Technology Transfer Tactics™

The monthly advisor on best practices in technology transfer

PTAB and Section 101 challenges present obstacles to commercialization

TTOs struggle to adjust patenting, licensing strategies under the America Invents Act

As its moniker suggests, the America Invents Act (AIA) was supposed to make things better for innovators, but nearly seven years after the AIA was signed into law, reviews in the university technology transfer community are decidedly harsh. Instead of curbing litigation, the AIA has led to more of it, according to critics. The result is a severely dampened appetite for licensing and a bit of an open season for potential infringers.

Furthermore, recent court decisions have significantly narrowed the types of IP that can be patented -- particularly with respect to bioscience discoveries. This has led to unanticipated rejections at the USPTO and frustrated faculty researchers.

How are TTO directors responding to this state of affairs? They're certainly being more judicious when it comes to patenting decisions and where they invest their dollars. Further, with established companies now less inclined to license technologies, some TTOs are putting more energy behind start-ups to bring their innovations to market, although that's an expensive proposition. With a new administration in Washington, DC, there remains considerable uncertainty about where things go from here, but licensing professionals are all hoping for a better day as the case law surrounding the AIA evolves.

IP rights under siege

These are still relatively early days, but **Lesley Millar-Nicholson**, director of the technology licensing office at Massachusetts Institute of Technology (MIT) in Cambridge, MA, is particularly worried about the impact on university licensing of the Patent Trial and Appeal Board (PTAB). "[The] PTAB is like a looming silent giant that could come and wreak havoc to your IP portfolio at any time," she observes. "We [universities] can continue our practice of investing in patenting, taking account of first to file rules, which I think everyone has now gotten used to and adapted their filing practice and education of PIs accordingly. But we have to constantly remind ourselves of the potential for challenge through the PTAB, and therefore the monetary and other risks we are taking on."

Millar-Nicholson notes that she has experienced negative outcomes from PTAB reviews at both MIT and the University of Illinois at Urbana-Champaign where she previously served as director of the Office of Technology Management, but she acknowledges that it may be hard for other universities to gauge the potential damage from this process until they, too, get dinged.

"[Before the] PTAB, universities knew that filing patents came with the need to be able to enforce those patents to retain their value for other licensees, which could mean litigation and increased costs. Few universities have the wherewithal to litigate and would rely on contingency lawyers to assist in that process," explains Millar-Nicholson. "Now with the PTAB the risks are even greater given that for nominal cost a potentially infringing party can challenge the validity of your patent, and suddenly you have no claims left to license."

Orin Herskowitz, the senior vice president of intellectual property and tech transfer for Columbia University, and executive director of Columbia Technology Ventures (CTV), echoes these sentiments, and has serious concerns about the direction patent reform is taking in the United

States. "While the AIA may serve the needs of "Big Tech," the collective changes under the AIA -- and even more so in some of the patent reforms being contemplated -- would seriously undermine the strong IP rights required for any venture capitalist or company to invest the hundreds of millions required to bring products like therapeutics, diagnostics, medical devices, DNA sequencing, clean energy and advanced materials to market," he explains. "We are concerned that any further undermining of IP rights, whether through increased uncertainty around patentability, IPRs [inter partes review] that allow patents to be partially or fully killed even after issuance, and the removal of legal remedies like injunctions, could lead to a rapid decline in investment in these capital-intensive sectors. If that happens, there will be fewer life-saving drugs, devices and clean energy solutions, not to mention the jobs and taxes they could have created."

Small innovators at a disadvantage

Concerns about the PTAB and IPR proceedings are shared not just by universities, but across the entire licensing community, according to **Brian O'Shaughnessy,** president and chair of the board of the Licensing Executives Society (LES), and a partner in the Washington, DC office of Dinsmore. "It casts a cloud on the title and really the validity and the alienability of patent rights," he says. "Now there is a proceeding which, unfortunately, is just a little too easy to access, in my view, that essentially pulls the patent back into the patent office, exposes it to a standard of review that the application would have gotten before it even issued as a patent."

