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Pacific Northwest Perspective: The Impact of the America Invents Act on Nonprofit Global Health Organizations

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PACIFIC NORTHWEST PERSPECTIVE: THE IMPACT OF
THE AMERICA INVENTS ACT ON NONPROFIT
GLOBAL HEALTH ORGANIZATIONS

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ABSTRACT

The Leahy-Smith America Invents Act of 2011 (AIA) makes fundamental changes to the legislative landscape governing patent law in the United States and will bring about corresponding changes in the manner in which inventors and attorneys address patent issues. While the

* John Morgan, Seattle University School of Law, Class of 2014. My fantastic family deserves first thanks for their sustained support of my education and for always making me laugh. My scientific curiosity was sparked by Dr. Leslie Saucedo at the University of Puget Sound and developed at the Fred Hutchinson Cancer Research Center under the guidance of Drs. Cecilia Moens, Greg Walsh, and Adam Miller. Many others have taught and inspired me along the way, but I cannot name you all. Thank you for guiding me along a fascinating and rewarding journey.

** Veronica Sandoval, Seattle University School of Law, Class of 2013. Because most of the work for this manuscript occurred on weekends, nights, and other times that were inconvenient to my family, I want to thank my husband and my two boys for their patience, their support, and their endless encouragement. This project would not have been possible without the assistance and quality input of many others. The authors thank former Seattle University Law Review members Daniel Lee, Rachel Dunnington, and Ryan Dumm for their enthusiastic support of our work. Bob Menanteaux, information services librarian at Seattle University School of Law, gave cogent feedback and helped greatly in directing our research. Curt Malloy and Jessica Cohen of IDRI helped conceive the initial idea and consistently provided contemplated, constructive critiques throughout the process. Finally, our interviewees, who must remain anonymous, deserve many thanks for their time, willingness to participate, and thoughtful input.

law is newly implemented, inventors in all sectors of the economy are eager to formulate reactions to it. In this Article, we explore the effects of the AIA on nonprofit research organizations dedicated to global health and life sciences. We report the perspectives of counsel representing such organizations throughout the Pacific Northwest. We also consider the patent system, and the Act's effects on the system, in the context of scientific and humanitarian motivations.

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INTRODUCTION

Imagine the following scenario: A technology manager at a nonprofit bioscience research organization contacts her institution's patent counsel, excited to share an extremely promising advance from one of her labs—a new adjuvant system that greatly increases the efficacy of a developmental tuberculosis vaccine. The system works so well that she is certain that a large pharmaceutical company will pay a significant licensing fee for the technology. All that is needed, she thinks, is to file a patent application to protect the invention and help secure the funding required to deliver a new vaccine system to at-risk populations around the world. Additionally, this deal will provide crucial funding for the organization in a difficult economy.

Tragically, the benefits of this invention may not be realized. The researcher who developed the new system neglected to inform the technology manager about a symposium presentation during the invention's early stages, about a year ago. Cognizant of the existing patent laws, he did not distribute any printed publications regarding his invention, but a slideshow featuring his abstract was accessible on the symposium website for an undetermined length of time. Under the newly implemented America Invents Act (AIA), the invention may be considered available to the public for over a year and therefore not patentable. As a consequence of failing to file an application until after March 16, 2013, the nonprofit organization could lose out to a wealthier applicant—perhaps its potential licensee—under the new “first-inventor-to-file” priority system. With no patent to protect its intellectual property, the nonprofit loses control over a licensable technology, cannot attract investment to develop or deliver the adjuvant where it will do the most good, and loses a valuable source of revenue. This hypothetical, while somewhat simplistic and dramatic, illustrates the potential impact of the AIA on inventors in the nonprofit sectors.

Part I of this Article discusses the statutory and historical backdrop of both the U.S. patent system and the AIA. Part II examines nonprofit research organizations as innovators within the patent system and describes our inquiry into the AIA's effects—

real, perceived, or anticipated—on these innovators. This inquiry focuses on five aspects of the AIA that we identified as being of special concern to nonprofits. In Part III, we discuss the results of our qualitative survey on the aforementioned effects of the AIA on nonprofit innovators, as described by the in-house and outside counsel who represent such innovators in the Pacific Northwest.

I. THE U.S. PATENT SYSTEM AND THE AMERICAN INVENTS ACT

A. *Innovation and the U.S. Patent System*

Innovation has been celebrated in the United States since the Founding. It has been called “the key driver of competitiveness, wage and job growth, and long-term economic growth,”¹ and this valuation has resulted in an advanced system of intellectual property laws designed to foster innovation, as a mechanism for advancing society, by rewarding individual efforts.

In that spirit, the drafters of the Constitution empowered Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”² The resulting intellectual property laws enacted by Congress protect exclusive rights that are expressed in copyright,³ trademarks,⁴ and patents. A patent is an exclusive government-granted exclusive right to make, use, sell, or offer to sell a claimed invention for a limited time.⁵ The rightful holder of a patent is empowered to sell or license the patent, or to sue for damages or an injunction when the right is infringed. For a patent to issue, the invention must meet certain utility, novelty, and nonobviousness requirements as determined

¹ U.S. Dep’t of Commerce, *The Competitiveness and Innovative Capacity of the United States* (Jan. 2012) at 9, http://www.commerce.gov/sites/default/files/documents/2012/january/competes_010511_0.pdf.

² U.S. CONST. art.1, § 8, cl. 8.

³ See 17 U.S.C. § 102(a) (2006) (copyright given to the author of original works that are fixed and reproducible).

⁴ See 15 U.S.C. § 1127 (2006) (trademark protects a “word, name, symbol, or device” identifying unique goods).

⁵ AMY L. LANDERS, UNDERSTANDING PATENT LAW 1 (LexisNexis, 2nd ed. 2012) (defining “practicing” a patent).

by an examiner at the United States Patent and Trademark Office (USPTO).⁶ A patent application to the USPTO must also contain “one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or joint inventor regards as the invention.”⁷ Claims define the patented invention and determine its operative legal effect.⁸ If a patent issues, the holder obtains an exclusive right to the invention for twenty years from the initial filing date of the application.

In a global marketplace, the value of exclusive rights to an invention is potentially massive. A recent study showed that the 2,000 largest global companies invested more than \$640 billion in research and development in 2008.⁹ In the United States, the number of patents issued annually has increased from roughly 70,000 in the 1980s to well over 200,000 in the 2000s, with over 8 million total patents issued since the late eighteenth century.¹⁰ In the short term, this trend looks set to continue.¹¹

⁶ A patentable invention is one that is truly novel, provides a function, and is not obvious, in light of previous knowledge, to an inventor of ordinary skill in the art. See U.S. Patent and Trademark Office (USPTO), *Novelty and Nonobviousness, Conditions for Obtaining a Patent* (Nov. 2011), http://www.uspto.gov/patents/resources/general_info_concerning_patents.jsp#heading-5. See also 35 U.S.C. § 112(a) (requiring a “written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains”) (emphasis added).

⁷ 35 U.S.C. § 112(b) (2006).

⁸ LANDERS, *supra* note 5, at 57.

⁹ Joint Research Centre (EC), INSTITUTE FOR PROSPECTIVE TECHNOLOGICAL STUDIES, *The 2009 EU Industrial R&D Investment Scoreboard*, at 16, (2009), <http://iri.jrc.ec.europa.eu/scoreboard09.html;jsessionid=py3jSywRGLKbzyB14vrGv452FddZzjW9D9FdT7ysvyDnyRLgljpX!-573964881!1390997617993>. We converted the figure from euros to U.S. dollars using the average conversion value for the year 2008, calculated using data from X-Rates, available at <http://www.x-rates.com/average/?from=EUR&to=USD&amount=1.00&year=2008>.

¹⁰ USPTO, *U.S. Patent Activity, Calendar Years 1790 to the Present*, http://www.uspto.gov/web/offices/ac/ido/oeip/taf/h_counts.htm (last visited Feb. 6, 2014).

¹¹ See Dennis Crouch, *USPTO Grant Rate: 2013 Forecast*, PATENTLYO (Jan. 8, 2013, 11:19 AM), <http://www.patentlyo.com/patent/2013/01/uspto->

B. Legislative Background and Context

As patent activity in the United States has grown in scope and intensity, evolution has been necessary to achieve positive societal outcomes through a system predicated on private incentives. Since the Patent Act of 1790, the system has undergone continual amendment, with the last major changes made in 1952.¹² Recently, commentators have cited the high costs of litigation, common abuses of the patent system,¹³ and the divide between U.S. and foreign practices to justify further legislative address.¹⁴

To that end, some legislators attempted revisions via the proposed Patent Reform Acts of 2005, 2007, and 2009. Various provisions in these bills attempted to decrease the overall costs and sheer amount of patent litigation while raising the quality, efficiency, and international compatibility of the patent system.¹⁵ However, it was not until January 2011 that Senators Patrick Leahy of Vermont and Lamar Smith of Texas co-sponsored a successful bill, enacted as the AIA in September of that year.¹⁶ The AIA's central provisions took effect on March 16, 2013.

Given its economic significance, the bill was unsurprisingly

[grant-rate-2013-forecast.html](#) (stating that the USPTO, shortly after issuing a single-day record of 5,633 utility patents on Jan. 8, 2013, projects issuing a record 290,000 patents this year).

¹² *US Patents—A Brief History*, THE BUSINESS OF PATENTS (Feb 7, 2014), <http://www.the-business-of-patents.com/us-patents.html>.

¹³ One common complaint among small inventors is that frivolous lawsuits filed by larger entities (often non-practicing entities or “patent trolls”) stifle innovative progress because inventors spend valuable resources defending against the claim that would be better spent on R&D. See Ben Lee, *Twitter: It's time for patent trolls to bear the cost of frivolous lawsuits*, GIGAOM (Oct. 8, 2012, 6:00 AM), <http://gigaom.com/2012/10/08/twitter-time-for-trolls-to-pay-full-price-for-patent-mischief>. See also Charles Duhigg and Steve Lohr, *The Patent, Used as a Sword*, N.Y. TIMES (Oct. 7, 2012), <http://www.nytimes.com/2012/10/08/technology/patent-wars-among-tech-giants-can-stifle-competition.html?pagewanted=all>.

¹⁴ Jason Rantanen, Lee Petherbridge & Jay P. Kesan, *America Invents, More or Less?*, 160 U. PA. L. REV. 229 (2012).

¹⁵ *Patent Reform Act of 2009*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/111/s515#summary> (last visited Feb. 3, 2014).

¹⁶ See *A Companion to Science and Engineering Indicators 2008*, NAT'L SCIENCE BD. (Jan. 2008), <http://www.nsf.gov/statistics/nsb0803/start.htm>.

subject to intense lobbying efforts as it wound its way through Congress. Large corporations in the financial services, pharmaceutical, and computer/telecommunications industries were strong proponents of the proposed AIA. Notably in favor were such established entities as Microsoft, IBM, GE, Caterpillar, Dow Chemical, PepsiCo, and Procter & Gamble.¹⁷ Newer technology industry actors, including Google, Apple, Yahoo!, and eBay favored the move to “first-to-file” but disapproved of the proposed legislation because they feared it would raise the costs of the patent challenge system, ultimately detracting from valuable research and development (R&D) efforts.¹⁸

In notable opposition to the AIA, the National Small Business Association (NSBA) claimed that the law was severely tilted “against small innovators and in the favor of large, multinational corporations.”¹⁹ According to the NSBA, small entities are the most efficient drivers of the patent system, but are greatly disadvantaged under a first-to-file regime, which favors large companies that can quickly file fully developed applications.²⁰ Many commentators shared this concern.²¹ Further, the NSBA interpreted the AIA to “gut” a one-year grace period prior to filing a patent application, during which inventors could raise capital and create partnerships without fear that disclosures would become prior art.²² Thus, some tension existed between small and big

¹⁷ See Kurt Mackie, *Q&A: A Patent Attorney Explains How the ‘America Invents Act’ Will Affect Tech*, REDMOND MAGAZINE (Sep. 20, 2011), available at <http://redmondmag.com/articles/2011/09/20/impact-of-america-invents-on-tech.aspx>.

