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DID THE AMERICA INVENTS ACT CHANGE UNIVERSITY TECHNOLOGY TRANSFER?

*Cynthia L. Dahl**

INTRODUCTION

The Leahy-Smith America Invents Act (AIA)¹ is approaching its ten year anniversary. When it was signed into law in 2011, it was intended to be the grandest overhaul of the U.S. patent system in fifty years. As a consequence, the AIA makes bold and sweeping changes to the U.S. patent filing system that impact which patents issue, give certain advantages to a subset of filers, and greatly expand the ability to challenge the validity of a patent even after it has issued.

Universities stood to be especially affected by the AIA. Changes that force a patent owner to file quickly to secure rights are particularly challenging to universities, where discoveries are often early stage and there is a culture of disclosure. In addition, the AIA's changes to establish and clarify procedures to invalidate patents even after they are granted casts a pall over the long-term value of patents. Given the number of patents that universities file and the great value of some of their patent assets, the AIA shifts were cause for concern. The AIA's potential to make both securing and maintaining patent coverage more difficult caused university technology transfer offices² (TTOs) to fear the law would chip away at their business model based on protecting and licensing inventions.

Although some articles discussed possible or preliminary effects that the AIA changes would have on university TTOs³, there has been no

* Practice Professor of Law, University of Pennsylvania Carey School of Law. Thank you to the TTO officials whose comments within made this article possible, and for Isabel Kim (Penn Carey Law JD '21) for the citation support.

¹ Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified in scattered sections of 35 U.S.C.). Parts of the AIA were phased in at different times from September, 2011 through March, 2013.

² The technology transfer office is the department of a university charged with protecting and licensing university inventions.

³ For background information on the subject, *see generally* MacWright, Robert, Three Years after the America Invents Act: Practical Effects on University Tech Transfer, *les Nouvelles - Journal of the Licensing Executives Society*, Volume LII, No. 3, June 2017. Available at SSRN: <https://ssrn.com/abstract=2961434>; John Morgana and Veronica

comprehensive analysis of the actual effects. It is therefore well overdue for analysis. With the benefit of almost a decade of time and distance, we can gather a much more accurate picture of the AIA's actual effects on TTOs. Barring large legislative changes, these effects are unlikely to change over the next several years.

My analysis concludes that the effects of the AIA on TTOs have been nuanced. Some changes have caused more worry than actual effect and have therefore not had a big impact. Some changes, especially those designed to specifically give universities certain advantages, ironically have not granted the positive effect intended. But some AIA changes have coincided with important shifts in TTO operations. TTOs report a number of interesting trends that are impacting their missions, many of which dovetail with the AIA changes, such that the effect is combined. For example, TTOs report a substantial reduction in their licensing business in certain fields based on what they see as a general devaluing of patents overall. Whether patent devaluing happened in part because of the AIA changes, or whether the AIA changes came about because of a climate where patents were being devalued is a topic for another paper. However, TTOs' reactions to both AIA effects and general trends are illustrative for all entities that rely on licensing patent assets as a business model. And to the extent that patents play an important role in incentivizing innovation, examining these effects is critical.

Section I of this article sets the context for the discussion. It starts with a brief overview of the AIA changes that are the most relevant to TTOs. I focus on five topics: i) the shift to a first inventor to file ("first to file") system; ii) changes to the definition of prior art; iii) changes specifically designed to give universities an advantage (including a) immunity from the prior commercial use defense and b) use of micro entity fees); and iv) the establishment and clarification of post grant challenge procedures, including *inter partes* review (IPR) proceedings⁴. Since the few articles on this subject were written years ago, postulating about the future effects, it was critical to gather evidence from the TTOs themselves to understand the actual effects of the AIA. This Section I concludes by describing the survey

Sandoval, *Pacific Northwest Perspective: The Impact of the America Invents Act on Nonprofit Global Health Organizations*, 9 WASH J.L. TECH. & ARTS 177 (2013).

⁴ For a much more in depth analysis of the effect of post grant proceedings on TTOs, see generally Dahl, Cynthia, *Reviewing Inter Partes Review Five Years In: The View From University Technology Transfer Offices* (2020). In *The Research Handbook on Intellectual Property and Technology Transfer* (Jacob H. Rooksby ed., Edward Elgar Publ. 2020), U of Penn Law School, Public Law Research Paper No. 20-23, Available at SSRN: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3660028

I conducted with eighteen TTOs in order to gather the instructive anecdotal evidence presented herein.

Section II contains a deeper discussion of each of the AIA changes and their implications, in the words of the TTOs themselves. There are four subsections, corresponding to the topics I queried. Finally, my discussions with the TTOs also uncovered broader generalizations, as the TTOs started to place the AIA changes into context and speculate about current challenges and potential trends for patent licensing that will play out over the next years. These very interesting points are summarized and discussed in Section III. While these comments were gathered from my discussion with TTO offices, they have broad applicability to other patent-centric industries and parties.

I. SUMMARY OF THE CHANGES IMPLEMENTED IN THE AIA THAT HAVE SPECIFIC RELEVANCE TO TTOS

Perhaps the most significant change in the AIA involves aligning the U.S. patent filing priority system to the patent priority system followed by the rest of the world. Through the AIA, Congress shifted the United States Patent and Trademark Office (USPTO) from a “first to invent” system to a “first to file” system. Under the new rubric, the USPTO awards the exclusive rights under a patent to the first inventor to file a patent for an invention, whether or not they were the first to invent. Critics worried that the first to file system would negatively impact smaller organizations and individuals that could not afford to analyze their inventions and file patent applications as quickly and consistently as larger and more moneyed entities⁵. However, the first to file system also impacts universities more significantly than other parties because of the university culture of disclosure and their focus on early stage research, as explained in full in Section II(A), below.

In the AIA, Congress also broadened the universe of applicable prior art. Because inventions cannot be patented if they are not new, before issuing a patent, the USPTO must ensure that an invention has never been disclosed before, either through another patent or in other public ways. All such disclosures are called “prior art.” Before the AIA, only certain kinds of

⁵ See David S. Abrams & R. Polk Wagner, *Poisoning the Next Apple? The America Invents Act and Individual Inventors*, 65 STAN. L. REV. 517, 520 (2013); Eric P. Vandenburg, *America Invents Act: How It Affects Small Businesses*, 50 Idaho L. Rev. 201, 219-220 (2014).

disclosures could count as prior art, and if the inventor himself disclosed, there was a one-year “grace period” for the inventor to file a patent before his own disclosure counted as prior art against himself.⁶ The AIA broadens the universe of possible prior art in two significant ways. First, it allows for new categories of disclosures to constitute prior art⁷. Second, it broadens the possible timeframe for acceptable prior art citations⁸. Adding to the universe of possible prior art in so many additional ways makes it less likely for an idea to be “new,” thereby restricting the number of patents that can issue.

Universities also receive special treatment under the AIA through at least two new provisions directed especially to them. First, Congress specifically shielded universities from potential infringers’ “prior commercial use” defense⁹. Under the AIA, an infringer can defend against infringement by proving that they had been engaged in prior commercial use of the patented invention before the patent owner filed the patent. However, Congress drafted an exception to that defense for university inventions, such that a would-be infringer’s prior commercial use of the university technology would still be considered infringing¹⁰. Second, Congress created a new “micro entity” classification, which allows inventors with a certain (low) level of income that had also filed relatively few patents to pay lower patent filing and maintenance fees. Congress allowed universities to also take advantage of micro entity status, regardless of revenue and regardless of the number of patents filed¹¹.

And finally, under the AIA, Congress extended, clarified, or created procedures to allow parties to challenge the validity of issued patents. Depending on the subject matter of the patent, and how long ago it issued, challengers can challenge an issued patent under procedures including Post Grant Review, Covered Business Method review or *Inter Partes* Review (IPR). In particular, IPRs are the most potentially relevant procedures for universities, since they address the most valuable university patents and can be used later in the patent term, once the patent has been licensed and commercialized through a product.

⁶ The one year grace period applies for patents later filed in the U.S. Importantly, the grace period is not applicable in most countries around the world. In these so-called “absolute novelty” countries (like China), any disclosure before filing a patent can invalidate the patent. This is why it is imperative to evaluate foreign filing priorities before disclosure.

⁷ See 35 U.S.C. §102(a)(1).

⁸ See 35 U.S.C. §102(a)(2).

⁹ See 35 U.S.C. §273.

¹⁰ See 35 U.S.C. §273(e)(5)

¹¹ See 35 U.S.C. §123(d).

As predicted, the shift to a first to file system changed TTO patent filing policies somewhat, although the effect has been muted for TTOs that had already filed many patents overseas. Changes to the definition of prior art have similarly made TTOs much more cautious about what they file and when, although most have not changed what they say when they warn inventors about disclosure. Surprisingly, the provisions that were passed specifically to benefit universities, including offering immunity from the prior commercial use defense and instituting micro entity fees, appear not to have made a significant difference for TTOs at all. And while fear of the effect of post grant procedures has been substantial, the actual effect has been much more subtle, for reasons related to the mission of TTOs and the early stage nature of university technology¹².

In each case the employees at the TTO designated the person that I should speak to who was most knowledgeable about the effect of changes from the AIA. Although the titles of each of the representatives I interviewed varied (as did the hierarchical structure of the TTO), generally I spoke to either the head of licensing for the TTO, or the highest ranking legal officer for the TTO. In a few cases I spoke to more than one person within the TTO, for example when my questions crossed between the expertise of two people, or when the highest ranking person with the relevant information was relatively new to the office.

I began the interview by eliciting information about their knowledge of the AIA changes I was focused on, and any policies implemented by their TTO in response (including changes to filing strategies, enforcement strategies, or budgeting). In each case, I typed written notes during the interview, taking down answers word for word whenever possible to allow for direct quotations. Some of the TTOs requested that their comments remained anonymous or that the statistics be reported in aggregate. In most cases, this was because the TTOs had active IPR proceedings, or because they were concerned about potential licensees or potential patent challengers learning about their attitudes toward enforcement or other policies. As a result, while the statements below are near direct quotations from the interviews, I do not attribute the comments to the specific TTO that made them.

¹² See Dahl, *supra* note 4.

II. EFFECTS OF THE AIA ON TECHNOLOGY TRANSFER OFFICES

A. Shift to a First to File System

1. After the AIA, some TTOs now file patents more quickly, but the biggest policy changes promote application quality

When the U.S. changed to a first to file system, TTOs faced a tension. On the one hand, they needed to file patent applications as early as possible to increase the likelihood that they could secure exclusive rights. But on the other hand, especially with questions about patentable subject matter and enablement, TTOs were strategically incentivized to wait to file until the inventions was developed enough to support a robust set of patent claims.

Although all patent-centric industries continue to face this tension, universities have more pronounced challenges about deciding when to file patents because of their circumstances and mission. First, unlike in industry, university inventions might be general and not directed to solve a specific industry problem. This means that it is hard to gauge the invention's eventual value or potential for commercialization at the stage when it is necessary to file a patent. Second, huge numbers of inventions across a broad spectrum of subject matter force universities to rank and prioritize inventions without necessarily having the deep contextual knowledge required to evaluate value. Third, universities must make quicker decisions about patenting because of the academic world's publishing culture and the likelihood that other researchers are working and publishing in similar spaces. The TTO must decide whether or not to patent likely at the same time as the inventor is publishing their results, even before there is sufficient supporting data for the invention. Fourth, unlike in industry, there can be a culture prejudiced against commercialization at universities, which leads the inventor to deprioritize patenting and reveal the invention only when their publication is imminent, if not already past. Finally, universities may be pushed prematurely into making a patenting decision by an industry partner or the demands of the Bayh-Dole Act or other government reporting requirements. And compounding the difficulty presented by all these situations is the feeling that there are very high stakes at play in making the right decision. The university's licensing business model may demand that the university have a patent in order to indicate value to potential licensees.