While the PTAB was proposed as an alternative to litigation, O'Shaughnessy maintains that it has actually turned out to be an adjunct to litigation, with more than 80% of the cases put into IPR also being the subject of litigation.

"What is happening is if a patent holder goes to enforce her patents against an alleged infringer, the alleged infringer can turn around and put the patent into an IPR proceeding, assuming they can get the petition granted," relates O'Shaughnessy. "And now all of a sudden, instead of the patent being eligible for the presumption of validity and the higher standard of proof to prove invalidity, it essentially gets pulled back into the patent office and examination starts all over again."

At this point the patent will be examined as if it is an application, explains O'Shaughnessy. "It doesn't get the presumption of validity. The claims are interpreted according to the broadest reasonable interpretation," he says. "That means that claims can be interpreted in a way other than what the examiner initially understood them to be in prosecution."

The underlying problem, according to O'Shaughnessy, is that the patent office is not standing behind its product, in effect rescinding patents that it has already granted. O'Shaughnessy likens the situation to buying a property, building a skyscraper on it, and then the same organization that granted you the deed comes back ten years later and says it made a mistake and that the property is not, in fact, yours.

Obviously, that kind of behavior would dampen the appetite for investment, and that is exactly what is happening to licensing. "People either don't take a license or they don't license the IP to utilize it because they might feel as though they don't need the IP or that the IP can be too readily challenged," offers O'Shaughnessy. "As a result…we have created a de facto compulsory licensing regime where, in combination with other cases that have developed over the years, it is now very difficult to get an injunction, and it is difficult to get enhanced damages -- for willful infringement, for example."

O'Shaughnessy maintains that what these changes have done is tilt the system dramatically against small innovators who don't have the resources to sue the big companies. "They are trying to elbow their way into the marketplace with a new and innovative product, but yet they are going to get crushed by a bigger company with more resources at its disposal," he says. "Something that was intended to be a cheap alternative to litigation has instead become a tool for those with greater resources and patience to play out the clock and to beat out the little guy."

Patentability in question

The Office of Technology Transfer (OTT) at Emory University in Atlanta, GA has not yet faced any IPRs, but it has been hit with a significantly higher number of rejections in the USPTO related to Section 101, the portion of the AIA that states

what constitutes patentable subject matter. "It has negatively impacted what we can patent, and technologies that were previously patentable under that case law are no longer," observes **Laura Fahey Fritts**, director of license and patent strategy and chief IP counsel for the OTT. "Decisions that have come out of the Supreme Court under 101…have created a significant amount of frustration among our faculty members."

What is the problem? Until recently, Section 101 was interpreted very broadly by the Supreme Court to include things like recombinant DNA and software with appropriate limitations, but in recent years, through a series of high-profile court cases (*Mayo v. Prometheus* in 2012, *Association for Molecular Pathology v. Myriad Genetics* in 2013, *Alice Corporation v. CLS Bank International* in 2014, etc.) the Supreme Court has constrained that interpretation quite significantly, observes O'Shaughnessy. "Consequently, there are fewer things that are patentable today than there were 20 to 25 years ago," he says.

Major implications for biotech

These changes in interpretation have big implications for the U.S. biotech industry, notes O'Shaughnessy. "The reason why we have a biotech industry, and why the U.S. is home to the most vibrant biotech industry, is because early on in the development of biotechnology as a commercial pursuit, almost the rest of the entire world did not permit patents on recombinant DNA or DNA-oriented technologies, but we did," he says. "As a result the vast majority of the biotech companies in the world that were successful were formed and grown in the U.S."

Wanting to get in on the boom in biotechnology development that was occurring in the U.S., other countries evolved, changing their policies so that they, too, enabled patents on DNA-oriented technologies, explains O'Shaughnessy. "Now a lot of that investment is going overseas where it used to all come to the United States," he says. "We are going back toward the position that was held by much of the rest of the world while the rest of the world is moving in the direction of more liberal interpretation of patentable subject matter to include DNA technology."