¹⁸ *Id.*

¹⁹ Nat’l Small Bus. Ass’n, *NSBA Cautions Lawmakers Against Patent Reform*, (Sep. 7, 2011) <http://www.nsba.biz/content/4181.shtml>.

²⁰ Nat’l Small Bus. Ass’n, *Patent Reform: Small business concerns are fundamental to any discussion concerning patent reform* (May 2012), <http://www.nsba.biz/wp-content/uploads/2012/05/Patent-Reform.pdf>.

²¹ See, e.g., Clyde Prestowitz, *The Prevent American Invention Act*, FOREIGN POLICY (May 16, 2011), available at http://prestowitz.foreignpolicy.com/posts/2011/05/16/the_prevent_american_invention_act.

²² Nat’l Small Bus. Ass’n, *Patent Reform Bill Will Crush Small-Business Innovation*, NSBA LATEST NEWS (June 22, 2011), <http://www.nsba.biz/content/4008.shtml>.

business with respect to the AIA. The perspective the academic and nonprofit sectors, another significant innovating community, did not receive as much attention.

II. THE POTENTIAL IMPACT OF THE AIA ON NONPROFIT INNOVATION

Nonprofit innovators at government entities, independent research centers, foundations, hospitals, and universities operate under much different circumstances—and often with quite different goals—than their counterparts in the for-profit world. From bone marrow transplants to satellite communication, nonprofit entities have made significant inventive contributions to many vital technological fields.²³ If applying technology to solve compelling problems is a desired outcome of the patent system, then any assessment of that system must consider the state of medicine and public health.

While for-profit companies typically mass-produce and bring therapeutics to the commercial market, most of the basic research advancing health science in this country is conducted at publicly funded universities and other nonprofit research centers.²⁴ These

²³ For example, the first successful bone marrow transplant was conducted at the Fred Hutchinson Cancer Research Center by Dr. E. Donnell Thomas in 1956, see Fred Hutchinson Cancer Research Ctr., *Impact of Dr. E. Donnell Thomas's Work*, <http://www.fhcr.org/en/about/honors-awards/nobel-laureates/thomas/thomas-impact.html> (last accessed Mar. 30, 2013), while work at the National Aeronautics and Space Administration (NASA) has produced or led to such advances as water filters, adjustable smoke alarms, cochlear implants, insulin pumps, arterial imaging technology, and major advances in long-distance telecommunications. See, e.g., Patrick J. Kiger and Marianne English, *Top 10 NASA Inventions*, HOWSTUFFWORKS, <http://www.howstuffworks.com/innovation/inventions/top-5-nasa-inventions.htm#page=3> (last accessed Apr. 4, 2013).

²⁴ See Nat'l Sci. Found., *A Companion to Science and Engineering Indicators 2008*, (Jan., 2008), <http://www.nsf.gov/statistics/nsb0803/start.htm> (“Federal funding is the primary source of basic research support in the U.S. (over 59% in 2006), of which about 56% is carried out by academic institutions. U.S. basic research is also funded by foundations (about 10%), universities and colleges (about 10%), and state and local governments (about 3.5% through funding of academic basic research”).

research institutions make notable contributions to economic activity²⁵ and play a major role in commercializing early-stage inventions.²⁶ Although nonprofit organizations freely disseminate much of their work for the benefit of the public, substantial benefits can be realized when discoveries from nonprofit research enter the commercial sector for development into useful products and processes. The landmark 1980 Bayh-Dole Act²⁷ has been an extraordinarily successful mechanism for facilitating the transfer of basic discoveries into the commercial sector for development.²⁸

The general goals of nonprofit research institutions are to increase the scope of knowledge in relevant fields; publish findings

²⁵ Nonprofit research organizations have contributed between \$199-\$836 billion of U.S. gross domestic product from 1996-2010. See Lori Pressman et al., *The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2010*, BIOTECHNOLOGY IND. ORG. (June 20, 2012), <http://www.bio.org/sites/default/files/BIOEconomicImpact2012June20.pdf>.

²⁶ Frank X. Curci, *Life Sciences: Changes in patent law challenge nonprofit bioscience institutions*, PUGET SOUND BUS. J., July 13, 2012, <http://www.bizjournals.com/seattle/print-edition/2012/07/13/life-sciences-changes-in-patent-law.html?page=all>.

²⁷ Pub. L. 96-517 (authorizing universities and small businesses to retain patent and licensing rights to inventions resulting from federally funded research and requiring recipients of federal funds “to maximize the use of their research findings by making them available to the research community and the public at large and through their timely and effective transfer to industry for development.”). See also NATIONAL INSTITUTES OF HEALTH, *Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts*, 59 Fed. Reg. 55673, 55674–79, Nov. 8, 1994, available at <http://grants.nih.gov/grants/guide/notice-files/not94-213.html> (last accessed Feb. 7, 2013).

²⁸ See Memorandum from the Ass’n of Am. Univ. et al. to Office of Sci. and Tech. Policy and Nat’l Econ. Council on Commercialization of Univ. Research (May 10, 2010), available at <http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=10808> (noting that prior to 1981 fewer than 250 patents were issued to United States universities annually, and laboratory discoveries were seldom commercialized for the public benefit). See also *Association of University Technology Managers U.S. Licensing Activity Survey Highlights* (2011), http://www.autm.net/AM/Template.cfm?Section=FY_2011_Licensing_Activity_Survey&Template=/CM/ContentDisplay.cfm&ContentID=8731 (finding that 4,700 United States patents were issued to United States universities during 2011, while 671 new start-up companies were formed and 591 new products were introduced based upon university inventions).

and secure further funding; and, depending on the institution, implement the findings to solve the problem. The governing objective for many nonprofit health science organizations is to treat or eradicate diseases such as cancer, tuberculosis, or malaria through therapeutics, vaccines, public health mechanisms, or other means. The nonprofit model subsumes economic gain to problem-solving goals. Nonetheless, licensing technology plays an important role in the nonprofit sector because licensing technology to commercial actors for development and introduction to market is mutually beneficial for both nonprofit and commercial actors.

Patents are critical to enabling this process. Identifying, cultivating, and selling commercially successful health science products is an extremely expensive and risky process²⁹ involving numerous failed candidates and experimental setbacks.³⁰ For a nonprofit to realize the promise of a given innovation, it must be marketed to commercial partners as a viable, low-risk investment. The security of the innovation's intellectual property mitigates the risk of an investment. Nonprofits, therefore, are motivated to protect their intellectual property.

Other features of nonprofit bioscience research organizations distinguish them from similar innovating communities as well. While curing a certain disease may be a nonprofit research organization's mission, innovation in furtherance of that mission is largely practiced by academic scientists, whose individual aims may diverge from those of the parent organization. The time a researcher spends with a given organization may be relatively short (graduate or fellowship tenures often range from three to six

²⁹ The average input cost for a commercially available drug is in excess of \$1 billion. See Roger Collier, *Drug development costs hard to swallow*, CAN. MED. ASS'N. JOURNAL (Feb. 3, 2009), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2630351/pdf/20090203s00009p279.pdf>.

³⁰ More than 6,000 completely new chemical compounds are synthesized for every one drug that ultimately comes to market. See Gregory A. Petsko, *When failure should be the option*, BIOMEDCENTRAL (May 21, 2010), <http://www.biomedcentral.com/1741-7007/8/61>. See also Sandra Krajlevic, Peter J. Stambrook & Kresimir Pavelic, *Accelerating drug discovery*, EMBO REPORTS (Sept. 2004), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1299137>.

years). In that context, these scientists are incentivized to publish their work as a primary goal. Disclosing a promising development can enhance a researcher's career and advance scientific knowledge. Thus, most researchers are not as concerned with exploring commercial opportunities as they are with producing quality research and securing research funding.³¹

As such, the major aims of the innovators and the nonprofit research entity they innovate "for" are sometimes imperfectly matched. These factors, in the context of commercial and legal realities, create a unique set of considerations regarding intellectual property protection. The leadership and administration of such organizations, as well as the attorneys who counsel them, must assess intellectual property practices against the nonprofits' goals and limited resources.³² A high concentration of nonprofit research

³¹ This assertion is based on the Authors' respective experiences in academic science and the opinions of our survey respondents.

³² A complete exploration of the patent system and its role in promoting positive advances necessarily encompasses an examination and critique of whether patents are a necessary or even desirable way to spur innovation. This Article assumes that patent law is a fixed construct in our social landscape, and that it does provide certain benefits and incentives to innovators across the for-profit and nonprofit spectrum. Our scope is accordingly limited to how nonprofits can best operate and how systemic changes affect nonprofit research. However, there are certainly examples of unpatented biotechnology benefitting the world (e.g., the polio vaccine was never patented), and many serious criticisms of the patent system exist. Critics claim, for example, that patents reward the already wealthy, monopoly slows innovation and worthy uses of technology, bad patents on already-known inventions are commonly issued, patents permit non-practicing entities to depress the efficacy and affordability of using technology, patents on human genes or food products are unfavorable for a number of reasons, patents reward only incremental improvements in pharmaceutical products, rather than actually solving health problems, and that such patents raise drug costs to prohibitive levels, depriving the poor from that benefit and enriching shareholders in large pharmaceutical companies. See generally Richard A. Posner, *Why There Are Too Many Patents In America*, THE ATLANTIC (July 12, 2012), <http://www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725/>.

Inventors may choose alternatives to patenting, such as publishing defensively to prevent a patent by another and providing the invention freely to the world, providing federal "prize money" to compensate inventors for forgoing a patent monopoly, pursuing exclusive licenses to ensure that customers do not use a competing product but permitting others to use the idea,

and funding organizations is found in the Pacific Northwest,³³ including the Bill & Melinda Gates Foundation, the University of Washington, Fred Hutchinson Cancer Research Center, the Infectious Disease Research Institute, Washington State University, Seattle Biomedical Research Institution, PATH, Seattle Children's Research Hospital, Oregon Health Sciences University, and the Institute for Systems Biology. These entities focus on advancing science and solving worldwide public health issues.

To create our survey, we identified five aspects of the AIA likely to most impact these and similar nonprofit research organizations: (i) The transition from a "first-to-invent" to a "first-inventor-to-file" (FITF) system, (ii) the prior commercial use defense to infringement claims and accompanying university exception, (iii) the expanded definition of prior art and changes to the inventor's one-year pre-filing grace period, (iv) the amended third party patent challenge system, and (v) the implementation of derivation proceedings and new post-grant challenge procedures. We will present each of these aspects of the AIA before discussing the survey response data.

A. *First-Inventor-to-File*

Among the most significant changes under the AIA is a shift from a first-to-invent system to an FITF system, which went into effect on March 16, 2013.³⁴ Prior to the AIA, the United States issued patents based on a first-to-invent system, whereby patent priority went to the first inventor in fact, rather than to the first inventor to file for a patent.³⁵ In contrast, the AIA awards patent

and implementing "utility models," which have a shorter duration and are cheaper and easier to obtain. *See, e.g.*, World Intellectual Prop. Org., *Protecting Innovations by Utility Models*, http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm (last visited Feb. 6, 2014).

³³ A recent tally listed over 40 biology focused nonprofits, academic institutions, and support organizations in the region. *See* Stewart Lyman, *Seattle (NW) Biotechnology Resource Page*, LYMAN BIOPHARMA CONSULTING LLC, <http://www.lymanbiopharma.com/seattlebionon-profits.html> (last visited Feb. 6, 2014).

³⁴ H.R. 1249 § 3(b), 112th Cong. (2011).

³⁵ 35 U.S.C § 102(g) (1952).

rights to the first inventor to file, thereby placing a premium on filing as soon as possible. Whether the first applicant actually represents the first completion of the invention is irrelevant.³⁶ This system comports with similar first-to-file patent systems in most other countries.

