America Invents?

Against First-to-File Patenting in the United States

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Synopsis

On September 16, 2011 President Barack Obama signed the Leahy-Smith America Invents Act (AIA henceforth) into law, making several fundamental changes to the federal patent statute (35 USC) that have significant effects on protecting and owning innovations in the United States that came into effect on March 16, 2013. In my view, the changes introduce a competitive unfairness to claiming patent rights domestically for startups, small businesses, individual inventors and other parties of lesser financial means desiring to protect their ideas at the expense of greater harmony with international patenting systems. This paper is a legal analysis if the America Invents Act and its implications for the practical aspects of biotechnological development. I do not claim to be an outright legal authority on the matters herein discussed, but rather hope to offer a thoughtful analysis of the issues presented in light of the letter of law. I ask the reader to excuse any important decisions or subtle interpretations that may have been overlooked.

Introduction

Patenting is a complex and detailed process mediated by legal counsel and cost up to $7,000 in attorney's fees for patenting something as simple as an ice cube tray. For "highly complex" inventions such as an MRI scanner, fees may exceed $15,000, and these costs can further increase if extensive patent searching and/or legal opinions are needed (Quinn 2014). Moreover, according to the National Institutes of Health, the average cost of a patent lawsuit was about $10 million (NIH/ NHGRI 2002 and Raidt 2015). These expenses are certainly non-trivial, especially for startup companies and small businesses, who may have skeletal workforces and thin budgets.

The America Invents Act changed the U.S.'s "first-to-invent" (FTI) patent rights assignment system, in which the first party to innovate is granted patent rights with proper evidence, to a "first-inventor-to-file" (FITF) system that grants patent rights to the first party who files a patent application with the United States Patent and Trademark Office (USPTO). This change is found in Part II of 35 USC, most concisely the form of a definition in §100.1.2:

> "(2) The effective filing date for a claimed invention in an application for reissue or reissued patent shall be determined by deeming the claim to the invention to have been contained in the patent for which reissue was sought."

Practically, this change is frustrating because it shifts the focus from the actual innovator and his or her original idea to the innovator that can file a patent application with the United States Patent and Trademark office the fastest.

Under the FITF system, filing date and conception are equated through the assignment of priority to the filing date rather that evidence of earliest conception. Positively, this harmonizes the

pursuit of domestic and international patent rights such that innovators can be confident that their ideas are protected equally and for the same reasons at home and abroad. The Act also expands the definition of prior art to any public disclosure made within 1 year prior to the filing date by a party other than the inventor or a third party on behalf of the inventor. Specifically, the law states, "…a person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention." (§102.a)

Before the America Invents filing, provisions took effect on March 13, 2013, an inventor discovering that another party claimed patent rights to his or her invention could legally engage that party to assert patent rights to that invention by presenting proper evidence to support a claim to patent rights before the United States Supreme Court. These "interference proceedings" allowed an inventor to claim rights to an invention by showing proper demonstrating original conception or reduction to practice of the invention at a time prior to the third-party patent holder or applicant through exposition (in biotech/biomedicine) of laboratory notebooks, catalogued data or other time stamped official materials. This is no longer possible because of the American Invents Act, which eliminates interference proceedings and therefore the possibility for one to claim ownership to an invention for which a patent application has been filed._ Therefore, an inventor can lose his or her rights to their idea as a result of the America Invents Act if another party files first.

The Issue

In the setting of the first-to-file system, intense competition to file the first patent application for a new innovation becomes a central tenet of claiming and protecting patent rights in the United States. The resulting competitive dynamics, made possible by provisions of the America Invents Act, put undue stress on smaller entities of lesser means because they reduce the pursuit of patent rights to a race to the USPTO. Moreover, the provisions inadvertently create financial and logistical barriers associated with research, development, legal and administrative expenses that may dissuade small parties or individuals from taking the up front risk of pursuing and developing a potentially disruptive idea into a marketable invention because of the efficiency and magnitude the robust manpower and capital of industry giants enables. In combination with existing economic disparities between small and large biotechnology entities, the rift between small and large firms widens further. Therefore, the America Invents Act, and specifically its institution of the first-to-file system and its implications, puts innovators of lesser means at a fundamental disadvantage against larger entities with robust human and financial capital in pursuing patent rights.