AIA has changed our decision if and when to file a bit...we file earlier because of the "first to file." At least we consider it. I don't have a good perspective on the stats, but we do file early if we know of competitive activity. We rely on the inventor to tell us "this is hot," "[a third party] published this," or "I saw this at

the conference.” We have to decide the value of the technology and if we think we can beat someone, we will file. But that accelerates everything...the regulations for reporting IP for the government impact this too. We have to report in an earlier fashion on whether we are going to file; government is starting to pressure us on timelines, and we are starting to have to report earlier, so we need to decide [on patenting] at 9-10 months. This is from Bayh-Dole requirements and also NIST [National Institute of Standards and Technology] regulations. This all plays into early filing and early decision making; it shrinks the amount of time that you have to develop supporting data.

TTOs responded to the tension in a number of ways. Especially right after the AIA passed, some TTOs tightened up their patent filing policies in order to maximize their ability to file quickly, in response to both real and perceived pressure from their institutions or faculty inventors.

[First to file] has definitely tightened up timelines and we give more education to inventors on what a grace period means or doesn't mean or [that we're] not sure anymore. We also make decisions on whether to file patents over disclosures within a month and take no more than another month to file with attorneys – we made them aware of new schedules. We are always on top of our filing, but now [we have] more urgency and a better process so that we file on what is ready.

We are filing earlier...AIA came about a few years after a change in our office, so it was not just [about the] AIA. About 2011, we changed from making more conservative filings once we were sure about the market and patentability – we got feedback that we were too conservative because we had such early stage tech, it was hard to spot the winners. We became less stringent – [we] file[d] on more tech, gave more [inventions] a chance. We would cull [the patents] later on – we'd file any provisional that might have a chance. Not stupid filing, but permissive. When the AIA happened, that fit nicely, and we ramped it up even more, and became even more permissive in filing.

Even TTOs that did not speed up their patent filing felt the effects of the first to file system shift. TTOs started worrying that current practices were leading to weaker patent applications. While this is more forgivable in a first to invent system, because provisional patents could be rewritten without fear of a later-filed provisional from another party taking precedent, it is riskier in a first to file system. A later-filing applicant could take all rights if the earlier-filed provisional patent was not complete. Thus, the AIA shift to first to file tipped the scales in the TTO tension toward establishing policies that guaranteed that a filed patent would issue with the strongest claims possible, even if it meant filing a little later.

For example, while some TTOs had a policy to file bare bones cover sheet provisional applications before the AIA¹³, most now do not trust cover sheet provisionals to stand up to more rigorous patent prosecution. Most TTOs are also now hiring outside attorneys to draft their first patent applications, whether a more complete provisional or a nonprovisional:

Before the AIA, we filed in-house provisional patents. We don't do that anymore. Since the AIA, we have used outside counsel to file all of our provisionals. We file fewer things and at greater cost. We are worried about having a complete application because of all the higher bars (enablement, etc.), you can't get away with things...previously [we used] cover sheet provisionals; not any more.

While most TTOs are no longer using cover sheet provisionals, they are still using provisional applications because it is attractive to be able to hold an early priority date while still taking a year to find a licensee. However, TTOs are ensuring that those provisional applications are more complete, and for really important inventions, some TTOs are occasionally filing several provisional applications for an invention as it develops. This practice is leading to stronger and more complete patent filings, although it does also lead to higher costs.

We may have to file a barer provisional knowing there is a publication coming up, and then we can file a second provisional with more data. We maybe didn't do that before the AIA, filing multiple provisionals when we have new data. But generally, we file the provisional first; in most cases that's the process.

We take a more modern approach to spend more money at the provisional stage because we want to get data into the patent in a meaningful way to get broad coverage... *Do you use multiple provisionals?* Sometimes – my paralegal team hates it. We may file two to three provisionals within the one-year window, if there is development in the window and we are far enough away from conversion. We only do that for tech that - based on internal research and potential feedback from the market – we think is hot and the asset is more likely to be licensed and someday subject to a dispute. It is a small batch that have multiple provisionals.

¹³ Provisional patent applications are a quicker and more economical type of filing in that they have fewer requirements than nonprovisional patent applications. Provisional patent applications only require a description of the invention and drawings (if any). They need not include any claims and are also not reviewed by the USPTO. So long as a nonprovisional application is filed within a year of a provisional application, the inventor receives priority back to the provisional patent application filing date for any material sufficiently disclosed. Cover sheet provisionals are barer still – they often use an inventor-provided description, and simply add the required filing cover sheet. The danger with provisionals – which becomes even more acute with cover sheet provisionals – is that the written description of the invention may not be complete enough to meet enablement and best mode requirements of the later-filed nonprovisional patent. If the nonprovisional patent cannot rely on the provisional patent because the description of the invention is incomplete, then the inventor loses the early filing advantage of the provisional patent.

In general, TTOs have become more worried about patent issuance, and therefore patent quality, than speed. They are not as willing to take a chance on a somewhat incomplete patent, even if they are forced to sacrifice earlier timing. For example, several TTOs report they are increasingly refusing to file patents for inventions that do not have enough data to be fully enabled, unless there is a clear reason to take a chance on filing. And no TTO feels comfortable relying absolutely on the presumed grace period (that an inventor can wait a year after their own disclosure to file), because the disclosure rules under the AIA have become more complicated.¹⁴

Filing more complete patents is not antithetical to urgency. Patents have to stand up to scrutiny and issue. If I have to give [inventors] six more months to get more data to build a better patent, that is a good tradeoff. So, we haven't responded [to the AIA] by filing any earlier, but we have changed to make filings more complete....

Because TTOs are being more stringent about which inventions they choose to patent, with the goal of drafting a patent that will issue, TTOs recognize they need to work closely with inventors.¹⁵ Many are striving to improve communication with principal investigators (PIs), educating them on how disclosure can limit rights and what constitutes enablement.

...We have to be more diligent in reaching out to faculty – when is the right time to file the application? Typically, I'll have discussions with faculty, and they might be 6-12 months out from their first publication. Some are nervous that there is someone out there that might file first, but we get one shot, so we say – when you are putting together a draft for that first poster or talk, before you give the talk, come talk to us and we will put it together for patent counsel. Do the prior art search and go ahead and file. We are not going to hold up publication, but we time it so that we file when we have the most data possible.

[First to file] changes our discussion with faculty; we tell them they have to have more than an idea to file. They need to understand [the concept of] enabling data and how it impacts potential [patent] claims. As simple as it may seem, this is a stretch for a lot... We have to engage with them earlier, even before they patent, to get more valuable IP. There is much less value in a cover sheet [provisional] patent. So, AIA changes will end up in forcing engaging with the inventor substantively earlier.

So, in summary, for those TTOs for whom a shift to a first to file system caused policy changes, some are indeed filing earlier, and they have adapted their procedures to ensure they can. But even more TTOs are responding to first to file by focusing on the completeness and the quality of their early

¹⁴ See section II(B) below for a discussion of changes to the definition of prior art.

¹⁵ For more thoughts on TTO efforts to enlist inventors to achieve better technology transfer results, also see section III(E).

applications. Although there may be an increased urgency to file, TTOs want to ensure that when they do file, they can maintain the early priority date because the patent will actually issue.

2. Other TTOs report no policy changes, based on prior widespread foreign filing and university publication culture

Although many TTOs made substantive policy changes including earlier filing and establishing more exacting standards and better communication with inventors in an attempt to secure better patent claims, some TTOs say that they did not have to adapt post-AIA at all because they had already instituted relevant protective practices before the AIA was adopted. This is especially true for TTOs that had already been filing many patents in foreign jurisdictions, where first to file was already the norm, and for those that had long dealt with the pressure imposed on filing decisions by their inventors' need to publish early even before all data is collected.

The university might be less likely to file abroad than [as compared to] industry, so AIA would change the process in that scenario. But if before AIA you had a practice that included filing in Europe, you always had to file before disclosure anyway because [Europe] never used a grace period. Also, the difference is that in industry, you can control disclosure. At a university, there is a strong interest in – even a need for – publication. In my opinion, most of the time, we are filing way too early – in industry, you waited to file until you HAD to disclose and get the benefit of all that additional work on enablement. In the university, you almost never have that luxury. You make a decision to file based on the publication schedule. It is not likely to be accepted in publication unless it is new and interesting, so it will be new, but maybe not filled out enough to be a good patent.

Everyone was freaking out when [first to file] happened, but we've always had this [first to file rubric] outside of the US, and for the most part we want[ed] to preserve ability to have foreign patent protection just in case. We have always lived in that realm.

For example, while some TTOs had been relying on more basic “cover sheet” provisionals before the AIA, or filing a variety of applications in-house, many TTOs were already filing only fairly complete provisional applications before the AIA. Some of those TTOs more concerned about the quality of even initial applications were also already filing serial provisionals, to cover the situation where an important invention experienced significant changes during the wait to file a nonprovisional application. Although across the board more TTOs are filing more completely drafted provisional applications post-AIA, this is not a new phenomenon for some TTOs.

For all the publicity, for a long time for us the incentive has been to file a good provisional “asap.” No one was waiting around based on the fact that we could prove we were first to invent....[we needed to file early and completely] for reasons of international rights, plus our inventors were going to publish, so that drives filing. We need to preserve foreign rights, so we file pre-publication. The first inventor to file was also usually the one who won in an interference [proceeding] anyway – so we always wanted to be first.... The AIA is interesting, but it hasn’t really changed how we do business.

In summary, the AIA’s first to file mandate did cause some TTO policies to shift, but perhaps not in the expected ways and not across the board. While the AIA did emphasize the need for U.S. entities to make filing decisions early in the life cycle of an invention, perhaps in part because universities *already* were forced to engage in this early decision making process because of publication mandates and foreign filing, the net change for those who implemented new policies was not to emphasize early filing. What most new policies focused on instead was the need to make more *quality* early filings. This has played out in policies to file fewer cover sheet provisionals, hiring more outside drafting help, turning away inventions that are not complete or have already been disclosed, and engaging in more serial provisional filings to capture additional improvements at an earliest possible date. That way when the patents are actually considered, more claims get through. This shift toward more complete and defensible patents has additional advantages as well. Better patent drafting helps patents to withstand the effects of the broadened post grant procedures of the AIA. It also helps patents to more effectively withstand attacks from a growing universe of prior art.

B. Changes Regarding Prior Art

1. TTOs must grapple with a new, broader AIA definition of prior art

Besides the shift to a first to file system, the AIA significantly broadened the universe of possible prior art. The definition of prior art is critical because it defines the boundaries of whether an invention is “new” or “nonobvious” for purposes of patentability. If an invention has prior art, the inventor no longer may file a patent. An inventor can even become prior art to herself. More possible prior art means getting a patent is much harder, since an idea is less likely to be new or nonobvious. More possible prior art also means there are more opportunities to challenge a patent after it issues.

The AIA first broadened the definition of prior art to include more types of disclosures¹⁶. Publications, even those overseas and in different languages, had always constituted prior art, but the AIA added international uses and sales to the universe of possible invalidating disclosures. This is the case even if those uses and sales were covered by non-disclosure agreements or otherwise kept out of the public eye.¹⁷ Further, the AIA added a new phrase to the definition of invalidating disclosures to include activities that make the subject of the patent “otherwise available to the public.”¹⁸ This specifically includes public oral disclosures, including speeches and talks, conferences, certain meetings, and otherwise other situations where the public can hear about the invention. Given the prevalence of opportunities for oral disclosures in a university, this change in the definition of prior art is especially meaningful for TTOs. It also sets up uncertainty. Is a lecture “available” if the audience members are university students only? What if it is a session open to the school but not advertised to the public? This uncertainty makes TTO’s analysis of what constitutes prior art to an invention, and what disclosures they warn inventors to avoid, more complicated.

