

December 1, 2022

The Honorable Kathi Vidal
Director
U.S. Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Dear Director Vidal:

As a group, we represent some of the most innovative, R&D-intensive companies in the United States, the startups and investors leading to disruptive breakthroughs and the technology transfer experts at our nation's leading research universities. Together, we form the core elements of the U.S. innovation ecosystem; and the strength of the U.S. patent system is our lifeblood. We seek patents of high quality; and we depend on the ability to effectively enforce them.

We believe that the quality of patents issued by the U.S. Patent and Trademark Office (USPTO) continues to be unsurpassed; and we credit your ongoing focus on patent quality and making our innovation system more diverse. However, we are increasingly concerned that the USPTO seemingly does not itself trust the validity of the patents it issues which makes them increasingly vulnerable to invalidation and therefore significantly less reliable.

In particular, the Patent Trial and Appeal Board (PTAB) has primarily become a venue for large, incumbent technology implementers to target patented technologies developed by smaller, more disruptive competitors. This is demonstrated by the volume of Inter Partes Reviews (IPRs) filed by large technology companies (including companies based in China) and the serial nature of many of these petitions (including those filed by the same or similarly situated petitioners). The America Invents Act intended the IPR and Post Grant Review (PGR) processes to provide "quick and effective" alternatives to litigation, and they were explicitly not intended to, "*be used as tools for harassment or a means to prevent market entry through repeated litigation and administrative attacks on the validity of a patent.*" Yet this is precisely what IPRs, in particular, have become. There are multiple examples of innovative U.S. companies with homegrown innovations that have faced multiple IPRs on the same patent, often after the patent has previously been found valid by PTAB itself and/or in an Article III court. There is simply no valid legal or public interest rationale for this. In fact, it is harmful to our innovation ecosystem.

You have stated your intention to review and potentially reform the current process under which PTAB considers issues such as the standing of relevant parties, joinder and discretionary denial of serial and duplicative IPR petitions. We applaud this effort and would like to provide the following specific recommendations that would significantly reduce PTAB abuse currently faced by innovative companies and research organizations. We believe all of these recommendations are consistent with the clear intent of the America Invents Act.

- **Respect for Court Decisions:** Establish a rebuttable presumption that any petitions seeking IPR of patents that were the subject of a validity determination by an Article III court in any matter will be denied unless the petitioner would have standing to bring a validity challenge in an Article III court.
- **Limits on Duplicative Challenges:** Clarify that, following any district court validity determination or any final written decision in an IPR or PGR, the patent is presumed valid for the purposes of institution of an IPR brought by any petitioner. Therefore, the Board will deny institution of IPR on the same patent unless the petitioner both:
 - relies on new art that could not have been raised in the prior district court litigation, IPR, or PGR; and
 - presents new art showing unpatentability by clear and convincing evidence.
- **Meaningful estoppel:** All petitioners should be required to stipulate that if the Board institutes an IPR or PGR, they will not raise or maintain in district court any art or argument that they raised or reasonably could have raised in the IPR or PGR petition. Such a stipulation must be made as a matter of course in any IPR petition, and the failure to so stipulate is grounds for immediate dismissal with prejudice. A breach of that stipulation during the course of an IPR is further grounds for immediate dismissal as well as a review for sanctions against the petitioner.
- **Reduce Joinder Gamesmanship:** Establish a rebuttable presumption that a petitioner that is time barred or would otherwise be denied institution cannot be joined to an existing IPR. If the presumption is overcome, such petitioner may be joined solely in an understudy role and may under no circumstances be promoted to the role of lead petitioner. Accordingly, an IPR cannot be maintained solely by such a petitioner (or petitioners).

We appreciate your consideration of the critically important issue of reforming the PTAB process to re-establish a balance that is needed by the innovative and disruptive companies and organizations that drive our economy. More specifically, we hope that these recommendations provide an effective roadmap for the types of reforms that will help achieve this goal.

Respectfully,

Alliance of Startups and Inventors for Jobs
 AUTM
 Biotechnology Industry Organization

Innovation Alliance
 Medical Device Manufacturers Association