International harmonization was a key goal of the AIA, but the United States' FITF system is discernible from the traditional international first-to-file system.³⁷ Under a traditional first-to-file system, absolute novelty is required in order to obtain a patent; that is, no patent can be granted if there is a prior use or publication of information relating to the invention.³⁸ By contrast, the AIA maintains a one-year grace period, dating back from the inventor's filing date, wherein certain disclosures of the invention will not bar patentability. This grace period has been modified and is addressed in Part II(d).

In addition, the "effective filing date" under the AIA is either the actual filing date of the nonprovisional application or the filing date of the provisional application that the applicant is entitled to claim.³⁹ While a provisional application cannot result in a patent, under a relation-back theory, the application gives a later

³⁶ Wendy H. Schact & John R. Thomas, *The Leahy-Smith America Invents Act: Innovation Issues*, Cong. Research Serv., C.R.S. R4201 (2013), available at <https://www.fas.org/sgp/crs/misc/R42014.pdf>.

³⁷ Wendell Ray Guffey & Kimberly Schreiber, *America Invents Act: The Switch to a First-to-File*, 68 J. Mo. B. 156 (2012), available at <http://www.mobar.org/uploadedFiles/Home/Publications/Journal/2012/05-06/invents-act.pdf>.

³⁸ See Gene Quinn, *America Invents: A Simple Guide to Patent Reform, Part 1*, IPWATCHDOG (January 9, 2013, 12:30 PM), <http://www.ipwatchdog.com/2011/09/26/america-invents-a-simple-guide-to-patent-reform-part-1/id=19427/>.

³⁹ The various circumstances that can determine the appropriate filing date are described in under 35 U.S.C. §§ 119, 120, 121, or 365(a)-(c). H.R. 1249 §3 (2011). A provisional application must include a specification and drawing, but does not need to include a claim. See 35 U.S.C. § 111(b) (2011). In contrast, a nonprovisional application must include a specification, a drawing, and an oath and be accompanied by the appropriate fee and signed by the inventor. 35 U.S.C. § 111. The specification of a nonprovisional must include one or more distinct claims about the invention. 35 U.S.C. § 112(b) (2011).

nonprovisional application the benefit of the provisional filing date for priority purposes.

B. Prior Commercial Use and the University Exception

Predating the AIA, the American Inventors Protection Act of 1999 provided a “prior commercial use” defense against infringement claims for commercial users of a “method of doing or conducting business” that was later patented by another.⁴⁰ If a company retained an invention as a trade secret,⁴¹ and a competitor later created and patented the invention, the first company would be able to raise the prior commercial use defense against an infringement claim and thus continue using the method. Without this defense, a trade secret owner accused of infringement would have to choose whether to pay a licensing fee to the patent holder or pursue litigation to invalidate the patent.

The AIA expands the prior commercial use defense beyond the scope of business method patents to include any type of invention.⁴² That is, the defense is now available to persons who independently employed the invention in the United States in connection with an internal commercial use, an arm’s length sale, or an arm’s length transfer of a useful end result of the commercial use.⁴³ This defense, however, is subject to limitations and exceptions. It is personal and may not be licensed, assigned, or

⁴⁰ USPTO, *Report on the Prior User Rights Defense*, Report to Congress at 6 (2012), available at http://www.uspto.gov/aia_implementation/20120113-pur_report.pdf

⁴¹ Trade secret law is concerned with the protection of technological and commercial information that is not generally known in the trade against unauthorized commercial use by others. See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 473 (1990) (“The subject of a trade secret must be secret, and must not be of public knowledge or of a general knowledge in the trade or business.”).

⁴² 35 U.S.C. § 273(a) (2011).

⁴³ USPTO, *Report on the Prior User Rights Defense*, at 7 (Jan. 2012), http://www.uspto.gov/aia_implementation/20120113-pur_report.pdf (explaining that to assert the defense, the prior user must establish that the “relevant activities occurred more than one year before the earlier of (1) the filing date of the patent application or (2) the date of public disclosure by the patentee during the patentee’s grace period.”).

transferred except as part of a good faith transfer of the entire entity or of the particular line of business.⁴⁴ In the event of such a transfer, the acquiring party may not expand use of the subject matter entitled to the defense beyond the original geographic site of the “prior use.”⁴⁵ Further, a special limited exemption is provided for universities: the prior use defense cannot be used against universities or university technology transfer organizations.⁴⁶

C. Prior Art Expansion and the Modified One-year Grace Period

Whether an invention is sufficiently novel to receive patent protection depends on the state of the art in the field. Prior art under the AIA is any information available to the public before the time at which the inventor files a patent application.⁴⁷ Submitted applications are vetted by an examiner at the USPTO against art in the relevant field for patentability, novelty, and nonobviousness.⁴⁸ If these and other criteria are met, a patent should issue for an invention that was not claimed, taught, or made obvious by the prior art. Otherwise, a patent will not issue or, if improperly issued, will be invalid. Accordingly, inventors often survey the prior art before committing to patent prosecution—a costly effort.⁴⁹ A change to the prior art system could seriously impact prosecution costs and the likelihood of obtaining a patent.

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ H.R. 1249 § 5. The university exception does not apply “if any of the activities required to reduce to practice the subject matter of the claimed invention could not have been undertaken using funds provided by the Federal Government.” 35 U.S.C. § 273(e)(5)(B).

⁴⁷ Under the AIA, prior art can take the form of a publication, patent, patent application, sale, or other public knowledge, use, or offer for sale related to the invention. *See* 35 U.S.C. § 102(a)(1).

⁴⁸ Patent applications are considered for applicable subject matter, novelty and nonobviousness under 35 U.S.C. §§ 101, 102, and 103, respectively.

⁴⁹ One notable practitioner prices patent searches at \$1200-\$2400, and overall prosecution costs between \$5,000 and \$15,000. *See* Gene Quinn, *The Cost of Obtaining a Patent in the U.S.*, IPWATCHDOG (Jan. 28, 2011), <http://www.ipwatchdog.com/2011/01/28/the-cost-of-obtaining-patent/id=14668/>.

Comporting with Congress's intent to harmonize the new FITF system with foreign systems, the AIA makes significant changes to the prior art element. Under the new 35 U.S.C. § 102(a), the pool of prior art now includes any public use, sale, or other disclosure of the invention that renders it "otherwise available to the public," measured back from the effective filing date—in the U.S. or a foreign country—rather than the date of invention.⁵⁰ Novelty and nonobviousness will both be determined as of the filing date.⁵¹

The new § 102(a) poses multiple challenges for applicants. First, the expanded international pool of potential prior art means that applicants must vet their inventions against a wider collection of information that could be material to patentability.⁵² For a patent to issue, the claimed invention must survive this information and any other related art before the examiner.

The phrase "or otherwise available to the public" in § 102(a)(1) further complicates the scope of prior art. Observers have expressed confusion over its meaning,⁵³ and question whether the phrase modifies the preceding "on sale" category—meaning that public sales, but not secret sales (or unpublished pending

⁵⁰ Orlando Lopez, *The Prior Art Expansion Under the AIA*, LEXOLOGY (Sep. 18, 2012), <http://www.lexology.com/library/detail.aspx?g=6e2a1f97-213e-42ef-ab22-3e3141f1faa3> ("No longer is the date of invention important — the important date now is the effective filing date. This change introduces a game-changing race to the patent office where the first to file wins.").

⁵¹ See, e.g., Jay Pattumudo, *The Scope of Prior Art by Others Under AIA and a Comparison with European and Japanese Patent Law*, PATENT BARISTAS (May 9, 2013), <http://www.patentbaristas.com/archives/2013/05/09/the-scope-of-prior-art-by-others-under-aia-and-a-comparison-with-european-and-japanese-patent-law-what-every-scientist-and-corporate-executive-needs-to-know>.

⁵² Lopez, *supra* note 50.

⁵³ See USPTO, *Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act* (discussion of Public Comment 13), 77 Fed. Reg. 11059 (Feb. 14, 2013), <https://www.federalregister.gov/articles/2013/02/14/2013-03450/examination-guidelines-for-implementing-the-first-inventor-to-file-provisions-of-the-leahy-smith#p-238>; Pier D. DeRoo & Michael J. Flibbert, *Does the AIA Require Public Availability for "On Sale" Prior Art?*, BLOOMBERG LAW REPORTS, Mar. 19, 2012, available at <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=b78c8ba4-db29-48da-b1ba-ec2119083300>.

applications), continue to be prior art—or stands alone, casting all sales activity as potential prior art.⁵⁴

As an additional consequence of the shift to FITF, inventors can no longer “swear back” past a prior art reference. Under the first-to-invent system, an inventor could prove, by sworn affidavit, an invention date preceding that of a prior art reference.⁵⁵ Patent prosecutors no longer have this strategic tool to help them prove original inventorship.⁵⁶

Section 102(b) defines the exceptions to prior art under § 102(a). Previously, inventors enjoyed a one-year grace period, dated from the filing date, that foreclosed the specter of prior art in which the claimed invention was published or patented in any country, or in public use or on sale in the United States.⁵⁷ The new § 102(b)(1) expands the grace period to include disclosures of the invention—or subject matter thereof—by the inventor, a joint inventor, or one who obtained the information from the inventor.⁵⁸

The modifications to the grace period have generated considerable confusion.⁵⁹ Some practitioners interpret the statute to create a “first-to-publish” system whereby publication defeats all subsequent third-party prior art.⁶⁰ Under the USPTO’s proposed rules of interpretation, however, only those third-party disclosures that are identical or “substantially identical” to the inventor’s

⁵⁴ See *id.* See also Dennis Crouch, *Did the AIA Eliminate Secret Prior Art?* PATENTLYO (Oct. 10, 2012), <http://www.patentlyo.com/patent/2012/10/did-the-aia-eliminate-secret-prior-art.html>; Matthew R. Osenga, *America Invents Act—Secret Prior Art*, INVENTIVESTEP (March 11, 2013, 2:20 PM), <http://inventivestep.net/2013/03/11/america-invents-act-secret-prior-art/>.

⁵⁵ Lopez, *supra* note 50.

⁵⁶ See *Id.*

⁵⁷ For an excellent side-by-side comparison pre-AIA and AIA provisions, see *Comparison Of Selected Sections Of Pre-AIA and AIA U.S. Patent Law*, INTELLECTUAL PROPERTY OWNERS ASS’N (Oct. 19, 2011), http://www.wilmerhale.com/files/upload/IPO_AIA_Chart.pdf.

⁵⁸ 35 U.S.C § 102(b)(1)(b) (2011).

⁵⁹ See, e.g., Gene Quinn, *Defending the USPTO interpretation of the new grace period*, IPWATCHDOG (Sep. 9, 2012), <http://www.ipwatchdog.com/2012/09/09/defending-the-uspto-interpretation-of-the-new-grace-period/id=27903>.

⁶⁰ See, e.g., Letter from Univ. of Cal. Office of Gen. Counsel to Office of Patent Legal Admin. (Oct. 4, 2012), available at http://www.uspto.gov/patents/law/comments/uc_20121004.pdf.

initial disclosure will not be counted as prior art.⁶¹ Any subsequent disclosure that contains even insubstantial changes from the original may still count as prior art.⁶²

Finally, the AIA allows parties to a joint development agreement to remove one another's prior art from consideration when seeking a patent.⁶³ Under this rule, a nonprofit engaged in a joint development agreement could file a patent application without fearing prior art in the form of another partner's previous application. This provision was included to promote joint research activities consistent with the Cooperative Research and Technology Enhancement (CREATE) Act of 2004.⁶⁴

These changes have significant implications for nonprofit research organizations. Researchers typically present their work numerous times at lab meetings and public forums culminating in the publication of an article on their research in an academic journal. Whether and when an invention is publicly disclosed greatly affects patentability, and nonprofits seeking to protect intellectual property must be thoughtful with respect to disclosures. Changes to the prior art and the one-year grace period add complexity to these considerations.

