In both the House[17] and Senate[18], the fiscal year 2013 appropriations process is on track to afford the USPTO nearly $3 billion to invest in securing opportunities for strong patents, timely issued. The Director of the Office has been abundantly clear about what is at stake – placing the USPTO in a position that it might serve as an engine for investing in new technologies – and a source of quality new American jobs.

Lilly would like to applaud the efforts of the Office to set fees at an aggregate level sufficient to ensure the Office can move forward to hire and train the professional staff that it needs, both to address its steady-state workload needs from new patent filings and to vanquish its accumulated backlog of unexamined patent applications; to acquire the advanced IT capabilities that can drive improvements in the productivity and quality of all its operations (and, over the longer term, therefore, work to reduce the costs and burdens on patent applicants and other users of the Office's services); and to maintain an adequate reserve fund to assure that it can sustain its operations in the face of fluctuations in fee collections from fiscal year to fiscal year.

We are aware that some have expressed concern that the fee levels impose too great a burden on users of the patent system. That is a concern that we, however, do not share.

Our interests differ not at all from other users of USPTO services. We expect the Office to be frugally and efficiently operated. We expect constant improvements in

---

Leadership offices in both the House and the Senate, and with the Administration, to achieve the principle that all patent user fees be used to fund USPTO, and only USPTO, operations. It is important to emphasize that USPTO is 100 percent user fee funded and that there are no taxpayer dollars appropriated to the agency. We are mindful of the growing federal budgetary challenges and of the possibility of sequestration or other extraordinary measures to better control federal spending. It is the expectation and hope of stakeholders that all USPTO user fees remain fully, solely, and timely available to the agency, no matter what pressures arise to divert or delay these funds. We stand prepared to work with the Committee as you make sure that the anti-diversion provisions of the AIA are implemented going forward."

[17] See http://appropriations.house.gov/UploadedFiles/CJS-FY13-FULL_COMMITTEE_REPORT.pdf at p. 15.

[18] "**Patent and Trademark Office (PTO)** – The [Senate] bill provides $2.93 billion for PTO, allowing the agency to spend all of its expected fee revenue for fiscal year 2013. The bill continues the reserve fund authorized by the America Invents Act." See http://www.appropriations.senate.gov/news.cfm?method=news.download&id=e016ad78-5f89-418b-b51a-eebf0eba72b9, April 17, 2012 on FY2013 CJS Appropriations.

USPTO operations that place a downward pressure on its fees, as well as any need to increase its fees. When the Office invests in creating new capabilities, whether IT-related or otherwise, we expect that those investments produce a positive return in terms of increased quality or productivity – again creating the opportunity for a fee-change trajectory with a negative slope.

Over the past three years, however, we have seen nothing in the manner in which the USPTO has operated – or proposed to operate – that is inconsistent with these shared expectations among all users of the patent system.

Rather than seeing an aggregate fee price tag for users of $3 billion as a sign of a bloated Office, we look behind the number and see an Office dedicated to becoming *lean and clean*. It is literally staffing up to clean out a backlog of unexamined applications that are a disgrace to the U.S. patent system. A backlog model is a terrible model for us to set on the global IP stage.

We see the Office beefing up its IT "weight room." What the USPTO is proposing on the information technology front is by and large "lean mass," not adipose tissue. Patent examiners will be able to exercise their authority with better systems for accessing needed information and better systems for efficiently communicating with patent applicants. While we will – as will other users – constantly be on the lookout for opportunities to suggest ways in which the resource needs of the Office can be lessened, what $3 billion in user fees in 2013 will do for the Office is assure it will be adequately nourished.

We are particularly concerned, therefore, with those who believe that proposed fee levels are significantly too high, and that a percentage cut in fee levels, somewhere in the *double-digit* range would be warranted. Lilly believes that taking such a step would be to set out on a path towards a chronically malnourished USPTO. Some more modest fee cut might leave the USPTO with the resources it needs to operate, no doubt. However, we are wary of any fee cut, however modest it might appear on its face, if it would mean delaying or denying the USPTO the resources it needs to best serve the public interest and the best interests of patent applicants – both of which deserve prompt patent examination accomplished in a high-quality manner.

Lilly would not want its testimony to suggest sanguinity over the substantial ramp-up of USPTO user fees. Rather, our analysis of the impact of the USPTO's fees is grounded in the aggregate costs of patenting today, only a modest portion of which is represented by USPTO fees. Knocking 10% off the proposed 2013 fees levels would at best result in only a very small aggregate reduction in the cost to secure a U.S. patent. It follows, therefore, that even a smaller cut in USPTO fee levels, i.e., somewhere in the single digit range, would be even more modest in terms of its potential impact on the total costs of patenting.

This leads us to ask the penny-wise-and-pound-foolish question, especially given the non-zero-sum aspect of improving USPTO capabilities and performance.

A high-performing USPTO, able to tackle the examination of patent applications promptly after they are filed – and funded at a level to have the capabilities for doing so – would likely lead to a significant reduction in the direct costs of seeking and securing patents. Increasing fee levels to produce a sustained performance by the Office would mean that patent examination would take less time – potentially much less time – and would result in fewer iterations in the examiner-application communication process that typically precedes the final allowance of a patent application. This could mean a significant reduction in what is typically the most costly aspect of securing a patent, the fees charged by the patent professionals that represent patent applications before the USPTO.

For Lilly, therefore, we see 2013 fee-setting, at least at the macroeconomic level, as a win-win-win for the USPTO, the patent community, and the broader public interest. The Office becomes a better and more attractive place to work, capable of nurturing and demanding higher levels of performance. The user community supports building the capabilities that will mean a more efficient and productive USPTO capable of issuing strong patents more rapidly at an overall lower cost to patent applicants. And, of course, the public benefits both from the more favorable environment for protecting innovation and from the more effective administration of the patent system.

There is a final dimension to Office fee-setting that provides a similar tradeoff between investments needed over the short term and potential savings for users over the longer term. For the first time in many decades, the United States has a substantive patent law that is at the forefront of the best thinking on how to define the principles for establishing whether a patent should be held valid or not. With the AIA, we have stripped out of our law the subjective elements of the law of patent validity, as well as the non-transparent aspects under which the right to a patent could be forfeited based upon the secret or private activities of either the inventor or of competitors working in the field of the invention. In the 21st century, our former patent law lagged the rest of the world in transparency and objectivity in the parameters defining what makes a good and valid patent; it denied us the leadership role globally we rightly deserve.

Moreover, with the AIA, the United States has further solidified its position as having a substantive patent law most favorable to inventors who may elect to publicly disclose an invention before applying for a patent or who work in teams or with collaboration partners in creating new and potentially patentable technology. In an era when many inventions are made through such collaboration and when facile means exists for public dissemination of information, such inventor- and collaboration-friendly features again critically define what should lie at the essence of a 21st century patent law.

With what I and many others have described as the world's first 21st century patent system, the United States is now positioned to lead the efforts at greater international patent harmonization. As I noted earlier, U.S. interests in stronger and more effective patent laws globally would be best served if the AIA's provisions on patent validity became the mold and model for 21st century patent laws across the globe.

This aspiration – for domestic leadership on international patent harmonization issues – requires USPTO resources be taken from its user-fee collections to fund those efforts. The resources are needed to sustain a USPTO equipped to take the lead in international forums where international agreements on greater patent harmonization can be realized. This requires an investment in people and programs by the Office that, however, will carry a quite modest price tag over the next several years.

If such USPTO-led efforts were to succeed, they could lead to a dramatic reduction in the costs of patenting globally. If patent harmonization succeeded on just the issues of novelty and non-obviousness over the prior art, i.e., the question of whether the invention to be patented was sufficiently different from technology that had already been disclosed by others at the time the patent was sought, the cost savings for patent applicants could be staggering. It would open the potential for a patent application to be examined once under a globally harmonized standard and – with little incremental effort or cost – to be patented many times – in many countries around the world that might agree to observe the identical patentability standard.

I continue to emphasize the theme of investments being made today that produce positive returns in the years ahead because – in both areas cited above – the relative costs are so modest and the potential returns are so magnificent. Imagine, within a year or so of seeking a patent, not only having a clear idea of what subject matter can be validly patented, but having a sense that those rights could be secured across the whole of the industrialized world!

This prospect, at least in Lilly's view, is one important part of the promise that lies in the provisions of the AIA relating to the financing of USPTO activities and the importance of implementing those provisions in the manner that the Office has proposed to do – prudently and carefully investing today's fees in activities that may profoundly change the face of patenting by the end of this decade.

## THE USPTO MUST RETHINK TWO ASPECTS OF FEE-SETTING POLICY

Just as it is important, we believe, to acknowledge the areas where the Office has made sound choices in implementation of its fee-setting responsibilities, it is of equal importance to constructively criticize the efforts of the Office in areas where it has – at least in Lilly's view – deviated from optimal policy choices. There are two such areas that bear some discussion. In both instances, they raise the question of whether USPTO implementation is at odds with congressional intent.

In very important respects, fee setting is patent policy setting. The Office can implicitly or explicitly set fees based upon policy choices. In addition, fees, once set, have policy impacts. Let me offer two examples below of areas where Lilly believes that

the Office needs to carefully reconsider as its proposed fees are finalized and as those fees once finalized are modified in the future.[19]

**POST-GRANT REVIEW FEE-SETTING BASED ON NUMBER OF CLAIMS**

First, with respect to the new post-grant review procedures, the Office proposed to set fees based upon the number of patent claims that are being challenged by the PGR petitioner. While the Office's rationale for doing so evidences reasonableness on its face, the policy consequences of implementing the fees as proposed would make it financially prohibitive for someone wishing to challenge a patent containing an inordinately large number of nearly identical, nearly redundant claims.

The claims-based proposed fees would have two undesirable consequences. First, they would discourage challenges to some of the most problematic patents issued by the Office – those drafted with a prolixity of claims, often with a Byzantine interrelationship among the claims. Patents of this type can be difficult to challenge in court and the Office's expertise in examining patents with convoluted claim structures make it the superior venue for addressing important issues over the validity of such patents. Second, the proposed fee structure would likely have the effect of encouraging patent applicants – who might seek to reduce the prospect that their patents might be effectively challenged in a post-grant review proceeding – to craft more larger and elaborate claim structures.

Both these outcomes would be undesirable. A better policy choice would be to set the fees for a PGR petition at a level that was independent of the number of patent claims challenged, but focused instead on the number of issues of patent validity for which the review was being sought, or simply setting the PGR petition fee.

Based on the public input that the Office has received on this issue, it appears that the Office will reconsider its proposal for having a fee structure for post-grant review based upon the number of claims for which a review is being sought. If it does so, it will

[19] In identifying areas where we believe that the proposed fees represent inferior policy choices, it is useful to reflect on another aspect of the implementation efforts of the Office that are of particular relevance to the Office's fee-setting efforts, but apply with equal force to all its AIA implementation activity. The Office has gone out of its way to facilitate criticism of the choices it has made in implementation. This has happened because of the transparency of the Office's efforts and, indeed, the accessibility of the Office and its senior leadership throughout the process. It is possible for members of the public to comment in meaningful ways on the approach to each of the key AIA implementation issues in large measure because of the commendable candor and openness with which the Office has operated. The Office has additionally offered in open forums much detail about the background and rationale for its proposals. On many issues, its thought processes and its considerations based upon its own internal workings have been freely discussed with the user community. By making its thought-processes known, it has facilitated criticism of the Office's proposals – and encouraged back-and-forth dialogue. The transparency and candor with which the Office has approached its fee-setting and other rulemaking efforts is particularly laudable because patent policy is among the most important public policy impacting the long-term economic prosperity of the United States. Indeed, as noted above, the authority given to the Office to set fees for services it provides the Office no less than the authority to set patent policy: which activities within the Office are subsidized – and by how much – as well as which activities will be disproportionately burdened by fees in excess of any costs carry profoundly important policy implications.

produce a level playing field for patent challengers that might require a modest increase in the cost for all PGR petitions. In doing so, the Office could assure that it would have the resources needed in the event that a post-grant review that sought review of a larger number of patent claims required more resources from the Office than a review involving only a small number of patent claims.

Such an outcome, particularly in the initial phases of development of the Office's PGR capabilities would appear to have a preferable set of consequences as a matter of policy. If the use of PGR was modestly deterred because of a somewhat higher petition fee in the early going, the lower utilization of PGR initially would afford the Office the time needed to build its capabilities, and might help assure that the petitions being filed did not exceed the Office's capacity to handle them. Moreover, over the longer haul, it would afford the Office with information needed to titrate fees for PGR in order to strike the optimal policy balance, so that whatever subsidy might be appropriate would neither unduly encourage nor unduly discourage PGR use based on the fee level being set.

**SUPPLEMENTAL EXAMINATION – LIMITATION ON ITEMS CONSIDERED**

A more concerning aspect of the Office's fee-setting activities relates to the new supplemental examination procedure. Here the Office has been explicit that it is setting fees in a manner calculated to moderate or even discourage the use of supplemental examination: "Set supplemental examination fees slightly above cost to encourage applicants to provide all relevant information during initial examination, which facilitates compact prosecution"[20]. Although perhaps not self-evident, such a statement turns sound logic and good policy on its head and represents a most unfortunate development.

Why so?

One of the grave challenges facing the U.S. patent system is not that patent applicants provide too little information to patent examiners, but most patent applicants provide too much information, particularly too much information of little or no consequence to patentability. To compound this issue, patent applicants have a disincentive to provide any characterization or commentary on the potential significance of the information that is provided. "Tell much, say little" or "over-disclose, under-explain" are typical patent procurement mantras that are observed by the wisest patent applicants today. In the ultimate irony, it is the Office's own "duty of candor" (and the "inequitable conduct" unenforceability defense in the courts) that impedes the type of focused, candid patent applicant-patent examiner dialogue that might lead to better examined patents.

Supplemental examination was conceived in part to actually reverse the incentives under the current law to *over-provide* and *under-analyze* information that sometimes appears by the shovel full in USPTO patent application files. In a nutshell, the availability of the "safety valve" of supplemental examination was intended to encourage

[20] http://www.uspto.gov/aia_implementation/fee_setting_-_ppac_hearing_executive_summary_7feb12.pdf, slide 8.

patent applicants to provide only truly important information to patent examiners – that which is needed to assure patent examination is complete and accurate – and to be able to reasonably characterize the significance of the information being provided.