We always pushed [inventors] to disclose – but there is an additional degree of uncertainty in the status around that now. We always have struggled with the idea of what it means to be publicly known. Outside counsel is probably more cautious post AIA – they ask more questions. Particularly when the disclosure is not printed materials. They always asked, but with a bit more sensitivity now. Was it “open to the public” or a closed door meeting? The challenge is that seminars are open to anyone, there is not an expectation that anyone in a seminar believes that information shared is confidential. There may be only [X university] people there, but that is not the standard. Could others have been there? Thesis defenses are closed, but portions might not be. So, in sum, we are careful.

The AIA also increased the period of time during which invalidating prior art can be created¹⁹. Under the AIA, prior art can now invalidate a patent

¹⁶ 35 U.S.C. 102 (a)(1) ((a) “Novelty; Prior Art.—A person shall be entitled to a patent unless— (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention;...”)

¹⁷ A recent Supreme Court case entitled *Helsinn v. Teva Pharmaceuticals* considered this question specifically. They decided unanimously that new language added to 35 U.S.C. 102(a)(1) through the AIA did not change the definition of the “on sale” bar to carve out so-called secret sales, where the party buying the product was bound not to reveal even the existence of the sale. Such secret sales are still invalidating activity constituting disclosure. *Helsinn v. Teva Pharmaceuticals*, 139 S.Ct. 628 (2019).

¹⁸ 35 U.S.C. 102(a)(1).

¹⁹ See 35 U.S.C. §102(a)(2) (“(a) Novelty; Prior Art.—A person shall be entitled to a patent unless— ... (2) the claimed invention was described in a patent issued under section 151, or

application if it existed at or before the effective date of the patent application's *filing*, not the date of *invention* of the idea patented. By expanding the time frame during which prior art can be created up to the date a patent is eventually filed, there is a chance of more prior art. Although the "effective date" of filing can be earlier under certain circumstances when there are related earlier-filed patent applications,²⁰ the AIA's change still means that the date when other inventions can be considered prior art is not frozen at the date of invention. Any delay in filing a patent application necessarily increases the span of time during which potential prior art can be created, which could invalidate an application.

2. Since the AIA changes to the definition of prior art also impacts the U.S. grace period, TTOs are relying on it less

The AIA does preserve a grace period from pre-AIA days that allows inventors to file a U.S. patent within one year of their disclosure without that disclosure becoming an invalidating instance of prior art.²¹ In other words, the U.S. is really a first to disclose system, since a discloser retains the right to file a patent, but the disclosure counts as prior art to any other would-be third party patent filer. This grace period applies to all inventor-originated disclosures, which includes disclosures by the inventor himself, any joint-inventors, either in combination with the inventor or not, and – importantly – any other party who "obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor."²² This last phrase prevents a third party who found out about the invention from the inventor from disclosing themselves, thereby ruining the inventor's ability to patent their own invention.

The AIA also specifically addresses a conflict that may arise when multiple disclosures occur during the grace period. Although it is clear that an

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.")

²⁰ See 35 U.S.C. §§100(i); MPEP §2152.01 Detailed Discussion of AIA 35 U.S.C. 102(a) and (b) [R-10.2019], available at <https://www.uspto.gov/web/offices/pac/mpep/s2152.html>

²¹ See 35 U.S.C. §102(b)(1)(A) (" (b) Exceptions.— (1) Disclosures made 1 year or less before the effective filing date of the claimed invention.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if— (A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor;...")

²² *Id.*

inventor-originated disclosure within a year of filing will not invalidate a later-filed patent, can third-party disclosures that also occur within the grace period invalidate the patent? So long as an inventor-originated disclosure occurs first, it does not matter how many other third-party disclosures occur during the intervening one-year period of time; none are invalidating disclosures.²³

However, even with the AIA clarifications on the point, there are some important limits to the grace period, which lead TTOs to be cautious about relying on its protection. Most importantly, the patent is only protected from an otherwise invalidating third party disclosure only to the extent that the earlier inventor-originated disclosure constitutes the same “subject matter” as the later third party disclosure. There will always be a question of whether the subject matter of the third party’s disclosure is close enough to the subject matter of the inventor-originated disclosure to be preempted. In addition, if the third party disclosure describes both the invention and improvements, besides the question about whether the content is still the same subject matter as was in the inventor-originated disclosure, the third party will gain rights over the improvements, and at the very least narrow the inventor’s eventual patent claims. It is especially sobering to consider that even third party improvements that are obvious over what is disclosed in the inventor-originated disclosure can take the invalidating third party disclosure beyond the same “subject matter.” And of course, if those improvements also render the subject matter of the inventor-originated disclosure obvious, not only will the third party disclosure not be preempted, but it will invalidate the inventor’s later filed patent on obviousness grounds.

Faculty members also sometimes inadvertently create problematic disclosures because they might not recognize the difference between a co-author for purposes of an article and a joint inventor for purposes of a patent. Because of the publishing imperative at a university, authors may publish an article about the invention without mentioning any of the inventors, or inventors may add authors onto an article, regardless of whether they are joint inventors. When the article is published before the patent is filed, even though technically an inventor-originated disclosure may be authored by “another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor,²⁴” if the disclosure authors are different than the list of inventors, an Examiner may cite the disclosure against the patent as invalidating piece of prior art.

²³ See 35 U.S.C. §102 (b)(1)(B).

²⁴ 35 U.S.C. §102(b)(1)(A).

Although the patent owner may file a response with the Examiner explaining that the subject matter of the disclosure was obtained from the inventor or the joint inventor, it takes time and money to sort out.

There is no grace period for other publications anymore. We have talked to inventors to encourage them to disclose sooner to us because we have to file sooner because of the different definition [of prior art]. We have had issues where a publication mentioned our inventor, and it was published before we filed a provisional... There is a problem when there are authors that are not inventors... We don't think they totally get it that inventorship is not the same as authorship. When you have authors that are not inventors, the article can constitute prior art. They also don't want to think about it... Because they have different reasons for disclosing (and naming authors), they are not as focused on the patenting as we are.

Even if an earlier filed third party disclosure is a patent application instead of an article, it would still constitute invalidating prior art.²⁵ However, such an application would not be invalidating (and in fact would be itself invalidated) if the third party filer obtained the subject matter of the application directly or indirectly from the inventor or a joint inventor.²⁶ The AIA established an administrative procedure called a “derivation proceeding” to resolve such conflicts.²⁷ Discovering the proper origin of the subject matter disclosed in a patent application is critical to deciding if the application constitutes prior art in a first to file system.

TTOs are therefore wary of relying on the grace period to their detriment. Disclosures may jeopardize a patent's validity, or at the very least cause uncertainty that takes time and money to resolve. As a result, at least two TTOs refuse to file a patent when there have been any disclosures of the invention at all.

If anything comes out that we can't rely on the grace period, that would be hard. We wonder how if the grace period will hold up or not. We have heard of offices that are not filing if they have to rely on the grace period – turning away inventors if they've disclosed at all. Before they might have just gone for an application – especially engineering inventions. Sometimes for them especially the U.S. market is the most important. Filing might have been viable before but now saying “you're out of luck. “

We are now not filing after a public disclosure... Even though the AIA preserves the grace period, you never know what could happen, so we want to proceed as if we were in a pure first to file jurisdiction. We are not as concerned about claim scope as

²⁵ 35 U.S.C. 102(a)(2).

²⁶ Third party patents are also not invalidating prior art if they share a co-owner with the later-filed patent.

²⁷ 35 U.S.C. §135.

concerned about getting into problems later – being challenged by another inventor who filed first. [It's] easier to just...not file [after] disclosure.

Even though there are safeguards in place to help parties manage the risk of invalidating disclosures, the grace period is far from foolproof.

3. TTOs have changed inward-facing policies, but not inventor-facing policies

The AIA's broader definition of prior art has complicated a patentability analysis and changed some filing practices. However, it has not changed the information that TTOs collect from inventors or their efforts to educate.

For example, the forms that inventors submit to the TTOs when they disclose their inventions (invention disclosure forms or IDFs) might have been expected to change post-AIA. TTOs have long collected information about invention conception, since the date and circumstances of conception were very relevant in a first to invent system. Pre-AIA there was even an administrative "interference" proceeding that would decide which inventor had the first conception and therefore deserved rights.²⁸ But in a first to file system, there is no longer a need to hold an administrative proceeding to decide who was the first to invent.

However counterintuitive, TTOs give a well-reasoned response why they still gather invention conception information, and therefore why they have not updated their IDFs. Not only the information itself, but the process of gathering it is helpful to the TTOs. For example, although interference proceedings are no longer necessary after the AIA, it is still sometimes necessary to hold *derivation* proceedings, to decide whether a piece of claimed prior art was "derived" from the inventor's prior publication. Information about dates of inventorship could provide helpful evidence to prove derivation. Information on conception process and dates could also guide counsel to the relevant lab notebook pages with the right information to help when they are drafting claims. Or the conception information could prove inventorship when such information is important for purposes of a contract, as with a sponsored research agreement.

We've continued with asking for date of invention. If we have to prove derivation, it could still be useful. It comes up in first to file sometimes – the more sophisticated faculty know that if we don't get a stake in the ground, it might be a problem. We put

²⁸ This procedure has been discontinued under the AIA. The text describing the old procedure may be found at [https://www.bitlaw.com/source/35usc/135_\(pre%E2%80%91AIA\).html](https://www.bitlaw.com/source/35usc/135_(pre%E2%80%91AIA).html).

that information down just in case – we have not been through a derivation proceeding yet, but I imagine it could be helpful.

We still gather inventor information to clarify “who is the inventor;” for example we try to figure out in an Interinstitutional Agreement who invented it, so we still gather the info... We were dealing with another university, and their inventor answered date of invention by saying “ask X” (our inventor) – that tipped us off that our guy was probably the sole inventor, and sure enough we found that he is the sole inventor. The other university filed the patent on our behalf – but the claim set is 90% ours versus 10% theirs. [We were] glad we asked the date of conception!

We have kept the section on date of conception because other aspects of the tech transfer process relate to conception dates. For example, a sponsored research agreement might say any invention conceived “during the period of this agreement...”. It is good to know when that is, because [if the invention was conceived earlier or later] an external contract might apply. It also helps for if we ever need to do a derivation proceeding. And the date could also be important if we need it to help us to research through lab notebooks. We could pinpoint the right pages.

Similarly, TTOs have not changed how they educate their faculty about new changes to the definition of prior art. Part of the reason is that the changes to the prior art analysis are nuanced and fact based, and TTOs would rather follow a conservative policy of no disclosure at all than create a conditional policy that could lead to a costly mistake. Most TTOs had already had a pre-AIA policy that faculty should file an invention disclosure form to alert the TTO to the invention before *any* disclosure. TTOs were not inclined after the AIA passed to narrow that policy and give faculty members any more discretion to decide when disclosures were invalidating and when filing an IDF was advisable.

We have been (and other tech transfer offices have been too) using the term “public disclosure” instead of “prior art” all along; our inventors have been assuming all along that everything was a problem. So, no re-education is needed.

We keep telling PIs to tell us about inventions early and often. Our philosophy has always been that anything is a disclosure. The AIA has not changed how faculty tend to disclose – usually through papers and publications and talks – so that type of disclosure hasn’t changed. We never have split hairs [on defining disclosure] because that gets you in trouble. We always said any disclosure was a disclosure.