My Position

<u>Risk, Resources, and the Race to the USPTO</u>

Small biotechnology firms and startup companies produce novel technologies capable of supporting a revolution in biomedical research and the diagnosis and treatment of diseases. However, the ingenuity of these smaller firms is not often backed by the same magnitude of capital found at large biopharmaceutical and biotechnology entities working on problems in the same

sphere. That is, these smaller companies are posed with much greater risk when deciding to pursue an idea for commercial application because the up front costs for R&D coupled with the expense for patent application may represent a large portion of their net worth, making the decision to develop a technology and pursue patent rights a major financial barrier if larger corporations are pursuing the same or similar ideas. As such, these parties, as well as non-incorporated parties, may not have the financial means or staffing to aggressively pursue patents for their inventions as soon as they are conceived.

In biotechnology specifically, the time and effort expended by legal counsel needed to properly research and prepare a patent application for a chemical drug, biologic, imaging system or other innovation can be exorbitantly expensive. For technologies that may greatly improve society by aiding or accelerating biomedical research and healthcare such as cancer immunotherapies, genetic tests, vaccines antibiotics, imaging systems and similar products, the magnitude of effort and money involved is also non-trivial because it effects the speed at which these products become widely available to the public. Moreover, conception and development of such inventions can cost millions or billions of dollars, even before market entrance is a remote possibility. These facts imply that even if a small entity wanted to protect their ideas or challenge the patent rights of large corporation, it would, at a minimum, be difficult in inverse proportion to the net worth of the company. More strongly, small entities may be dissuaded, have to delay, or be completely unable to pursue patent protection due to the exorbitant associated cost.

For pharmaceutical drugs, the estimated cost of development though marketing approval is $2.6 billion, and the process takes over a decade or more due to the time it takes to engineer compounds, test in pre-clinical and clinical trials, then analyze the resulting data for submission to the Food and Drug Administration. (Tufts 2014) An investment this large is within the means of large biopharmaceutical or medical device companies, e.g. Bristol-Myers Squibb, Pfizer, Merck,

Novartis, Siemens, General Electric etc.. However, it is likely well outside the means of smaller entities (e.g. new businesses, independent startups, startups founded by academic scientists) looking to bring a new idea or disruptive technology into the commercial space quickly, unless they are lucky enough to have a connection with a university or research institute. In addition to robust research and development funding, innovators at larger entities also enjoy advantages over smaller entities that facilitate the patenting process. In-house legal counsel are hired specifically to manage the matters and concerns of their employer, and may work day in and day out on a single legal issue for a company. Moreover, large biopharmaceutical and biotechnology entities often have specialized counsel within their legal departments concentrating on particular issues. For example, a lawyer at Pfizer may specialize in antibody patents for oncology, while his colleagues focus on psychiatric drugs, analgesics or over the counter medications. These counsel can, by their specialization and focus, provide guidance and services to the company that, when summed, confer a massive amount of technical expertise and experience to their employers that enable the latter to handle legal matters quickly and efficiently. This may not me the case at smaller firms that may have a handful, one, or no legal counsel on permanent staff due to the associated costs of doing so. These smaller firms likely would therefore, on average, operate less efficiently with regard to legal matters than large companies, which can delay their development and strength of impact compared to larger firms.

Beyond robust legal counsel, large biotechnology and medical device companies also enjoy the luxury of diverse partnerships that can be forged because of their robust net worth. Large entities, due to their (usually) high net worth, can simultaneously forge partnerships with major universities and research institutes around the world, expediting research and development by distribution and collaboration—a luxury that a small biotechnology startup could not enjoy as easily, if at all. The same principle applies to marketing power: While a small company may have to develop its own marketing materials in-house and therefore have to support writers, designers,

advertising professionals and other executives, a large firm could outsource this work to an advertising agency and simply work closely with them to approve developed material quickly, then deploy it globally. These variables further tip the scales toward large entities of robust financial means with regard to their ability to expedite product development and, as will be discussed below, also quickly secure federal rights to the innovations and inventions that result from R&D, even if another party is the true innovator.

Since the America Invents Act states that patent rights belong to the party capable of filing an application with the USPTO the fastest, it creates unfair competition for innovators of lesser means, thereby undermining the innovative spirit to which it's title refers. Prior to the AIA, the party holding the earliest evidence of an invention's conception or practice could claim patent rights in the United States. However, now, the first inventor to file a patent application with the USPTO is (if their application is approved) granted patent rights based on the filing date of that application, not on proof of original conception. This frustrates the spirit of innovation in the Unites States and, moreover, very saliently favors the operational capabilities of large, established entities with exorbitant human and financial capital.