Then, after the patent issues, if it appears that information may have been missing, inadequately considered or incorrect in the original examination – and may raise a question of patentability – the patent owner can return to the USPTO, have information considered, reconsidered or corrected in the original examination record – and, if necessary have the entire patent reexamined to eliminate any invalid claims.

The win-win-win outcome for the patent applicant, patent examiner, and the public lies, therefore, in assuring the viability of the supplemental examination mechanism, not discouraging its use through fee-setting authority. Properly encouraged, the new procedure would make the initial patent examination more efficient for patent applicants and patent examinations, more focused on information important to patentability, and more compact. It would also assure that no question of patentability would remain for commercially important patents in which the initial examination might not have considered all such information or considered it adequately or correctly.

Thus, Lilly would urge that the USPTO rethink its implementation of supplemental examination from the ground up to assure its viability and accessibility to patent owners. We have done so in a submission directly to the USPTO.[21]

The Lilly submission lays out much of what is wrong with the USPTO's proposed rules. At the top of that list, however, is the inexplicable limitation of the request for supplemental examination to 10 items of information per request. This limitation may mean that patent owners will make the work of the USPTO more difficult by forcing the Office to coordinate information contained in multiple requests, and excessive costs on patent owners by forcing them to pay separate fees for the multiple "supplemental examination" filings and assuring that appropriate cross-references are made between the information in one filing that can only be completely understood by considering information contained in a separate filing.

***Implementing the AIA – The Next Generation of Substantive Legislative Improvements***

In the current issue of the magazine of the Intellectual Property Law Section of the American Bar Association, I raised the topic of post-AIA statutory changes to the AIA.[22] The title of the article was "*The Remaining "To Do" List on Patent Reform: Consolidation and Optimization*." The thesis of this article was a simple one:

> There are, I believe, some near-term opportunities for further legislative intervention in the patent statute that would not require either rethinking or retreating from the reforms already enacted into law. Rather, they represent

[21] See http://www.uspto.gov/patents/law/comments/sup_exam/xs_e-eli_20120322.pdf.
[22] Robert A. Armitage, *Perspective*, ABA IPL Section Landslide 4:5 (April-May 2012) at p.1.

areas for further change that could *consolidate* the many achievements of the AIA and, indeed, *optimize* their potential for greater transparency, objectivity, predictability, and simplicity in the operation of the U.S. patent system.

Let me briefly outline those provisions and their potential importance to the fullest possible realization of the AIA:

- Replace the requirement for an "oath or declaration" of the inventor with a patent applicant's express statement that it has obtained the right to file the application for patent from the inventor that the patent applicant has named in its application for patent. This would replace a pure formality, nowhere else required in the world, with an affirmative representation from the patent applicant that could be routinely provided with each new patent filing.

- Remove the option for a patent applicant to opt-out of mandatory publication of pending patent applications at 18 months from the original patent filing. This option, which had a justification under the pre-AIA patent law (albeit a strained one), simply has no place in a patent system where an inventor's patent filing, once published categorically bars any later-filing patent applicant from obtaining a patent either on the inventor's disclosed invention or on any subject matter that would constitute a trivial or otherwise obvious variation on the disclosure in the patent filing. Rather than exposing the inventor whose application was published to a "priority" challenge from a later-filing patent applicant spurred into action by the publication of the earlier-filed patent application, the AIA provides this categorical protection for inventors who seek patents—but only once their patent applications are published.

- Eliminate the complex provisions and practices that exist around "patent term adjustments" (35 U.S.C. §154(b)) based on delays in the USPTO issuing a patent. With the emergence of "priority examination" and its success in securing prompt issuance of patents for patent applicants desiring the patenting process to move quickly to a decision, there is little justification remaining for adjusting a 20-year patent term based upon delays in granting a patent.

- Move the U.S. patent system to the international norm of annual patent maintenance fees, in place of the current practice in which these fees must be prepaid for multiple years into the future at various (arbitrary) periods after a patent has issued. Doing so would move U.S. patent law to the international norm and allow more inventors to keep more patents for longer periods of time by avoiding the need to pre-pay fees for keeping patents in force years in advance.

- Repeal the "best mode" requirement. Congress eliminated the consequences of failing to comply with the "best mode" requirement for good reason – it was among the most absurdly subjective requirements in the U.S. patent law and its

repeal was recommended not once, but twice, in the National Academies' recommendations for a 21st century patent system. It is another impediment to the United States fully assuming a leadership role on international patent harmonization.

- End, once and for all, the plague of "inequitable conduct" allegations in patent infringement litigation. For a host of reasons, this doctrine in the post-AIA world makes less, not more, policy sense than it ever did. If a fraud is perpetrated on the USPTO in order to issue an invalid patent, then declaring the invalid patent cannot be enforced is not deterrent to the fraud – it is merely a redundant punishment. If the supposed fraud resulted in the issuance of an entirely valid patent – the same patent that would have issued absent the supposed fraud – then the punishment is absurdly draconian. Indeed, it is simply perverse to speak of a "fraud" when the only fruits of the supposed bad conduct are obtaining an entirely valid, fully justified patent property right. By ending the "inequitable conduct" defense through remedial legislation the United States would – again – be moving to the international mainstream of patent law, where such a doctrine has no counterpart.

If these half-dozen reforms could be accomplished, U.S. patent law would become even more transparent, objective, predictable and simple. Its contours would be further aligned with "best practices" that domestic constituencies in the patent community have long urged be placed into U.S. law. Our law would be more aligned and better harmonized with "best practices" outside the United States. Indeed, the 2004 recommendations of the National Academies of Science on the needs of a 21st century patent system would be more fully realized.[23]

***Implementing the AIA – Technical and Other Conforming Changes to the New Law***

For a patent law as long and complex as the AIA, there are surprisingly few areas where Congress should consider changes of a technical or conforming nature to eliminate drafting errors or assure the effectiveness of new provisions placed into law. Several of the more important areas where technical or other conforming changes to the new law have been under discussion deserve at least some brief explanation.

**JUDICIAL ESTOPPEL PROVISION FOR POST-GRANT REVIEW**

The proponents of the new post-grant review procedure introduced into U.S. patent law under the AIA (Lilly among them), see this procedure as a global "best practice." It was designed from the ground up in the AIA largely to avoid the many drawbacks – for both patent owners and patent challengers – of the post-grant opposition procedures in use under the European Patent Convention.

[23] See "A Patent System for the 21st Century," Stephen A. Merrill, Richard C. Levin, and Mark B. Myers, Editors, Committee on Intellectual Property Rights in the Knowledge-Based Economy, National Research Council, National Academies of Science (2004).

However, a technical error during the legislative process that resulted in H.R 1249 becoming law inadvertently raised the estoppel from issues raised to include issues that "reasonably could have been raised." This term appears in Chapter 31's inter partes review provisions in §§315(e)(1) and (2), respectively treating estoppel issues relating to further proceedings in the USPTO and civil actions in the courts, as well as Chapter 32's PGR provision in §325(e)(1), treating estoppel issues relating again to further proceedings in the USPTO. However, it's further presence in §325(e)(2), the judicial estoppel provision for PGR, was an inadvertent legislative error that merits prompt correction.

S. 23, which passed the U.S. Senate by a 95-5 margin on March 8, 2011, contained a corresponding §325(e)(2) that limited the judicial estoppel in PGR to "any ground that the petitioner *raised* during a post grant review of the claim that resulted in a final written decision … ." [Emphasis added.] This was a provision that was specifically supported – and the alternative inadvertently introduced into H.R 1249 was specifically opposed – by the major proponents of comprehensive patent reform in this Congress – the Coalition for 21st Century Patent Reform, the Intellectual Property Law Section of the American Bar Association, and the American Intellectual Property Law Association, among others.

The provision now in §325(e)(2) threatens to turn PGR into a dead letter, with an estoppel so draconian in character that it would be highly problematic for a patent challenger to use. The reason is quite simple – while inter partes review is limited to issues of novelty and non-obviousness based upon published materials only – creating a narrow (albeit desirable) reach for an "or reasonably could have been raised" estoppel, the PGR proceeding cover any and every possible defense that could later be raised against a patent in the courts.

Thus, if nothing else is accomplished through a technical amendments process, this technical mistake in the transit of H.R 1249 through Congress should be remedied.

## "GRACE PERIOD" ENHANCEMENT – PUBLISHING AS PRIORITY

While the inventor- and collaboration-friendly features of the AIA's new definition of "prior art" in §102 already form a world-leading framework for defining a patent law for the 21st century, recent calls from the university community have raised the issue of whether the provisions of H.R 1249 might have better protected inventors under a relatively rare hypothetical situation in which the inventor who has already published on an invention then decides nonetheless to apply for a patent but discovers that in the interim between the inventor's own publication and its patent application filing date that someone else has either applied for a patent or published on subject matter that was both discovered and created independently of the inventor and was somewhat different from anything that the inventor published and then subsequently sought to patent.

In this situation – where the independent work of an independent creator that is published or contained in a patent filing *differs* from what an inventor has *earlier*

*published and later sought to patent* – the intervening publication/patent filing to the extent of any differences from what the inventor earlier published remains as prior art to the inventor's later patent filing and, thus, might render a claim to what the inventor has earlier published in its later patent filing obvious and unpatentable.

This situation can arise because an earlier publication by a inventor, for "grace period" purposes is not given the same effect as the inventor would have enjoyed had the inventor sought a patent (*e.g.*, filed a provisional patent application) in lieu of or contemporaneously with the publication of the invention. Nothing in the adoption of the first-inventor-to-file principle is, however, in any way or to any extent inconsistent with providing that an inventor disclosing an invention in a printed publication be given all the benefits, at least for "grace period" purposes, as though a provisional patent filing had been undertaken by the inventor.[24]

While it is critical to not provide an inventor who publishes any type of advantage over an inventor who makes a provisional patent filing, a statutory change providing greater parity between the two could represent good patent policy. The mechanism for doing so could be to provide an inventor who has published on an invention to seek a patent during the one-year period after the publication and treat the publication as though it had constituted a provisional patent filing for whatever it disclosed. This would mean that any claimed invention in the inventor's nonprovisional patent filing could claim the date of the publication as the effective filing date of the claimed invention *if the disclosure in the printed publication would have been sufficient to establish the right to such an effective filing date had it appeared instead in a provisional patent filing.*[25]

---

[24] The rationale for doing so was set out 30 years ago, as the prime mechanism for effecting a grace period as part of a first-inventor-to-file system. See, Robert A. Armitage, *Reform of the Law on Interference: A New Role for an Ancient Institution in the Context of a First-to-File System*, 64 J. PAT. OFF. SOC'Y 663 (1982) at pp.678-9: "As a remedy from the harsh, patent-defeating effect which arises when an inventor's own publication is immediately an element of prior art, new section 119 provides that such prior publications can become the basis for a new right of priority. When this right of priority is asserted in accordance with new section 119(a), the inventor's effective filing date for his patent application directed to the published invention becomes the publication date itself. In this manner, the prior art effect of publication is avoided and a new type of one year grace period is effectively introduced into the statutory scheme, one consistent with the first[-inventor]-to-file principles of prior art determinations enumerated above."

[25] A possible statutory mechanism for accomplishing this result is the following:

GRACE PERIOD.—Section 102(b) of title 35, United States Code, is amended by inserting at the end:

"(3) DISCLOSURES FOLLOWING THE INVENTOR'S PUBLICATION DESCRIBING A CLAIMED INVENTION.—A disclosure shall not be prior art to a claimed invention under subsection (a) if—

"(A) before such disclosure was made available to the public or was effectively filed, the claimed invention had been described by the inventor or a joint inventor of the claimed invention, or another who obtained the claimed invention directly or indirectly from the inventor or joint inventor, in a printed publication;

"(B) the effective filing date for the claimed invention, disregarding any claim for priority under section 119, 365(a), or 365(b), was one year or less from the date the claimed invention was described in the printed publication; and

"(C) the description in the printed publication would have been sufficient under section 119(e)(1) for establishing an effective filing date for the claimed invention under section 100(i)(1)(B)."

The Committee should give careful consideration to the further enhancement of the "grace period" to address the concerns that have been raised within the university community. Appropriately implemented, the additional protection for inventors who inadvertently publish before seeking a patent is consistent with the principle that the patent law should be as inventor-friendly as possible, given the overarching responsibility that patenting rules should also remain transparent and objective.

Moreover, the public interest otherwise would be well served by the "printed publication = provisional patent filing" for effective filing date purposes by encouraging inventors who do publish not to "double stack" the one-year periods that can delay the start of the 20-year patent term until a nonprovisional patent filing takes places, as well as delay the timing of an 18-month publication of pending patent applications.

**PRIOR USER DEFENSE – PROTECTING DOMESTIC MANUFACTURING**

One of the achievements of the AIA that appeared to be beyond reach until very near the end of the legislative road to enactment was improvement to the prior user defense. Fortunately, Congress was able to expand the prior user defense by recrafting the provisions of §273 from the ground up. Importantly, the archaic requirement for explicitly establishing a "reduction to practice" was removed, as well as the limitation to patents for methods of doing or conducting business.

However, there are at least three limitations to the defense that continue to dilute the effectiveness of the defense for companies that invest in the United States – creating domestic facilities and employing U.S. workers. These limitations merit removal to assure fair protection of these U.S. operations from belatedly sought patents. I had the opportunity to testify at length in a hearing before the Subcommittee on Intellectual Property, Competition and the Internet on February 1 and described in more specifics during my prior testimony the work that remains undone on this defense:

- Remove the remaining language that restricts the use of the defense to some types of patents. The defense should apply in a non-discriminatory manner to any patent for which commercial activities in the United States have been completed before a patent seeking to disrupt those activities was sought.
- Remove the one-year holdout period that restricts the defense to considering only the commercial activities in the United States that had been completed more than one year before the patent filing.
- Include the ability to rely on the completion of substantial preparations in the United States for commercial use in the United States as a basis for entitlement to asserting the defense against a later-sought patent.[26]

[26] The changes to the post-AIA §273 that would be needed to make needed improvements in the prior user defense could be accomplished fairly simply:

PRIOR USE.—Section 273) of title 35, United States Code, is amended by—

(1) striking "consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process,";

While Lilly stands proudly among those domestic interests that are proponents of strong and effective patent rights, we are equally adamant in our belief that Congress wisely created the prior-user defense against those rights. The effectiveness of the AIA's provisions should be revisited. As I stated in concluding my testimony last February, what appears to be yet missing is the needed consensus for doing so:

> Congress should now look to develop a consensus on three areas in the law that would benefit U.S.-based manufacturers: *opening the [prior user] defense to patent claims of all types, eliminating the 1-year "hold back" period before the defense can be established, and permitting the completion of substantial preparations for commercialization to be a sufficient trigger for asserting the defense*. U.S. patent law should give those who choose the United States as the place to invest in creating manufacturing facilities – and providing jobs for American workers – the same immunity from charges of patent infringement that investors in creating jobs here would enjoy had they instead invested in creating foreign-based manufacturing plants. Let's develop the consensus needed to get this done forthwith.

