

A First Look at the Impact of Recent Rule Changes on Patent Owner Preliminary Responses

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On May 2, 2016, long-awaited rule changes went into effect for practice before the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office (USPTO).¹ One of the newly implemented rules offers patent owners an opportunity to provide a more robust preliminary response to a petition for inter partes review (IPR), covered business method (CBM) review, or post-grant review (PGR), with “new” testimonial evidence. Previously, petitioners could include testimonial evidence prepared for the proceeding with their petitions but patent owners were precluded from doing so with their preliminary responses,² an asymmetric situation that unfairly favored petitioners, according to some commentators.³ This article reviews tactical considerations for and against inclusion of new testimonial evidence⁴ in patent owner preliminary responses. The authors also review IPR proceedings filed after the rule changes took effect, to gauge the prevalence and impact of new testimonial evidence submitted by patent owners in support of their preliminary responses.

Rule Changes and Patent Owner Considerations

Prior to the May 2, 2016, rule changes, petitioners were permitted to support PTAB petitions with testimonial evidence, but patent owners were barred from providing “new” testimonial evidence with their preliminary responses to such petitions.⁵ The PTAB had clarified that testimonial evidence that substantively addressed patentability, and that was created after the filing of the petition for the proceeding-at-issue, or a related proceeding, would be considered “new” and would therefore not be permitted.⁶ While the Trial Practice Guide identified certain instances in which patent owners could seek leave to file new testimonial evidence, it clarified that such evidence would only be permitted when found to be in the interests of justice.⁷

The USPTO, addressing concerns that this asymmetry in permissible evidence disadvantaged patent owners, amended the rules to permit patent owners to file testimonial evidence without any limit on scope with their optional preliminary responses.⁸ In the comments to the amended rules, the PTAB also clarified that just as there is “no negative inference on [a] patent owner’s choice to forgo an opportunity to file a preliminary response, no negative inference will be drawn if a patent owner decides not to present new testimonial evidence with a preliminary response.”⁹

Because the time frame for the preliminary phase of a PTAB trial proceeding is limited by statute and generally does not allow for cross-examination of a patent owner’s declarant as a matter of right, the benefit to patent owners from this change has been curtailed under the rules in at least two ways.¹⁰ First, the rules provide petitioners the opportunity to seek leave to file a reply to a preliminary response with a showing of good cause.¹¹ Second, and more importantly, the rules require the PTAB to view genuine issues of material fact created by the testimonial evidence “in the light most favorable to the petitioner solely for purposes of deciding whether to institute.”¹² This presumption was added to the rules to preserve a petitioner’s ability to challenge statements made by the patent owner’s declarant, which may be done as of right during an instituted trial.¹³

Allowing expert testimony in preliminary responses has opened up a range of considerations for patent owners responding to petitions pursuant to the America Invents Act (AIA). Previously, a patent owner only needed to decide if it would file a preliminary response during the preliminary phase of an AIA trial. Now, a patent owner must also decide whether to include expert testimony, which may effectively “lock in” the patent owner’s positions early in the proceeding. Additionally, a patent owner must balance the anticipated usefulness of the expert testimony in preventing institution of the proceeding against the possibility of the PTAB determining that the testimony creates a factual dispute that may not be resolved pre-institution. In the latter case, an expert declaration filed with a preliminary response may preview the patent owner’s positions to the petitioner prior to the deposition of the petitioner’s expert in an instituted trial.¹⁴ Further, a patent owner’s declarant could be subjected to an additional seven hours of deposition time if the patent owner relies on testimony of the same declarant in support of its response during the trial phase of an instituted proceeding.¹⁵

Data from Recent Cases (Post-Rule Changes)

We analyzed IPR proceedings filed after the rule changes took effect to gauge the prevalence and impact of testimonial evidence submitted by patent owners in support of their preliminary responses. In this section, we describe the methodology used to gather data, and present the obtained results.

We used Docket Navigator® (www.docketnavigator.com) to find all preliminary responses filed in IPR proceedings between May 1, 2016, and November 28, 2016. We excluded preliminary responses that merely contained a disclaimer of claims by the patent owner and also excluded filings of a waiver of preliminary response, resulting in 655 preliminary responses that formed the basis for our analysis. Patent owners submitted at least one declaration in support of 224 of these 655 preliminary responses (34 percent), as shown in figure 1.

We also reviewed the available case data from the perspective of decisions by the PTAB to institute proceedings. For the purposes of this analysis, we considered decisions to institute as being binary—denial of IPR, or institution of IPR on at least one ground of invalidity for at least one claim. Data regarding institution decisions are summarized in table 1.