A Possible Solution to the Problem

The obvious solution to the problem brought about by the America Invents Act is to revert the United States back to a first-to-invent system for the assignment of patent rights. However, given the contemporary dynamics of the American government, this solution seems unlikely, especially with an administration intensely focused on further developing the United States as a global presence. Therefore, another solution to the competition problem created by the America Invents Act, without reverting back to the first-to-invent system, is to revise 35 USC §102.a to be

narrower. The AIA phrase "otherwise available to the public" (35 USC §102.a) is, according to the USPTO, a new "catch-all term" that includes, "an oral presentation at a scientific meeting, a demonstration at a trade show, a lecture or speech, a statement made on a radio or talk show, or a YouTube video, Web site, or other online material" (USPTO). Although these provisions harmonize U.S. patenting policy with the international community, the broad language introduced by the AIA makes it very difficult for small entities to fairly compete in terms of disclosure with large entities.

The implication of this section of the law is that if evidence of invention exists in any medium anywhere around the world, it can be invoked as prior art to deny the patentability of an invention. Prima facie, this is advantageous to small firms, as a blog post, online video or other free electronic publication may imply rights to an innovation in litigation. However, the same dynamic applies to large entities who, by leveraging robust resources such as marketing firms, could disseminate official information to the global community in a matter of days or shorter through press releases, branded and unbranded advertising campaigns, public events, trade shows or conferences, etc. The large firms have a distinct advantage in terms of scale that, again, increases the feasibility of and motivates American innovators to become a greater presence in the international community, however the imbalance in competition leaves small American innovators at a loss when establishing prior art due to their leaner financial stature and operational robustness.

Striking "otherwise available to the public," and revising the text of the AIA to narrow the definition of prior art is one alternative solution to quelling the implications of the AIA and leveling disclosure dynamics between small and large entities. For example, the following changes (underline and strikethrough) could be made to 35 USC §102.a:

> "the claimed invention was patented, described in a printed or electronic publication, or in public use, or on sale, or otherwise available to the public before the effective filing date of the claimed invention." (35 USC §102.a, modified)

These small changes would still allow the law to address disclosures on a broad spectrum of electronic media including, but not limited to, blog posts, YouTube videos, publicly available files, company websites, university websites, commercials and other avenues. However, the elimination of "otherwise available to the public" protects against construction of the phrase to encompass any means of disclosure, and the possibility that a litigant or could frame an innocuous comment as the expression of an invention he or she had in mind, and use this as an assertion in court. Whether or not something such as a comment on a radio or talk show or an informal online disclosure is indeed representative of a party's actual possession of an idea for an invention is unprovable, as one could always tell a reasonable story as to how an idea came to be held in mind. By modifying "publication" with "electronic," instead of using "any public disclosure," the law has a stricter implication for web-based and digital disclosure because the language most potently references a written text. If revised as above, the construction of "electronic publication" can be left to the courts to decide on a case-by-case basis, and decisions can precise the definition. This is advantageous over the current text, which suggests that even, for example, a 140-character Twitter post to a public account can serve as prior art. This may be possible in some cases, however making this possibility a permanent statute seems worrisome because parties could exploit it with media campaigns and advertising to mark a stake in the intellectual ground and block true innovators' pursuit of patent rights without doing any real innovative work or reduction to practice.

Opposing Positions

Proponents of the America Invents Act maintain that its provisions bring United States patent policy in better alignment with other nations that use the first-to-file system, making it easier for American inventors to pursue patent rights in the U.S. and abroad concurrently. Under the AIA, it is true that American inventors will experience less confusion when protecting their ideas abroad because U.S. law now reflects that of the international community more closely. The America Invents Act also introduces several provisions that are designed to cater to "small and micro-entities" filing for patent application through changes in fee structure. (§123.a and §141.Sec10.b), which provides some financial relief to small entities that cannot be enjoyed by large parties.