Lilly would urge the Committee to continue the dialogue, especially with the university community, with the aim of achieving a consensus on the desirability of a simple, balanced and straightforward set of changes to the post-AIA law on the prior use defense. As with the proposals to further enhance the "grace period," changes to the prior user defense will reopen discussions that reached closure with the enactment of the AIA.

On both the "grace period" and "prior user defense" issues, there are good, perhaps compelling, policy reasons for doing so. The immediate task ahead is forging what is good policy into a broader consensus that in fact it is such.

---

(2) striking "at least 1 year" and inserting "or substantial preparations for such use were completed"; and

(3) inserting in subsection (e), at the end—

"(6) DILIGENCE REQUIRED.—Substantial preparations for commercial use of subject matter of a claimed invention shall be deemed to have been completed under subsection (a) only if prior to the effective filing date of the claimed invention —

"(A) diligent efforts had commenced and thereafter continued in the United States until the commercial use of such subject matter was accomplished and

"(B) the activities relied upon to demonstrate completion of substantial preparations were carried out in the United States and constituted the preponderance of the investments required to accomplish the commercial use of such subject matter."

***Tackling the "Inequitable Conduct" Issue As a Final Element of AIA Implementation***

Before turning its attention to the collection of time-urgent AIA implementation issues, the USPTO had proposed rules to address its "duty of candor and good faith," which is also known as its "duty of disclosure." Lilly had the opportunity to provide some detailed comments on this proposed rulemaking.[27]

Although not directly required under any provision of the AIA, it appears highly desirable for the Office to address this "duty" in light of the post-AIA world in which what does or does not determine patentability of an invention is publicly accessible information alone, and the public at large can participate in the patenting process, both before a patent issues and in the aftermath of the grant of a U.S. patent by the Office.

Lilly recently outlined the gist of what the USPTO might do with its "duty of disclosure." Under the AIA, it must become a duty placed with equal measure and effect both upon patent applicants and members of the public who will be challenging the right of the inventor to secure or retain a patent. Under the Lilly proposal, the USPTO would regulate the duty by:

> • Imposing no incremental duty or responsibility on *anyone* appearing before the USPTO other than compliance with 18 U.S.C. § 1001(a).
>
> • Assuming [for itself the] full responsibility for identifying and applying information available to the public that is material to the examination of any application for patent.
>
> • Requiring that, should patent applicants wish to cite publicly available information to the USPTO, such information must have particular significance and its relevance must be identified.
>
> • Providing that any individual's duty or responsibility to supply information to the USPTO in a matter or proceeding is satisfied by providing the information to a registered practitioner retained to represent the individual in the matter or proceeding.
>
> • Limiting any duty or responsibility to provide to the USPTO non-public information solely to information required to reach an accurate and correct determination of the issue before the USPTO.
>
> • Stating by rule that information available to the public, but not cited by the USPTO [during patent

[27] See Letter from Robert A. Armitage, Senior Vice President, Eli Lilly and Company, to The Honorable David J. Kappos, Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office, (Sept. 19, 2011) at http://www.uspto.gov/patents/law/comments/x_ac58-e_elililly_20110919.pdf.

> examination], is to be deemed to have been considered by the USPTO, but found to be of no relevance.[28]

This approach would, of course, much more closely align USPTO practices with those of other countries that have long imposed only transparent requirements for patenting and long permitted public participation in the patenting process. It would discourage excessive, largely defensive disclosures of information to the USPTO. It would pave the way for the USPTO to impose meaningful requirements in situations where applicants would elect to provide publicly available information. Again, as with other aspects of AIA implementation, it could allow the United States to assume a role as the mold and model for patent systems around the world.

Thus, when the rulemaking required to implement the AIA is completed, Lilly would urge the USPTO to turn its attention back to the possibility of more efficient and complete patent examination for the post-AIA patents – those patents that will be subject to the AIA's largely transparent and objective patenting rules – through a 21st century approach to the patent applicant's duties and responsibilities in connection with the patenting process. In doing so, it can leverage public participation with patent applicant incentives for more concise, relevant, and otherwise meaningful disclosures of information to patent examiners.

***Finalizing the Proposed Rules for Implementing Key AIA Provisions***

**SUPPLEMENTAL EXAMINATION RULEMAKING**

One of the most significant set of accomplishments in the AIA was the new ability, after a patent has issued, for a patent owner to seek to have information considered, reconsidered or corrected in connection with the Office's examination of that patent. Where the patent owner comes forward with such information, the Office is first given the task of determining if a substantial new question of patentability is created by the information being considered, reconsidered or corrected and, if so, then to reexamination of each such issue so that any unpatentable claims might be removed from the patent.

Self-evidently, use of such a procedure has significant public benefits. The examination record for the patent becomes more complete and correct. The assurance that the claims remaining in the patent are valid ones is reinforced – the patent claims will have been twice examined by the Office. In subsequent patent litigation, the courts will be deciding the validity of the patent on the enhanced examination record and will not be faced with pleadings of "inequitable conduct" based upon the missing or incorrect information in the original examination record if the information was considered, reconsidered or corrected in the supplemental examination.

---

[28] Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, supra, at p. 132.

Congress created these new proceedings with the intent that they would be used by patent owners – they are remedial provisions whose provisions ought to be accorded a liberal construction. Viewed in this light, there are a pair of features of the Office's proposed rules that require changes in the final rulemaking for these provisions to reach their promise of improving patent quality, patent reliability, and patent system integrity:

- The Office would limit a single supplemental examination request to 10 individual items. There should be no limitation. Instead, the Office should consider a fee-per-item charge for items in a petition in excess of 10.

- The Office imposes burdensome requirements on requesters. The purpose of the supplemental examination is to identify whether a substantial new question of patentability exists. This is the same type of issue (in a more limited context) that the USPTO determines on a regular basis in ex parte reexamination (chapter 30, title 35). What should be required in a supplemental examination request should be a simple and straightforward discussion of the information to be considered, reconsidered or corrected so the Office can readily reach that determination.

There are creative ways in which the Office might use supplemental examination to encourage patent applicants to make more focused, concise, and relevant disclosures of information in the original patent examination – to make it more compact and efficient – using supplemental examination as a "safety valve" where information of secondary importance might be given consideration in the case of patents of particular commercial significance. What follows is a description of the potential in supplemental examination that might be realized, given a USPTO willingness to pursue a more creative implementation of the new statute:

> The broad availability of supplemental examination, coupled with its rapid timeline, affords the USPTO the ability to offer applicants new and creative patent prosecution options that make use of the availability of supplemental examination. One such option merits consideration.
>
> For a patent applicant desiring that the USPTO consider a substantial number of potentially relevant items that might qualify as prior art, the USPTO could provide, by regulation, that such items could be submitted under a two-tiered approach. The tier one items could be a limited number of the most pertinent disclosures, to which the actual examination of the patent would be confined. Tier two items would be remaining items that potentially qualify as prior art. For tier two prior art, before enforcing the patent, the patent applicant may wish to assure that they have been considered by the USPTO and affirmed as raising no substantial question of patentability.

Rulemaking might provide that patent applicants be permitted to defer submission, to the USPTO, of all tier two items until either after the notice of allowance has been secured or the patent has issued. In order to do so, the patent applicant would be permitted to make an election to submit only items deemed by the applicant to be of the most relevance to patentability. A patent applicant, making such election, would be required to submit a concise description of the relevance or significance of each tier one item as part of the election. By electing to provide to the USPTO any tier two items only after allowance or issuance, the applicant would be deemed, by the USPTO, to have requested supplemental examination with respect to such tier two items immediately upon grant of the patent.

Again by regulation, the USPTO could provide that all fees for the supplemental examination would be waived, except in the situation where the supplemental examination triggered a reexamination of the patent and the reexamination required some modification of the claims of the patent. In such a case, all required fees for supplemental examination would fully apply.

The impact of such a procedure, in the vast majority of circumstances, would be a more efficient initial examination of the application for patent, because of the more focused and complete assessment of the possible prior art provided by the patent applicant. Additionally, the examined application could issue more promptly. Once issued, the supplemental examination, which would commence immediately upon issuance, would then assess the significance of the tier two items. In most situations, the secondary items should not uncover any substantial new question of patentability. Thus, typically, the supplemental examination could conclude within three months after the patent issued.

If a follow-on reexamination were needed because a question of patentability had been detected, it presumably would be limited to one or more relatively narrow issues, and be relatively quickly and efficiently resolved. If any material prior art were identified in tier two, such that the patent claims required modification, then the patent applicant could not be subject to unenforceability for misconduct later, but would pay the full-freight fees for the supplemental examination/reexamination.

Without a rulemaking that encourages the use of this new procedure, it is certain to delay or defer the ability for it to realize its full promise. Lilly looks forward to a set

of final rules designed to assure that the proceeding will be useful to patent owners and assure that supplemental examination is set to realize its enormous promise for improving the quality of U.S. patents.

## THE "INVENTOR'S OATH" AND "ASSIGNEE FILING" RULEMAKING

Another area where the proposed USPTO implementing rules need a change of direction as the final rulemaking approaches lies in the efforts to implement the new assignee filing regime and simplify the statements required of the inventor in connection with an application for patent. The deficiencies in the Office's proposed rules have been well documented. Lilly itself filed comments on the rules, attempting to lay out a path forward that would be far simpler for the Office to administer and simpler for patent applicants to use in seeking patents.[29]

This is an area where the Office's persistence in a transparent process, marked by affirmative outreach to the patent community and constructive engagement through USPTO-private sector dialogue appears poised to pay huge dividends for the patent system. It is clear from statements USPTO officials have made in public forums that they are considering several alternatives to the rules as proposed. They have indicated support for technical amendments to the AIA that would further simplify the task of the Office and the effort required of patent applicants.

Lilly's hope is that when the final rulemaking appears it will implement the assignee filing provisions of the AIA in the most complete manner as the Office can muster and that it would limit the extent of any required inventor's statements to what is essential to assure that no fraud is being practiced, and whatever patent filing is made is an inventor-authorized one.

Otherwise, Lilly has urged that the burden of providing all other information needed for a timely and efficient examination of applications for patent be placed on the patent applicant – which typically will not be the inventor but an entity to whom the inventor has assigned the right to seek and obtain a patent.

If the final rules accomplish this objective in the fullest possible manner, U.S. patent law would be largely harmonized with patent laws outside the United States on the issue of this type of formality in the patenting process. Again, as the United States seeks to be a leader in adopting international "best patent practices," minimization of formalities required for a complete patent filing is an essential component.

## IMPLEMENTING THE NEW PGR AND IPR PROCEEDINGS

Among the most important policy choices that the USPTO will be called upon to make will be in the new post-issuance proceedings authorized under the AIA. The rulemaking for the new post-grant review and inter partes review proceedings must walk along a fine line in dealing with a host of implementation issues. They must, first and

[29] http://www.uspto.gov/patents/law/comments/oath/xo_e-lilly_20120305.pdf.

foremost, afford patent owners a full and fair opportunity to defend the validity of their issued patents. Of no less importance, however, is the objective of providing patent challengers a full and fair opportunity to present evidence and arguments contesting the validity of issued patents.

Fairness and balance are not the only constraining factors in this rulemaking. These procedures must be concluded within a statutory timeframe of one year. Additionally, these procedures need to be economical for their participants. Rules must be cost-conscious of both the USPTO resources devoted to these proceedings and the cost of participation by those who are parties thereto.

When the Office issues its final rules in a few months, it is likely to be only the first iteration of what will be an ongoing effort to rethink and refine how these proceedings can be best crafted. Experience with these procedures will, in fact, be the best teacher – for both the USPTO and the participants in these proceedings – for drafting the optimal set of regulations under which they will be conducted. Thus, for the USPTO and for the patent user community the question to be asked is what the *initial* round of rulemaking on these procedures should provide? What is the best starting point from which further iterations over the years can be made that will optimize the fairness, balance, timing and economics of their use?

Lilly has strong views on what the initial effort at rulemaking should look like. Indeed, the best expression of them is in the joint submission of the Post-Issuance Working Group chartered by the Intellectual Property Law Section of the American Bar Association, the American Intellectual Property Law Association and the Intellectual Property Owners Association. These three groups have one important common element – they represent patent constituencies that will both be patent challengers petitioning to institute PGRs and IPRs and the patent owners who will be defending against those challenges. Moreover, the working group brought a wealth of real-world litigation experience to bear of its recommendations for first-round rulemaking.

Our unqualified support for the Post-Issuance Working Group's efforts is based on large measure on our belief that this may not be the final placement of the fulcrum for balancing these PGR/IPR proceedings, but is the best manner in which to set out the rules under which proceedings should be governed initially and with which to gain the experience needed to further titrate the governing procedures. There are several critical elements to the Post-Issuance Working Group's efforts that give us the confidence that the first-generation of rulemaking should incorporate these suggestions *in toto*.

Foremost in our minds are the issues of tightly controlling discovery once these proceedings are instituted and assuring that unnecessary procedural steps do not make the costs of participation too great for patent applicants and the burdens of administration too onerous for the administrative patent judges who will be assigned to handling them. The brilliance of the proposals of the Post-Issuance Working Group is that they address the knottiest issues in the most efficient manner for all parties involved.

The Post-Issuance Working Group proposed that the petitioner lay out the complete case against the patent together with the petition for instituting the proceeding. Additionally, without any required motion practice, the Group proposed that the petitioner would provide such additional information as would be necessary for a fair proceeding for the patent owner.