If TTOs have changed anything about their policies at all, TTOs that had previously asked faculty to file an IDF before a publication are clarifying that “disclosure” now is not limited to publications, or in fact to written communications. TTOs do not make a point of revealing that the prior art standard has changed at all, but just relay the new disclosure rules in a broadly worded and straightforward way.

We talk to them and remind them that this is the standard that we have to apply. It has changed since pre- AIA, but we don't point that out, we just give them the standard.

We have changed our approach slightly, overall, in a sense. But faculty members did not know what the prior rules were, so we have made no real shift in what we ask them to do.

The new rules are too subtle for most [faculty], especially the inventor community. I am privileged to serve at a great research university... there's a long and trusted relationship [between the TTO and faculty]. We interface with them and educate the community that if there is a patentable invention, they should file an IDF before they disclose it to the public. We have always worked hard to get them to do that. We do *a lot* to make sure they do.

As a second reason why TTOs are not educating the faculty on AIA changes, TTOs believe that faculty would not welcome the training, so the cost would not be worth the advantages. TTOs believe that many faculty members are focused on publishing rather than on patenting and might not consider if their actions inhibit an ability to patent. As a result, most TTOs have resolved to explain disclosure and the new prior art rules on a lab by lab or more individualized basis, and even then, only if it is necessary. More often, they will interpret the rules on behalf of the faculty.

It hasn't impacted how we work with the PIs. We educate them the best we can, but other than providing education and being diligent, and staying in close contact, we can't control the activities of faculty. We give them deference and plead with them to keep us in the loop, but that's what we can do...[Also,] for an organization of our size, it can be tough to get [training] sessions in place. In smaller contexts like speaking to a department, maybe we talk to them about it...We try to educate them as best we can, but at the end of the day, unless it impacts notoriety or funding, it is the rare case that they will think about checking our information and figuring out if an action is a disclosure.

We deal with training on a case by case basis, when we get time, and we can't cover it in detail. So, any education that is happening is on a one-on-one basis. When we have a disclosure, we go through the prior art analysis. We are probably doing more pre-IDF meetings and talking about it [disclosure]. But in some ways, it depends on the level of faculty understanding. We can have different levels of conversations. Patent agents can do a good job of educating the faculty; it is better than the law firms because we don't have to pay [the agents]. But the training is not prophylactic.

Finally, TTOs are concerned about preserving and nurturing relationships with faculty, which can play out in simplifying and limiting the requirements they place on them. They fear giving faculty any reason not to engage with the TTO. So, to the extent that they can limit their expectations of faculty and state those expectations plainly, TTOs would prefer that approach. TTOs may opt not to share nuance with faculty about

prior art and disclosure, in favor of a simply stated blanket rule to file an IDF when there is any disclosure.

It's not that they can't handle it, but we are just careful with getting into minutiae because they sometimes don't care. If they are interested, I will talk about it. But I don't want to turn them off, I want to make it easy to work with us...[AIA changes to the prior art definitions] hasn't made a change because I am talking them on a continual basis, so they are aware of what's going on. We know when to pull the trigger [and file a patent]. I just use the new [AIA prior art] framework over the existing facts and make the evaluation.

We try not to make the bar high, not to let disclosing be a burden. We try to help them get that information to us.

So, in summary, TTOs are assuming the burden of understanding and interpreting the new AIA rules, and they are preserving maximum options to file patents by requiring faculty to file IDFs conservatively. This is an appropriately conservative approach, since the patent asset ultimately belongs to the university. Similarly, given the uncertain interpretation of the new AIA exceptions, and given that occasionally the grace period might not apply, some TTOs are refusing to file patents at all when their IDF filing rules are not followed. TTOs have an obligation to maximize their chances of licensing their patent assets, and to be judicious with limited TTO resources. If the patent might not issue because of an invalidating disclosure, the TTOs would rather not to have spent the money pursuing the patent. In any event, TTOs are more cautious about disclosures, and ask more questions about the circumstances of disclosures, before they file.

We say disclosure is any event where people can walk in without being invited. It is always about the licenseability. Would it hold up under due diligence?

We would always file in advance of whatever was a disclosure – we are still doing the same, even if the definition is broader now. Issue is that when we don't know about the disclosure – now we are more careful to figure out what was disclosed before we file. There are plenty of instances where the faculty member has disclosed under the new rules and we do not file. We have changed our behavior around faculty who are disclosing, and we are more critical of [IDF] disclosures when they come in. We used to file and hope, but now we are more cautious before we file, [because of] wasting money.

C. AIA Changes Specifically Designed for Universities

A few AIA changes were particularly directed to help universities. The AIA granted universities an exception to an infringer's defense of prior commercial use, as well as the ability to file patent applications under much reduced "micro entity" fees, even though universities have a budget many

times that of a typical individual micro entity inventor. Sadly, and somewhat remarkably, universities are taking *little to no* advantage of either of the newly-granted rights, although a small legislative fix could address that.

1. Universities cannot take advantage of their prior commercial use defense carve out because they seldom enforce.

The AIA codified a court-created “prior commercial use” defense, and expanded it to apply to more than just business method patent infringement²⁹. Going forward, accused infringers could be excused by proving their “commercial use” of the patented technology more than one year before the patentee either disclosed the subject matter or filed the patent³⁰. If successful, the accused infringer could continue to practice the patented technology without repercussion, but only at the sites where they had used the technology before the patent was filed or the invention was disclosed³¹.

However, the AIA specifically carved out exceptions to the use of the prior commercial use defense. Of particular note, the defense does not apply when the infringement involves university-owned inventions.³² In other words, even if the alleged infringer had been using the same invention before the university patent was filed, they would still be held liable for infringement by their current use. As a result, theoretically once the patent issues, the university could enjoin the infringer’s use of the technology and collect damages stemming from any use starting from the university patent’s filing date.

But universities by and large cannot and do not take advantage of this remarkable advantage. First, the prior commercial use defense is very seldom employed by alleged infringers³³. Because of the exceptions, the clear and convincing standard of proof, the possibility of enhanced damages if the defense fails, the fact that the defense only applies to those patent claims that were in commercial use, and the fact that the commercial use had to have started more than a year before patent filing or disclosure,

²⁹ See 35 U.S.C. §273

³⁰ If the “commercial use” was also public, the use can also potentially constitute prior art that could be used to invalidate the patent they are accused of infringing.

³¹ See 35 U.S.C. §273 (e)(1)(C)

³² See 35 U.S.C. §273(e)(5).

³³ See Coby Nixon, *Prior User Defense Still Unpopular with Accused Infringers*, Law360, Sept 3, 2015, available at <https://www.law360.com/articles/697190>

infringers might rely on other defenses first³⁴. Second, universities do not often enforce their patents. University technology is usually very early stage, so there are not often products based on the technology out in the world, and if there are, they have not built up enough revenue to make enforcement financially worthwhile. In addition, enforcing a patent sometimes creates awkward results for a university. If the university is a public university, it is technically the taxpayers that fund the litigation, which may be a difficult case to make. Or the market of competitors may be very small and incestuous, and today's infringer might be tomorrow's partner. Or the alleged infringing company may be connected to the university in some way, for example, as an important employer for graduates, if they are owned or directed by alumni, or if they donate to or otherwise support university facilities or programs. It may not make sense to jeopardize the relationship. Finally, enforcing a patent may be seen by some as outside the mission of a university, which is traditionally focused on creating inventions and getting them out into the world. If the invention is being used, even by an alleged infringer, it might be considered counter to the university mission to enjoin that use. Universities generally only enforce when there has been egregious behavior, the technology is licensed and the licensees want the university to enforce, the litigation expenses are covered, there is a solid financial upside, the patent is very valuable, and the administration (and development office) supports the suit. These stars seldom align.

Is it worth it for XX University as a whole? The TTO represents one aspect, but [we are] not all of XX. You don't make friends this way. We have donors, partners, etc. There's not been much enforcement in the last few years. We can't separate from the university. And overall, it's not like our office brings in more than development, so we have to listen...If they want to give money to research or hire our students, we're just not going to [enforce]. It doesn't make sense to us...Relationships are now far more complicated because students going there, starting their own companies, professors or alumni on boards, a very complicated mine field you have to navigate. We have to be pretty positive about the validity and the strength [of the argument] that someone's product infringes before we would consider it... it is so much more complicated when we are a university rather than a corporation.

Since the carve out to a litigation defense is only valuable if there is a litigation, and since litigations concerning university patents are so rare, the usefulness of the carve out is limited. The carve out might be transferable to an exclusive licensee, since the exception seems to apply to all inventions that were university-owned at the time of invention, regardless of who is

³⁴ *Id.*

doing the enforcing³⁵. However, this transfer is yet untested in the courts.³⁶ In any event, would be-licensees of university patents are not drawn to license by any value provided by this potential carve out, and it remains relatively unused in the TTO world. No TTO I interviewed had taken advantage of the carve out, and some mentioned that they could not see a scenario where they would be able to use it, even if only to convey value in a potential licensing deal. If the design behind the carve out was to convey an advantage to universities and their patents, it is not fulfilling its promise.

It hasn't come up; it is hard to imagine when it would. Because universities file [patents] very early in the process, it would have to be right in line with what a company is already doing. Faculty members usually have ideas that are too early and will morph when the idea is productized.

It would be possibly helpful, although we don't sue much. I wonder if our exclusive licensee could benefit? That's interesting – that plus IPRs, we are probably missing out on opportunities to make our licensees know that they have additional value in their license by virtue of the fact that we are a university. But in reality, startup licensees are not even thinking about substantive rights when they license – they are thinking: what does investor want to see, and what will help me make money. It's almost as if getting a license is checking the box. They want the ability to practice and a clean chain of title. They might not actually look at the patents, let alone get into the weeds of the rights.

2. Universities cannot take advantage of micro-entity status because the law as drafted is unworkable for their current policies

Besides the AIA granting universities a special carve out to the prior commercial use defense, the AIA also allowed universities to take advantage of reduced patent filing fees. The pre-AIA pricing structure already allowed for small entities to pay about 50% less than large entities to file a patent. But the AIA then created a third category of “micro entity” patent filers, who would pay even lower patent fees at only about 25% of the large entity rate.³⁷ Together with only the smallest companies that had filed the fewest patents, the AIA specifically allowed U.S. universities to

³⁵ 35 U.S.C. §273(e)(5) (“A person commercially using subject matter to which subsection (a) applies may not assert a defense under this section if the claimed invention with respect to which the defense is asserted was, at the time the invention was made, owned or subject to an obligation of assignment to either an institution of higher education (as defined in section 101(a) of the [Higher Education Act of 1965](#) ([20 U.S.C. 1001\(a\)](#)),^[1] or a technology transfer organization whose primary purpose is to facilitate the commercialization of technologies developed by one or more such institutions of higher education.”)

³⁶ As of August 3, 2020, the author could find no case where an alleged infringer attempted to use the prior commercial use defense against an exclusive licensee to a university patent.

³⁷ See 35 U.S.C. §123.

qualify to pay these new lowest-tier micro entity fees³⁸. Using the micro entity fees can result in substantial savings over the lifetime of the patent³⁹.

However, many TTOs report that they are wary of taking advantage of filing with micro entity status, even though the law specifically was drafted to include universities. Sadly, there is widespread uncertainty and confusion about the law's application, shared by both the universities and the counsel and companies that advise them.⁴⁰ Several TTOs could not articulate why they could not or did not use the micro entity designation, but just that that was the decision that had been made. Not all of the TTOs eschew the opportunity. A minority of TTOs I interviewed have found a way to claim micro entity status, especially for certain categories of filings. But most TTOs have concluded that the potential savings of filing with micro entity status are not large enough to justify the cost of additional administration and perceived potential risk.