In addition to considering the raw number of declarations submitted by patent owners, we reviewed each declaration to determine the scope of the subjects discussed. Because the preliminary response is a patent owner's only opportunity to argue against the institution of an IPR trial, we noted that patent owners seem to be relying on declarations that accompany the preliminary responses to rebut various aspects of prior art challenges. Particularly, it was noted that the vast majority of declarations submitted by patent owners discussed the disclosure of specific prior art references, including in the context of anticipation rejections under 35 U.S.C. § 102 and obviousness rejections under § 103. In response to proposed obviousness rejections, declarants for patent owners have discussed deficiencies in petitioners' disclosure of individual prior art references, as well as the lack of motivation to combine various references.

Declarants for patent owners have also opined on other issues relating to prior art, such as the level of skill in the art,¹⁶ the state of the art at the time of the invention,¹⁷ antedating a prior art reference,¹⁸ experiments performed by a petitioner (e.g., to support arguments regarding the disclosure of prior art references),¹⁹ accessibility of prior art references,²⁰ and secondary considerations (e.g., commercial success) supporting a finding of nonobviousness.²¹ Additionally, declarants for patent owners have opined regarding invention issues such as conception and reduction to practice,²² overview of the subject matter of the patent,²³ and claim construction.²⁴

On occasion, a patent owner has submitted multiple declarations in support of a preliminary response. In one instance, for example, multiple declarants opined on prior art issues in support of a single preliminary response;²⁵ in other instances, one declarant has opined on prior art issues and another has opined on secondary considerations;²⁶ and in yet other instances, multiple declarants have opined on secondary considerations with one of them also opining on prior art.²⁷ Thus, patent owners have used declarations in support of preliminary responses in various ways to address different factual scenarios. One patent owner even submitted four separate declarations: one by the president of the patent owner, another regarding prior art, another regarding preparation of samples involved in experiments conducted by the petitioner, and a fourth regarding the purity of the samples.²⁸ Of course, while multiple declarations may ideally be desirable to address various issues in an effort to stave off institution of an IPR trial, cost (e.g., up to tens of thousands of dollars per declarant, including preparation of the declaration and preparation for cross-examination) and timing (less than three months between the petition and the preliminary response) may constrain those numbers. More data is necessary to understand the impact, if any, of the filing of multiple declarations.

PTAB's Treatment of Declarations in Support of Preliminary Responses

The purpose of a preliminary response by a patent owner in an IPR proceeding is to dissuade the PTAB from instituting a trial, and the recent rule changes were promulgated to address the concern that patent owners were at a distinct disadvantage relative to petitioners at the pre-institution stage. One

might ask whether the ability to submit declarations with a preliminary response would in fact increase the patent owner's chances of convincing the PTAB to deny institution of an IPR. This is a particularly relevant question given the time and expense associated with preparing and submitting such declarations.

While the PTAB will take into account a patent owner's preliminary response including any declaration that is filed, the rules explain that "a genuine issue of material fact created by such testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an *inter partes* review."²⁹ The PTAB has cited to this provision in cases where, for example, the petitioner and the patent owner provide conflicting expert testimony on the teachings of a prior art reference,³⁰ and where the experts for the petitioner and the patent owner disagree over whether a prior art reference inherently produces a given result.³¹ In these cases, the PTAB has instituted review and indicated that the issues can be further developed at trial.

According to the USPTO's statistics as of September 30, 2016,³² since the enactment of IPR proceedings there have been 1,901 IPR trials instituted and 1,075 IPR petitions denied, corresponding to an overall IPR denial rate of about 36 percent. Based on 194 instituted IPR trials and 123 denials, the denial rate since the rule changes in May 2016 has been at about 39 percent. Drilling down further, however, to consider only IPR proceedings in which a patent owner submitted a declaration in support of its preliminary response, the denial rate appears to reflect the overall IPR denial rate at about 35 percent (based on 75 IPR trials instituted and 41 IPR petitions denied). Because of the small sample size to date, more data will be needed to determine whether the submission of a declaration has an appreciable effect on the denial rate.

Conclusion

Patent owners have been availing themselves of the opportunity provided by the PTAB's recent rule changes to submit declarations with their preliminary responses in IPR proceedings. In the cases examined by the authors, patent owners submitted such supporting declarations about 34 percent of the time, although that figure may change as patent owners and the PTAB adjust to such submissions. Declarations in support of preliminary responses have covered a variety of issues, most commonly the scope of prior art disclosures. In the limited number of institution decisions issued after the rule changes, there has been some evidence that the PTAB breaks ties in favor of petitioners at least at the institution decision stage. That factor, as well as various other considerations such as exposure of declarants to cross-examination and the time and cost associated with preparing and submitting declarations, may influence the decision of whether to submit a declaration in support of a patent owner's preliminary response. As more data becomes available on the use of such declarations and their impact on case outcomes, this aspect of IPR practice is likely to gain increased predictability.