As one example, if the patent challenger were to build its case on obviousness, i.e., attempted to present expert evidence with its petition that the invention would have been readily apparent to a person of ordinary skill in the art requiring only routine skill and no undue effort to arrive at the patented invention, then the patent challenger would be obligated to reveal facts known to it that would be contrary to and rebut these assertions.

For example, if the patent challenger's own engineers had repeatedly attempted and failed to solve the problem that was resolved through the patented invention, such facts represent objective criteria that would support a determination that the patented invention was not in fact obvious. As another example, consider the situation where a patent challenger hired five experts, working in isolation from one another, to attempt to repeat the key teaching in the patent on which its patentability (*e.g.*, "operability under §112(a)) would depend. In such a case, the petitioner could not submit the affidavit of the one (and only one) of the five experts who failed to confirm "operability" *without also providing an initial disclosure* of the work done its four remaining experts whose experiments categorically confirmed the patent's operability. Forcing the patent owner into a cat-and-mouse discovery motion practice after the institution of the PGR would only encourage this type of gamesmanship – and gross unfairness – that the working group's proposed rules so effectively would operate to discourage.

On the basis of the foregoing, the Post-Issuance Working Group proposed that the petitioner would be obliged to make an initial disclosure of precisely this type of information so that the patent owner would not need to seek discovery of this type once the PGR or IPR was instituted. Since it is precisely the type of relevant evidence that the patent owner would be entitled to discover if obviousness were raised as a defense to a lawsuit alleging infringement of a patent, it is the type of evidence that needs to be efficiently provided to the patent owner in defending the same type of invalidity allegation in a PGR. The attempt of the Post-Issuance Working Group is to limit the fodder for discovery disputes post-institution by getting all the relevant facts and evidence before the Office and the parties as the proceedings are being instituted.

Available discovery – and the limitations thereon in key respects (who can be deposed and how long such depositions may be) – should be explicit in the rules. The administrative patent judge assigned to a proceeding should have authority to address special circumstances. The underlying principle at work is that discovery – and initial disclosures – should be mandated to assure fairness, but strictly limited to defined parameters otherwise. *It should not be the result of a case-by-case determination, requiring parties to request discovery that should be available as a matter of course, or*

*to respond to requests for burdensome discovery requests – and be forced to bear the costs of doing so.*

If a discovery regime so constructed proves with experience to be less than optimal, it would be relatively easy to titrate, by affording administrative patent judges greater flexibility and greater control over individual PGR/IPR proceedings in future rulemaking. However, it is unlikely to be as easy to reverse course – to move closer to the working group's proposals – if the starting point is greater flexibility and more complete control before the administrative patent judges.

PGR and IPR proceedings would be rendered both fair and administratively feasible under relatively strict limitations on post-institution discovery for two reasons. The first reason, of course, is the requirement that all of the patent challenger's evidence of invalidity must be provided with the petition and the types of initial disclosure that would normally complete the patent's validity picture would come pre-institution, not on post-institution discovery motions. The second reason is that the new proceeding inherently addresses issues where discovery of the inventor or the patent applicant is most typically unnecessary. Although PGR is open to all issues of patent invalidity that an accused infringer could raise in defending a patent infringement lawsuit, only those patents fully subject to the AIA may be brought into PGR.

For AIA patents, all the so-called "loss of right to patent" provisions are repealed. Patent owners can no longer avoid prior art that would otherwise invalidate a patent by asserting an earlier date of invention. Additionally, only information accessible to the public can constitute prior art capable of invalidating a patent. The other requirements for a valid patent are entirely objective – and are based on what the patent disclosure would enable a skilled person to accomplish based on the patent disclosure and how such a person would understand and interpret the patented invention. Nothing the inventor or the patent applicant did or did not do, knew or did not know, contemplated or did not contemplate will ordinarily be of any possible relevance to the validity of the patent.

Hence, in almost every situation, the patent challenger can present its complete invalidity case in its petition for instituting a PGR – since patent invalidity will generally turn solely on what information was publicly accessible before the patent was sought and post-institution discovery of the patent owner will typically not be appropriate, much less relevant, except to the extent the patent owner engages experts to support its contentions with respect to the validity of the patent. Given the Post-Issuance Working Group's proposals are accepted, the patent challenger will be in a similar posture. The patent owner, except for deposing individuals indentified in the PGR petition as experts, or having factually relevant information, should have little or no need for additional discovery in a typical PGR proceeding.

As earlier suggested, this Post-Issuance Working Group's proposal may prove optimal in striking the right balance and may prove to be the epitome of efficiency. Absent real-world experience with these proceedings, the opposite conclusion cannot be dismissed out of hand – that the front-loading of all invalidity evidence coupled with an

initial disclosure of the types of potentially relevant information otherwise operates poorly in practice.

However, as between a post-institution, motion-intensive discovery model in the proposed rules and a pre-institution, front-loaded, initial-disclosure model advocated by the Post-Issuance Working Group, Lilly sees the best hypothesis to test as PGR and IPR are being rolled out initially is the latter approach. It would be far easier for the Office to titrate down the Post-Issuance Working Group's proposal than to find a path to morph the proposed rules into the Post-Issuance Working Group model if that (or something close to it) is indeed the best path forward.

***Conclusions***

The Committee should take justifiable pride in its efforts to see H.R 1249 become the Leahy-Smith America Invents Act. It holds enormous promise for the United States. It places the United States in the leadership position globally on patent system operation and patent system policy issues. The efforts of the United States Patent and Trademark Office to implement the new law should be informed both by Congress' manifest intent to create a more transparent, objective, predictable and simple patent law and by the need to make changes here that can become the mold and model for the rest of the world to emulate.

The next important step along this path will be the publication of draft patent examination guidelines for implementation of the first-inventor-to-file "prior art" standards set out in new §102 of the patent statute, followed by final rules. It will be important that the USPTO's examination guidelines clearly reflect the congressional intent that the United States have a transparent and objective law on patentability and that the Office's final rulemaking otherwise vindicate the tremendous promise of our remarkable new patent law.

May 16, 2012
Indianapolis, Indiana

Lilly
Answers That Matter.

**Appendices to the**
Statement of
Robert A. Armitage
Senior Vice President and General Counsel
Eli Lilly and Company, Indianapolis, Indiana
Before

The United States House of Representatives
Committee on the Judiciary
On

"Implementation of the Leahy-Smith America Invents Act"

Wednesday
May 16, 2012

Excerpts from *Understanding the America Invents Act and Its Implications for Patenting* (AIPLA Q. J. 40:1, 2012)
pp. A2-A7

*Landslide* Magazine Perspectives on the America Invents Act (5-Part Series; 2011-2012)
pp. A8-A16

The America Invents Act: Will it be the Nation's Most Significant Patent Act Since 1790? (Thomson Reuters – Patents in the 21st Century, 2012)
pp. A17-A19

## I. OVERVIEW—AN HISTORIC REFORM, CAPPING A THREE-DECADE REVOLUTION IN U.S. PATENT LAW

On September 16, 2011, Public Law 112-29,[1] the Leahy-Smith America Invents Act ("AIA") became law. Congress acted "[t]o amend title 35, United States Code, to provide for patent reform."[2] The new law represents a comprehensive reform of the law of patentability and patent enforceability. In addition, the AIA makes dramatic changes to the role of the public in the patenting process.

For inventors, patent applicants, patent owners, and the patent professionals who assist them in the process of seeking and securing patents, it is important to understand the new law and its implications for patenting. A review of the historical context from which these new patenting rules arose can assist in gaining a fuller understanding of Congress' mission to reform patent law.

In a nutshell, the AIA completes a 30-year journey to remake, in their entirety, each of the foundational assumptions underlying the operation of the U.S. patent system.[3] It is no exaggeration to assert that the patenting process in the United States, as it existed from the 1790s through the 1970s, was stunningly different from the new patenting regime resulting from the AIA's comprehensive reform measures.

### A. *Problems with the Pre-1980 U.S. Patent System*

The old patenting process in the United States was a secret one, hidden from public view. From 1836 until the start of this century, determining the patentability of an invention consisted exclusively of a secret, non-public

1 Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

2 *Id.*

3 *See generally* Robert A. Armitage, *Reform of the Law on Interference: A New Role for an Ancient Institution in the Context of a First-to-File System*, 64 J. PAT. OFF. SOC'Y 663 (1982) (making the case for creating a comprehensive and coordinated set of reforms to U.S. patent law, centered on adoption of the first-inventor-to-file principle, mandatory publication of patent applications at 18 months from initial filing, and a patent term that provided patents would expire 20 years from the initial patent filing). This paper was based on the author's work to secure support from the American Intellectual Property Law Association for these reforms and was initially drafted during his tenure as chair of its Patent Interference Committee. *Id.* at 663.



dialogue between the patent applicant and the patent examiner.[4] Indeed, except during the past decade, the first inkling that a U.S. patent might issue for an invention often arrived on the very day the patent on the invention was actually issued.[5]

In addition, prior to the AIA, critical information that might be necessary for a patent examiner to analyze to determine the patentability of an invention could include secret information, unavailable to the public.[6] Private information only known to the inventor or patent owner could be highly material to the patent examiner's decision to allow a patent to issue. This dependency on an applicant's private knowledge made it critical that the patent applicant proactively provide to the patent examiner, at the outset of the patent examination process, sufficient information to assure that the examination could be accurate and complete in assessing patentability.[7]

Some of this essential information had an absurdly subjective character, encouraging second-guessing as to whether the inventor had been fully candid with the patent examiner.[8] The ultimate in such subjectivity was a requirement

4 *See* Patent Act of 1836, §§ 7-8, 5 Stat. 117, 119-21 (describing the patent examination process).

5 Congress acted in 1999 to make pending patent applications open to public inspection. *See* Act of Nov. 29, 1999, Pub. L. No. 106-113, § 4001, 113 Stat. 1501, 1501A-552.

6 *See* 35 U.S.C. §§ 102(b) and (g) (2006), under which the inventor's secret commercial uses (even offers for sale) and secret inventions, made by other inventors not yet made public, can bar the ability to secure a valid patent. *See, e.g.*, Evans Cooling Systems, Inc. v. General Motors Corp., 125 F.3d 1448, 1454 (Fed. Cir. 1997) (holding that a secret contract between a third party who misappropriated the invention and the inventor to sell one year before filing patent application triggered the "on-sale bar" and thus the patent was anticipated, and as such, invalid).

7 *See* 37 C.F.R. §§ 1.97-98 (2011), providing for "information disclosure statements" to be submitted by patent applicants, and 37 C.F.R. § 1.56, otherwise setting out an affirmative requirement to provide information "material" to the patent examination.

8 *See* Robert A. Armitage, *Leahy-Smith America Invents Act: Will It Be The Nation's Most Significant Patent Act Since 1790?*, LEGAL BACKGROUNDER (Sept. 23, 2011), http://www.wlf.org/Upload/legalstudies/legalbackgrounder/09-23-11Armitage_LegalBackgrounder.pdf (discussing "best mode" as an example

that first appeared in U.S. patent law in 1952 that inventors must disclose what they "contemplated" as their "best mode" for carrying out their respective inventions.[9]

The validity of any issued patent could, in addition, depend upon other secret information—unavailable to the public, much less the patent applicant—that was held privately in the hands of other parties. Notably, prior inventions of others made in (or introduced into) the United States could destroy the patentability of a patent applicant's claimed invention, even if there were no contemporaneous public clues that such inventions had been independently made by others and, if so, when.[10]

For members of the public, another price of the pervasive patent secrecy was the absence of any meaningful opportunity for a member of the public to participate in the decision of the United States Patent and Trademark Office ("USPTO") to issue a U.S. patent. Moreover, except in recent decades, even if a patent issued by the USPTO was manifestly invalid, there was no post-issuance opportunity to contest a patent examiner's clearly incorrect determination of patentability.[11]



of a subjective standard that historically has been considered in assessing whether a patent should be granted).

9 *Compare* Patent Act of 1952, Pub. L. No. 593, § 112, 66 Stat. 792, 798 ("The specification shall . . . set forth the best mode contemplated by the inventor of carrying out his invention."), *with* Patent Act of 1870, ch. 230, § 26, 16 Stat. 198, 201 (providing "in case of a machine, [the inventor] shall explain the principle thereof, and the best mode in which he has contemplated *applying that principle* so as to *distinguish it from other inventions*." (emphasis added)). Prior to 1870, there was no requirement whatsoever in the patent laws relating to a "best mode." From this quite limited requirement in 1870, on its face intended to allow a new machine to be distinguished in its operation from other inventions, Congress appears to have derived the "best mode" requirement in the Patent Act of 1952, which remained a requirement for a valid patent until the AIA. *See* Patent Act of 1952 § 112.

10 *See, e.g.*, Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987) ("Section 102(g) . . . is one type of 'anticipation,' i.e., prior invention by another of the same invention.").

11 Ex parte patent reexamination, which allowed any person at any time after patent issuance to request patent claims be canceled based on patents and printed publications was introduced in an amendment to the Patent Act in 1980. *See* Act of Dec. 12, 1980, Pub. L. No. 96-517, §§ 301 *et seq.*, 94 Stat. 3015, 3015.



Lastly, other than for patents sought since 1995, the date when patent protection would ultimately expire could depend in significant measure on the attitude of the patent applicant in securing the patent. Patent expiration was measured at 17 years from the date the patent was *ultimately issued*, not the date when the patent was *originally sought*.[12] If a patent applicant were eager to issue a patent, it was possible for a patent to grant within a year from patent filing, with patent expiration then taking place less than 18 years after the patent was first sought.[13]

The impact of this yardstick for measuring patent life meant that the less eager the patent applicant was to see its patent filing proceed to a final patent grant, the longer the public would need to wait for the issued patent to eventually expire. Not uncommon were patents that expired 30 or 40 or even 50 years after the invention was made and the patent for it initially sought.[14]

The curious nature of the pre-1980s U.S. patent law produced a further perversity for patent applicants. It created a body of jurisprudence where the courts permitted patent infringers to call into question every judgment the patent applicant made in the course of securing a patent. Even if the resulting patent

12 As part of the transition to the new filing-based patent term, Congress provided a best-of-both-worlds transitional provision that extended the 17-year patent terms from issuance for previously issued patents to not less than 20-years from the original patent filing date. *See* U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2701 (8th ed. 2001) (Latest Revision, Jul. 2010) [hereinafter MPEP] ("All patents (other than design patents) that were in force on June 8, 1995, or that issued on an application that was filed before June 8, 1995, have a term that is the greater of the 'twenty-year term' or seventeen years from the patent grant.").

