

**Chairman Chuck Grassley
Questions for the Record**

**Hearing on “S. 1137, the “PATENT Act” – Finding Effective Solutions to
Address Abusive Patent Practices”**

United States Senate Committee on the Judiciary

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- 1. We have heard about perceived inequities with the Patent and Trademark Office’s IPR and PGR proceeding. Some are concerned that the proceedings are unfair and put patent holders at a disadvantage. What do you believe is the most important issue that must be dealt with to make these proceedings more balanced for both patent holders and petitioners?*

Answer:

The IPR and PGR provisions enacted under the AIA were intended to provide a faster and less costly means to adjudicate patent validity than in the district courts. However, in an effort to timely address a deluge of IPR and PGR petitions, these proceedings have been implemented in a manner that lack basic due process protections and unfairly prejudices patent owners as evidenced by higher invalidity rates than found in district court. This concern is particularly acute in the biopharmaceutical industry, where Congress has already enacted specific patent litigation frameworks in district court in the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act, both of which reflect a careful balance of the interests of the parties and the public. The stakes are high—if there is a reduced confidence in the patent system, the biopharmaceutical industry will innovate less, invest less, and employ fewer. To that end, there will fewer ground-breaking therapies for patients.

While there are number of potential improvements that would level the playing field with respect to these proceedings that I discuss below, the most fundamental issue is the differences in claim construction and evidentiary standards applied by the USPTO’s Patent Trial & Appeal Board (PTAB) and the district courts. The PTAB construes patents claims by their “broadest reasonable interpretation” (BRI) rather than the district court approach of construing a patent claim in view of its ordinary and customary meaning to one skilled in the art. Moreover, the PTAB determine patents validity by a preponderance of the evidence standard, rather than by the more rigorous clear and convincing standard applied by the district courts to granted patents. Last, district courts recognize that a granted patent has a presumption of validity and that the burden of proof to the contrary remains on the challenger throughout litigation. Taken together, the lack of uniform standards tilts IPR and PGR proceedings in favor of the challenger.

Legislation that clearly requires the courts and the PTAB to apply uniform standards will increase fairness and predictability in these proceedings. It would reduce potential gamesmanship by ensuring that both venues are viewed equally from a merits-perspective, and reduce duplicative proceedings as each venue would respect the other's finding since they are applying equivalent standards. Most importantly, it would restore confidence in a patent system that has encouraged innovators to invent, invest and employ since our country began.

2. *How do we strike the right balance to ensure that IPR proceedings – which many see as valuable in terms of invalidating weak patents – are not rendered ineffective?*

Answer:

Providing basic fairness to IPR and PGR proceedings is an important step in restoring the promise of the AIA to provide a faster and less costly means to challenge patent validity, in a manner that provides due process for both the patent holder and challenger. There are three procedural changes that, if enacted together, would more fairly balance these proceedings, aid in their efficient adjudication to the benefit of both patent owners and challengers, and provide faith and predictability in a patent system.

First, as discussed in my answer to question 1, the PTAB should apply the same claim construction standard as district courts, rather than the BRI standard. The PTAB should also respect the presumption of validity for granted patents, and apply the same “clear and convincing” evidentiary standard as applied in district courts for establishing invalidity of a patent, rather than the more lenient “preponderance of the evidence” standard.

Second, patent owners should be permitted to make minor amendments to claims during an IPR/PGR proceeding. If a patent owner wants to have an opportunity to make more substantial amendments, the patent owner may remove any of the challenged claims by filing a request for reissue or reexamination prior to institution of the IPR/PGR.

Third, the procedural rules governing IPR and PGR should be revised to ensure equal opportunity to submit evidence, reduce potential bias by having someone other than the PTAB merits panel decide whether to institute the petition, and by permit live testimony on key issues where warranted.

These changes do not tilt the results in favor of the patent holder, but rather put both parties on equal footing as Congress intended when enacting the AIA. “Weak” patents will be found invalid in a fair proceeding, and closer cases will be properly decided based on the evidence and standards that have been historically applied and available to granted patents in the courts. The above-proposed changes strike the right balance by increasing fairness and predictability, supporting consistency in outcomes in each venue, and reducing duplicative proceedings.