The perceived risks fall into a few categories. First, the AIA's designation of "applicant" and limited definition of an "institution of higher education" is problematic for TTOs.⁴¹ "Applicants" qualifying for the micro entity status must be the individuals who are university employees or those who have or will assign or license their interest in the application to a university⁴². In other words, the applicant is the inventor, not the university itself. This is troubling to TTOs, who would like the university to be the applicant, such that they are able to control the prosecution and do not need to worry about executing assignments from the inventor.

We had done the analysis, and the savings were not enough to justify the risk...of having it incorrect...We asked a law firm, and they reported, and there was also a public forum in March 2013 that stated if the university is the applicant, the university will not qualify for micro-entity status. So, we don't do it; we don't want to have to have the inventor apply.

³⁸ See 35 U.S.C. §123(d).

³⁹ See the USPTO patent fee filing table at <https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule>.

⁴⁰ Several TTOs named outside counsel as well as patent annuity vendors who counseled them not to file under micro-entity status.

⁴¹ See 35 U.S.C. §§123(d)(1) and (d)(2).

⁴² *Id.* ("For purposes of this section, a micro entity shall include an applicant who certifies that—(1) the applicant's employer, from which the applicant obtains the majority of the applicant's income, is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)); or (2) the applicant has assigned, granted, conveyed, or is under an obligation by contract or law, to assign, grant, or convey, a license or other ownership interest in the particular applications to such an institution of higher education.")

Some TTOs have also concluded that because of the unique structure of the patent protecting and licensing entity in their university (e.g. some are technically under a Board of Regents, or some are more accurately separately organized charitable organizations), they might not qualify as a “institution of higher education” under the AIA statute⁴³.

We determined that we don’t qualify. The XXX owns all IP, and that isn’t an institution that has students. We are defined under [state] law as “higher education,” but XXX does not meet the definition under the federal regulations. We’ve had some conversations about this as a university system – we haven’t gone to micro entity as a whole. One other XXX school has had a *licensee* pressure them to pay micro entity fees. But I have stated that I don’t think they apply.

It’s not super clear that we are eligible. There is a lack of clarity in terms of what constitutes qualification. We are a small entity, but my memory is that [applying as a micro entity] is too risky – that the savings weren’t worth the risk. It’s terrible really – the savings would mount up over time.

And finally, because Europe’s rules about listing applicants on patents are more stringent than those in the U.S., TTOs are reluctant to file under micro-entity status in any situation where they might file a foreign equivalent for the U.S. patent. One TTO cited the 2018 EPO case where Broad Institute lost European patent rights over its CRISPR technology because the applicants on the PCT patent application were listed differently than the applicants on the U.S. provisional application to which it claimed priority, as a cautionary tale of the high stakes involved in listing applicants correctly⁴⁴.

If we know a technology is destined for foreign filing, we may not bother with micro entity because we can name the university as the applicant out of the gate. The right to claim priority (EU rules) becomes complicated – [in the EU] you have to have a clear assignment of right from inventor to applicant or clear obligation to assign.

Besides the definitions of “applicant” and “institution of higher education” being problematic, TTOs are also wary of administrative requirements that

⁴³ The AIA borrows the definition of “institution of higher education” from the Higher Education Act of 1956, which states that an “institution of higher education” has students, provides a program of education, and is accredited by a nationally recognized accrediting agency. *See* 20 U.S.C. §1001(a).

⁴⁴ The preliminary EPO opinion is at <https://register.epo.org/application?documentId=E0A0SBDR0119511&number=EP13818570&lng=en&npl=false>. *See* Mark Summerfield, Loss of CRISPR Priority in Europe is a Warning to All Patent Applicants, *Patentology*, January 28, 2018 (available at <https://blog.patentology.com.au/2018/01/loss-of-crispr-priority-in-europe-is.html>).

are more burdensome on micro entities than on small entities. Entities that elect micro entity status must recertify their status at every fee payment, whereas it is only necessary to restate small entity status at three junctures: when paying filing, issue, and maintenance fees. An entity may naturally move from qualifying for micro to small entity status, or small to large entity status upon licensing patent rights. Should an entity pay at an incorrect status level, the patent may be ruled invalid if the mistake is deemed to be in bad faith. Therefore, electing to file as a micro entity presents some additional risk over filing as a small entity, as well as administrative burden. Establishing a policy to administer filing under micro entity status would force TTOs to create new processes and assume a somewhat higher risk.

We were so excited, we were counting money, so sure it would save us, but the individual faculty member has to be applicant, so I'm not sure which university this is helping....There is enough of a cloud over it that it is a headache. We have to switch midstream too, like if we license to a bigger entity. We went around and around with outside counsel when it first changed, and it looked like would be chaotic. If we licensed the patent, it had to be transferred, and it was not worth it in case docketing was wrong....The USPTO said it was going to be a big thing for us, and it wasn't, and then they raised prices for everyone else (which ended up being us).

We didn't want to have to track when [the entity status] changed. When you license, you are no longer a micro-entity. As a small entity, we are licensing to small entities often, so it's not as much of an issue. Part of it is not wanting to have to track that change and making an error.

One final worry is that even though the micro-entity status was specifically extended to university filers, it can never realistically apply to a significant category of university patents. Many university inventions are co-invented by federal employees, or result from grant funding from federal agencies, or are subject to cooperative research and development agreements (CRDAs) with federal agencies, for example with the Veterans Administration or the National Institute of Health. In each of these scenarios, the federal government is granted a license to any resulting patents. However, because micro entity status does not apply whenever the patented invention is licensed to *any* entity that is not also a micro entity, and the federal government is not a micro entity, micro entity status will never apply to any of these scenarios⁴⁵. In fact, the USPTO recently drew a distinction between

⁴⁵ 35 U.S.C. §123(a) ("In General.—For purposes of this title, the term "micro entity" means an applicant who makes a certification that the applicant—...(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,

small entity status and micro entity status on this point in its recent rulemaking proposing changes to 37 CFR 1.27, the definition of “small entity”⁴⁶. While the USPTO is trying to correct a misstep in the law whereby now certain arrangements with the federal government defeat a claim for small entity status whereby others do not, the USPTO specifically stated that it was not correcting any application to micro entity status.⁴⁷

As a result, a very few of the TTOs I interviewed have seriously considered or do take advantage of using micro-entity status. Even those that do come close to using it, or do, acknowledge the shortcomings and use it only in limited cases. Generally, they will use it for only certain patent filings, where they can control or eliminate the risks enumerated above.

We use micro-entity when it is unlikely there will be a foreign filing, where potentially - despite marketing efforts - it is less likely to be licensed, where we have invested in the provisional and want to file a nonprovisional in US, but the prospects are not great for licensing.

I remember we looked at it and thought it might be a good idea to do it for issued patents with no licensee when we were going to keep the patent alive. It seemed low risk when we were going to not have to do much of anything with the USPTO. It would be especially relevant if it was a borderline case that we didn't mind dropping if the inventor didn't cooperate. But ultimately, we decided not to [start filing under micro-entity status] because of administrative burdens.

Extending micro-entity status to universities patents may have been well-intentioned, but it was flawed in the execution. For universities to be able to take advantage of the provision, there would need to be a legislative fix that would: i) allow the university to be the applicant; ii) broaden the term “institution of higher education” to encompass other TTO structures; iii)

had a gross income, as defined in section 61(a) of the Internal Revenue Code of 1986, exceeding 3 times the median household income for that preceding calendar year, as most recently reported by the Bureau of the Census.”)

⁴⁶ See Federal Register, Proposed Rulemaking, Small Entity Government Use License Exception, February 5, 2020. <https://www.federalregister.gov/documents/2020/02/05/2020-01687/small-entity-government-use-license-exception> (“Although the USPTO can provide for government use license exceptions for small entity status qualification, these exceptions cannot apply to micro entities. The reason for this is that the statute authorizing micro entity patent fee discounts...disqualifies an entity from micro entity status if they have assigned, granted, or conveyed a license or other ownership interest in the invention to an entity that exceeded the gross income limitAccordingly, a government use license may not disqualify an applicant from a small entity status, but would disqualify the applicant from micro entity status. For consistency, this would apply to micro entity status on the “institution of higher education basis” under section 1.29(d) as well as micro entity status on the “gross income basis” under section 1.29(a).”).

⁴⁷ *Id.*

allow a forgiving grace period to update filing status, particularly when the TTO does not have knowledge that the patent has been licensed; and iv) allow a carve out for federal licenses such that when universities collaborate or get funding from the federal government, their micro entity status is not defeated by the mandatory license.

D. Changes to Post-Grant Review Processes

One of the most important changes of the AIA, which had the potential to undermine patent value and thereby uniquely harm entities with a patent licensing business model, was to codify and expand post-grant patent challenge procedures⁴⁸. These new and extended opportunities to challenge patents, even after grant, made enforcement a much riskier gamble. As soon as a patent owner filed an enforcement litigation, the accused infringer could defend itself by attacking and hopefully invalidate the patent, using a quick and relatively inexpensive administrative challenge procedure. Particularly the newly-created *inter partes* review (IPR) procedure was worrisome for universities because although the grounds for challenge were narrow, the price to file an IPR was relatively modest and the timeline to institute an IPR extended into later years, when the chances of the patent having been licensed or even productized were higher. This AIA shift had the potential to change TTO filing practices (e.g. should the chance of attack weigh into the decision of whether to file a patent? are there defensive filing strategies?), budgeting (e.g. should they put aside a fund to defend patents against attack?), enforcement (e.g. should it be even more limited?), and even licensing (e.g. does the threat of post grant challenge devalue the licensed patent?).

This topic is so nuanced and important that a full analysis, including TTO interview responses, is included in a separate article⁴⁹. However, the present discussion would not be complete without at least a mention of the results. In sum, I found that while the post grant challenge processes introduced or clarified under the AIA -- in particular the institution of the new IPR procedure -- initially worried TTOs greatly, they have not been the force for change that TTOs expected.

1. The risk of IPR has not changed TTO budgeting practices

TTOs have not altered their budgets to accommodate the possibility and risk of IPRs. This is primarily because they haven't had to; they haven't

⁴⁸ See 35 U.S.C. Chapters 31 and 32 (§§311-319 and §§321-329).

⁴⁹ See Dahl, *supra* note 4.

experienced many IPRs. IPRs tend to occur when patents are being enforced, and universities do not often enforce their patents. Universities similarly almost never go on the offensive to file offensive IPRs, because the incentive to do that comes when a commercial product is potentially infringing. Since universities generally license out their patents to other parties to commercialize, and since university patents are generally over early stage technologies, a university would generally never be in a position to want to invalidate a third party patent.

2. The risk of IPR has not changed TTO filing habits

Similarly, IPRs have not caused universities to greatly alter their patent filing practices. Potentially the threat of IPR might cause the TTO to consider filing more patents in areas where IPRs have been less successful, or in areas where more patents have been deemed valid. Similarly, TTOs might consider the threat of IPR in the drafting, choosing to draft once the patent for the invention is most defensible.

TTOs are indeed concerned about enforceability of patents and certain filings being vulnerable to invalidation. However, although universities are increasingly striving for more complete and potentially enforceable patents, by avoiding cover sheet provisionals and ensuring that patents are fully enabled before filing (see Section II(A) above), they ascribe this shift to the AIA first to file and prior art definition changes rather than to a fear of IPR. Furthermore, the TTOs explained that their mission makes them wary of changing their filings practices. Since a mission of the university is to generally protect and license out technologies invented at the university, they feel an obligation to support inventors from all different schools and programs. There have been some changes to filing practice because of a sense of a broader patent devaluing (see Section III(A) below), but they do not ascribe this shift specifically to IPRs.