13 Under the Patent Act of 1952, a patent expired seventeen years from the date of issue, thus if a patent issued within a year of filing, the expiration of the patent would be less than 18 years from initial patent filing. *See generally* Patent Act of 1952 § 154 ("Every patent shall . . . grant to the patentee . . . for the term of seventeen years . . . .").

14 *See, e.g.*, *In re* Hogan, 559 F.2d 595, 597 (C.C.P.A. 1977) (finding the patentability of the patent application in dispute depended on the earliest priority date in 1953, thus the patent once issued would expire 17 years from the issue date, which was after 1977–more than 24 years after the date of original filing date).

was entirely valid, it could be nonetheless declared unenforceable due to a supposed fraud arising from the patent applicant's conduct before the USPTO.

### B. *Rationales Behind the Pre-1980 U.S. Patent System*

The criticality of non-public information in the hands of the patent applicant—and the abundant sources of possible mischief arising from withheld information or falsified information—led the USPTO to impose an affirmative duty to disclose information to patent examiners.[15] The courts contemporaneously issued holdings indicating that the patent applicant bore an *uncompromising duty* of candor and good faith.[16] An error or omission in the communications from patent applicant to patent examiner could result in a statutorily valid patent that was permanently unenforceable because of the patent procurement misstep.

As an aggregated result of these features, the U.S. patent system operated non-transparently, with great subjectivity, and with distressing unpredictability. It could only be characterized, especially in comparison to the most advanced foreign counterparts, as a patent system of mindless complexity. Unpredictable patent life, unpredictable sources of invalidity, and unpredictable enforceability could trump patent exclusivity–the primary incentive for making the investments necessary to bring patented innovations to commercialization.

With the AIA, Congress completed a statutory patent revolution, 30 years in the making. Each of the foregoing foundational aspects of U.S. patent laws has now been turned on its head.



15 *See generally* 57 Fed. Reg. 2007, 2034 (Jan. 17, 1992) (codified at 37 C.F.R. § 1.56 (2011)).

16 *See* Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 818 (1944) ("Those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it all facts concerning possible fraud or inequitableness underlying the applications in issue. This duty is not excused by reasonable doubts as to the sufficiency of the proof of the inequitable conduct nor by resort to independent legal advice. Public interest demands that all facts relevant to such matters be submitted formally or informally to the Patent Office, which can then pass upon the sufficiency of the evidence. Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies.") (internal citations omitted).



The much-needed reforms to the patent system commenced, timidly at first, with the Patent Act of 1980,[17] creating a new "ex parte reexamination" procedure. It afforded members of the public a highly limited opportunity to raise an issue of patentability before the USPTO in connection with an issued U.S. patent.[18] However, the limited nature of the public involvement in this *ex parte* proceeding has meant that, even today, it is of little use to members of the public concerned over an apparently invalid patent.

The next significant reforms to U.S. patent law arrived with the Uruguay Round Agreements Act of 1994 ("URAA of 1994"),[19] and the American Inventors Protection Act of 1999 ("AIPA of 1999").[20] Together, these two Acts made three significant improvements to the operation of the U.S. patent system by: (1) requiring publication of most pending patent applications at 18 months after the initial patent filing;[21] (2) limiting most issued patents to a term expiring 20 years after the formal (nonprovisional) patent filing in the United States;[22] and (3) broadening the opportunity to challenge an issued U.S. patent through a new *inter partes* mechanism—albeit a mechanism still highly limited in its reach (i.e., to very narrow patentability issues arising from patents and printed publications).

Only with the enactment of the AIA did Congress finally abandon altogether relative timidity in its approach to patent reform. Through a 130-page bill[23] and over a six-year legislative process,[24] Congress transformed the U.S. patent system from one of non-transparency, subjectivity, unpredictability, and excessive complexity, to one that will operate with near-complete transparency, objectiveness, predictability and simplicity in the principles that govern patentability and patent validity.

17 Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015.

18 *Id.* § 302.

19 Uruguay Round Agreements Act, Pub. L. No. 103–465, § 101, 108 Stat. 4809 (1994).

20 Act of Nov. 29, 1999, Pub. L. No. 106-113, § 4001, 113 Stat. 1501, 1501A-552.

21 *Id.* § 4502.

22 Uruguay Round Agreements Act § 532.

23 *See* America Invents Act, H.R. 1249, 112th Cong. (2011).

24 *See* H.R. 2795, 109th Cong. (2005) (originally introduced on June 5, 2005, this bill began the active congressional consideration of the key patent reforms that ultimately became part of the Leahy-Smith America Invents Act).

### C. *Changes in the U.S. Patent System Resulting From the AIA*

In the future, most patent applications will not only be promptly published, but members of the public will have the opportunity to submit information relevant to patentability that the patent examiner must consider *before* making a decision to issue a patent.[25] After a patent has been issued, members of the public will have the opportunity to return to the USPTO and challenge a patent on *any validity issue that could be raised as a defense to patent infringement in the courts*.[26] Indeed, this new opportunity to challenge patent validity back in the USPTO will be conducted before technically and legally trained administrative patent judges and must run to completion within a year (at most 18 months) from commencement.[27] A right to appeal to the Court of Appeals for the Federal Circuit assures that these proceedings can involve a full vetting of patentability issues.[28]

This profound reversal in the patenting process—with the public's role being transformed from blinded spectator to full participant—was made possible because of the manner in which the AIA rewrites basic rules for patentability of applications for patents and validity of patents once issued. Simply, the AIA limits patentability issues in a manner that renders the new post-grant patent challenge mechanisms administratively feasible.

Under the AIA, the new post-grant reviews will be confined to what are essentially questions of law, with limited factual underpinnings needed to make those essentially legal assessments. Most importantly, the determination of whether a claimed invention is *sufficiently different* (i.e., novel and non-obvious) from previously existing technology (i.e., the "prior art") to merit a patent has changed in fundamental ways.[29] The constituents of the "prior art" are now assessed on the basis of disclosed subject matter that qualifies as either *available to*

[25] Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 8, § 122, 125 Stat. 315-16 (2011) (amending § 122 to add a new subsection (e)).

[26] *Id.* sec. 6, § 321.

[27] *Id.* sec. 6, § 326.

[28] *See generally id.* sec. 6 (amending title 35, United States Code, to add a new Chapter 32 (35 U.S.C. §§ 321-329) providing a new post-grant review proceeding).

[29] *Id.* sec. 8, § 102(a).



*the public* prior to the inventor's patent filing or having been *described* in an earlier-filed patent application that subsequently became *available to the public*.[30]

This new, transparent definition for what qualifies as "prior art," which is then used to determine the novelty and non-obviousness of a claimed invention,[31] sits alongside the three remaining core legal issues of patent validity: (1) is the claimed invention *sufficiently disclosed* in the patent such that it identifies the embodiments of the invention and enables them to be put to a specific, practical and substantial use;[32] (2) are the claims of the patent *sufficiently definite* to reasonably differentiate the subject matter being patented from subject matter that is not;[33] and (3) are the claims of the patent confined to subject matter that is *sufficiently concrete*, such that the invention relates to a process, machine, manufacture or composition of matter that is expressed in terms that are not excessively conceptual or otherwise abstract?[34]

[30] *Id.* sec. 3, § 102(a)-(b) (defining scope and content of prior art through an overarching requirement for disclosures to be publically available to qualify as prior art).

[31] An established patent law rubric is that "'anticipation is the epitome of obviousness.'" Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548 (Fed. Cir. 1983).

[32] *See* 35 U.S.C. § 112 (2006). The section 112 requirements that bear on a patent's validity or enforceability are enablement and written description. "[W]hether a specification sufficiently enables a claim under 35 U.S.C. § 112, para. 1 (1988), enablement is a question of law reviewed *de novo*, which may involve subsidiary questions of fact reviewed for clear error." *In re* Epstein, 32 F.3d 1559, 1568 (Fed. Cir. 1994). The "written description" requirement, i.e., the requirement that the specification of the patent identify the embodiments of the claimed invention, is, thus, a requirement to demonstrate in the patent document the completed conception of the invention, which is likewise a question of law. *See* Scott v. Koyama, 281 F.3d 1243, 1246 (Fed. Cir. 2002) ("Priority of invention is a question of law, based on findings of evidentiary fact directed to conception, reduction to practice, and diligence."); *see also* Ellsworth v. Moore, 61 U.S.P.Q.2d 1499, 1506 (B.P.A.I. Nov. 20, 2001) (noting "conception" is an issue of law).

[33] *See* 35 U.S.C. § 112.

[34] *Id.* §§ 101, 112. The section 101 requirement for subject-matter eligibility is a question of law. *See* Arrhythmia Research Tech., Inc. v. Corazonix Corp., 958 F.2d 1053, 1055-56 (Fed. Cir. 1992) (explaining that "[w]hether a claim is directed to statutory subject matter is a question of law" and further noting

Given that further reforms under the AIA mean that the naming of an inventor in an application or patent can now be corrected irrespective of any contention of "deceptive intention" in the original inventor naming, this question of law should have no impact on a patent's validity in any forum where the validity of the patent is being contested.[35] Why so? The available remedial actions to correct the naming of the inventor can be undertaken in almost any imaginable circumstance, including in the AIA's new "supplemental examination" proceeding.[36]

The same can be said for holding a patent invalid based upon a defective "oath" of the inventor. Not only does the AIA reduce the requirement for the inventor's oath or declaration to nothing more than a one-time obligation to make two required statements,[37] which the patent applicant can simply incorporate into an inventor's assignment of the invention, but a new statutory "savings clause" now expressly permits correction of any such oath at any time.[38] Once corrected, any prior defect can no longer be a basis for invalidity or unenforceability of the patent.

Yet another AIA provision insulates the patent owner against invalidity or unenforceability of a patent on the basis that the "best mode" contemplated by the inventor at the time of the patent filing was not included in the patent specification.[39] This insulation extended to prohibit consideration of the "best mode" issue in any post-issuance proceeding before the USPTO.[40]

A final effort at curbing unenforceability and opening remedial measures in the patent statute is found in Congress' decision to eliminate all provisions containing restrictions or limitations based upon "deceptive intention."[41] Indeed,



that "determination of this question may require findings of underlying facts specific to the particular subject matter and its mode of claiming").

35 *See* C.R. Bard. Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1352 (Fed. Cir. 1998) (finding "[i]nventorship is a question of law, applied to relevant facts").

36 Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 12, § 257(a), 125 Stat. 284, 325 (2011).

37 *Id.* sec. 4, § 115(b).

38 *Id.* sec. 4, § 115(h)(3).

39 *Id.* sec. 15.

40 *Id.*

41 *See id.* sec. 20.



for the first time since the 1836 Patent Act, the words "deceptive intention" appear nowhere in the U.S. patent code.[42]

In the aggregate, therefore, it is virtually unimaginable that the USPTO, in a post-issuance proceeding or a court hearing an invalidity defense, would be required to address a patentability issue other than the four core issues of sufficient *differentiation, disclosure, definiteness, and concreteness*.

As a further safety valve, the new supplemental examination proceeding assures that a valid patent can be fully enforceable, even if errors or omissions were made in the original examination of the patent that would otherwise trigger its permanent unenforceability.[43] The patent owner is required under this provision to seek (and conclude) the supplemental examination procedure before attempting to enforce the patent.[44]

The congressional intent in this long litany of remedial provisions added to the patent statute—and the ejection from the law of ancient proscriptions on remedial measures based upon "deceptive intention"—appears unmistakable.[45] In reforming the patent law so that *publicly available* information alone drives most patentability determinations and the patenting process itself is largely open to the public—in that the public has a right to participate in the patenting process both before and after the patent has issued—Congress intended to place on an equal footing the *equitable conduct expectations* of both patent applicants and public participants in the patenting process.[46]

Whatever the role of an individual appearing in proceedings before the USPTO, the participants ought to be subject to the same conduct rules and bear the same consequences for misconduct. In a broader sense, the expectations for

42 *Compare* 35 U.S.C. §§ 116, 251, 253, 256, 288 (2006) (all including the phrase "without deceptive intention"), *with* Leahy-Smith America Invents Act, sec. 20 (striking "deceptive intention" from listed sections in Title 35).

43 Leahy-Smith America Invents Act, sec. 12, § 257.

44 *Id.* sec. 12, § 257(c)(2)(B).

45 The most comprehensive understanding of congressional intent in enacting the key provisions of the AIA that are treated in this article is found in Joseph D. Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. B.J. 435 (forthcoming March 2012). Nothing in the present analysis departs, knowingly at least, from the guide provided therein.

46 *See id.*

proper conduct before the USPTO in a public proceeding, largely considering the import of information available to the public, should be no different from conduct expectations of participants in all other proceedings before any other administrative agency.

### D. *Consequences of the Changes in the U.S. Patent System Resulting From the AIA*

From the most mundane (permitting the patent owner to file for a patent as the assignee and trivializing full compliance with the requirement for an "inventor's oath"), to the most profound (banishing the concept of "deceptive intention" from the patent statute and affording patent owners a remedy for correcting all errors and omissions made in the original examination of a patent through the new supplemental examination), to the most substantive (elimination of all subjective and non-transparent tests for patentability in favor of a patent law in which the validity of a patent is assessed through information available to the public), the AIA did not shirk from working reform where the consequence would be greater transparency, objectivity, predictability, and simplicity in the operation of the U.S. patent system. This Article attempts to set out how these changes to the patent statute can be best understood and best applied by those affected by the patenting process.

## II. THE VOCABULARY OF THE NEW PATENT LAW: UNDERSTANDING THE NEW NOMENCLATURE

Congress placed important new definitions in the patent statute. Newly defined terms are used in the most critical passages of the revised code, setting forth the substantive patent law.[47] To assure the fullest possible understanding of the new statute, an introductory primer is in order.

For the first time, several of the most commonly used terms in patent parlance—"inventor," "claimed invention," and "effective filing date" for a

[47] 35 U.S.C. § 100 sets out explicit statutory definitions. However, other provisions of the patent statute now contain similarly explicit definitions. *See, e.g.*, Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 10, § 123, 125 Stat. 284, 318 (2011).



