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AUTM's Comments on the USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (Docket ID Number: PTO-2022-0025)

AUTM is the non-profit leader in efforts to educate, promote and inspire professionals to support the further development of academic research that drives innovation and changes the world. Our community is comprised of more than 3,000 members who work in more than 800 universities, research centers, hospitals, businesses and government organizations around the globe. AUTM's members are primarily from academic settings (67%). 15% are practicing attorneys and 5% are from industry. AUTM appreciates the opportunity to provide these comments on the USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights.

AUTM members in academic settings are focused on advancing early-stage inventions and other technologies to the marketplace primarily through licensing to partners (i.e., implementers). Between 2011 and 2020 (the most recent decade for which we have data), our skilled professionals filed over 150,000 patents for academic inventors and over 17,000 in 2020 alone. Between 2011 and 2020 our U.S. members negotiated over 60,000 intellectual property license agreements on behalf of U.S. universities and academic research institutions, and in 2020 alone over 8,000 such license agreements. Thus, AUTM has valuable insights and an important voice with respect to intellectual property matters generally and patents in particular. We applaud the United States Patent and Trademark Office (USPTO) for its efforts to bolster the robustness and reliability of patents such that the time-limited, exclusive rights secured thereby incentivize innovation and promote economic prosperity and national security for all Americans.

Introduction

This request for comments (RFC) is seeking public input on a number of USPTO initiatives directed to "bolstering the robustness and reliability of patents to incentivize and protect new and nonobvious inventions while facilitating the broader dissemination of public knowledge to promote innovation and competition." According to the request, it arose from two sources. First, the President's Executive Order dated July 9, 2021 entitled "Promoting Competition in the American Economy" 86 FR 36987 (July 14, 2021) ("Competition E.O.") and the exchange of letters that resulted therefrom, and second, from a June 8, 2022 letter to the USPTO from six (6) U.S. Senators regarding so-called "patent thickets."

Address the Obvious Problem

The stated principal objective of the Competition E.O. is to increase generic and biosimilar competition in the prescription pharmaceuticals marketplace. This generic/biosimilar competition, however, necessarily requires that these pharmaceutical products exist in the marketplace first as branded products. Thus, more branded pharmaceutical products will ultimately result in more generics and biosimilars further increasing the type of marketplace competition as called for in the Competition E.O. It is crucial to note then that, since more branded pharmaceutical products ultimately result in more generic and biosimilar competition, the essential policy predicate must be to promote the discovery and development of new branded pharmaceutical products. The best way to promote the discovery and development of new branded products is to restore the system of robust and reliable (i.e., strong) patent rights we once enjoyed.

AUTM is concerned, however, that the proposed initiatives will, on the whole, have the opposite effect. That said, we applaud the commitment to provide more examination time and more examiner training and fully expect to those changes to improve the reliability and robustness of issued patents as well as the patent prosecution process itself. Unfortunately, the proposed initiatives will have, at best, zero measurable positive impact on the strength of U.S. patent rights. In AUTM's view, the more likely result is that the proposed initiatives, if implemented, will have the opposite effect. They will weaken U.S. patent rights.

There is only one way to improve the robustness and reliability of U.S. patent rights and that is to actually target that which in recent years has reduced their reliability and robustness. In other words, to increase the reliability of patents, the US must dramatically reform or eliminate the IPR procedure and restore the ability of successful plaintiffs to obtain injunctive relief. In addition, to increase the robustness of patents, the U.S. must eliminate the current uncertainty surrounding subject matter eligibility.

IPR and the inability to obtain injunctive relief undermine the reliability of patents because precisely at the moment the patent holder is ready to redeem the time-limited exclusionary right (i.e., the moment the product finally becomes successful in the marketplace) the product covered

by the patent immediately faces a copycat because there was little threat of injunction and any attempt to obtain money damages for acts of infringement is thwarted by the accused infringer's successful challenge to the patent via IPR. In other words, the patent holder cannot rely on the patent to fulfill its promise as set forth in the Constitution and is, therefore, unable to generate the return on investment central to subsequent entrepreneurial endeavors. This unpredictability favors established actors with deep pockets. It also favors organizations able to rely on trade secrets to further develop and distribute their technology. Universities cannot use trade secrets. Thus, patent uncertainty disadvantages universities and nonprofits overall, and the startup companies and people the USPTO seeks to welcome to our innovation ecosystem.

Similarly, the current uncertainty surrounding subject matter eligibility undermines the robustness of patents because no one can be sure what constitutes eligible subject matter and even then, it seems to be overly dependent on how the invention is claimed or what district court judge or Federal Circuit panel ultimately reviews it. In other words, the current *Alice/Mayo* test turns the eligibility of many claims into a crapshoot. The best approach, at present, is to draft claims that are unnecessarily narrow, intentionally giving up scope in attempt to provide the specificity seemingly required by the current jurisprudence to survive the inevitable eligibility challenge. Universities and other nonprofits are particularly harmed by this uncertainty. They have limited resources to invest in patent protection are afraid to squander them on a patent application that will not issue. In the extreme, then, they often decide not to file a patent application on affected technologies regardless of their erstwhile potential. There is nothing less robust than a patent that was never applied for. This lack of robustness makes technology transfer more difficult. Inventions covered by patents with narrow scope are more difficult to license because it limits licensees' ability to exclude competitors and thus makes it more difficult for them to recover their investment. Inventions not covered by a patent are nearly impossible to license. The result there is an unacceptable number of potentially breakthrough technologies sitting on a shelf wasting away reminiscent of the years prior to the passage of the Bayh-Dole Act.