3. The risk of IPR has not impacted how often TTOs enforce their patents

Although TTOs are wary of the effect an IPR would have on patent value, the AIA did not substantially change how often TTOs choose to enforce their patents. First, university enforcement was already rare. Second, many TTOs point out that the risk of an IPR is only one of many factors they consider when deciding whether to enforce. As stated above in Section II(C), choosing to enforce depends on internal processes and politics, sometimes the relationship of the university with the state, the importance of the patent, the potential damages, and any downside to the university of a

litigation against the potential infringer, among other considerations. So many factors go into whether or not to enforce such that the risk of an IPR is not determinative.

4. The risk of IPR has not changed TTO licensing strategy

Finally, since a patent is an asset, and an IPR can potentially undermine the asset's value if the patent is declared invalid, has the existence of an IPR procedure negatively affected negotiations and therefore changed anything about TTO licensing strategy? Are potential licensees less willing to license or at the very least pay as much as they would have?

Interestingly, the TTOs do not attribute any change to licensing prevalence or negotiation strategy due to IPRs. They do attribute changes to licensing to a general devaluing of patents, discussed in Section III(A) below, but they do not think those changes stem from the IPR procedure.

First, TTOs claim that most of their licensees have never heard of IPRs, are relatively unsophisticated in terms of patent litigation strategy, and are in the moment of licensing focused much more on the short rather than the long term. A start-up venture may only see licensing a patent as a necessary step on the way to prototyping their product and developing a market. Finally, even should the licensee be savvy about patent litigation and enforcement, they are assuming that they will never have to be in court. IPRs are very downstream for all licensees.

Second, the TTOs make the very valid point that technologies and the patents that cover them are not interchangeable; either the licensee needs to license this patent or doesn't have to do so. The licensee is not deciding between patents that they think are more or less strong. So even if a patent is vulnerable to an IPR, unless the licensee wants to potentially infringe and take their chance against the university in court, they will license the patent regardless of IPR risk.

Some state university TTOs mentioned that they had tried to use the fact that they had a sovereign immunity defense to IPRs to enhance their negotiating power with licensees but found that the argument was not persuasive. Because licensees are in general not worried about the threat of IPR, the fact that some universities might have a defense to IPR procedures

provides no solace. In addition, recent court cases have cast doubt on a university sovereign immunity argument in any event⁵⁰.

III. MORE GENERALIZED TTO CONCERNS AND POLICY CHANGES FOR TTO 2.0

Besides issues brought to the forefront by the AIA, in closing, what other issues are concerning TTOs? What do they foresee as being challenges over the next ten years, and what creative solutions do they propose to meet the challenges?

A. TTOs are trying to control for the risk of what they perceive as a general decline in patent asset value

Although there has been a recent hopeful uptick in patent eligibility rates⁵¹ across at least some USPC Classes, it has been a hard decade for entities that rely on patent value as a business model. Furthermore, because of post grant proceedings, even issued patents continue to be open to challenge for years. At times unclear and evolving guidance for USPTO examiners, especially in certain practice areas, together with Supreme Court and Federal Circuit cases that have muddied rather than clarified patentability and enablement requirements, have resulted in TTOs worrying about the chance that a patent will issue at all, let alone be upheld if challenged. Compounded by worries about potential loss of rights if a patent fails under the new first to file system, TTOs have a sense that patents are losing some of their value. This devaluing of the patent asset also affects TTO licensing. Licensors may not want to invest in an asset with an uncertain long-term value.

The AIA and USPTO make it much harder to get broad claims; the [patent asset] product isn't as strong as it used to be. My coming back [to a university from industry] after 14 years, licensing was never easy, but it is much harder now.

In addition, TTOs are dismayed that there appears to be less of a downside to proceeding to use without a license. Besides new ways to challenge

⁵⁰ See *Regents of the University of Minnesota v. LSI Corp.*, Nos. 18-1559 et al. (Fed. Cir. June 14, 2019) (“[State] sovereign immunity does not apply to suits brought by the United States, including agency proceedings commenced by the United States.”)

⁵¹ See Christopher King, Further Thawing: Patent Eligibility Rates Continue Trending Upward in the Wake of USPTO Guidance, Fenwick and West LLP, BilskiBlog, July 2, 2020, available at <https://www.jdsupra.com/legalnews/further-thawing-patent-eligibility-50795/>; USPTO Open Data Portal, Allowance Rate by USPC Class, interactive chart found at <https://developer.uspto.gov/visualization/allowance-rate-uspc-class>.

patents, TTOs explain that the risk of a large punishment for patent infringement seems milder, with fewer injunctions being awarded in court, lower damages awards, and some awards tied to a presumed reasonable royalty. Together with the fact that universities do not often file suits to enforce their patents, TTOs bemoan that there is less of a structural incentive for a would-be infringer to pay for a license. This is quite worrisome given that the TTO budget is somewhat connected to the revenue that TTOs bring in.

Overall there's a new lack of respect for patent rights (rather - lack of fear that if you don't license that you will be sued)...We are hearing "this is great science, really interesting, but no way are we taking a license, at least for now, unless you sue us – and even if you do, there are ways we can get out of it." A lot of large companies now seem to have a blanket policy not to license. Is this due to IPR's? Possibly part of it, but more probably aggregate lessening of value for patents. It is near impossible for us to get an injunction. Hard to get large damages.

In order to control for the risk of patent devaluation, many TTOs have shifted their patent filing strategies on which technologies they choose to protect through patent, and how and when. Whereas before TTOs might have filed a provisional patent over most disclosures, increasingly they focus protection on technologies that are far enough along to support a robust patent, and they are willing to wait for more development as necessary. TTOs also favor filing patents that will have fewer disclosure vulnerabilities over those with potential problems. And TTOs favor protecting those technologies in areas that are generally more likely to bring in revenue, or that have a ready market and licensees that have already indicated interest. Since the TTO's ultimate concern is whether the issued patent will have enough value to license out, they eliminate a substantial amount of risk if they file when there is a ready licensee pushing for the patent application. Being more exacting about which technologies get patent protection also helps TTOs to control for some of the risk.

We pick and choose what to file on – it needs to be fully enabled. Filing follows the funding (as before the AIA): 80% life sciences and medicines and a few filings in physical sciences and engineering. The salient question when we are licensing is "is this thing going to issue?" And we have curtailed our foreign filings as well, unless we have a licensee in place. We get one shot to file. Not going to hold up publication but will wait to file until we have as much data as possible.

We definitely need more detailed specifications, and there has to be a market proposition. We do much more diligence around that now, especially in the engineering or quasi-engineering space; we are much more mindful. We have even set up a committee to get information and confirm whether we should file. We don't want to miss an opportunity, but we really want to look at areas where we'd like to see more

patents, especially in areas where the technology has in the past walked out the door with the PI.

Decisions about what to file comes down mostly to licenseability, and a balance of cost and completeness.

Although it is completely understandable, not every TTO is onboard with what they see a perversion of a mission to promote and protect inventions across the university. In addition, if TTOs prioritize filing the patents that already have an interested licensee or that they believe have a higher chance of being issued, these TTOs worry about the possibility of missing out on protecting an important invention. They also wonder if they are ultimately protecting the right technology, if they would not have filed a patent but for the insistence of the licensee. When that licensee is the start-up company headed by the inventor, and it has an uncertain chance of future funding or success, those TTOs wonder whether that filing is strategically wise.

Every other graduate student wants to start new company. That is exciting, and nice that we have more potential licensees, but sometimes they don't get the company going and the patent lies fallow. They give an urgency to the patent filing, so the TTO will file, but it is not always the right decision.

But as entities that ultimately make their revenue from filing and licensing patents, TTOs have to balance their mission with an effective response to market forces.

B. TTOs are licensing more to start-ups and less to big companies, especially in the physical sciences, but also in therapeutics

I would refer you back to the difficult challenge of licensing in physical sciences and engineering; this is very challenging across many universities. Can you get a deal done with a large entity? Definitely. Is it commercially significant? Maybe. You can probably get a flat fee, but a royalty-bearing license that makes money is really hard, and the AIA has made it harder. Is there anything for us to do? We are looking for creative and fair ways to bring tech to the public. Are there ways to break the logjam? We are thinking about that.

TTOs believe they are experiencing a cultural shift where big companies, especially in the physical sciences are moving away from licensing. This might partly be due to a perception that the risk of punishment for infringement is lower than the cost of licensing the patent. However, TTOs also surmise that a turn away from licensing is also driven by the nature of the products that the patent licenses would support and the realities of those markets.

Physical sciences products like electronics and medical devices incorporate many patented technologies into one product, so licensing every relevant patent could get prohibitively expensive. In addition, the patented technologies may be buried deep within the product, such that it is hard to detect infringement. It might be strategically advantageous for a company to wait to be accused of infringement before licensing a patent. Finally, the early stage nature of university patents works against the TTO's ability to license. The product the company markets is often much more specific than the more general claims of a patent, so infringement might be more of a nuanced argument. These physical sciences patents are also particularly vulnerable to prosecution issues and post grant challenges, so a license is a less sure investment. In general, TTOs are finding that individual physical sciences patents are difficult to license.

Physical sciences companies are less about licensing. Infringement is not enough of a threat. Maybe they would change something small to design around the patent; that's tough to enforce. The inventions are all incremental. They don't bother contacting us, and they don't come to us to license a single patent.

TTOs are also having difficulty licensing therapeutics patents to large pharmaceutical companies. Increasingly, large pharmaceutical companies are outsourcing their research and thus are expecting phase III or at least phase II results before they will license the technology. Such a level of testing is often beyond the reach of a university lab, unless the university itself is sponsoring a start-up. Generally, deals with such large companies are more often about ongoing research than a one-off license. If a license happens, it is structured as a flat fee rather than a more lucrative royalty-based payout.

Everyone's trying to figure out how to license, protect, commercialize better. Challenges are how do you interact with industry, get them interested, market to companies. Large companies don't really directly license university IP – you see some announcements about specific deals, but those are more specific research deals. Don't see large companies directly licensing, particularly in life sciences, because our inventions are so early stage. In life sciences, startups are important in moving tech forward to the point where large companies will invest. Biggest question for us when I was in industry were that we wanted to see Phase 2 data. University tech is not going to get there alone. *Do you license at all in the physical sciences?* Yes, in medical devices, we have a big company that is about analytical chemistry. But we license mostly with small companies.

The changes in courts, law, market, cause us to adapt how we best get technology into the market. Pharmaceutical companies are taking less risk on for early stage drugs; now more development has to be done before licensing. That's resulting in more emphasis on entrepreneurship and start-ups – we are putting more resources into early stage technology.

As a result, TTOs are looking for creative ways to appeal to different or additional licensing markets. They do deals with medium to large companies for freedom to operate purposes, or when a medium-sized company is looking to build a portfolio of assets. They also report that life sciences companies do still license patents, because when one patent can cover the heart of a product, it is harder to design around the patent, licensing is straightforward, and an infringement lawsuit has a more extreme downside. However, TTOs are starting to rely on start-up companies for more of their licensing, especially university spin-offs that build a product entirely around one patent. TTOs are looking for ways to become more “entrepreneur friendly” in their quest to get university technology out into the world. These entrepreneurial ventures can either market the technology themselves or act as an incubator to develop the invention to the point where a larger company would be interested in taking out a sublicense.

Licensing seems to be overall up significantly, just not to existing companies; there is more action in the startup space. Software patents, at least half are going to newly-formed companies. Therapeutics – all going to small companies. Large pharmaceutical companies are not buying; they want phase 3, which is more data than a university is able to show.