These changes also affect patent prosecution. Because of the changes to prior art, nonprofits may need to perform due diligence on a larger pool of prior art. The resource demands of these

⁶¹ Manual of Patent Examining Procedure (MPEP) § 2112, available at <http://www.uspto.gov/web/offices/pac/mpep/s2112.html>.

⁶² See Arpita Battacharyya, Ph.D. and Eric P. Raciti, *The Not-So-Amazing Grace Period Under the AIA*, CIPA JOURNAL (Sep. 2012), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=4acad2aa-4430-4d87-a197-3a202ac17c5b>.

⁶³ 35 U.S.C. § 102(c) (2011).

⁶⁴ See AIA 35 U.S.C. § 102(b)(2) (2011), available at <http://www.govtrack.us/congress/bills/112/hr1249/text>. See also Robert A. Armitage, *Understanding the America Invents Act and its Implications for Patenting*, 40 AIPLA Q.J. 1, 24–26 (2012) (“the Cooperative Research and Technology Enhancement (CREATE) Act of 2004 completed pre-AIA § 103. It sought to extend “co-worker” benefits of the AIPA to research collaborators by treating patent filings under joint research agreements as though they had been commonly assigned. The aggregate result of the pre-AIA amendments to § 103 was that...the AIP A/CREATE Act changes followed as a new § 103(c).” (internal citations omitted)).

broader prior art searches could affect some nonprofits' patenting decisions.

D. Third-Party Challenge System

Prior to implementation of the AIA, the *ex parte* nature of patent applications meant that third parties were generally excluded from the application and review processes. However, a narrow exception allowed third parties to submit prior art in connection with a pending application, but not to comment upon, explain, or argue about the submission.⁶⁵ The procedure was designed to improve the quality of issuances by augmenting the examiner's prior art search, but it was rarely practiced.⁶⁶ The AIA encourages expanded third-party prior art submissions by allowing third parties who submit prior art to concisely describe the relevance of the submitted art.⁶⁷

In addition to improving the quality of patents granted and shortening the examination period, the third party submission

⁶⁵ 37 C.F.R. § 1.99 (2011).

⁶⁶ LANDERS, *supra* note 5, at 27.

⁶⁷ 35 U.S.C. § 122(e)(2) (2011) ("Any third party may submit for consideration and inclusion in the record of a patent application, any patent, published patent application, or other printed publication of potential relevance to the examination of the application (provided that certain requirements are met) within the later of either six months from the challenged application's publication or from the USPTO's first rejection of any claim in the application."). *See also Preissuance Submissions by Third Parties*, AIARULEMAKING.COM, <http://www.aiarulemaking.com/rulemaking-topics/group-2/third-party-submission-prior-art-patent-application.php> ("Another change benefitting third parties is the extended time period that such submissions will be accepted. This time period will be the earlier of: 1) the date of a notice of allowance, or 2) the later of six months after the date of publication or the date of a first Office action on the merits."); USPTO, *Press Release 12-60: USPTO Encourages Third Parties to Participate in Review of Pending Patent Applications*, USPTO.GOV (Sep. 20, 2012), <http://www.uspto.gov/news/pr/2012/12-60.jsp> ("[T]he submission by third parties of prior art . . . allows the USPTO to tap directly into the U.S. innovation community. Submissions provide a fuller, more exhaustive scope of materials for examiners to review in determining the novelty of a given application. This new mechanism will help ensure that truly novel, useful, and non-obvious innovations obtain the intellectual property protection they deserve").

system allows parties, for a small fee,⁶⁸ to anonymously or openly object to a patent's issuance. Patent applicants thus must consider strategies to defend against third-party submissions and identify those parties as potential competitors, licensees, or partners.⁶⁹

E. Derivation Proceedings and Post-Grant Review

In conjunction with the move to FITF, and in an attempt to improve administrative alternatives to litigation, the AIA revises the means by which one challenges a patent's validity. Previously, the USPTO Board of Patent Appeals and Interferences conducted interference proceedings—to ascertain priority of inventorship—and patent reexamination procedures in both *ex parte* and *inter partes* formats. These proceedings, and the changes to the system under the AIA, will be examined in turn.

Under the first-to-invent system, a third party could challenge a pending patent application or unexpired patent on the grounds that the patentee was not the first to invent. If the claimed patents in dispute met certain requirements, a panel of administrative judges would conduct an interference proceeding to assess the evidence (without discovery) and arguments of the parties. Interferences were considered a cost-effective alternative to patent litigation,⁷⁰ though the mean cost of an interference proceeding has been

⁶⁸ \$180 per ten documents submitted. *See* Changes To Implement the Preissuance Submissions by Third Parties Provision of the Leahy-Smith America Invents Act, 77 F.R. 3, 453 (Jan. 5 2012) (to be codified at 37 C.F.R. Part 1), <http://www.gpo.gov/fdsys/pkg/FR-2012-01-05/pdf/2011-33811.pdf>. *See also* USPTO *Third Party Preissuance Submission under CFR 1.290 Instructions for Paper Filing*, available at http://www.uspto.gov/forms/3prsubmission_instructions.pdf (last visited April 5, 2013).

⁶⁹ *See, e.g., Proposed New Rules Under AIA to Affect Third Party Submissions of Prior Art*, BRINKS, HOFER, GILSON & LIONE (May 31, 2012), http://www.brinkshofer.com/news_events/3406-proposed-new-rules-under-aia-affect-third-party-submissions-prior-art.

⁷⁰ One estimate puts the average costs of a patent litigation at roughly \$2.5M, dependent on the amount in controversy and the type of technology involved. American Intellectual Property Law Association, *Report of the Economic Survey, 2011*, IPISC (2013), available at <http://www.patentinsurance.com/iprisk/aipla-survey/>.

estimated at over \$650,000⁷¹—likely a prohibitive figure for nonprofits.⁷² Although interferences will no longer be conducted under the AIA, derivation proceedings will now determine whether the first filer derived the invention from the petitioning party and thus ascertain priority and inventorship.⁷³

A number of post-grant proceedings have defined the USPTO's role in adjudicating patent disputes.⁷⁴ Prior to implementation of the AIA, a party challenging the validity of a patent outside of litigation could request ex parte or inter partes reexamination by the USPTO.⁷⁵ In a significant revision of the post-grant challenge system, the AIA eliminates inter partes reexamination, replaces it with post-grant review and inter partes review, and creates supplemental examinations. These changes were designed to increase the availability of cost-effective alternatives to patent litigation.⁷⁶

Comporting with the AIA's goal of producing better patents and rectifying improper issuances, the post-grant and inter partes review procedures are designed to expedite challenges.⁷⁷ Limited

⁷¹ Herbert D. Hart, III, *An Interference: What, When, And How Much Does It Cost?*, AM. BAR ASS'N SECTION OF INTELLECTUAL PROP. LAW, 9 (Apr. 2007), <http://www.mcandrews-ip.com/files/article/Hart%20-%20Interference%20What%20When%20How%20Much%20%20ABA%20IPL%2013%20Apr%2007%20Logo.pdf>.

⁷² This observation is based on comments from our survey respondents as well as outside sources. See, e.g., Gene Quinn, *Reform Doing Away with Interference Proceedings & First to Invent*, IPWATCHDOG (Mar. 26, 2010), <http://www.ipwatchdog.com/2010/03/26/reform-doing-away-with-interference-proceedings-first-to-invent/id=9859/> (“With that cost [\$(650,000)], not many independent inventors or small businesses are going to be able to foot that bill.”).

⁷³ See LANDERS, *supra* note 5, at 56.

⁷⁴ It should be noted that the USPTO does not adjudicate infringement actions or breach of contract related to a patent. These are matters for the federal and state courts.

⁷⁵ *Inter Partes Review*, AM. INVENTS ACT, <http://www.aiarulemaking.com/rulemaking-topics/group-2/inter-partes-review.php> (last visited Feb. 6, 2014).

⁷⁶ *Id.*

⁷⁷ See Lawrence A. Stahl and Donald H. Heckenberg, *The Scope and Ramifications of the New Post-Grant and Inter Partes Review Proceedings at the USPTO*. FITZPATRICKCELLA.COM, <http://www.fitzpatrickcella.com/>

discovery and a guaranteed hearing in post-grant review permit an initial opportunity to address troublesome patents, while the second window (nine months or more post-issuance) of inter partes review protects patentees by narrowing the grounds for review and types of evidence accepted.⁷⁸

Finally, the AIA creates supplemental examinations, which enable patent owners to assess the strength of their patents—and preempt third-party challenge or ex parte reexamination—by submitting additional information that allows the USPTO to “consider, reconsider, or correct information believed to be relevant to the patent.”⁷⁹ These examinations also provide patent owners with “amnesty” against charges of inequitable conduct—information provided in a supplemental examination cannot be used to render a patent unenforceable.⁸⁰

III. THE SURVEY: DATA ANALYSIS

To assess the AIA’s impact, realized or anticipated, on nonprofit bioscience and global health research, we surveyed in-house (n = 10) and outside attorneys (n = 7) representing organizations throughout the region. The participating organizations varied greatly in terms of age, size, available resources, stated goals, and means of achieving those goals. For example, while some institutions conduct basic research and seek

DB6EDC/assets/files/News/Fitz_PTO_1_4_8.pdf, (last accessed Feb. 7, 2014).

⁷⁸ LANDERS, *supra* note 5, at 57.

⁷⁹ 35 U.S.C. § 257(a) (2011).

⁸⁰ See LANDERS, *supra* note 5, at 54. Inequitable conduct is an affirmative defense to a claim of patent infringement. Essentially, the defense asserts that the patent is unenforceable due to the patentee’s fraudulent withholding of, or submission of, material information to the USPTO during prosecution “but for which” a patent would not have issued. See *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (“To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO. The accused infringer must prove both elements—intent and materiality—by clear and convincing evidence. If the accused infringer meets its burden, then the district court must weigh the equities to determine whether the applicant’s conduct before the PTO warrants rendering the entire patent unenforceable.”).

licensing agreements to commercially develop promising technologies, others determine how to best allocate grants to further specific research or initiatives. Some larger entities with greater resources have internal technology transfer and commercialization departments that are not present in smaller entities.⁸¹

In this section, we discuss the qualitative responses of in-house and outside counsel to our survey. For each area of the law, we include a brief summary of the changes to that area, followed by the questions we posed (in bold) and the responses by each group. Please note that we sought global perspectives on the new law, as distinct from the specific concerns of any particular organization. Our data set represents cumulative, qualitative responses, and does not represent the views of any particular organization.

A. First-Inventor-To-File

The AIA converts the patent priority system from first-to-invent to FITF. We first surveyed respondents on the transition to FITF and its effects on nonprofit R&D and patent practices:

1. In your opinion, will FITF impact nonprofit organizations' research and development? Why or why not?

In-house counsel generally answered that FITF will probably not impact nonprofit R&D for two reasons. First, research scientists at nonprofit organizations are generally not focused on patenting their inventions; rather, they are driven by a desire to expand knowledge and make beneficial discoveries. Because most nonprofit research is funded by grants, scientists focus mainly on publishing and writing grant proposals.

Second, when nonprofit organizations decide to protect their biotechnology inventions, internal practices already follow the international first-to-file and absolute novelty standards. For this reason, if research produces a seemingly novel innovation, the

⁸¹ The respondents to our survey pointed out that even well-funded private nonprofits possess far fewer resources than a large, state-funded research university.

nonprofit organization has typically filed a provisional application to secure a patent placeholder before any disclosure is made. For most respondents, then, adherence to best practices will mitigate the effects of FITF on nonprofit research and development.

However, some in-house respondents noted that the AIA might impact research and development by increasing pressure to “race to the USPTO” to file cover sheet provisional applications. The problem with this scenario is that the provisional application, produced under pressure and probably with a bare minimum of data to support the disclosure, will not satisfy the first-paragraph requirements of § 112⁸² (written description⁸³ and enablement⁸⁴).