Now, AUTM fully recognizes that the USPTO cannot, on its own, implement the necessary changes described above. Clearly, these changes will require Congressional action. That said, in its role as the administration's chief advisor on all things patent, the USPTO can have a significant impact in bringing about these changes by (i) prioritizing them over initiatives that will have, at best, a cosmetic effect on the robustness and reliability of U.S. patent rights and (ii) by becoming a more proactive advocate for them especially because these changes will drive the intended result called for in the Competition E.O.

As mentioned above, AUTM also believes that certain of the proposed initiatives could be harmful to U.S. innovation by weakening patents rights. Again, this weakening will be particularly acute for university technology transfer.

Don't Invent Problems in Continuation, OTDP and Restriction Practice Where None Exist

First, the RFC implies that additional requirements could be in the offing before claims in continuation applications could issue. Any additional requirements here would be a mistake. Current U.S. continuation practice is not broken. It is well-established, stable and is consistent with strong patent rights. The request appears to be seeking to emulate the hyper-technical European practice which will be unfamiliar and unnatural to many U.S. practitioners. These new requirements, then, will likely result in more office actions and increased costs for university patent owners. Thus, the USPTO's efforts would be better served focusing on fixing the unreliability and uncertainty discussed earlier.

Current U.S. continuation practice supports university technology transfer because, in a world governed by the first-inventor-to-file provisions of the America Invents Act (AIA), university licensees are now licensing inventions whose patent applications were filed at a very early stage. Thus, given the long development horizon, patent owners and their licensees strongly prefer to keep an application pending so as to give them the greatest opportunity to fine tune the claims to cover the product that eventually emerges or to accommodate and changes in the ever-evolving patent law. University technology transfer professionals see this routinely in the small molecule therapeutics space. Initial applications are often filed with hundreds of described and enabled novel compositions of matter but, at that point, no one has any idea which of those compounds has any clinical potential. That information comes later through painstaking further research and clinical development. As lead compounds emerge, it is important to be able to build claims around those handful of compounds and current continuation practice makes that possible. If it were to suddenly become more difficult to keep an application pending due to a change in continuation practice, it would become much more difficult to protect those lead compounds. Such a change would inject significantly greater risk into an already risky endeavor for the licensees. As a result, technology transfer would undoubtedly suffer as would the development of important new pharmaceutical products.

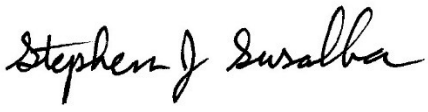
Next, the RFC implies that limits or additional requirements would be placed on OTDP practice. Any such actions would also be a mistake. This non-statutory, judge-made doctrine is already challenging enough. We do not need to make it more difficult by requiring stipulations that claims are not patentable distinct prior to filing terminal disclaimers. Again, in a first-inventor-to-file world, when working with very early-stage technologies, what might appear to be an obvious variation early-on, could ultimately be the basis for a novel feature that establishes the improvement that upends the market once the actual product is finalized. We fear that the potential unintended consequences of the proposed changes are too great for early-stage technologies coming out of universities; particularly when the terminal disclaimer system that presently exists has resulted in patentees being able to satisfactorily manage a doctrine we'd prefer not exist in the first place.

Lastly, the RFC suggests that changes to the restriction requirement/divisional practice is under consideration. As above, we do not support any changes to these practices. At present, these practices are also well-established and well-functioning. We know of no systemic problems. The current practice supports early-stage technologies on multiple fronts not the least of which is that they allow universities to file a single initial application protecting the technology while it is further developed and potential partners are identified. This approach allows one application to be filed which keeps the filing fees and drafting costs down and helps to minimize the time commitment for an already over-extended TTO staff. Eliminating the ability to file serial divisional applications would also impede the technology transfer process. As before, working with early-stage technologies lends itself to serial filings because technology evolution is a dynamic, often sporadic, process. Its timing is very hard to predict. Requiring all the applications to be filed within a set period of time would unduly and unnecessarily require AUTM members to make filing decisions when they are not prepared to do so resulting in unnecessary expenses or lost opportunities for additional protections rendering many inventions unprotected and unlicensable.

Conclusion

In conclusion, AUTM appreciates the opportunity to provide comments on this important issue. AUTM strongly supports reliable and robust patent rights. Strong patents are our members' oxygen. That said, we believe the efforts here should be directed to the elephant in the room; namely, their unreliability driven by patentees' (and licensees') inability to obtain injunctive relief and the constant threat of a IPR as well as their uncertainty driven by the current state of patent subject matter eligibility. We believe that we can have no greater impact on the reliability and robustness of patents than by resolving these issues. We further believe that strong patent rights promote competition because they facilitate market entry of new startups by attracting investors and commercialization partners which might not otherwise have committed to develop and distribute the technology for public benefit. Finally, we must be successful as our technological superiority and thus our national security and economic prosperity depend on our ability to restore robust and reliable patent rights. In addition, the fierce marketplace competition that will undoubtedly follow will benefit all Americans in the form of more choices, lower prices and increased job opportunities.

Sincerely,



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