## IX. CONCLUSIONS

The America Invents Act has made many significant changes to the patenting landscape in the United States. It is a giant step toward a more transparent patent system, where a person skilled in the technology of a particular patent and knowledgeable in patent law can review a patent, reference only publicly accessible sources of information, and make a complete and accurate assessment of the validity of the patent. At its core, the AIA seeks a more objective patent law, where subjective issues like an inventor's contemplations or a patent applicant's intent bear no relevance to any issue of validity or enforceability of the patent. It is a patent law that, in many situations, may require no discovery of the inventor to determine if a claimed invention is patentable.

Congress took bold steps to reach these goals. The "loss of right to patent" provisions were all repealed. The "best mode" requirement was made a functional dead letter. All references to "deceptive intention" were stripped from the patent law. A new "supplemental examination" procedure was instituted to address any error or omission in the original examination of a patent and bar the defense of patent unenforceability once the procedure has run to completion. Finally and most dramatically, it concisely limited "prior art" on which the novelty and non-obviousness of a claimed invention was to be assessed. Nothing can qualify as prior art absent representing a prior public disclosure or an earlier patent filing naming another inventor that subsequently became publicly accessible—casting aside 175 years of a more complicated, subjective, and uncertain standard for patenting.

Thus, without question, *transparent, objective, predictable* and *simple* are four words that should come to describe the hallmarks of the new patent law arising from this historic legislative achievement. Those four words suggest a fifth that appears to be equally apt. *Remarkable*.

# Perspective

By Robert A. Armitage

# The World's First 21st Century Patent Law (Maybe): The Leahy-Smith America Invents Act

As this issue of *Landslide*® magazine heads to press, the legislative fate of the Leahy-Smith America Invents Act, H.R. 1249, is unknown. We all may still be wondering whether the nearly identical bills that passed by wide margins in both the House and the Senate will eventually become law. On the other hand, by the time this issue hits the streets, the Section may be taking justifiable credit for helping to get a new patent law across the congressional finish line.

We were among the earliest supporters of the 2004 legislative recommendations of the National Academies that form the core of the Act. Our public enthusiasm for these patent reforms dates back to the Section's testimony on April 20, 2005, at the House Judiciary Committee hearing that launched the legislative push for reform. The strong support for an ambitious agenda of patent reforms expressed at this hearing led Chairman Lamar Smith (R-TX) to introduce H.R. 1249's predecessor, H.R. 2795, in June 2005. Nearly simultaneous with this bill's introduction, the Section released its comprehensive White Paper, *Agenda for 21st Century Patent Reform*, laying out the value and virtues of making truly revolutionary changes to our patent laws. After gestating over these past six years, the Act—assuming its enactment—will represent the world's first truly 21st century patent law, and it holds the promise of becoming this young century's most significant patent law.

**How so and why so?**

H.R. 1249 establishes a streamlined patentability and patent validity law, the hallmarks of which lie in its transparency, objectivity, predictability and simplicity. Congress has managed to boil patentability law down to four requirements for a claimed invention in a patent to be valid:

- *Sufficient differentiation* from the prior art. "Prior art" is defined in a simple and transparent manner as subject matter that, at the time of an inventor's patent filing, was already available to the public, or available from a previously-filed U.S. patent or published U.S. application for patent, subject to the inventor-friendly and collaboration-friendly "grace period" and "self-collision protection" provisions that have long been part of U.S. patent law.
- *Sufficient disclosure* in the inventor's patent filing to identify the embodiments of the claimed invention and enable them to be put to a specific, practical, and substantial use.
- *Sufficient definiteness* in the inventor's patent claims, to reasonably identify the subject matter being claimed from that not being claimed.
- *Sufficient concreteness* in the subject matter claimed, such that the process or product being claimed is not excessively conceptual or otherwise abstract.

The legal nature of these four patentability pillars means that the most fact-intensive aspect of much patent litigation will be a transparent one: *What became available to the public when?* This fact-finding will determine "obviousness," which is ultimately a question of law. Likewise, the requirement for a "sufficient disclosure" is an objective one, which under current jurisprudence is essentially a question of law ("enablement" historically having been so recognized and "written description" now being a test of whether the embodiments of the invention have been sufficiently identified to evidence a complete "conception," another question of law). Lastly, "sufficient definiteness" and "sufficient concreteness" each represent questions of law with limited fact-based predicates.

Making a patent filing will become much simpler, with technicalities and technical traps being swept away. The new law will provide the opportunity to eliminate any ground of invalidity connected with incorrect inventorship or defects in the formalities in connection with a patent filing. The law will permit assignee filing, provide the option to replace a separate "inventor's oath" with a simple statement in an inventor's assignment, eliminate any requirement to file successive or supplemental oaths, add a comprehensive "savings clause" to correct any defects in an inventor's oath or declaration, and liberalize correcting mistakes in naming inventors.

One salutary benefit of the foregoing is that discovery in patent litigation may be greatly curtailed. For many patents, there will be *no discovery from the inventor or the patent owner that will be relevant to patent validity*. With the demise of the "best mode" requirement, repeal of the *Metallizing Engineering* doctrine (an inventor's forfeiture of the right to patent based upon secret use, sale, or offer for sale of the invention), the elimination of the *Oddzon* doctrine (private knowledge obtained from others forming prior art for obviousness purposes), and the disappearance of an inventor's invention date as relevant to determining prior art, *nothing of substance will typically remain in patentability law that lends relevance to the inventor's knowledge, contemplations, actions, or activities—unless available to the public before the patent was sought*.

The Act's simple, clear, and objective patentability law—although over 220 years in the making—may prove to have been well worth the wait and, as global patent harmonization discussions recommence, the mold and model for the rest of the world to now emulate. ■

**Robert A. Armitage** is chair of the ABA Section of Intellectual Property Law. He serves as senior vice president and general counsel at Eli Lilly and Company in Indianapolis, Indiana. He can be reached at armitage_robert_a@lilly.com



Published in *Landslide* Volume 4, Number 1, September/October 2011. 

# Perspective

By Robert A. Armitage

## The Leahy-Smith America Invents Act: The Once-Secret Patenting Process Grows More Public

The most significant new patent legislation of this young century has now been signed into law by President Obama. As I noted in the last issue of *Landslide*® magazine, the playbook describing key provisions of the America Invents Act can be found in the comprehensive White Paper, "Agenda for 21st Century Patent Reform," by the ABA Section of Intellectual Property Law. Our Section's priorities for patent reform ended up being closely aligned with the agendas of many other constituencies, whose combined efforts made this new law possible.

One of the most significant Section-supported aspects of the new law can be found in a collection of provisions providing greater public participation in the patenting process. For nearly two centuries, the public was ignored in decisions taken by the United States Patent and Trademark Office (USPTO) in deciding which patents should issue and which should be kept in force. Prior to 1980, all "patent examination" was a two-way discussion between patent applicant and patent examiner. The public was clued into the goings-on only on the day the patent issued.

Once a patent issued, there was no role or redress for members of the public. The USPTO simply had no jurisdiction that allowed it to process a complaint from a member of the public alleging that the USPTO should not have granted a patent in the first place.

Given the growing importance of patents to the economy (and the financial consequences for businesses defending in court against a patent that never should have been granted), this 19th century "help not wanted" model for patent examination began to erode as the 20th century was drawing to a close. Congress took two important, but tentative, legislative steps before the millennium to provide a much more significant role for the public in matters of patenting.

First came Public Law 96-517 in December 1980. It created a new procedure now known as "ex parte reexamination," under which a member of the public could request that the USPTO address a "substantial new question of patentability" of a claimed invention in a patent arising from a patent or printed publication.

Then, weeks before the turn of the millennium, the American Inventors Protection Act of 1999 made a pair of additional concessions to the public. The first was to mandate the publication of pending applications within 18 months from the original patent filing date for the vast majority of U.S. patent applicants. The other was to augment the 1980 ex parte reexamination with a new and parallel "inter partes reexamination."

Under the 1999 inter partes reexamination, an individual requesting the reexamination was given a right to participate more fully in the reexamination process and the right to appeal a decision made in the patent owner's favor all the way to the Federal Circuit. Unfortunately, the good intentions in the reexamination statute were not immediately matched by an equally good execution in the USPTO of its new responsibilities. As a result, these steps did not quiet the calls for a more effective means for the public to participate actively in decisions of the USPTO on whether an invention merited a patent.

The America Invents Act has now added three new procedures to U.S. patent law that hold the promise of being best-in-world vehicles for public participation in the patenting process. The first of the three procedures expressly authorizes public submissions of prior art to the USPTO before it can make a final decision to issue a patent. The latter two procedures are now termed "post-grant review" and "inter partes review" and will represent entirely new proceedings in the USPTO. As these new proceedings are implemented, the "inter partes reexamination" will be phased down and out.

The new "post-grant review" has an impressive promise. It will allow a member of the public to raise any issue of patentability in the USPTO that could be a defense to the validity of an issued patent raised by a defendant in patent infringement litigation. It offers discovery, albeit highly limited, to both the patent owner and the public petitioner seeking the review.

The post-grant review proceeding must move to completion within one year from its initiation. The proceeding is heavily "front loaded," with petitioners seeking a review being required to present all of the evidence upon which the USPTO would base its invalidity determination in the initial petition for the review. The new procedure calls for *adjudication* of the issues in dispute, not an *examination*, and, thus, these proceedings will be conducted before administrative patent judges.

To prevent the new procedure from being used as a tool to harass patent owners, the USPTO is required to limit use of these reviews to issues on which a showing has been made that it is more likely than not that the claimed invention

**Robert A. Armitage** is chair of the ABA Section of Intellectual Property Law. He serves as senior vice president and general counsel at Eli Lilly and Company in Indianapolis, Indiana. He can be reached at armitage_robert_a@lilly.com.



Published in *Landslide* Volume 4, Number 2, November/December 2011. 

at issue is invalid. Also, such reviews can be sought only during the first nine months after a patent has issued.

The new "inter partes review" is virtually a carbon copy of "post-grant review," with three principal exceptions. It is limited to the same patentability issues that were available under the reexamination laws, but under a higher threshold, one requiring a reasonable likelihood that the claimed invention in the patent is invalid. Lastly, inter partes review cannot be commenced until after the time for seeking a post-grant review has run and, if a post-grant review has been initiated, has concluded.

As I noted in the last issue of *Landslide*, the new legislation's simple, clear, and objective patentability law deserves much of the credit for making these new mechanisms for the public in the patenting process possible. As with the new U.S. patentability law, the new U.S. public participation vehicles merit discussion as a mold and model for the rest of the world to now emulate. ■

# Perspective

By Robert A. Armitage

## The Role of the America Invents Act in Ending the Plague of "Inequitable Conduct" Allegations

The process for patenting in the United States has been remade from the ground up over the span of my professional career. Back in the day (the 1790s through the 1970s), patent examination was conducted in secret between a patent applicant and a patent examiner. The first inkling the public was given that a patent was being sought for an invention was often on the very day that this secret review process in the USPTO was concluded and the patent was finally granted.

Much of the information on which patentability rested was not available from public sources. The patent examiner was dependent on the patent applicant's willingness to be candid and forthcoming with the raft of nonpublic information that might be essential to reaching an accurate assessment of patentability.

Even worse, when the examination process finished and the patent issued, there was no public forum within the USPTO in which to raise an issue of patentability, even if the patent was mistakenly issued. No matter how blatantly invalid the patent, the public had no recourse back in the USPTO.

The enactment of the America Invents Act (AIA) has completed the turning upside down of each of these foundational premises for patenting in America. Almost all U.S. patent applications are now published promptly after filing. Virtually everything needed for the USPTO to issue a valid patent under the AIA's patenting rules will come from sources of information available to the public.

Members of the public will enjoy new opportunities to submit information that must be considered by a patent examiner before the examiner is permitted to issue a patent. Then, once a patent is issued, any member of the public can seek cancellation of the patent on any ground of invalidity that might later be raised in court.

This revolution of transparency in the patenting process, and public participation in the work of the USPTO, has taken over 30 years to drive to completion. However, the patent applicant's "duty of disclosure" and the desirability of an "inequitable conduct" unenforceability defense to a patent's infringement have not been commensurately rethought.

As an example, as the role of the public in the patent process has been elevated, no real thought has been given to the "duty of candor and good faith" that should reside on these public participants. Indeed, going forward under the America Invents Act, the so-called "duty of candor and good faith," really a restatement of the obligation of honesty in dealing with all federal entities set out in 18 U.S.C. § 1001(a), must apply as pervasively to public participants in the patenting process as it applies to patent applicants themselves.

Congress, of course, was not oblivious to the fact that attention was needed to the elements of the patent statute relating to the patent applicant's duty of honesty as it revolutionized core concepts of patenting in the AIA. In the area of unenforceability of patents based upon applicant conduct, Congress made clear it was time to cut back on a host of misconduct-related provisions in the law:

- All references to "deceptive intent" are stripped out of the patent statute. Remedial measures that have been heretofore dependent upon the ability to show absence of deceptive intent are no more.
- A new "safe harbor" provision precludes unenforceability based upon a defective inventor's oath (or the new "required statements"). Indeed, under the new law, the incorrect naming of inventors can always be corrected and, once corrected, removes any grounds for invalidity or unenforceability associated with the faulty inventor naming.
- A faulty "best mode" disclosure not only cannot be a ground for invalidity, but cannot be raised as a basis for alleging a patent is unenforceable.
- Finally, and most dramatically, a new supplemental examination procedure is created in which "errors and omissions" in the original examination of a patent can be corrected and, once this has been accomplished, the patent cannot be held unenforceable based on the failure to disclose or incorrect disclosure of the information considered, reconsidered, or corrected during the supplemental examination.

These changes to U.S. patent law would, by themselves, have been sufficient for the America Invents Act to have been one of the most significant set of changes to the U.S. patent statute in decades, perhaps since the Patent Act of 1836, where the term "deception intention" first appeared in the patent code. It is possible that this collection of changes may, at long last, spell the end of the "inequitable conduct" plague in patent litigation.