⁸² The disclosure requirements under 35 U.S.C. § 112, ¶ 1 include written description, enablement, and best mode. Specifically, that provision states that the specification “shall contain a *written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable* any person skilled in the art to which it pertains [. . .] to make and use the same, and shall set forth the *best mode* contemplated by the inventor or joint inventor of carrying out his invention.” 35 U.S.C. § 112 (2011) (emphasis added).

⁸³ The written description requirement has several policy objectives. In *Ariad*, the court held that there is a separate written description and enablement requirement under 35 U.S.C. § 112, first paragraph. *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1341 (Fed. Cir. 2010) (en banc). The written description requirement has several policy objectives. “[T]he ‘essential goal’ of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed.” In *re Barker*, 559 F.2d 588, 592 n.4 (C.C.P.A.CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. *See Regents of the Univ. of Cal. v. Eli Lilly*, 119 F.3d 1559, 1566, (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). The written description requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor’s obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

⁸⁴ To satisfy the enablement requirement under 35 U.S.C. § 112, first paragraph, a patent application must provide sufficient disclosure to enable a person skilled in the art to make and use the claimed invention. One skilled in the art would be enabled to practice the claimed invention if it would not require undue experimentation to make and use the claimed invention and the claims are not of undue breadth in view of the scope of the disclosure provided by the specification. The *Wands* factors are considered by courts when determining

As such, some anticipate that nonprofit organizations will respond to FITF by tightening internal procedures to make sure that scientists do not disclose before filing and that the application is as strong as possible.

Outside counsel generally agreed with the in-house position, suggesting that FITF will not impact nonprofit organizations' research because those organizations already follow international standards. The grace period changes generate some uncertainty, discussed *infra*, but the best practice for nonprofit organizations remains to file early and often.

Outside counsel gave four reasons for this filing practice: first, when considering the costs of patenting, which are low relative to the high potential value of patent protection, inventors are advised to err on the side of filing on the invention at its early stage of development.⁸⁵ Second, they pointed out that novelty and obviousness requirements incentivize early filing in order to establish priority over prior art that may render the subject matter anticipated or obvious.⁸⁶ Finally, outside counsel stressed that the formerly common practice of “swearing behind” a prior art reference to prove an earlier date of invention would no longer be an option under the FITF. One caveat that outside counsel highlighted was that the pressure to be the first to file may affect the quality and scope of the disclosure made. That is, the disclosure may not support future claims that would have benefited from the earlier priority date. The practice of filing early and often could potentially increase the frequency of applications and affect

whether there is sufficient evidence to support a determination does not satisfy the enablement requirement and whether any necessary experimentation is “undue.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

⁸⁵ See, e.g., Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 69 (2009).

⁸⁶ See Lee A. Hollaar, LEGAL PROTECTION OF DIGITAL INFORMATION IN CHAPTER 4: AN OVERVIEW OF PATENTS: VI—ANTICIPATION AND OBVIOUSNESS (2002), available at <http://digital-law-online.info/lpdi1.0/treatise57.html> (last accessed Feb. 7, 2014) (“If a claim reads on a single item of prior art – a printed publication or a product – then that item of prior art “anticipates” the claim must be rejected under Section 102 [...] Section 103 bars a claim if it is obvious based on a combination of two or more items of prior art, or differs in an obvious way from an item of prior art.”)

resource allocation; thus, the next question we asked was the following:

2. In your opinion, will the FITF system affect when provisional or nonprovisional applications are filed? Why or why not?

In-house counsel generally felt that the FITF system would not affect when nonprofit organizations file applications for three reasons. First, they recalled that nonprofits have long practiced under international first-to-file standards. Second, frequent filing practices have been in place to account for ongoing disclosures by their scientists. Third, budget constraints mean that the number of applications filed is unlikely to increase.

A few respondents again suggested that the “race to file” under FITF might diminish the value of provisional applications. As noted *supra*, there is a danger that quickly filed provisional applications might not satisfy § 112. Under pre-AIA law, it was standard practice for biotechnology inventors to record a plan for a project and use that as the date of conception.⁸⁷ The inventor would then work diligently to make and test the invention before filing an application.⁸⁸ However, under the AIA, this approach creates a risk that the first inventor is blocked from obtaining a patent by another’s patent application or publication.⁸⁹ Therefore, a rush to produce and file an application before the invention’s reduction to practice may be the new standard.

Even if the inventor is the first to file, the application will be vulnerable to rejection by the PTO—or, if a patent issues, to later validity challenges—if the initial disclosure does not sufficiently describe the invention to show that the inventor was actually in possession of the invention at the time of application.⁹⁰ Thus, for an inventor to claim the benefit of a provisional filing date, the

⁸⁷ George Yu, *How the First-To-File Provisions of the America Invents Act Will Affect Biotechnology*, SCHIFFHARDIN (Feb. 1, 2012), [http://www.schiffhardin.com/File%20Library/Publications%20\(File%20Based\)/PDF/yu_sfdj_020112.pdf](http://www.schiffhardin.com/File%20Library/Publications%20(File%20Based)/PDF/yu_sfdj_020112.pdf).

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

provisional application must fully support the claims included in the nonprovisional patent application. The claims must be described and enabled by the provisional application, and an FITF-induced rush to file might compromise the patentability and value of an invention.

Outside counsel were split on this question. Some believed that nonprofit organizations would change patent filing practices due to FITF for three reasons. First, nonprofit organizations might increase the number of provisional applications that are filed in order to secure patent protection in the United States, even though foreign protection would be jeopardized under the international absolute novelty standard.⁹¹ The one-year grace period should continue to give U.S. applicants time to prepare and file their applications after disclosure. Consequently, some outside counsel predicted an increase in early provisional applications filed immediately after disclosure.

Second, the need for selectivity and resource management under FITF will be exacerbated by the generally poor economic environment, which may further depress nonprofits' ability to file early and often. Although the filing fee for a provisional application in the United States is relatively low,⁹² nonprofit

⁹¹ See European Patent Office, European Patent Convention Art. 54(2) available at <http://www.epo.org/law-practice/legal-texts/html/epc/2013/e/ar54.html> ("The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.").

⁹² A provisional application filing fee is \$250 (\$125 for small entities), compared with \$1,250 for a nonprovisional application. Under 35 U.S.C. § 41(h)(1), fees charged under 35 U.S.C. § 41(a), (b), and (d)(1) shall be reduced by 50 percent with respect to their application to any small business concern as defined under § 3 of the Small Business Act, and to any independent inventor or nonprofit organization as defined in regulations issued by the Director. 35 U.S.C. § 41. The reduced fees include patent application filing fees including the basic filing fee, search fee, examination fee, application size fee, and excess claims fees (37 C.F.R. § 1.16) extension of time, revival, and appeal fees (37 C.F.R. § 1.17), patent issue fees (37 C.F.R. § 1.18), statutory disclaimer fee (37 C.F.R. § 1.20(d)), and maintenance fees on patents (37 C.F.R. § 1.20). See USPTO, MPEP § 509.02, available at <http://www.uspto.gov/web/offices/pac/mpep>.

organizations still have nominal budgets that restrict the number of provisional applications filed.⁹³ Because biotechnology patents are generally protected worldwide, and because nonprofit organizations have restricted budgets, these organizations will need to exercise even more care when deciding where to file for a patent.⁹⁴ Finally, the number, type, and timing of patent applications filed depend on the nonprofit organizations' intellectual property strategy. As of this writing, two pressing questions for patent applicants are whether to file a provisional application before March 16, 2013 and whether to switch an existing provisional application to nonprovisional status before March 16, 2013.⁹⁵

Other outside counsel believe that FITF will not have an impact on when nonprofits file for two reasons, both related to existing best practices. First, the current practice of filing under an international first-to-file regime suggests that disclosure management will not change much in response to FITF. Second, investing resources to file a supportive provisional application that satisfies § 112 should be the primary concern, even though frequent filing is almost equally important. To recall, only those

⁹³ For a complete list of filing, prosecution and maintenance fees, see USPTO, *Fee Schedule*, <http://www.uspto.gov/web/offices/ac/qs/ope/fee010114.htm> (last revised Jan. 16, 2014).

⁹⁴ *The U.S. 2011 Global Patent & IP Trends Indicator: An in-depth look at the foreign filing strategies of U.S. patent owners*, INNOVIA (2011), <http://de.inovia.com/news/110228-inovia-Global-Patent-IP-Trends.jsp>. A 2011 survey of nearly 150 companies, universities, and nonprofits that assessed the impact economic conditions on global IP strategy and outlook reported that nearly 60 percent of respondents are working on a reduced IP budget and many are taking further steps to reduce patent costs. Forty-five percent of those surveyed did not file into Japan in 2010 because of the high cost and low cost-to-benefit ratio; that is, the patent owner had to justify the success rate of getting a patent in Japan, (approximately 20 percent) in light of the high filing cost. Due to such high costs, companies tend to file in China for foreign protection, reserving only extremely valuable filings for Japanese foreign jurisdiction.

⁹⁵ This means that if the provisional application was converted after the March 16 changeover date, any claim directed to disclosure that was not supported by the original first-to-invent provisional application will be treated under the FITF regime. See Leonid Kravets, *First-to-File Patent Law Is Imminent, But What Will It Mean?*, TECHCRUNCH (Apr. 8, 2013), <http://techcrunch.com/2013/02/16/first-to-file-a-primer/>.

aspects of an invention that are supported by the provisional disclosure will receive the benefit of the provisional priority date.⁹⁶

B. Prior Commercial Use and the University Exception

The AIA expands the prior commercial use defense to include all manner of patented inventions.⁹⁷ This defense to a claim of infringement derives from commercial use of the invention prior to another's patenting the invention,⁹⁸ and is an option for securing continued use without fear of infringement.⁹⁹ Under the AIA, instead of obtaining patent protection and disclosing the invention, a user may practice the invention secretly and, if challenged, rely on the prior commercial use defense to avoid liability.¹⁰⁰ With this in mind, we asked:

1. In your opinion, will nonprofit organizations benefit from the prior commercial use defense? Why or why not?

In-house counsel mostly answered that nonprofits would not benefit from the commercial use defense because they are not generally involved in “commercial” activity. Further, nonprofits are infrequent targets for patent litigation due to their public profile and relative lack of money. Hence, a defense to infringement claims is unlikely to be of special interest to nonprofits. However, one respondent opined that the AIA introduces uncertainty by failing to specifically define “commercial process.” Though the statutory language and legislative history support a broad interpretation of the term,¹⁰¹ the specific activities that will be

⁹⁶ Timothy D. Casey & Juan C. Quiroz, *What Innovators Need to Know—and Need to Do—Under the America Invents Act*, AMERICAN INNOVATORS FOR PATENT REFORM, at 4 (Jan. 2012), available at <http://www.aminn.org/files/WhitePaper-AmericaInventsAct-Jan2012-2.pdf>.

⁹⁷ *Id.*

⁹⁸ 35 U.S.C. § 273(a) (2011).

⁹⁹ Michael Dixon, *The Sweeping Changes of the 2011 America Invents Act*, WESTLAW, at 7 (2012), <http://www.mofo.com/files/uploads/images/120206-patents-21st-century.pdf>.

¹⁰⁰ *Id.*

¹⁰¹ Craig R. Smith, *The Prior Use Defense Under AIA*, LAW 360 (Nov. 9,

protected under this provision are uncertain and will likely be determined through litigation.

A minority of outside counsel believed that the prior commercial use defense's university exception may benefit nonprofit organizations when a university was involved in the research project or if the nonprofit was determined to have "university" status. Some also expected that where the public was the intended beneficiary of the prior use, as generally occurs at nonprofit research organizations like hospitals, the use will be deemed commercial for the purpose of obtaining the defense.

The defense may also benefit nonprofits in the context of licensing—if the defense is transferrable to a licensee, patents may hold much greater value. Although the general rule is that the prior user defense is personal and cannot be transferred in isolation, it can be transferred as part of a larger good faith sale of the business or line of business, which may include licenses.¹⁰² How this applies in the licensing context remains to be seen. The attorneys also stressed that the prior user defense cannot be raised against universities.