The real problem is not so much the judicial rulings themselves, but how they are being interpreted by officials at the USPTO, stresses O'Shaughnessy. "They are interpreting the case law in an unduly strict manner, so that things that really should be patentable under the Mayo and Myriad cases, for example, are determined by the patent office not to be patentable," he says. "Consequently, applications that were filed either prior to those decisions or shortly thereafter, which had every expectation of being issued, now are being subject to serial rejections based on a mishmash of case law where examiners are misconstruing the case law according to certain guidelines that the USPTO has published."

O'Shaughnessy adds that there is a good deal of inconsistency within the USPTO regarding how its own guidelines should be interpreted, resulting in applications that should be issued being subjected to endless rounds of examination and rejection. In many cases, people will simply give up, he says. "Products don't come to market, and society as a whole is harmed because innovation is quashed," observes O'Shaughnessy.

The impact at Emory is that faculty members are disappointed that the OTT can no longer file patent applications on their biomarkers in the United States, explains Fritts. "We are constantly looking for ways that we can identify patentable subject matter based on what the current understanding of the law is," she says.

One option Fritts is considering is to file applications under the Paris Convention for the Protection of Industrial Property, a multilateral treaty that is more than a century old, but was most recently revised in 1979. The treaty has more than 177 member countries, including the United States. "It is an application that allows you to file more broadly than just in the United States," she says. "By doing that, it gives us a little bit of extra time in hopes that the law in the U.S. could change, and then it also gives us the option to pursue protection outside of the United States for, particularly, the biomarkers, so that we can protect the technology and possibly license it outside of the U.S."

A turn toward start-ups

Columbia University has responded to the AIA-driven changes by focusing more intently on start-ups, observes Herskowitz. "We at CTV have found that not only is IP important to start-ups, but

startups are increasingly important to our IP," he says. "Start-ups are increasingly often the only way that our technology can make it through the valley of death, and hence, eventually become products on the market that generate jobs, taxes, exports and life-saving or life-improving products."

Herskowitz notes that over the past decade, the number of patent-backed start-ups emerging from Columbia has grown from 5 to 25 per year, to the point where start-ups are now accounting for nearly half of all CTV's exclusive licenses. However, he acknowledges that such a transition comes at a cost. "Unfortunately, technologies in start-ups in particular require a tremendous investment in both time and money to get to market," he says.

Emory is also keenly interested in start-ups, although Fritts notes that this focus pre-dates the AIA as well as the Section 101 changes regarding what constitutes patentable subject matter. "Particularly in biotech-type technologies, [a start-up provides] a bit more freedom and flexibility to pursue the research [investigators] need to pursue without having to deal with the bureaucracy of a larger company," she says. "Start-ups are a bit more agile."

Extra due diligence

Going forward, savvy technology transfer directors are taking more time with their decisions on whether to patent IP, and they're paying close attention to developing case law. "I recommend talking with as many people as possible and getting as much input as you can from colleagues and outside counsel. That has certainly been of value to us," advises Fritts.

She also advises colleagues to keep an eye on the prosecution of patent applications on technologies that are similar to technologies that they have in the pipeline. "See the arguments a company is making to get over the rejections that you anticipate facing for your own technologies," says Fritts.

The extra due diligence is necessary for the time being, according to Fritts. "Once we have a better understanding of what arguments we can make to get over these rejections, and we can make sure we have the right information in our patent applications, this might not require the same amount of time," she says. "The Section 101 rejections have been a very difficult obstacle for biotech in particular, and I keep seeing the potential for the laws to change and remain hopeful that they will."

Millar-Nicholson offers similar advice. "Sign up for news alerts and news feeds about issues, talk with peer institutions about their approaches and speak to universities that have been through a PTAB process to ascertain how it came about and what they did to manage through the process," she says. "Certainly, if you are concerned about infringers, go through a very deliberate process of working out the risks and benefits, and make sure you have all your ducks in a row before approaching them to take a license or discuss their potential use of your IP."

O'Shaughnessy can't predict what will happen at the USPTO under this new administration, but he hopes there is a growing understanding of the importance of IP as an economic driver. "By and large, the IP community feels that the pendulum has swung way too far in the direction of an anti-IP philosophy, and that the pendulum needs to start coming back," he says. "We need to give inventors and investors greater confidence in the reliability of the system."

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