How effective Congress has been at addressing the "inequitable conduct" issue may well be determined by the implementation of the new provisions on "supplemental examination." For a supplemental examination to have an impact on a pleading of "inequitable conduct," the process in the USPTO must have run to completion before an enforcement action is commenced. Under the new law, the USPTO must

**Robert A. Armitage** is chair of the ABA Section of Intellectual Property Law. He serves as senior vice president and general counsel at Eli Lilly and Company in Indianapolis, Indiana. He can be reached at armitage_robert_a@lilly.com.



Published in *Landslide* Volume 4, Number 3, January/February 2012. 

reexamine the involved patent on any issue of patentability where the new or corrected information raises a substantial patentability question.

Thus, this new procedure will allow the USPTO to cancel any invalid patent claims, leaving the patent owner with only those claims found valid after the new or corrected information was considered. While an infringer then loses the opportunity for an "inequitable conduct" pleading on the errors and omissions that were remedied, the public has greater assurance that whatever remains of the original patent was reconfirmed as patentable based on a complete and accurate examination record.

As I noted in the last issue of *Landslide*® magazine, our new patent law represents a mold and the model for the rest of the world to now emulate in many respects. Following the lead of the rest of the civilized world in taking "inequitable conduct" considerations out of the mainstream of patent litigation certainly reinforces that American role modeling. ■

# Perspective

By Robert A. Armitage

# International Patent Harmonization
## Requisites, Ripeness, and Realism

"I urge us all to begin the process of patent law harmonization anew, now. I urge us all to search for common ground. I urge us all to let best global policy and best practices be our guide."[1]

Under Secretary Kappos spoke those words nearly a year ago at a conference in London. Five months later, Congress passed the Leahy-Smith America Invents Act (AIA). It implemented the 2004 recommendations made by the National Academies of Science calling for greater harmonization of U.S. patent law principles with those of our major trading partners.

The new U.S. patent law can lay claim to setting a new global standard for defining "prior art" and a set of exceptions from "prior art" that best assure an inventor- and collaboration-friendly law. The global patent community now has at least one template for crafting a treaty harmonizing patent laws on the issues of novelty and nonobviousness.

Looking beyond these issues, however, what should be the *requisites* for movement towards greater global patent harmonization? What further topics are now *ripe* for harmonizing? What might be *realistic* expectations for such efforts during the decade ahead?

### Requisites

Kappos got it just right. While compromise lies at the heart of most successful endeavors, patent harmonization should not be a series of compromises. Compromising may be the negotiating ticket for achieving a treaty to address global warming or reaching an accord to end a labor dispute between players and team owners of a professional sports league. It is not, however, a constructive path to building a better patent law—no country wants to degrade its patent laws, in any material respect, just for the sake of making them be just like the second-rate laws of its harmonization partners.

The AIA itself is an instructive example of how to advance harmonization of substantive patent law. We adopted the first-inventor-to-file principle because of a broad domestic consensus that it represented the *better practice* relative to the first-to-invent law that existed in the United States before the enactment of the AIA. Indeed, the first-inventor-to-file principle was simply one of a number of AIA "better practices" for which a domestic consensus had been achieved.

How did that consensus develop and emerge? It was, again, the USPTO that took the lead in fostering a "best practice" consensus.

In a 2001 *Federal Register* notice, the USPTO sought views on no less than 17 harmonization-related issues, including: "As to priority of invention, the United States currently adheres to a first-to-invent system. The remainder of the world uses a first-to-file rule in determining the right to a patent. Please comment as to which standard is the 'best practice' for a harmonized, global patent system."[2]

Dozens of domestic entities and individuals responded to the 2001 notice, expressing views on the first-inventor-to-file principle and how best to implement it.[3] Reading the responses, it becomes clear that a consensus emerged, not just on the principle of adopting a first-inventor-to-file rule, but on numerous details of its implementation.

When Congress sought to write the new statute, it drew on the domestic consensus from 2001. It provided a globalized "prior art" standard, rejected Europe's novelty-only "prior art" rule for earlier patent filings, retired the *Hilmer* doctrine, ended each of the § 102 "patent forfeiture" doctrines, and secured a strong "grace period" for inventors who publish before patenting.

The domestic road traveled from 2001 to 2011 reflects the prime requisite for proceeding with greater international harmonization of substantive patent law principles. The road begins with the *identification* of the "best practices" for crafting a patent law. It continues by then *testing the identified practices for possible consensus*.

Hence, as the patent community looks ahead to possible international agreements under which greater global harmony among patent laws is to be realized, these two requisites should remain paramount. What can we identify as the better way? What consensus exists that it is in fact better?

### Ripeness

Were a patent law treaty to be concluded, its purpose would be to constrain the direction in which the substantive patent law might further develop and limit (or, at a minimum, greatly complicate) the degree to which national laws could later be changed. This necessarily leads to a second consideration. What substantive law issues are truly ripe to be confined with treaty language—so that there is confidence that imposing such constraints and complications is appropriate?

Several aspects of the substantive patent law illustrate potential ripeness issues.

Both Europe and the United States require that an invention must be *sufficiently differentiated* from the "prior art" to be validly patented. In Europe,

*Continued on page 2*

**Robert A. Armitage** is chair of the ABA Section of Intellectual Property Law. He serves as senior vice president and general counsel at Eli Lilly and Company in Indianapolis, Indiana. He can be reached at armitage_robert_a@lilly.com.

the requirement is for an "*inventive step*" under which the inventor must lay out the "problem" for which the invention provides an inventive "solution." The United States uses a more general *nonobviousness* requirement tied to the differences in *the subject matter as a whole* sought to be patented.

As between the more straightjacketed "problem-solution" approach and the more general "subject matter as a whole" approach, has one or the other emerged as a better practice? It appears that global support may be ripening for a decision on whether the AIA's incarnation of the nonobviousness standard now represents the better global standard.[4]

Moreover, a treaty is not the vehicle to test or try some new idea or new legal formulation. Consider the issue of whether a claimed invention has been *sufficiently disclosed* to be validly patented. In 1952, Congress added to domestic law what was then a newly-formulated disclosure standard, the "best mode" requirement. A mere 60 years later, under the AIA, Congress has now eviscerated that requirement, based on a broad domestic consensus that its elimination was a "better practice."

Similarly, the 1952 Patent Act laid out a requirement that inventors must identify the embodiments of a claimed invention in order to have a sufficient disclosure. This is the so-called "written description" test. However, both the existence and desirability of a separate "written description" requirement have been regularly contested since 1952, with the issue only being definitively resolved by the Federal Circuit *en banc* with its *Ariad* decision in 2010.[5]

Is the current U.S. law for a sufficient disclosure the global "best practice" and is it now ripe for imposing as the global standard? Alternatively, is more deliberation necessary to arrive at the optimal global principles for a sufficient disclosure in a patent filing?

Finally, the most problematic issue for would-be harmonizers is the issue of subject matter eligibility for patenting. Here, a multiplicity of ripeness concerns exists.

In the United States, the eligibility for patenting of genomic-related inventions remains the subject of active contention. Historic limitations on the patenting of inventions encompassing "mental steps" now appear to be undergoing a much-needed renascence. Much of this churning in the law comes from the Supreme Court intervention to nix patenting of excessive conceptual or otherwise abstract subject matter.[6]

Across the Atlantic, Europe limits its patents to inventions "capable of industrial application." It applies a "technological invention" test to screen out whatever subject matter appears undesirable as an area for patenting.

The scope and import of these various patent-eligibility approaches are barely comprehensible to most patent professionals. Is anything in this area ripe for harmonizing? Or would continuing disharmony for a time allow for the development of better defined, more cogent legal concepts under which patent-eligible subject matter might be identified?

## Realism

More global and globally consistent rules defining what can be validly patented hold the promise of strengthening patent systems everywhere. In 1973, the European Patent Convention offered a glimpse of what might be possible among a group of countries willing to forge a *compromise* to address their differing approaches to patenting. Today, the America Invents Act demonstrates what can be accomplished by setting out to identify "best practices" and then building a consensus on their content.

If greater international patent harmonization is achieved, it will hopefully come with less of the 20th century approach, as reflected in the EPC compromise, and more in the 21st century methodology of achieving a consensus on "best practices," as was the case with the AIA. Realistically, therefore, there may be a long road ahead to substantive patent law harmonization, especially given the areas where "best practices" remain to be defined and a global consensus as to their content has yet to be sought. ■

## Endnotes

1. David Kappos, *A Global Call for Harmonization*, USPTO.GOV (April 5, 2011), http://www.uspto.gov/news/speeches/2011/kappos_london.jsp.

2. 66 Fed. Reg. 15409-15411 (March 19, 2001).

3. United States Patent and Trademark Office, Comments Regarding the International Effort to Harmonize the Substantive Requirements of Patent Laws, USPTO.GOV, http://www.uspto.gov/web/offices/dcom/olia/harmonization/.

4. See AIPPI Resolution Q217. The patentability criterion of inventive step/nonobviousness, dated Oct. 18, 2011 (ExCo Hyderabad), noting "almost unanimous indication by the Groups of the desirability of harmonization on the definition and criteria for inventive step/nonobviousness."

5. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (*en banc*).

6. Bilski v. Kappos, 130 S. Ct. 3218 (2010).

# Perspective

By Robert A. Armitage

## The Remaining "To Do" List on Patent Reform

### Consolidation and Optimization

The United States Patent and Trademark Office (USPTO) is marching along with the immense efforts needed to complete regulations to implement the Leahy-Smith America Invents Act (AIA). Within the patent profession—notably within the Patent Division of the ABA Section of Intellectual Property Law—there have been prolific and heroic efforts to assist the USPTO in the rule writing needed to bring the AIA to life.

If there is one oft-expressed hope of many participants in the AIA's legislative and regulatory phases, it is that successful conclusion of these efforts will yield a sustained period of reflection. "No New Patent Laws!"—at least not until the new law now on the books is digested and its impacts, for better or worse, are more fully understood.

I would offer a dissenting view—or perhaps a more nuanced one. There are, I believe, some near-term opportunities for further legislative intervention in the patent statute that would not require either rethinking or retreating from the reforms already enacted into law. Rather, they represent areas for further change that could *consolidate* the many achievements of the AIA and, indeed, *optimize* their potential for greater transparency, objectivity, predictability, and simplicity in the operation of the U.S. patent system.

Let's start with a very simple proposal for refining legislation that cannot possibly be controversial in light of what the AIA has already achieved: eliminate altogether the required statement of the inventor under the new 35 U.S.C. § 115 (the so-called "oath or declaration" requirement). In place of this archaic provision, augment the explicit requirement (already in new § 115) that the patent applicant must name the inventor by incorporating a further requirement that the patent applicant itself, if not the inventor, must provide an applicant's express statement that it has obtained the right to file the application for patent from the inventor named in the application for patent. Since, for over 99 percent of patents filed, there is no real dispute over either the inventorship or the ownership, there is no real justification for any formality beyond a statutory requirement that the patent application identify both inventor and applicant.

Next, allow me to move to what should be regarded as a mere correction: remedying an oversight in the implementation of the AIA's new first-inventor-to-file principle. The AIA failed to eliminate the option for a patent applicant to opt out of mandatory publication of pending application for patent at 18 months from the initial application filing. Congress should now do so. The soon-to-be-extinct first-to-invent system exposed the inventor of a patent application, once published, to the specter of a later-filing patent applicant, having been spurred by the publication, to seek to muscle its way into a patent interference with the published patent application by alleging an earlier invention date. All that nonsense in U.S. patent law will now end. With the new law now on the books, the 18-month publication of all pending patent filings benefits all patent applicants. In particular, it assures the patent application of any subsequently-filing inventor can be rejected by a patent examiner based upon the earlier-filed application, but only once that earlier application has published. Having ended any risk to the inventor of early publishing, keeping the option in place merely diminishes the transparency of the new law, without any policy justification for so doing.

"Patent term adjustment" is another feature of U.S. patent law whose policy justification has been mooted by virtue of the improvements in the patent examination process under the AIA. If, by 2013/2014, it is clear that patent applicants have access in the USPTO to an effective system for accelerating the examination of their patent applications, then electing the new "priority examination" option will better serve the interests of both patent applicants and the public than the belated remedy, for a slow-to-issue patent, of tacking time on to the end of the 20-year patent term. For applicants electing a more leisurely approach to securing their patents, there is little policy justification for adding extra patent term. For applicants eager to get a patent to issue and wanting at least a 17-year post-issuance patent term, "priority examination" represents a mechanism that should be able to guarantee such eager applicants a route to issuance consuming no more than three years of that 20-year statutory term.

As the USPTO has moved forward with its new fee-setting responsibilities, it is clear that patent maintenance fees will remain one of its sustaining revenue sources. However, unlike many other countries in which maintaining a patent in force can be achieved through the annual payment of a modest fee, U.S. law has, since the inception of maintenance fees in 1979, required "prepayment" of these fees. For example, at 11 years, six months after patent grant, a lump-sum fee must be paid to keep the patent in force for the remaining term of the patent. Fee-setting authority now gives the USPTO the flexibility it needs to move to annual maintenance fees on patents. Like the current fees, they can be progressive as the 20-year term

**Robert A. Armitage** is chair of the ABA Section of Intellectual Property Law. He serves as senior vice president and general counsel at Eli Lilly and Company in Indianapolis, Indiana. He can be reached at armitage_robert_a@lilly.com.



Published in *Landslide,* Volume 4, Number 5, May/June 2012. 

runs, but without the 3-, 7-, and 11-year "choke points" of current law.

Another area of compromise along the AIA's legislative journey that may now have matured into an area of consensus for further improvement relates to the "best mode" requirement. Congress nullified this requirement in the patent enforcement context, but left it untouched in the patent procurement context. This anomaly makes no sense and, indeed, there are hopeful signs that an emerging consensus on this point can lead to outright repeal through relatively swift legislative action.

The new law provided a grand compromise on the prior-user defense, putting the United States in greater alignment with the laws of other countries that protect a prior domestic commercialization of new technology from allegations of infringement of subsequently sought patents. The key feature of the compromise, which enabled universities to lend support for the AIA, was the exclusion of university-owned patents from the assertion of the defense. However, as the recent USPTO study of the use of this defense has now confirmed, U.S. law still falls short of international norms in three respects: (1) not recognizing completion of substantial efforts to commercialize as sufficient to trigger the defense, (2) the one-year hold-back provision after commercialization before the defense can be asserted, and (3) a limitation on the type of patent claims to which the defense applies. A new dialogue with the university community may yet produce a path forward to the consensus required to get these improvements enacted into law, perhaps forthwith.