In response to concerns that the prior commercial use defense would stifle innovation at universities, the legislature enacted the university exception, preventing assertion of the prior use defense

2011), <http://www.lalaw.com/news-events/publications/upload/THE-PRIOR-ART-DEFENSE-UNDER-AIA.pdf>. 35 U.S.C. § 273(c)—entitled "Additional commercial uses"—sets forth two qualifying commercial uses: (1) use or marketing during a premarketing regulatory review period, and (2) nonprofit laboratory use by universities, hospitals, and other nonprofit entities. The legislative history suggests that commercial use may begin early in the use or development of the technology. 35 U.S.C. § 273(c) (2011). Senator Leahy, one of the co-sponsors of the patent reform bill, stated that the prior use defenses vests when "innovative technology is first put into continuous internal use in the business of an innovator's enterprise with the objective of making a commercial product." See S. Doc. No. S5427 Senate (Sept. 8, 2011), available at <http://www.gpo.gov/fdsys/pkg/CREC-2011-09-08/pdf/CREC-2011-09-08-senate.pdf>.

¹⁰² See Peter A. Nieves, *A Stronger Patent Infringement Defense Due To Prior User Rights*, SHEEHAN PHINNEY (Feb. 21, 2013) <http://www.sheehan.com/publications/good-company-newsletter/A-Stronger-Patent-Infringement-Defense-Due-To-Prior-User-Rights.aspx>.

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against a university or its technology transfer organization.¹⁰³ However, the limiting language¹⁰⁴ of the exception appears to revive the defense against patents for inventions related to stem cell research or human cloning, as well as any other research areas that are prohibited from receiving federal funding.¹⁰⁵

2. In your opinion, how will the university exception benefit or disadvantage nonprofit organizations?

In-house counsel were split on this question. Some believed that the exception only covers universities and not other nonprofit organizations, which accounted for the bulk of our respondents. However, others believed that this protection may be available to non-university nonprofit organizations or licensees that foster collaborative relationships with universities. The scope of the exception will probably be determined by litigation. In-house respondents' responses were limited, which may reflect a lack of familiarity with this AIA provision, the infrequency of patent litigation involving nonprofits, or both.

Outside counsel largely anticipate that the exception will

¹⁰³ USPTO, REPORT ON THE PRIOR USER DEFENSE, 37 (2012), *available at* http://www.uspto.gov/aia_implementation/20120113-pur_report.pdf.

¹⁰⁴ This exception does not apply "if any of the activities required to reduce to practice the subject matter of the claimed invention could not have been undertaken using funds provided by the Federal Government." 35 U.S.C. § 273(e)(5)(B) (2011).

¹⁰⁵ Patents owned by universities or technology transfer organizations are subject to an exception from the expanded prior user defense, but this exception does not apply "if any of the activities required to reduce to practice the subject matter of the claimed invention could not have been undertaken using funds provided by the federal government." *See* Brad D. Pedersen, *US Patent Reform: What Really Changes*, PATTERSON THUENTE IP, (Sept. 23, 2011), *available at* <http://www.ptslaw.com/PatentReformSummaryOverviewWhitepaper.pdf>. The National Institute of Health federal grant guidelines prohibit research funding for human embryonic stem cells (hESCs), the derivation of stem cells from human embryos, or using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or in vitro fertilization embryos created for research purposes. *See NIH Grants Policy Statement*, NAT'L INST. OF HEALTH (Oct. 2012), http://grants.nih.gov/grants/policy/nihgps_2012/nihgps_ch4ch4index.htm.

benefit both university and non-university nonprofits by incentivizing relationships with universities. However, a few expect no impact because the defense is rarely invoked and has seen little to no successful assertion. The USPTO Report on the Prior User Rights Defense supports this expectation, noting that while the Federal Circuit has decided thousands of appeals on almost every imaginable patent doctrine, the Court has yet to address prior user rights.¹⁰⁶

C. Prior Art Expansion and the Modified One-Year Grace Period

The AIA expands the pool of prior art both geographically and categorically. Prior art now includes knowledge, use, or any activities rendering the invention “otherwise available to the public” in the United States or any other country. Further, the inventor’s one-year grace period is modified. We wondered whether navigating a larger pool of prior art might affect resource-limited nonprofits and whether the changes to the grace period held any special significance.

1. In your opinion, how will these changes affect nonprofit patent strategies?

In-house counsel answered that the AIA’s prior art provisions would not affect patent strategies for three reasons. First, nonprofits have historically operated from an international patent perspective in order to maximize the reach of beneficial innovations. Protecting intellectual property in multiple markets widens the potential pool of licensees and often enables the nonprofit to effect change where it matters. For example, an organization dedicated to fighting malaria in subtropical countries

¹⁰⁶ *Report on the Prior User Defense*, USPTO, at 31 (2012), http://www.uspto.gov/aia_implementation/20120113-pur_report.pdf (concluding that while prior user rights have been available in the United States since 1999 for business method patents, “only one case has been reported in which this defense has been raised,” and the court in that case did not reach the issue because the defense was untimely raised).

might limit its reach if it only pursued patent protection in the United States. If an invention addresses a problem that exists in both developed and developing countries, the nonprofit may leverage patent protection into a licensing agreement whereby the licensee reaps profits in advanced economies in exchange for discounting or giving away the developed product in poorer economies. Comprehensive patent protection across markets thus encourages mutually advantageous licensing opportunities, so international practices are favored.

Second, nonprofits rarely have the resources to conduct comprehensive prior art searches. In-house attorneys in this industry typically cannot focus solely on intellectual property, and a quick survey of publicly available patent databases will not suffice. Even subscriptions to patent-listing periodicals¹⁰⁷ may be prohibitively expensive, and the likelihood of as-yet-unpublished prior art cannot be assessed. A caveat exists where the innovation in question is highly valuable and exists in a tightly defined field of technology. In such circumstances, the likelihood of competition and licensing potentials are both high, and the nonprofit may spend more aggressively to obtain the patent.

However, given the nature of the technology, particularly where the research concerns rare diseases, few commercial “blockbusters” are anticipated. More often, attorneys must look to cheaper sources of information. For example, the investigators at these institutions often work in narrow fields and have a comprehensive understanding of the relevant art. Given the largely collaborative nature of the academic community, the likelihood that unanticipated prior art exists is fairly low. Furthermore, the academic journals that publish research advances act as a novelty

¹⁰⁷ Subscription-based commercial patent databases such as Delphion, MicroPatent, and LexisNexis provide updated lists of available patents, applications, and other information relevant to the state of a given patent area. The costs range widely from \$181-361/mo (Delphion), to \$7500/yr (MicroPatent) (note: these prices reflect only a couple of a wide range of patent prosecution products). See *Delphion Subscription Comparison Overview*, DELPHION, <http://www.delphion.com/products/research/products-compare2> (last accessed Feb. 6, 2014); *PatentWeb*, MICROPATENT, http://www.micropat.com/0/products_pw9809.html (last accessed Feb. 6, 2014).

filter; because journals seek to publish only novel findings, publication is a strong indicator of patentable novelty.

Third, due to licensing practices, nonprofits rarely need to expend significant resources on prior art searches. Most licensing deals are negotiated in the year following a provisional filing, and if an exclusive license is given, the licensee assumes responsibility for prosecuting the patent.¹⁰⁸ Whether the nonprofit or a licensee pursues the patent, it is common practice to file a PCT application¹⁰⁹ and allow an authorized patent assessor to provide an initial determination on patentability.¹¹⁰ For these reasons, particularly under an FITF regime, nonprofits will continue to file early and often.

Outside counsel largely echoed these points, but emphasized that clients should be educated as to changes in the law, such as the end of “swearing back” to defeat a prior art reference under the old system.¹¹¹ Filing prior to disclosure was also stressed, though, as discussed previously, the race to file might have the unintended effect of increasing the number of “coversheet provisional”

¹⁰⁸ The nature of the patent and the market largely determine whether a given license is exclusive or nonexclusive. See *University Technology Transfer: Questions and Answers*, UNIVERSITY OF CALIFORNIA TECHNOLOGY TRANSFER, <http://www.ucop.edu/ott/faculty/tech.html#6> (last accessed Mar. 30, 2013). (“Patents which are broad in scope and can be used in multiple industries, or patents that they are so basic that they form the building blocks for new technologies are most likely to be licensed non-exclusively [while universities] most frequently will grant exclusive licenses to patents that require significant private investment to reach the marketplace or are so embryonic that exclusivity is necessary to induce the investment needed to determine utility.”).

¹⁰⁹ Under the Patent Cooperation Treaty of 1970 (PCT), inventors in signatory states can file a unified PCT application to obtain a priority filing date in all other signatory states. Subsequent additional measures to meet jurisdictional requirements must follow to obtain actual patent protection. See James R. Cartiglia, *The Patent Cooperation Treaty: A Rational Approach to International Patent Filing*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 261, 262-63 (1994).

¹¹⁰ Inventions claimed in PCT applications are vetted by an authorized “International Searching Authority” (ISA) that issues to the applicant a written opinion on the patentability of the invention. See *id.* at 268.

¹¹¹ Lopez, *supra* note 50.

applications, which risk failing the written description and enablement requirements of § 112.¹¹²

Only one outside attorney suggested that the expanded field of prior art might depress the value of licensing agreements. Where comprehensive due diligence has not been completed, the expanded pool of prior art may represent increased uncertainty as to the novelty and nonobviousness of the invention. Therefore, licensees may attempt to shift this risk onto licensors with contingency clauses addressing the possibility of claim rejection by the USPTO or of a successful validity challenge. The nonprofit's response might include devoting more resources to prior art searches or grouping riskier or less-attractive patents with safer or more attractive patents in combined licensing agreements.

Going forward, challenges and questions remain with regard to prior art. How “otherwise available to the public” is interpreted by the MPEP¹¹³ and by the courts may impact the way that nonprofit research organizations share their work. If secret sales or offers to sell are no longer prior art, patent-holders may be incentivized to sell their inventions more freely, using non-disclosure language in contracts as a shield. Additionally, the AIA allows unknown prior art—given the benefit of an initial filing date despite only becoming public in a USPTO publication eighteen months later—to be used in assessing both the novelty and nonobviousness of a claimed invention.¹¹⁴ A larger pool of such art may affect patent valuations or prosecution decisions.

However, there are hints as to what prior art might look like under the AIA. In response to public commentary, the USPTO suggested that “otherwise available to the public” would likely be

¹¹² As mentioned *supra*, “coversheet” or “manuscript” provisionals refer to applications that contain only a written description and relevant drawings of the invention, as well as identifying information for the inventor. Such applications are generally submitted shortly after invention to secure a provisional filing date. See USPTO, PROVISIONAL APPLICATION FOR PATENT (Feb. 2011), <http://www.uspto.gov/patents/resources/types/provapp.jsp>.

¹¹³ The USPTO directs its examiners on applying the law to patent applications in the MPEP, available at <http://www.uspto.gov/web/offices/pac/mpep>.

¹¹⁴ Robert A. Armitage, *Understanding the America Invents Act and its Implications for Patenting*, 40 AIPLA Q.J. 1, 27.

assessed under the Federal Circuit's test: whether the material was "available to the extent that persons interested and ordinarily skilled in the subject matter of the art, exercising reasonable diligence, can locate it."¹¹⁵

Further, comments of the AIA drafters suggest that secret sales were not intended to become prior art.¹¹⁶ Taking this history into account, the USPTO has stated that it will interpret "the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. § 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art."¹¹⁷ This issue may still be resolved by the courts, however, and is likely to be tested.

2. Do you anticipate that the grace period rule will affect the collaborative nature of research and the quality of the resulting work? Why or why not?

