



# How to improve IPRs without tossing the baby out with the bath water



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April 11, 2017

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As [reported here by Gene Quinn](#), I resigned as Deputy Director of the United States Patent and Trademark Office (USPTO) effective January 20, 2017. Although I no longer have the privilege of working for the USPTO, I remain impressed by the all employees who have dedicated their careers to improving the Agency to better serve our country, and the world.

I had the opportunity to get to know many of the judges serving on the PTAB. In fact, I had the pleasure of serving on a panel of an IPR. I know first-hand that all of the judges are very hard working and faithfully execute the responsibilities bestowed upon them. Notwithstanding their hard work and the USPTO's initial efforts to establish a fair IPR system, the IPR process can (and should) be further improved.

In the *Leahy-Smith America Invents Act (AIA)*, Section 6, Chapter 31, § 316(a) Congress specifically granted the Director the responsibility to prescribe regulations “(2) setting forth the standards for the showing of sufficient grounds to institute a review under § 314(a)” and

“(4) establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title”. Congress instructed the Director, in § 316(b), to “consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter.”

In addition to providing for higher institution thresholds (§§ 314(a) and 324(a)), the AIA specifies that the Director should “take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office” (§ 325(d)), and should ensure that patent owners be protected from any “improper use of the proceeding” (§§ 316(a)(6) and 326(a)(6)). The Director is further given authority under § 315(d) where another proceeding or matter involving the patent is before the Office “to determine the manner in which the inter partes review or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination.”

It is clear that the current regulations are almost exclusively focused § 316(b)’s “the ability of the Office to timely complete proceedings” and not the other language of § 316(b): “the effect of any such regulation on the economy”, “the efficient administration of the Office” or “the integrity of the patent system.” Changes can be made to improve the IPR process without throwing the baby out with the bath water. Invalid patents can still be addressed at the USPTO while returning some of the lost integrity of the patent system.

With several years of experience and thousands of petitions, the IPR proceedings have proven to be a useful tool for addressing patents that are invalid based on printed publications. IPR’s are also subject to the abuses warned about during debate of the AIA. We are all well aware of the different policy positions between industries. One group is tired of fighting patent infringement litigations while the other needs certainty in their patent assets to protect substantial R&D investments. Although consensus is not possible, I present seven suggestions on ways the USPTO can improve the IPR process with all of § 316(b) in mind. I appreciate that suggestion II will be viewed as pandering to a specific industry and that suggestion V may not be easily accomplished. Nevertheless, I set forth all seven suggestions for discussion.

I. The patent owner should be allowed to petition the Director for a reconsideration of Institution, or in the Preliminary response, for the following reasons that specifically address Congress’ concerns:

A. The petition is based on the same or substantially the same art considered in prosecution. (*the integrity of the patent system*)

- B. Financial hardship of patent owner, including where the patent owner lacks the financial ability to fairly defend against an IPR/PGR, where the patent owner is a university or not-for-profit organization whose operations would be impaired if required to defend an IPR, where mounting such a defense would impair the patent owner's ability to develop, manufacture and/or market his/her invention, or where the patent owner is a small business or entity. *(effect on the economy)*
- C. An IPR would not resolve all outstanding issues of art-based validity where there is a district court action pending. *(the integrity of the patent system)*
- D. There are extensive discovery issues that cannot fairly be performed in the time frame allowed under the statute or which would require determination of expert credibility. *(efficient administration of the Office)*
- E. There is a demonstrated abuse of the IPR/PGR process by the petitioner. *(the integrity of the patent system)*
- F. Where institution of an IPR would likely disrupt the nascent or ongoing business of the patent owner, or the ability of that business to raise needed capital to further development, manufacture or marketing of the claimed invention. *(effect on the economy)*

II. It is clear that there is a peculiar public interest in making sure that the patent system foster the creation of FDA approved drugs. To address the effect on this critical area of the economy, the Director should personally decide the institution of an IPR for patents covering drug or therapeutic biologic products that are undergoing FDA-required clinical testing, regulatory review and/or approval. This would include those patents that may be listed in the FDA's "Orange Book" pursuant to the Hatch-Waxman Act or identified under the "patent dance" provisions of the BPCIA (the biosimilars act).

III. For the integrity of the patent system, establish a rebuttable presumption that the art is the same or substantially the same if the IPR invalidity contention as to a claim is based in whole or in part on a reference that was applied during the original examination to reject that claim, and to defer to earlier PTO determinations based on the same or similar prior art or arguments unless the determination is shown to be clearly wrong.

IV. For both the integrity of the patent system and the efficient administration of the Office, require the petitioner, as part of the original petition, to fully disclose all objective evidence of non-obviousness known to it weighing in favor of patentability, or that refutes or tends to refute any factual contention being advanced in the petition, including without limitation:

1. Copying
2. Inability to or ineffectiveness of design arounds
3. Commercial success
4. Contrary evidence reflected in petitioner's internal documents or public statements, including tributes to the claimed invention

V. For the integrity of the patent system, explore the options of having the PTAB coordinate with the district court where the challenged patent is the subject of pending litigation to determine if granting a petition will resolve all issues of 102 and 103 based on prior patents and printed publications, and to otherwise determine whether institution of an IPR would expedite the resolution of the litigation.

VI. For both the integrity of the patent system and the efficient administration of the Office, the USPTO should construe the "raised or reasonably could have been raised" provisions of the America Invents Act (AIA) to preclude the filing of a subsequent IPR by a petitioner, or its privies, that raises any issue that was or could reasonably have been raised in the earlier petition or in a concluded district court proceeding. Such a rule would minimize harassment of patent owners while still preserving the opportunity for aggrieved parties to have their challenges fully and fairly heard – but heard once.

VII. To preserve the integrity of the patent system, the Board should extending the duration of any IPR for up to 18 months where such an extension would serve the interests of justice and/or due process (including where additional discovery is needed in order to allow a patent owner to fairly defend against the petition). The statute already allows the USPTO to go beyond the 12-month time limit and up to 18 months, when appropriate, but so far there has been no case that has used the available additional six months.

By adopting these improvements to the IPR process the system will become fairer, afford patent owners more due process, and protect patent owners from harassment and hardship while still fulfilling the statutory mandate to provide an alternative forum for administrative resolution of validity challenges.

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