Relief for Domestic Small Entities

Speaking to the second point first, the Act states, in §123.a that,

> "the term 'micro entity' means an applicant who makes a certification that the applicant—(1) qualifies as a small entity, as defined in regulations issued by the Director; (2) has not been named as an inventor on more than 4 previously filed patent applications, other than applications filed in another country, provisional applications…or international applications filed…for which the basic national fee…was not paid; (3) did not, in the calendar year preceding the calendar year in which the applicable fee is being paid, have a gross income… exceeding 3 times the median household income for that preceding calendar year…(4) has not assigned, granted, or conveyed, and is not under an obligation by contract or law to assign, grant, or convey, a license or other ownership interest in the application concerned to

> an entity that, in the calendar year preceding the calendar year in which the applicable fee is being paid, had a gross income…exceeding 3 times the median household income for that preceding calendar year…"

And, regarding fees, in §141.Sec10.b states:

> "(b) SMALL AND MICRO ENTITIES.—The fees set or adjusted…for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents shall be reduced by 50 percent with respect to the application of such fees to any small entity that qualifies for reduced fees… and shall be reduced by 75 percent with respect to the application of such fees to any micro entity…"

These changes to the federal statutes will therefore provide relief to small entities and businesses filing patent applications with the USPTO. For small entities who, as expressed above, will likely be financially constrained, the easement on USPTO filing fees aims to provide relief to parties in such situations. These provisions of the act also have a significant degree of flexibility baked in, as they allow the Director of the USPTO to define the criteria for a small entity (§123.a.1). Creating a threshold for micro-entity status in terms of number of patents held is also beneficial, as it provides relief to first-time and early career inventors, allowing them to amass at least a handful of patents before they must relinquish micro-entity status and pay full fees to the USPTO when filing patient applications. (§123.a.2) This can facilitate the startup process for small companies and make creating a parent portfolio easier, therefore making the patent procurement process more financially tolerable in terms of business between innovating entities and the USPTO. The income caps linked to median

household income and ownership licensing also level the playing field for smaller entities just beginning to generate revenue independently. (§123.a.2)

International Harmony and Prior Art

Before the AIA, the United States was the only nation still using a first-to-invent system for patent rights. As such, filing date did not represent the assignment of priority patent rights in the U.S. and wherever the inventor was seeking foreign patent rights, and therefore created inconsistencies when American inventors sought patent protection abroad. Under the AIA, domestic and foreign priority dates are essentially equivalent if both applications support the same invention and the applicant submits documentation supporting granted foreign patent rights. In addition to harmonizing the date representative of U.S. and international priority rights, the system also establishes a clear demarcation for prior art that applies globally, further harmonizing inventors' domestic and international patent protection efforts.

This greatly broadens the definition of prior art such that it also applies internationally and further facilitates consistency between domestic and foreign applications for patent rights. That is, under the AIA, the USPTO and foreign governing bodies can examine the same body of prior art when evaluating a patent application. This further supports the Act's intent to streamline the patenting process for American innovators, making the criteria for originality in invention very straightforward, i.e. anything accessible in reality or on the internet. This simplifies patent litigation and evaluation of patentability and should provide some administrative relief for both innovators and the United States government.

Efficiency of Government

The administrative efficiency afforded by the AIA provisions will provide much needed relief to an already financially strapped and ideologically tumultuous government. The AIA's elimination of interference proceedings (§135.j.2.A) saves the U.S. government substantial time and money during the patenting process. Therefore, the law generally streamlines U.S. patenting practice by establishing an internationally unambiguous filing date and increases the efficiency of the patent system in general by eliminating the possibility of costly interference proceedings that may substantially delay patent processing and cause administrative hang-ups at the USPTO. To the latter point, influxes of patent litigation cases are a real logistical problem for the USPTO. In recent years, so called "patent trolling" by patent holding companies (PHCs) that exist precisely for patent litigation purposes on behalf of other entities account for a significant fraction of patent cases litigated. The provisions of the AIA are designed to quell the influx of patent litigations by eliminating interference proceedings and taking away the forum in which patent trolls have been able to exploit the patent system and the U.S. government.

Counter-arguments to Opposing Positions

For the above opposition reasons, the America Invents Act does indeed support the sentiment to which it title gestures insofar as it provides relief to micro-entities by offering discounts in patent filing fees and makes international pursuit of patent rights less complicated for domestic inventors and the USPTO. It may also have an inhibitory effect on gratuitous patent litigation. However, from a practical perspective, the costs of the domestic implications of the AIA outweigh the administrative and logistical benefits it affords.

Relief for Domestic Small Entities?