In-house counsel generally responded that collaboration would not be affected, although few supporting details were provided. As a group, they seemed less familiar with this change than did outside practitioners. This may have been due to the fact that in-house counsel practitioners do not specialize in patent law, or to

¹¹⁵ See USPTO, *Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act* (Feb. 14, 2013), <https://www.federalregister.gov/articles/2013/02/14/2013-03450/examination-guidelines-for-implementing-the-first-inventor-to-file-provisions-of-the-leahy-smith> (citing *Voter Verified, Inc. v. Premier Election Solutions, Inc.*, 687 F.3d 1374, 1380 (Fed. Cir. 2012) and *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006)).

¹¹⁶ See C.R., Senate, 23 CONG. REC. S5431 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl: "public uses and sales are prior art only if they make the invention available to the public."). See also 157 CONG. REC. S1496-S1497 (daily ed. Mar. 9, 2011) (statement of Sen. Leahy: § 102(a)(1) "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.").

¹¹⁷ USPTO, *Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act*, 78 Fed. Reg. 11060 (Feb. 14, 2013), http://www.uspto.gov/aia_implementation/FITF_Final_Guidelines_FR_2-14-2013.pdf.

inherent ambiguities in the statute. Patent education efforts within the institution were identified as an asset, but the ability to implement such efforts was resource-dependent. Larger nonprofits had more highly developed patent education and communication schemes, while entities with lesser means gave fewer seminars and presentations to their employees. However, all in-house counsel framed the question as one of strategic relevance: where freely disseminating an invention better serves the goals of a research organization than would a patent, the need for educating inventors on the patent system diminishes. Likewise, where recouping costs is not a concern—e.g., for low-overhead technologies like antibodies—, adherence to best patent practices is accordingly less important.

This may be changing, however. Counsel for one large entity stated that potential faculty members increasingly inquire as to the organization's technology transfer practices. The possible reasons for this interest were not speculated, but it is sensible for researchers to consider how conducive the institution's policies are to conducting compelling research and securing scarce funding. Patent infrastructure may be viewed as a limiting diversion of resources; alternatively, a researcher's proprietary interest might be a motivating factor. It is common for investigators to maintain a stake in the innovations their lab produces, and a patent may function as a revenue stream or as an asset for investigator to "spin off" to independently sell or license.¹¹⁸

In sum, in-house counsel did not give detailed responses as to whether the grace period changes would affect collaboration, but the generally felt that any impact would be negligible. Familiarity with international practices, including early filing and absolute novelty requirements, is expected to mitigate any growing pains. One in-house attorney stated that good collaborations are directed by intellectual property concerns; however, it is unclear how well the changes to the grace period are truly understood, and a few of in-house attorneys assessed the grace period as a false safety net.

Outside counsel answered that collaboration could well be

¹¹⁸ See, e.g., *Science and Policy Introduction: The New Spin on Spin-offs*, ORG. FOR ECONOMIC COOPERATION AND DEV., <http://www.oecd.org/science/scitech/introductionthenewspinonspin-offs.htm> (last visited Apr. 8, 2013).

detrimentally affected by a poor understanding of the new rules. Ambiguity in the grace period provision language has drawn criticism, including an official comment by the Washington State Patent Lawyers Association to the USPTO regarding the difficulties of the new grace period provision to the USPTO.¹¹⁹ An ill-timed disclosure may compromise the value of the invention and stifle an advance. On the other hand, the fear of such disclosures may hinder collaborative efforts. Thus, outside practitioners recommended educating clients about the law as described in subsection 3 *infra*.

Even where inventors firmly understand the law, outside counsel cited other areas of concern. One suggested that the need for quick reactions by inventors under the AIA might render collaborations more difficult, but acknowledged that this issue might be mitigated by familiarity with international practices.

¹¹⁹ E-mail and attached letter from Amanda Carmany-Rampey, Ph.D., Chair, Patent Office Rules and Practices Committee, Washington State Patent Law Association, to USPTO Undersecretary Kappos, Attention: Mary C. Till, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy (Oct. 5, 2012), *available at* http://www.uspto.gov/patents/law/comments/wspla_20121005-guid.pdf (“The legislative history of the AIA indicates [intent] to protect inventors who publically disclose their invention before filing a patent application by providing a grace period. The proposed examination guidelines, however, practically eliminate this grace period for any third-party disclosures that are not verbatim reproductions of a prior disclosure by the inventor or joint inventor The interpretation of 35 U.S.C. § 102(b)(1)(88B) and 35 U.S.C. § 102(b)(2)(88B) promulgated in the proposed examination guidelines unduly limits the applicability of the prior art exceptions with respect to subsequent, non-derived, third-party disclosures, such that the exceptions are practically meaningless. The proposed examination guidelines do not cite any authority for this interpretation; to the contrary, the proposed examination guidelines are directly in conflict with the legislative history of the AIA. Further, the proposed examination guidelines do not provide any examples of instances where two independent disclosures by an inventor and a subsequent third party would not have “insubstantial changes” or “trivial or obvious variations.” Without further guidance, it is reasonable to interpret the provisions of 35 U.S.C. § 102(b)(1)(88B) and 35 U.S.C. § 102(b)(2)(88B) as being applicable only in instances of *verbatim* reproduction, a scenario likely already provided for under 35 U.S.C. § 102(b)(1)(A) and 35 U.S.C. § 102(b)(2)(A). Thus, it is unclear when, if ever, the prior art exceptions under 35 U.S.C. § 102(b)(1)(88B) and 35 U.S.C. § 102(b)(2)(88B) would apply under the proposed examination guidelines.”).

Another perspective was that while the AIA incentivizes joint research collaborations by permitting collaborators to discount prior art by the other party,¹²⁰ the new disclosure rules place added importance on careful drafting and negotiation of collaboration agreements.

We noted that our in-house respondents represented a broad spectrum of nonprofits in terms of size, goals, and resources. Given the resource balancing act and other challenges imposed upon nonprofits by the AIA, we wondered whether outside counsel would provide different advice to nonprofits along this spectrum.

3. In light of these changes, how would you advise nonprofits at various stages of their development?

Despite the inquiry, outside counsel did not address nonprofits of any particular size or resource set. Rather, they simply stressed adherence to best practices, including careful management of disclosures, and noted the tension between filing early and often and obtaining sufficient data to satisfy § 112—though strong filings were prioritized over early filings. With respect to the FITF system, counsel reiterated their comments as described previously. The only emergent theme was an emphasis that under an international filing system, pre-AIA practices, such as filing in a foreign patent office before disclosing in the United States, are now obsolete with respect to U.S. priority.

The lack of clarity surrounding the new prior art categories and changes to the grace period also prompted the attorneys to stress intra-organizational communication and schedule-keeping so that any disclosure that is “available to the public” is preceded by a provisional application. The danger of manuscript provisional failing § 112 was reiterated, and filing early under FITF should be secondary to filing a strong provisional. A continuation that claims the priority date of the provisional application should be continually updated so that the “original disclosure” supports all relevant advances in a final nonprovisional application. Further, any reliance on the one-year grace period was discouraged. If the

¹²⁰ 35 U.S.C. § 102(c) (2011).

entity is involved in or seeking a collaboration, careful negotiation and drafting of intellectual property terms, particularly regarding disclosures and filing procedures, will be of paramount importance. A comprehensive understanding of the relevant arts is ideal, though this is a difficult goal to achieve.

Finally, outside practitioners emphasized the need to keep good notebooks and records of invention. Careful note taking allows inventors to track mistakes, avoid duplicative experimentation, and accurately record both results and inventions.¹²¹ Moreover, while interference proceedings are abolished by the AIA, good records remain invaluable in derivation proceedings. Respondents recommended that upon invention, an inventor's notebook should be signed and dated by a witness who understands both the invention and the state of the art. Of course, the reality is that notebooks will always be primarily for scientific purposes. Adherence to the best practices, from patent-conscious record-keeping to properly managing disclosures, will be difficult to ensure.

4. In your opinion, do your clients clearly understand what constitutes prior art and "disclosures" under the new law? If not, would you suggest taking steps to make this clearer?

While some in-house attorneys had previously stated that their scientists were well versed in the basics of patent law, outside practitioners felt differently. Several stated that new prior art system, and not FITE, represented the most significant change under the AIA. They recommended education programs at the nonprofit level to explain the law—one attorney suggested teaching programs for attorneys in CLE seminars—with a specific emphasis on three points related to prior art and the grace period.

¹²¹ The Stanford University Office of Technology Licensing provides a list of recommended best practices, including making sketches and written description upon invention, temporally consecutive entries, and comprehensive descriptions of experiments, equipment, and results. *See Suggestions for Keeping Laboratory Notebooks*, STANFORD UNIV. OFFICE OF TECH. LICENSING, http://otl.stanford.edu/inventors/resources/inventors_labnotebooks.html (last visited April 2, 2013).

First, “disclosures” have grown in complexity. Public disclosure can take myriad forms, including academic poster sessions, written abstracts for research talks, PowerPoint slides, and journal publications, all common features of academic research. One attorney speculated that a web posting regarding a future presentation might qualify. New media, such as blogs, personal websites, and online academic journals should also factor into disclosure considerations. Even patent-savvy innovators may be caught by surprise, as some online journals now publish uncorrected proofs of submitted articles before notice of formal publication to the author.¹²²

Second, outside counsel cautioned that the grace period changes are nuanced. As stated *supra*, the grace period does not create a “first to publish” system where publishing prior to filing defeats all subsequent art. Though the USPTO’s recently-released final examination guidelines adopt a softer stance towards grace period disclosures than had previously been discussed,¹²³ the

¹²² *Online in less time*, NATURE NEUROSCIENCE, Aug. 2001 at 767, available at http://www.nature.com/neuro/journal/v4/n8/pdf/nn0801_767a.pdf.

¹²³ In previous iterations of proposed examination guidelines, the USPTO had suggested that disclosures that differed only in trivial or insubstantial ways from the applicant’s initial disclosure would still become prior art against the inventor. However, this stance has been changed in response to public comment. See USPTO, EXAMINATION GUIDELINES FOR IMPLEMENTING THE FIRST INVENTOR TO FILE PROVISIONS OF THE LEAHY-SMITH AMERICA INVENTS ACT, F.R. 03450 (Office of the Federal Register Feb. 14, 2013), available at <https://www.federalregister.gov/articles/2013/02/14/2013-03450/examination-guidelines-for-implementing-the-first-inventor-to-file-provisions-of-the-leahy-smith> (“[T]hese examination guidelines also clarify, in response to the public comment, that there is no requirement that the mode of disclosure by an inventor or joint inventor (e.g., publication, public use, sale activity) be the same as the mode of disclosure of the intervening disclosure, (e.g., inventor discloses his invention at a trade show and also does not require the intervening disclosure is in a peer-reviewed journal). Additionally, there is no requirement that the disclosure by the inventor or a joint inventor be a verbatim or *ipsissimis verbis* disclosure of the intervening disclosure. In addition, these examination guidelines also clarify that in order for the exception based on a previous public disclosure of subject matter by the inventor or a joint inventor to apply. These guidelines also clarify that the exception applies to subject matter of the intervening disclosure that is simply a more general description of the subject matter previously publicly disclosed by the inventor or a joint inventor. . . . [I]f

governing rules for which disclosures will fall within the grace period and which will vitiate its protections remain to be seen.

Third, and crucially, the AIA grace period only extends to disclosures made in the United States.¹²⁴ Publications available in other jurisdictions immediately risk becoming prior art against the inventor, and the global interests of the research organization must factor into careful management of disclosures. Therefore, not all public disclosures are *per se* protected by the grace period and inventors must proceed carefully in making disclosures and in seeking patents. Early filing, awareness of the grace period rules, and general education regarding the AIA were stressed as critical adaptations to the new law.

To facilitate this education, the best practice is open communication between the nonprofit and a patent specialist. Presentations or training by an attorney can teach guiding principles to researchers, administration, and leadership and explain the role that patents can play in fulfilling the organization's mission. Within an organization, vertical channels of communication can promote early identification of valuable innovations and careful recording habits. The attorneys commented, however, that motivating researchers to implement such practices, rather than focusing solely on publishing, would be difficult.