Finally, it may be that the next Congress can make more explicit the implicit provisions of the AIA by enacting an express and categorical statutory bar to unenforceability pleadings based upon "inequitable conduct" allegations. In the patenting process dictated under the AIA—one that is open to the public, with public participation before and after the patent issues, and with the standards for determining patentability and patent validity turning almost entirely on information available to the public—a misconduct-based unenforceability doctrine imposed on otherwise valid and enforceable patent claims makes sense only if the misconduct in question infects the enforcement of the patent, i.e., is misconduct before the court perpetrated by an "unclean litigant."

The sum and substance of the above changes plays on themes familiar to those involved in the six-year journey that produced the AIA: the best patent system is one that is the most transparent, most objective, most predictable, and most simple. If that be the case, nothing says that Congress needs to wait to make what is now the world's best patent law even better. So, I would ask, "Why wait?" ■

# The America Invents Act: Will it be the Nation's Most Significant Patent Act Since 1790?

**By Robert A. Armitage, Esq.**
***Eli Lilly & Co.***

On Sept. 16 the 150-page Leahy-Smith America Invents Act, H.R. 1249, became law. It is, without question, significant, even record-setting, patent legislation.

The America Invents Act is — by far — the lengthiest patent act in our nation's history. It is more than double the size of the bill creating the 1952 Patent Act, which recodified the entirety of U.S. patent law from scratch.

The new act's legislative gestation consumed over six years. Only once before, in enacting the American Inventors Protection Act of 1999, did Congress take so long to bring a new patent law into being.

Being the lengthiest patent act of all time — and the slowest to transit Congress — constitute at best uninspiring superlatives. They hardly suggest that this new congressional work product might one day be acknowledged not just as a significant advance in U.S. patent law, but as the most significant since the first Congress crafted the first patent act in 1790.

To make good on such a brash and bold aspiration would be to fulfill a very tall order. It would require that the new law surpass in its implications and affect both the Patent Act of 1836 (creating the patent office and the modern system of patent examination) and the 1952 Patent Act (providing a complete and cogent, ground-up restatement of all U.S. patent law under a full statutory recodification). In other words, the America Invents Act needs to achieve nothing short of extraordinary credentials to top the significance of these two great patent acts of the 19th and 20th centuries.

Just why might the America Invents Act someday realize such an outsized potential? For the proponents of the new law, it holds the promise of accomplishing two things, each of which is potentially profound.

The first possible accomplishment would be to work a revolution in the criteria by which a new invention can be judged to have been validly patented in the United States. The new act both limits and then reshapes patenting rules to those that, both individually and collectively, are transparent, objective, predictable and simple. It also successfully retains and even enhances the historic inventor-friendly and collaboration-friendly features that have long set U.S. patent law apart from patent systems globally.

The second potential impact is even more ambitious: that our new patent law will serve as a beacon to guide future changes in foreign patent laws so that in the decades ahead, foreign patent laws would come to be built around the very same principles Congress enshrined in our new law. Should this potential be realized, greater harmonization of the world's patent laws may come to mean nothing more than foreign patent laws adopting the mold and model of America Invents Act provisions.

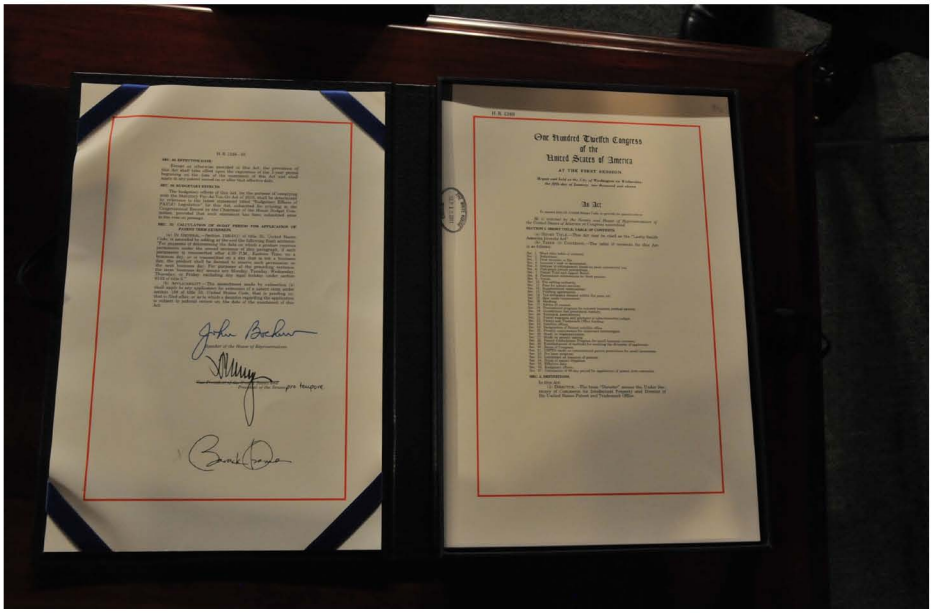


Photo by Sen. Patrick J. Leahy

***The America Invents Act, shown here after President Obama signed it, more than double the size of the bill creating the 1952 Patent Act, which recodified the entirety of U.S. patent law from scratch.***

## HOW DOMESTIC PATENT LAW PRINCIPLES WILL BE REVOLUTIONIZED

### *The New Law is TOPS*

The proponents of the America Invents Act sought a new patent law — and a reformed patent system — operating with greater transparency, objectivity, predictability and simplicity in the determination of whether a valid patent could be granted on an invention. To a quite stunning degree, they got what they were seeking with the enactment of the America Invents Act.

**Transparency.** Once the America Invents Act takes full effect, only information that has become available to the public before an inventor seeks a patent for an invention — or had become publicly available from an earlier patent filing by someone else — will be used to determine whether the invention to be patented is sufficiently different from pre-existing knowledge to merit a patent. To achieve this result, the America Invents Act erases from U.S. patent law an array of archaic principles and practices that resulted in secret knowledge or secret activities — sometimes secret activities undertaken by the inventor and other times secret work done by third parties — being cited to prevent

a patent from issuing or to destroy its validity once granted.

**Objectiveness.** In a similar manner, the new statute removes from existing patent law subjective tests that have historically been considered in the assessment of whether a patent is valid. When did the inventor first think of the invention in its completed form? On the day of the patent filing, what did the inventor contemplate would be the best mode for practicing the invention? These types of subjective inquires have no relevance under the America Invents Act. This full objectivity in patenting principles will be particularly relevant in assessing whether the inventor's patent filing sufficiently disclosed the new invention. Henceforth, a sufficient disclosure rests on two objective standards: whether the actual embodiments of the claimed invention are properly identified in the patent, and whether those embodiments could be put to a practical and substantial use based on the information provided by the inventor in the patent.

**Predictability.** To a remarkable extent, the new law secures greater predictability in the assessment of a patent's validity by removing unneeded patent law concepts that were fact-intensive and required much discovery during lawsuits to resolve. What remains is a patent law focused on legal standards in preference to extensive factual inquiries.

Predictability is further enhanced for inventors through a set of new remedial and "safe harbor" provisions aimed at permitting an inventor to address and rectify errors and omissions in the information provided to the U.S. Patent and Trademark Office prior to the grant of the patent. If an inventor is incorrectly named in the patent, the naming of the inventor can be more readily corrected. If the inventor supplied a deficient oath as to inventorship, a corrected substitute can be more readily provided and accepted. If other information was missing or incorrect during the original examination of the patent, the missing or corrected information can now be provided and considered in a new procedure that is specifically tailored for this purpose. In each of these respects, patents will become more predictably valid and predictably enforceable.

**Simplicity.** What the America Invents Act has in essence done is to boil the entirety of U.S. patent law down to a set of four largely legal questions and standards that, while they fully protect the public from overly broad or overly vague patents, require little discovery and minimal fact-finding. In a sentence, once the law fully takes hold, the validity for a patent will require no more than that an inventor's claimed invention be confined to subject matter that is:

- Sufficiently different from what was already available to the public (or previously disclosed in a publicly available patent filing made by someone else) as of the date that the inventor's patent was sought.
- Sufficiently disclosed so that the actual embodiments of the invention are identified and can be put to a substantial and practical use.
- Sufficiently definite so a skilled person reading the patent knows what is and is not being patented.
- Sufficiently concrete so that whatever is claimed in the patent is not excessively conceptual or otherwise abstract in character.

Once the new patent law is fully implemented, patents granted under it will be valid or invalid based on whether these four legal criteria are met, producing a patent law its proponents contend is TOPS: transparent, objective, predictable and simple. Indeed, by being TOPS, basing patenting on information available to the public and largely restricting the law to legally rather than factually grounded tests for patenting, it becomes possible that in much patent litigation, little — perhaps no — discovery from the inventor may be of any relevance to the validity of a patent. This, of course, would represent a profound reversal of the situation that applies under existing U.S. patent law.

> The statute successfully retains and even enhances the historic inventor-friendly and collaboration-friendly features that have long set U.S. patent law apart from patent systems globally.

### *U.S. Patent Law Becomes Even More Inventor-Friendly and Collaboration-Friendly*

Making the substantive patent law simpler and more transparent was, however, only the beginning of the benefits that supporters of the new act now tout. The United States has long recognized a "grace period" during which inventors who disclosed their inventions during the year before seeking patents were not subject to their own disclosures being used against them to destroy the validity of their patents.

The America Invents Act not only continues these protections for inventors, but further enhances them with a guarantee to the first inventor to publicly disclose an invention of the right either to patent the invention, provided a patent filing is made during the one-year grace period after the disclosure, or to dedicate the invention to the public, in the event the inventor elects not to seek a patent.

The same can be said for the so-called "collaboration-friendly" features of U.S. patent law. In 1999, and again in 2004, Congress amended patent law initially to protect co-workers, and later to protect all individuals working collaboratively under joint research agreements, from having their respective patent filings cited against one another as "prior art." Prior to these changes, an earlier-filed patent application of one such co-worker or collaborator could be cited as a ground for holding the later patent filings of any others unpatentable, even if the earlier patent filing had not become public at the time the later patent filing was made.

The America Invents Act reinforces these unique collaboration-friendly features of U.S. patent law by providing that such earlier patent filings cannot be cited to show either lack of novelty or obviousness in the later patent filing of another co-worker or collaborator. The ironclad protections of this type now found in U.S. patent law are unprecedented; foreign patent systems typically hamper collaborative work by allowing all of the earlier patent filings of inventors, co-workers and other collaborators to be cited as prior art to destroy the novelty of later-filed patents within the same organization or joint-research group.

Looking globally across patent systems today, it becomes clear that one and only one

patent system now exists that fully recognizes the realities of invention in the 21st century. In an era of cooperation and collaboration among research organizations, it is essential that patenting principles reflect that reality. The U.S. patent law now embodies the international "gold standard" for protecting the fruits of collaborative research — and can be credibly monikered as the world's first truly 21-century patent law.

### *How U.S. Law Will Set The Standard for the Public's Role in the Patenting Process*

As early as 1980, Congress recognized that the 1836 model of patent examination was deficient in failing to provide any formalized means for public participation in the patenting process. In that year, Congress passed a bill providing for the *ex parte* re-examination of previously issued patents, on the limited ground of whether a patent or other publication raised a substantial new question of patentability. These provisions were subsequently broadened in 1999 under the American Inventors Protection Act to add an *inter partes* re-examination procedure.

The America Invents Act phases out the 1999 *inter partes* procedure and instead offers what could prove to be the world's best provisions for public participation in the patenting process. First, the new law provides effective public participation early in the patenting process — before a decision to issue a patent is made by a patent examiner. It does so by providing a formal mechanism for submitting information relevant to whether the subject matter for which a patent is being sought is new and nonobvious — sufficiently different from the prior art to merit issuing a patent.

In a more sweeping set of statutory changes, the replacement for the 1999 re-examination law provides that both the patent owner and someone challenging a patent's validity can receive a prompt and fair adjudication of each significant validity issue raised by the challenger. The new procedures are termed "post-grant review" and "*inter partes* review," with the first available only during the period immediately after a patent issues and the latter available thereafter throughout the life of the patent.

These replacement procedures are to be conducted by legally trained, technically competent administrative patent judges, not (as under current law) patent examiners. They can only be initiated through a request that provides all the legal arguments and factual support for moving ahead with the proceeding at the time the request to challenge the patent is initially lodged with the Patent and Trademark Office. They are to be confined to addressing only issues where a serious question of validity has been established, an issue that is more likely than not to invalidate the patent or for which there is at least a reasonable likelihood of invalidation.

As a result of being "front loaded" with the relevant evidence and arguments of the challenger and limited to truly serious questions of patent validity, each of these new proceedings is subject to a one-year statutory deadline to reach a final decision. Because of the legal nature of the patent validity issues under the America Invents Act — and the limited nature of the factual matters that will underlie those legal determinations — the new procedures provide for limited discovery, assuring fairness while tightly controlling the time and costs required to get to a final resolution.

> What the America Invents Act has in essence done is to boil the entirety of U.S. patent law down to a set of four largely legal questions and standards that require little discovery and minimal fact-finding.

Again, the promise of the new law is nothing short of revolutionary. By moving away from the so-called "opposition" procedures used in Europe since the 1970s, where the European Patent Office typically takes five times — even 10 times — as long to resolve a "patent opposition" as the new U.S. law will permit, the new U.S. post-grant regime, if effectively implemented, may well earn the status of international gold standard for defining the mechanisms for public participation in the patenting process.

### *What The New Act Means for Efforts at Global Patent Cooperation and Harmonization*

The America Invents Act — the world's first truly 21-century patent law — contains all the elements needed for a patent system to operate effectively, efficiently, economically and equitably. If the decade ahead yields greater international patent cooperation and harmonization among patent systems around the world, the starting point for that effort should lie in the incorporation of its provisions into patent laws across the globe.

Should that promise be realized, the America Invents Act will have realized its full potential as the most significant patent act since 1790, not only for the United States, but for inventors and creators everywhere, as well as those who invest in the creation of new inventions, those who are employed producing and selling them, and, of course, those who are then able to benefit from them as consumers.

**Robert A. Armitage** is senior vice president and general counsel of **Eli Lilly & Co.** 