Of course licensing to a start-up company may require TTOs to agree to a deal with more modest royalties, draft patents over inventions they would possibly not prefer under different circumstances, and enter exclusive rather than nonexclusive licenses, since that is often required by investors to start-ups to guarantee their proprietary position in the marketplace. But the TTOs that license to start-up companies are monetizing university inventions and the technology is getting out of the lab and into the world. Even if the TTOs end up licensing for less favorable terms than would be ideal or than could have been possible a few years ago, the TTOs are following through on their mission to transfer early stage technology out of the university and into a product to benefit the consuming public.

C. Striving for metrics of “success” may sometimes conflict with a traditional technology transfer mission

TTOs’ potentially primary mission is to introduce university-invented technology to the world. But TTOs also must bring in enough licensing revenue to stay as close to revenue neutral as possible, support sometimes hundreds of inventors across all schools, and work within a limited budget.

Sometimes the demands on a TTO can cause it to act seemingly in conflict with its primary mission.

First, TTOs are having to reconsider past policies on patent enforcement. In order to maintain the integrity of the TTO license model, would-be licensees must expect that the TTO would enforce its patent rights through litigation if necessary. Yet until recently it has not been common practice for universities to enforce their patent rights, and in fact making a decision to enforce can still be fraught with political, administrative, and financial challenges. There is also a question whether universities involved in litigation are acting outside of mission. If the true mission is only to provide a bridge for the university technology to the world, perhaps the mission is accomplished through any use, even one that is infringing. Yet the TTO is also beholden to the faculty inventors of the technology. The university is not the only party harmed by infringement. TTOs understand that the faculty inventor suffers as well when licensing revenue goes unpaid. This sets up conflicting demands on the TTOs.

The appetite for enforcement used to be nonexistent; the politics are hell. Infringers may be connected to the university, like they may have funded a building. Also, if our mission is to get the technology used in the world, isn't our mission accomplished if someone is using it, even if they are infringing? The appetite to sue has picked up now somewhat among universities. But facts have to be bad faith. Our mission is use, but our client is also a series of inventors and it is hard to tell them don't worry about infringement.

Even given the conflicting demands, certain TTOs are loathe to embrace more enforcement. For them, universities should go out of their way not to be confused with other nonpracticing entities that have gotten a bad reputation for over-enforcement.

It may behoove schools strategically to act more like NPEs (nonpracticing entities) than I would want to do. The AIA has prompted that. If across universities our reputation starts to shift, that will have a negative impact on technology transfer and our role in commercialization in general. As a group I worry we may be starting to step away from the ethics associated with our missions as universities. We have a significant role to play in early stage research... We need to continue to take the high road in terms of what we do and leave the trolling to the trolls. I know there are schools that are going to go for it. They don't mind the bad press, and I don't think that's good. Universities are not supposed to have anything to do with the calculations of out-lawyering someone. It works against the premise of U.S. universities.

But overall most of the TTOs try to balance these conflicting demands by increasing yet calibrating their enforcement response. Especially given the fact that it is harder to license in the physical sciences, infringement may be

more egregious, and patent value may be seen to have decreased, they are lately less afraid to enforce under certain circumstances. They pick their battles carefully, but enforce their rights especially when the facts constitute bad faith, in order to preserve the integrity of their licensing programs. This might be a different approach than the more hard core resistance to enforcement in the past.

Our goal is to transfer research from labs to manufacturers for the benefit of everyone. It is harder to do that in certain tech spaces where efficient infringement is a viable option...Every patent owner knows if you do not enforce sometimes, you have no credibility. Our mission is tech transfer. When we would enforce, it is when the technology is significant, it is widely practiced, and our licensing overtures have gone ignored.

Besides the question of enforcement, TTOs are dealing with an increasing administrative burden. They must support sometimes hundreds of inventors across multiple schools, and handling payout arrangements and collaborative relationships is getting increasingly complicated. The mission of getting technology out into the world has become a much more complicated endeavor. Ironically as TTOs are looking for more creative ways to license in order to better continue to deliver on the technology transfer mission, the details may become overwhelming.

One of our biggest challenges is simply high volume; having a good database, keeping track of patents, paying inventors. Also, we need to note the rules in different jurisdictions. We have ownership issues with collaborations. We have to decide which country to file in first; this is not always in harmony. If you have inventors from different countries, sometimes two countries insist you file in that home country first. There are always extra steps you need to take.

Finally, TTOs are also facing conflicting demands related to their budget and prioritization. The reality is that TTOs have a limited amount of money to devote to patent filing. While their mission may be to serve all faculty, they cannot file a patent over every invention. It is hard to pick the technology that might be the most impactful, especially when many inventions are so early stage and in cutting edge fields. Yet TTOs must make these difficult decisions.

The challenge is trying to nurse and nurture so many products and technologies that have potential, having the time for them all. They are all early stage – hundreds in the portfolio. A lot could have potential, but we don't have the time and the money to advance all. How do we prioritize giving time to the higher potential projects, without ignoring the others? We have to serve all faculty.

The desire to be egalitarian may lead a TTO to file a patent that it might not prioritize otherwise (like for a university start-up) and may also push TTOs to file in those fields (like the physical sciences) where patents have a low likelihood of issuing and an even lower likelihood of being licensed. But given budget realities, TTOs may have to favor those prolific inventors who have had inventions hit it big before, those schools where inventions have a higher chance of being licensed, or inventions in those fields that are particularly competitive or hot. While this approach may not support a TTO's desire to be friendly to and supportive of all faculty, focusing effort may help the TTO to deliver better on its mission to transfer the technology, since it is prioritizing the technology that is most likely to be commercialized.

But we still have budget pressure, and have to deliver for the client, who is a bunch of solo inventors. They need the money and the recognition...Maybe we need to be more strategic about what patents we file, and file fewer non-life science patents. The only place where meaningful revenue comes in is in therapeutics.

D. Collaborations are more common, but are challenging to manage

Just as commercial licenses are becoming more difficult to secure, TTOs report that they see increasing opportunities for collaboration with foundations, NFPs and corporations, which bring grants, joint research arrangements, and offers to commercialize technology in the developing world. However, these collaborations are not without cost. Ownership issues, restrictions and contract terms that go against both parties' interest, and increased administrative burdens all frustrate TTOs.

Foundations and NFPs, for example, are increasingly "reaching through" their grants to demand more ownership or rights in the product that results from their funding. This can extend to downstream commercial rights, even when the original deal was designed to bring the technology to the developing world. And while many foundations and NFPs are sophisticated, some propose contract terms that demand rights that are either hard for the TTO to comply with, or that the foundation or NFP does not actually need. These demands can delay or even frustrate the deal. While TTOs are excited for these new opportunities to engage in meaningful productization, they are wary of the contract terms.

Collaborations are challenging. It used to be that foundation partners gave money and nothing more. They now want more. Their agreements are now quite onerous – they want more control and more ownership. They have become much more sophisticated on how they want their grant money spent and they are demanding a lot more. They see it more as a business...some partners are even starting to act like patent trolls in

the developing world for charitable purposes. For example, the university may do the basic research and license to them and they will fund the commercialization of a diagnostic instrument. We will provide a royalty free or very low rate license to use in the developing world. But now partners are also demanding that if they fund the developing world commercialization, they also get an exclusive commercial license for the developed world as well.

A lot of faculty are seeking and securing funding from NFPs. This can be challenging because the NFPs don't always know how to deal with IP, so they have had problematic terms in their contracts that don't make sense...Like they ask us to give them the first option to license, but they are not equipped to commercialize it. It slows down the negotiation. And a lot of groups have become more savvy about future revenue that comes out of their funding. But terms like these are difficult, because our funding or commercialization comes from many sources. How can you tell what revenue to attribute to their funding alone?

Collaborations with corporate partners are also on the rise. Although these collaborations are still seen by some as anathema to an academic mission of pursuing knowledge for knowledge's sake, such collaborations have resulted in not only a lucrative return, but also getting university knowledge out into the world to really help people. However, although the arrangements are increasingly embraced by the university, they carry some of the same costs as do the collaborations with foundations and NFPs. Increased numbers of all kinds of collaborations, many with more onerous demands than in the past, lead to increased TTO administrative cost. TTOs worry about compliance with contracts and managing the relationships between faculty and outside organizations. With more parties involved in commercializing the university technology, there is more chance for miscommunication and misunderstanding.

We have high profile arrangements and that makes our job difficult. We can't control who the PIs talk to or the money they use to develop. We are just waiting for some invention where we will have a competing situation where we are in trouble. Both sides will sue us because we didn't live up to the contract. Everyone wants a piece of the action, and control. Collaborations are GREAT, but they make things more complicated...Now we have another party to answer to and deal with and come to some agreement with. We now also get into more conflicts with our sister institutions. We used to be able to handle all the collaborations with a much smaller staff, but now we need more people just to handle compliance alone....Now we get more for our budget, but our administrative overhead goes up because things are becoming more complicated.

Finally, TTOs are worried about changes to government funding, and particularly changes to the Bayh-Dole Act.⁵² Much university research funding comes through grants from various government agencies, including

⁵² See 35 U.S.C. Chapter 18 (sections 200-212).

the National Institutes of Health, the National Science Foundation, the Department of Defense, DARPA, and the Veteran's Administration, among others. The Bayh-Dole Act permits a university to accept government funding and own and patent whatever they invent from that funding, only giving the government a royalty free license in return⁵³. There have been recent changes to the implementing regulations of the Bayh-Dole Act that force a university to file government paperwork more quickly and change the consequences of failing to timely report⁵⁴. Universities are worried about both the administrative burden of complying with the recent changes, as well as the possibility of additional as yet unforeseen changes that may further limit a grantee's rights to the invention funded by federal grants.

The new Bayh Dole changes have created an increased burden on university compliance. For example, failure to timely report, or elect title, to a Subject Invention to the government may provide the government with the right to take title. The old rule required the agency to act within 60 days of learning of such failure by the university, but now the government can take title at any time. Missing the disclosure or election deadline therefore creates a permanent defect in the university's ownership to the Subject Invention. This can create challenges when trying to license such IP.

Additionally, especially as control and commercialization of certain inventions—like therapeutics—have gotten more attention from Congress, the public, and the press, universities are increasingly worried that such inventions may be excluded from the favorable conditions of the Bayh-Dole Act. They worry that the government may step in to control pricing or demand a percentage of royalties.

They are talking about repealing Bayh-Dole, or the government seeking to retain royalties on inventions made with federal funding. They ask, "Why should the university profit from their technology? That's not consistent with your non-profit mission." There's been a lot of attention paid to XXX because of technology on pharmaceutical products that could be lifesaving in the developing world. They are asking, "What are you doing to make that affordable?"

⁵³ Technically, under the Bayh-Dole Act the government has "march-in" rights to the technology, which if executed, allow the government to force the grantee it funded to issue licenses and commercialize the invention. But the U.S. government has never exercised its march-in rights to any technology. National Institute for Standards and Technology (NIST), Return of Investment Initiative to Advance the President's Management Agenda, Final Green Paper, April 2019, at 29 ("The use of march-in is typically regarded as a last resort, and has never been exercised since the passage of the Bayh-Dole Act in 1980, because other less intrusive means have been better suited to solve the problem.")

⁵⁴ See 37 CFR §401; for explanation of the changes; see also Courtenay C. Brinckerhoff, Patent Related Changes to Bayh-Dole Act Regulations, Foley and Lardner LLP Insights, May 22, 2018, available at <https://www.foley.com/en/insights/publications/2018/05/patent-related-changes-to-bayhdole-act-regulations>.