D. Third-Party Challenge System

subject matter of the intervening disclosure is simply a more general description of the subject matter previously publicly disclosed by the inventor or a joint inventor, the exception in AIA 35 U.S.C. 102(b)(1)(B) applies to such subject matter of the intervening disclosure. The specific comments on this issue are also discussed in greater detail in the Responses to Specific Comments section.” (See Comment 31 and Response).

¹²⁴ A handful of other jurisdictions, including Canada and Australia, independently provide a one-year grace period. For all intents and purposes, U.S. filings receive grace period protection only in the United States. See Bill Herman, *The America Invents Act: practical upcoming implications—part II*, LEXOLOGY.COM (Feb. 4, 2013), <http://www.lexology.com/library/detail.aspx?g=3ab2164f-bb67-430d-b96b-5874f5db74be>.

The AIA enhances the ability for third party challengers to challenge a pending patent application by submitting prior art to the USPTO. Unlike pre-AIA law, the challenger can now include a concise description of the prior art to direct the examiner. We wondered whether nonprofits might react to an increased likelihood of challenge, or whether they were now more likely to participate in the challenge system.

1. In your opinion, will the third-party submission changes to the AIA affect resource allocation in the patent process and the resulting quality of the patented invention? Why or why not?

All counsel unanimously responded that while the challenge system might make for better patents, it would have no effect on how nonprofits allocated their resources or the quality of inventions produced. Only one in-house attorney mentioned having been involved with a challenge under the old system; the overwhelming message was that nonprofits are rarely subjected to such challenges and would not put any further resources into shoring up a given invention or application simply due to this provision of the AIA.

As with the prior art expansion, some outside attorneys noted that the increased likelihood of third-party challenges might affect patent valuations by potential licensees. Again, the nonprofit response may be providing more data or performing more due diligence than might have occurred prior to the AIA. Any such effort is likely to be made easier in the collaborative and open context of academic science, but still may constitute a burden for nonprofits. Shifting the perspective, we asked whether nonprofits were more likely to initiate or participate in third party challenges under the AIA:

2. Do you feel that nonprofits are more likely to participate in third party challenges? If so, how does this change your counsel?

In-house counsel generally answered that while the third party challenge system is more conducive to participation by nonprofit organizations, expectations of participation were mixed. Generally

speaking, these organizations are not as adversarial regarding their work as their for-profit counterparts and are less likely to challenge patents. Two attorneys stated that anything over the cost of an in-house provisional application would be disfavored, making third-party challenges unlikely.

Others responded from a risk-analysis perspective, stating that nonprofits may be involved when a licensee challenges a competitor's application. However, all attorneys agreed that participation will only occur if it furthers the nonprofit's goals. In the reverse situation, a higher likelihood of challenges against a nonprofit would probably encourage the nonprofit to license or cross-license with the challenger in order to diffuse the challenge and foreclose rejection by the USPTO or invalidation in litigation.

Outside counsel gave similar answers. A minority did suggest that, of all the new pre- or post-grant challenge options, the third-party challenge system represented the cheapest and most attractive option for nonprofits to participate. Moreover, the ability to participate anonymously may prove an attractive feature for image-conscious nonprofits.

However, this is balanced against the fact that even minimal added costs may preclude participation by resource-limited nonprofits. All outside counsel felt that challenges will not be a priority for nonprofits and that any participation will be tied to challenges by licensees. An exception may occur when the nonprofit is heavily invested in a particular area of technology and must, by necessity, influence the patent field.

One attorney cautioned that third party challenges are strategic gambles. Should the challenger fail, the submitted prior art will only strengthen the patent at issue and compromise any other avenue for challenge on the same grounds. Therefore, potential challenges should be evaluated against the strength of the patent as well as challenger's perceived chances in a post-grant proceeding or in litigation.

Since the challenge system was opened in an attempt to induce more participation, we wondered, whether a given nonprofit acts as a challenger or a defensive party, if the challenge system under the AIA is more equitable than it was previously.

3. In your opinion, does the AIA provide a more equitable challenge system for nonprofits? If so, why?

This question was not ideally drafted, as it elicited responses about the entire pre- and post-grant challenge system rather than specifically about third-party pre-issuance challenges. These responses are addressed in the next section. To the extent that third-party challenges were mentioned, all responding attorneys felt that this mechanism was somewhat more equitable to resource-challenged entities than the old system, but that on the whole, the AIA had not made the challenge system more equitable. We then proceeded to ask respondents specifically about the post-grant proceedings:

E. Derivation Proceedings and Post-Grant Validity Challenges

1. The AIA has introduces four new challenge proceedings, each with distinct features. Do you anticipate whether any, or all, of the new proceedings will be attractive or helpful to nonprofits? If so, why?

In-house counsel did not seem familiar with each of the new provisions, but the overwhelming consensus was that, despite the AIA's efforts to open up the challenge system, nonprofit organizations are still extremely unlikely to participate in any of the various challenges. Licensing practices and other considerations mean that nonprofits are unlikely to invalidate the patents of others. Furthermore, the costs of post-grant proceedings, while lower than litigation, are still prohibitive for nonprofits. Universities also highlighted the difficulty in convincing the state attorney general's office that such proceedings would be a worthy expenditure of taxpayer monies.

A few respondents mentioned that post-grant review, allowing a wider scope of prior art discovery, seemed like the most attractive post-issuance option but emphasized that participation was very unlikely. Derivations, on the other hand, could be helpful where collaborations go wrong or, alternatively, records of collaboration might help in a derivation proceeding against a third

party. One respondent made the illuminating point that while nonprofits, particularly those working on “neglected” diseases, are not often subject to suit in the current environment, changing global economic circumstances may change this dynamic.

Specifically, those entities focused on treating tropical or subtropical diseases, or afflictions not often considered in the major pharmaceutical markets of Japan, Europe, and the United States, could assume a more significant market role as countries like China, India, and Brazil grow in population and economic standing. In that event, market participants will scrutinize heretofore less-valuable patents more closely and a deeper understanding of the challenge system will be required of the holder.

Outside counsel echoed their in-house counterparts, emphasizing that since nonprofits are rarely the targets of patent litigation, they are not especially concerned with litigation alternatives. Post-grant review and inter partes review were considered too expensive and typically occur so late in the timeline of an invention that the nonprofit is no longer directly involved—licensees are much more likely to use these offensive weapons. One attorney pointed out that in the rare event that a nonprofit’s patent is subjected to post-grant review, the nonprofit need not spend on defense as they would in litigation; rather, the USPTO conducts the proceeding with a presumption of validity.¹²⁵

From a defensive perspective, outside attorneys felt that the new challenge system favored large corporations over nonprofit inventors. Wealthy businesses can more easily afford the fees and, thanks to the bifurcation of inter partes reexamination into post-grant review and inter partes review, now enjoy two opportunities to challenge the patents of smaller entities. Respondents thus felt that the new challenge system tilts in favor of large entities, is less equitable for nonprofits, and is unlikely to produce better patents.

Finally, outside attorneys cited supplemental examinations as a helpful way to prevent any future litigation and to clean up patent prosecution history. Whether the costs will be borne by a licensee or by the nonprofit remains to be seen. As with the changes to prior

¹²⁵ 35 U.S.C. § 282 (2011).

art, the one-year grace period, and the third party challenge system, a few outside attorneys speculated that the uncertainty created might reflect on patent valuations and licensing deals. The actual effect of this uncertainty is unclear and may take years of litigation to provide a proper foundation for risk assessment.

CONCLUSION

Because nonprofit bioscience organizations have unique goals, incentives, and challenges, we designed our survey to address those aspects of the AIA that we felt were likely to pose special challenges to them, either due to their collaborative and open-source nature or to the resource restrictions under which they often operate. Our results met some of our expectations, defied others, and added a great degree of nuance to our understanding of the AIA and of the challenges faced by our respondents.

The AIA reshaped the face of patent law in the United States by transitioning the priority system from first-to-invent to FITF. We expected this transition to a high-pace FITF system to further burden resource-limited nonprofits; we discovered, however, that the transition's effect was minimal because nonprofit organizations (due to licensing practices and the international nature of their guiding principles) were already practicing under the international first-to-file standard. Outside counsel warned, however, that a race to file could result in more manuscript provisional applications being filed and failing to satisfy the patentability requirements of § 112.

In-house counsel further did not expect the expanded prior commercial use defense to impact the generally non-commercial nature of nonprofits' research activities, but future litigation regarding the definition of a "commercial activity" could add relevance to this defense. Outside counsel foresaw that the defense, as well as the university exception, could be beneficial to licensees and may encourage collaboration with universities or other academic nonprofits that *may* fall into that category.

Likewise, in-house counsel did not expect much impact due to the changes regarding prior art and the one-year grace period. First, in-house counsel expect that, in narrow and highly specialized fields, their own inventors are effectively experts in the state of the

art, meaning that while prior art may “expand” for inventors in other sectors, scientists used to publishing, patenting, and collaborating on an international level would not experience any change due to an expanded field of prior art. Furthermore, international absolute novelty practices have meant that filing early is standard procedure, and to the extent that the U.S. one-year period is taken advantage of, in-house counsel did not foresee any specific change. Again, outside counsel urged greater resources be put toward understanding the new laws. They recommended education programs to relay to nonprofit innovators both the new definition of “public disclosures”—specifically, the ramifications of the “or otherwise available to the public” language in § 102(a)(1)—and the important nuances of the one-year grace period. Whether a subsequent disclosure of the invention is afforded the grace period or vitiates it is as yet unclear. For scientists whose general goal is to share their research in a variety of forums, proper disclosure management and careful collaboration practices require careful consideration under the AIA. One outside attorney pointed out that while nonprofit innovators may feel well-prepared for the AIA’s changes, the story may not be the same for potential licensees, who might consider the prior art and grace period rules as risks to patentability (e.g., whether the original provisional has satisfied the § 112 requirements and supports a final nonprovisional, or whether priority, novelty, or nonobviousness becomes an issue under the new rules) that depress the value of licenses. These complexities are not likely to be sorted out in litigation for several years and may require an adjustment period.

The AIA also introduced new ways in which the validity of patents can be challenged both before and after issuance, yet neither in-house nor outside counsel felt that third party challenges, derivation proceedings, *ex parte* reexamination, post-grant review, or *inter partes* review were particularly pertinent to nonprofits. Nonprofit organizations do not challenge patents; rather, they are interested in publishing, obtaining funding, and finding licensees for their technology. Prior to the AIA, nonprofits rarely engaged in any form of challenge because (a) they typically license out enforcement rights to a wealthier commercial partner with better incentives, and (b) they are rarely targeted for challenge or

litigation due to their narrow technological focus, lack of commercial presence, and the public relations issues that a plaintiff might expect in suing a nonprofit research organization. Although the AIA attempts to encourage a more thorough vetting process by expanding a variety of avenues for pre- and post-grant challenge, our respondents expect no reaction from nonprofits. Challenged entities are likely to seek licenses or cross-licenses with challengers rather than risk invalidation, and nonprofits remain extremely unlikely to engage as challengers. At this time, the challenge system is most likely to affect nonprofits only indirectly, with commercial partners and potential licensees reacting to the uncertainties of an expanded challenge system.

In sum, our survey indicates that most effects of the AIA on nonprofit science research and global health are likely to be secondary, creating risks and uncertainties for commercial licensing partners that may affect the ability of nonprofits to accomplish their individual missions both in the United States and around the world. We hope that this survey of nonprofit actors in the Pacific Northwest provokes thought and provides guidance to innovators—particularly with respect to disclosures—and patent practitioners in this and other communities. Science will only effect as much change as can be funded, and with the global economy a state of flux, understanding all means—including patents—for enabling laboratory advances, product development, and effective delivery is indispensable to fulfilling nonprofits' scientific and humanitarian missions.

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