Although the America Invents Act seems to provide relief to small entities pursuing patent rights through discounts on patent filing fees, this action is somewhat hollow, because a majority of the expenses for patenting are incurred before application to the USPTO in the form of research and development costs and legal fees for research, guidance, opinions and drafting. While the provisions in the AIA appear to provide relief by discounting the costs of patenting, in reality the discounts in filing fees as outlined in 35 USC §41 (which can add up to a few thousand dollars) still account for marginally less than the legal fees, and certainly less than research and development costs, incurred during the patent drafting process. The AIA sections concerning micro-entities do not address this practical reality, and therefore appear to more strongly advocate for small entities in theory than they do in practice. Moreover, after the signing of the AIA, the USPTO has increased their fees in 35 USC §41 multiple times, once in 2011, again in 2012, and again in 2013, contradicting the AIA's discounts (Fox 2011, Venable LLP 2012, Koenigbauer et al. 2013). Further, no provisions of the AIA have an effect on the costs or logistics of research and development conducted to arrive at a patentable invention, which also constitutes a significant fraction of an innovator's expenses while pursuing an idea.

International Harmony and Prior Art?

The international harmonization enabled by the provisions in the AIA align the inventive process in the United States with that experienced by foreign inventors, making American inventions and their owners more compatible with international colleagues and governing bodies. Proponents claim that this makes the United States a more relevant global presence in innovation and can

increase competitiveness. However, the domestic implications described in section IV above outweigh these benefits. Moreover, the United States is already a leading global innovator in several spaces, including computer and Web technology (Apple, Google, Microsoft etc.), biopharmaceuticals (Bristol-Myers Squibb, Pfizer etc.) and medical devices (General Electric etc.). Furthermore, changes to the definition of prior art under the AIA to encompass essentially all media make the determination of initial disclosure ambiguous. Is there exact phrasing that must be used for an idea to be legally disclosed? What is the precise definition of public access in the eyes of the USPTO? What diversity of people must have access to a disclosure for it to be considered truly "public"? These are salient questions that are left unspecified by the AIA. Many of these issues will likely arise in post-AIA court proceedings, however the text alone leaves much up to interpretation, and may spur a new kind of "trolling" more insidious than that of patent holding companies, in which ideas are systematically disseminated into the public forum in order to create defensible grounds for blocking claims to patent rights.

Efficiency of Government?

According to the White House, 62% of the total number of patent cases commenced in 2012 were asserted by patent holding entities. Provisions of the AIA are designed to quell this effect, and so the law does establish groundwork against gratuitous patent litigation that can inundate federal courts and impact the efficiency of government. However, against this point, the Act establishes "derivation proceedings" permitting patent holders to move their IP quarrels to the post-patent environment, the effects of which will be seen in the coming years. It is quite possible that post-grant litigation of patents could be markedly more time consuming and expensive for all

parties involved (including the USPTO) when patent holding companies devise strategies for prosecution in the post-grant environment.

Conclusion

The America Invents Act introduces a number of fundamental changes to the patent system of the United States. Pivotally, these include a change to a first-inventor-to-file system for assigning patent rights. As espoused above, this change undermines the ability of small entities of lesser means to claim rights to their inventions against large companies with robust human and financial capital capable of filing applications quickly with the USPTO. The AIA also introduces an extremely broad definition of prior art that makes disclosure ambiguous, which may complicate the patenting process generally. Although the provisions in the AIA harmonize the U.S. patent system with the international community, are poised to increase governing efficiency by minimizing the ease of bringing patent lawsuits to federal court, and provide some relief on filing fees for micro- and small entities, these provisions ultimately do not deliver on their promise of spurring innovation because they enable potentially expensive post-grant patent litigations, and do not provide any relief for legal or research and development costs that constitute the majority of a patent applicant's expenses.

An obvious solution to these problems is to revert back to a first-to-invent system, however this is admittedly idealistic and impractical given the law's very recent enactment. Alternatively, the law may be improved by narrowing the new definition of prior art to encompass electronic publications of a narrower scope, thereby preventing gratuitous disclosures analogous to the gratuitous patenting practice exemplified by patent holding companies. Over all, the important practical effects of the AIA have yet to realize because the law is so new, however acute monitoring of USPTO activity over the next few years will expose the loopholes and inconsistencies in the law,

hopefully supporting changes that will further level the playing field between small and large entities pursuing patent rights for their inventions..

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