In summary, as TTOs are looking for creative ways to commercialize university inventions, the appetite for collaborations is up, both among universities and among outside organizations. However, the collaborations do present risks and increase administrative cost. When asked if there may be a breaking point when they would need to turn away from some collaborations, especially with foundations and NFPs, TTOs were thoughtful. They concluded that it would be a net negative for the university as well as for innovation overall. Since foundations and NFPs often have altruistic motives, they surmised that scaling back collaborations would substantially affect what could be done for the developing world.

Do you think you will take less money from [foundations] in the future if this keeps up? I don't know! We need to figure out how to relate to and deal with foundations. Right now, it is somewhat up in the air. Would it affect your funding substantially? It would not have a major effect, but it would affect the developing world. It would be sad if that technology could not get out. For example, we are smoothing out photosynthetic production so that a particular plant increases its foodstuff. If [foundations] decide to be too pushy about owning the technology, that type of research will be not effective anymore.

E. TTOs are shifting their model in ways that would not have been possible even a few years ago

TTOs are simultaneously grappling with a perceived devaluing of their patent assets, a culture shift undercutting licensing in the physical sciences, competing metrics of success and collaborations that are difficult to navigate. TTOs have had to consider creative solutions.

One such solution to increase value and raise the likelihood of licensing in the physical sciences is to bundle assets to create custom licensing opportunities. By licensing an entire portfolio of patents in one deal, TTOs address a prior complaint that licensing only one patent in the physical sciences is not enough to support a company. At least one university is allowing companies to dictate which patents should go together, letting the market – or at the consumer – drive the decision. Such patent pooling might consist of a portfolio created from assets from all one institution, or might be inter-institutional for added breadth.

To deal with this, a new model is pooling engineering patents into a group and licensing as a group. Like a patent pool... license in a bundle. *Who decides what goes into a bundle?* Companies do – we are open to companies coming in and asking – we follow the market

An additional advantage of an inter-institutional patent pool is that universities may also combine enforcement resources for infringement or breach of contract. Pooling assets and resources gives the university power that they might not have as an individual licensor. A shift to more aggressive enforcement might still make some universities uncomfortable, but there is strength in numbers and attitudes are potentially changing.

I am amazed at all the creativity and experimentation across TTOs and their interest in trying new things. There could be something in banding together to help defend IPRs or enforcement. We need realistic and creative solutions. These patents we have in physical sciences are not valuable. But with a patent pool or banding together the patents that cover a certain industry and aggressively licensing them, including through enforcement, it might happen. But then we get into a dangerous zone of changing our mission. Five years ago, this would have been a nonstarter. But now maybe it's okay. Changing the model is driven by the impossibility of landing the big fish.

Besides bundling patents together (and bundling universities together), some TTOs are considering outsourcing follow-up marketing efforts. Because TTOs must use their limited budgets to maintain current licensing relationships and protect new technology, they may not have extra time and money to continue to market promising but as yet unlicensed patents. Armed with market savvy and technology tools, third parties on the other hand might be able to uncover additional value from issued patents. This is particularly helpful when maintenance fees are due and universities need to evaluate whether continuing to maintain an unlicensed patent is worth the cost.

Specifically seeking out practicing entities to approach them with offers to license is not traditionally within the TTO mission. As is the case with TTOs pursuing enforcement litigation, arguably the TTO's mission is met when the technology is in use, regardless of infringement. However, some TTOs see identifying and approaching potential licensees as a broader attempt to create a working relationship with the productizing company. Identifying and pursuing a potential licensee also helps the TTO meet other metrics by which success is measured: licensing revenue and support for university faculty members. So, this creative solution helps to not only extract additional value out of the patent and potentially secure a license when none was initially requested, but also addresses some of the additional missions of the TTO.

One thing interesting from a marketing effort standpoint is the ability to use third parties to remarket tech for which you as an institution have secured patents but haven't marketized. They can identify companies that might be interested in an asset. They can take your issued patents or applications, can run them through public

information and discover which other companies have cited your IP during prosecution. They can figure out if what we have could be of interest to a third party to license. People are pushing the boundaries of how to get stuff out there. Every tech we have gets a solid marketing push, but we don't have resources to circle back at issue, or first maintenance payment (three years later) to make a secondary push. It is interesting that [TTOs] are trying to leverage an outside of the box mechanism to give us another opportunity to monetize. *How is this different from finding infringers and issuing an "invitation to license?"* The intention is broader – [these third parties] make others aware of assets that might be of interest to them for legitimate licensing and business purposes. I can see the overlap with trolling, but the intent is broader than that.

In another kind of new collaboration, some TTOs are also helping faculty to use third party contract research organizations (CROs) to leverage their knowledge to get more research results. In especially the medical space, new technologies allow inventors to do additional experiments through CROs, which eventually leads to more university-owned inventions and potentially the number of valuable patents.

As technology progresses, it is becoming easier to do some experiments that we might not have been able to do before. This will lead to more discoveries, and ultimately more patents. Everyone is working with Contract Research Organizations and experiments are becoming automated; it is easier to run more experiments. The medical space is definitely impacted.

TTOs are also attempting to generate and safeguard patent value and long term relevance by employing prosecution strategies pulled from industry practices. For example, when a TTO has an especially valuable (and therefore vulnerable) patent, they can file continuations or divide claims into separate patents to help keep claims alive in case of attack. TTOs can also using re-examination strategies to shelter claims that are unchallenged by IPR and build their strength. And TTOs are being strategic about their initial drafting to try to make a patent over early stage technology relevant even to downstream productization. By drafting method claims and contracting for downstream commercial royalties, TTOs protect against a common complaint that university technology is too early stage to be infringed by the ultimate product. By drafting the patent with the ultimate user in mind, TTOs increase the value of their patent asset and better ensure a license arrangement.

This is the most acute issue really. TTOs might not be creative, but we are looking to industry to emulate what they are doing to get stronger patents that are inoculated from IPR. We are exploring reexamination strategies. We also are exploring continuation applications for valuable patents to allow the ability to add or amend claims in advance of any enforcement action.

We are trying to counteract [patent relevance questions] by covering the patented method and then getting downstream royalties for the product. We align the patent with the needs of the licensing company as they market the product.

Focusing on the ultimate use of the patent, and the licensee that would use it, is actually a much broader theme reported across TTOs. It is also a good summary of how TTOs are approaching technology transfer with new eyes. This approach not only affects decisions at the patent filing stage, but also impacts what TTOs try to affect even earlier, in the lab. TTOs are thinking strategically about not only what patents they file but how they can enlist the faculty in their attempts to make technology transfer more effective and successful.

TTOs describe efforts to reorient the faculty to ensure better patent and productization success. They speak about efforts to build more business-savvy faculty and an innovation-friendly ecosystem. This can range from advising faculty on how to build the sort of robust data sets that can more readily support a patent through issuance, to helping them to understand market needs so they can better focus research. TTOs describe tapping into the expertise of industry experts to guide all parts of the university to position research for better technology transfer success. This is especially important when the faculty are insulated from the companies that might become good partners for their research, and when faculty do not have a sense of open markets and what might be commercially successful.

We have to engage with [faculty] earlier, even before we patent, to get more valuable IP... Compare us to X [university] and Y [university] and Z [university] where their TTOs excel because they are more engaged with faculty, earlier. They file patents that are useful because their faculty live in an ecosystem where they are talking to VCs at their kids' soccer game. Their faculty understand how to enable patent claims.

It changes our discussion with faculty; we tell them they have to have more than an idea to file. They need to understand [the concept of] enabling data and how it impacts potential [patent] claims. As simple as it may seem, this is a stretch for a lot. Faculty with no experience in commercialization should direct research to an area that can help us enable a claim in a white space. This is thinking about things they haven't thought about before. We need similar education in thinking not just about claims, but market.

For those that worry that a practical and tailored approach to technology transfer operations might pervert the university's commitment to doing research for research's sake, the purpose of better alignment may not necessarily be for (only) commercial end. Because industry often relies on a profit motive, understanding the market might be key to guaranteeing technology transfer at all, for whatever purpose. Universities understand that even faculty and institutions that are not primarily driven by profit may

still be driven by an altruistic desire to get the research out into the world. Maximizing licensing to companies that would commercialize fulfills the promise of the purest of technology transfer missions.

We have patents over early stage technology and limited budgets. How do we attract a partner to exploit the IP? We are thinking about bringing in deep domain experts early in the process to help inventors define the market needs to help inform the experiments and figure out what could be patentable. That could result in better patents and better technology to provide to industry. Nobody is helping inventors find the right experiments to do and develop the data set that would be helpful to a patent. This could help inventors let the impact of their work become a reality. Most have altruistic philosophy and want to help somebody; blockade is if you can't find a partner. We are focused less on dollar value and more on societal impact. How can we put more things in play? How can we tailor the research to the right fit? It all strengthens the patent if you do it early enough. And it gives you the chance to possibly get the research into the world.

CONCLUSION

The America Invents Act significantly shifted patent practice in the United States. The first to file system now forces inventors to consider patenting on a quicker schedule. An expansion of the definition of prior art and the relevant time frame during which it can be produced makes patenting more precarious. The grace period is now less reliable, and forces inventors to prove derivation to an extent unnecessary when earlier invention dates were a shield. A new schedule of lower micro entity fees is boosting smaller inventors that might be disadvantaged by a first to file system. And IPRs and other post grant challenge procedures are heavily impacting patent litigation strategies.

Yet although the AIA changes have impacted university technology transfer in some ways, TTOs have also been shielded from the worst of the effects. Although TTOs are entirely dependent on strong patents because of their business model of protecting and licensing innovation, the university culture also prepared them for some AIA changes and inoculated them from others. For example, because of a norm of international patent filing, pre-AIA, TTOs had been already operating as if the U.S. were a first to file system, as are the other countries around the world. Because of the university culture of publication and a tendency for inventors to prioritize disclosure without necessarily thinking about patenting requirements, many TTOs had already strived to file patents before any disclosure and treated any disclosure as potentially invalidating. Finally, because patent enforcement through litigation is so rare for universities, TTOs were never going to need a carve out to a prior commercial use defense, and post grant

challenge procedures were not often a threat. For the most part, the AIA changes have brought much concern, but ultimately few concrete changes to university technology transfer policies and procedures.

What the AIA *has* sparked among university technology transfer is even more emphasis on filing patents that are complete and high quality. That is probably a positive outcome. Driven by limited TTO budgets, a larger universe of prior art post-AIA, and the risk of losing all rights in a first to file system if an insufficient patent loses priority, TTOs are being more judicious about what and when they file. They are also enlisting inventors in the efforts to increase patent quality, by educating them in how to collect more supporting data for the claims and target their research to a likely market or sure licensee. All of these efforts to create more robust and more relevant patents leads to better technology transfer outcomes.

Creating stronger patent assets also helps TTOs to respond to evolving general challenges to licensing university patents. TTOs have had to think creatively to continue to license especially in the physical sciences, but increasingly also to large pharmaceutical companies. Entertaining more creative collaborations with private companies, directing attention to new potential licensees like early stage companies, bundling assets into partner-tailored licensing packages, and considering targeted enforcement when infringement is egregious are all creative solutions that may not have been possible or necessary in a pre-AIA world. Each of these creative approaches is bolstered when the patent assets at issue are more likely to issue, less susceptible to attack, and more relevant for the business needs of the licensee. Given that licensing is a means to an end, TTOs that successfully license also successfully transfer the university technology into the world for the public benefit.

In the past ten years, TTOs have absorbed and reacted to the AIA and had positive effects. The AIA shifts are now the new normal. TTOs will next gird themselves to react to other cultural shifts they fear may challenge their licensing model. This will necessitate the same kind of creativity and cautious analysis with which they faced the AIA changes. In another ten years, we will be able to comment on the results.