Endnotes

1. Amendments to the Rules of Practice for Trials before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750 (Apr. 1, 2016) (effective May 1, 2016).

2. 37 C.F.R. § 42.107(c) (“The preliminary response shall not present new testimonial evidence beyond that already of record, except as authorized by the Board.”) (repealed 2016); *see* Changes to Implement Inter Partes Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents, 77 Fed. Reg. 48,680, 48,728 (Aug. 14, 2012).

3. Amendments to the Rules of Practice for Trials before the Patent Trial and Appeal Board, 80 Fed. Reg. 50,720, 50,725 (Aug. 20, 2015) (“Several commenters suggested that the patent owner should be allowed to rely on new testimonial evidence in its preliminary response to the petition given that the petitioner may rely upon such evidence in its petition, and that the current practice of not allowing a patent owner to rely on such evidence is unfair.”).

4. In trials before the PTAB, un compelled direct testimony is almost always presented by affidavit or declaration. 37 C.F.R. § 42.53(a).

5. 37 C.F.R. § 42.107(c) (repealed 2016).

6. *See, e.g.*, B/E Aerospace, Inc. v. MAG Aerospace Indus., LLC, No. IPR2014-01510, Paper No. 13 (P.T.A.B. Jan. 20, 2015).

7. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012) (“New testimonial evidence may be permitted where a party demonstrates that such evidence is in the interests of justice. For example, the Board may permit new testimonial evidence where it addresses issues relating to the petitioner’s standing, or where the Board determines that consideration of the identified evidence is necessary in the interests of justice as the evidence demonstrates that the trial may not be instituted.”).

8. 81 Fed. Reg. at 18,755 (codified at 37 C.F.R. §§ 42.107(a) (“The patent owner may file a preliminary response to the petition. The response is limited to setting forth the reasons why no *inter partes* review should be instituted under 35 U.S.C. 314 *and can include supporting evidence.*”), and 42.207(a) (“The patent owner may file a preliminary response to the petition. The response is limited to setting forth the reasons why no post-grant review should be instituted under 35 U.S.C. 324 *and can include supporting evidence.*”) (emphasis added)).

9. *Id.*

10. *Id.*

11. 37 C.F.R. § 42.108(c) (“A petitioner may seek leave to file a reply to the preliminary response in accordance with §§ 42.23 and 42.24(c). Any such request must make a showing of good cause.”).

12. *Id.* (“The Board’s decision will take into account a patent owner preliminary response where such a response is filed, including any testimonial evidence, but a genuine issue of material fact created by such testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an *inter partes* review.”).

13. 81 Fed. Reg. at 18,755.

14. Absent the filing of testimonial evidence pretrial, the petitioner’s declarant (deposed after institution but before the patentee response and traditional presentation of its direct testimony) has only the preliminary response to guide deposition preparation, assuming one is even filed.

15. *See* 37 CFR § 42.51(b)(1)(ii).

16. *See* Preliminary Response, Mohawk Energy Ltd. v. Enventure Global Tech. Inc., No. IPR2016-00954, Paper No. 5 (P.T.A.B. July 29, 2016).

17. *See* Preliminary Response, Mylan Pharm. Inc. v. UCB Pharma GmbH, No. IPR2016-00510, Paper No. 9 (P.T.A.B. May 2, 2016); Preliminary Response, Roxane Labs., Inc. v. Vanda Pharm. Inc., No. IPR2016-00690, Paper No. 7 (P.T.A.B. June 7, 2016); Preliminary Response, Mylan Labs. Ltd. v. Aventis Pharma S.A., No. IPR2016-00712, Paper No. 7 (P.T.A.B. June 24, 2016); Preliminary Response,

Baker Hughes Inc. v. Lubrizol Specialty Prods., Inc., No. IPR2016-00734, Paper No. 8 (P.T.A.B. July 6, 2016); Preliminary Response, Nipro Corp. v. NxStage Med., Inc., No. IPR2016-00744, Paper No. 7 (P.T.A.B. June 20, 2016); Preliminary Response, ARRIS Grp., Inc. v. Mobile Telecomms. Techs., LLC, No. IPR2016-00766, Paper No. 13 (P.T.A.B. June 27, 2016).

18. See Preliminary Response, Priceline.com LLC v. Int'l Bus. Machs. Corp., No. IPR2016-00608, Paper No. 11 (P.T.A.B. May 12, 2016).

19. See Preliminary Response, nXn Partners, LLC v. Nissan Chem. Indus., Ltd., No. IPR2016-00694, Paper No. 6 (P.T.A.B. June 3, 2016); Preliminary Response, Harvest Trading Grp., Inc. v. Vireo Sys., Inc., No. IPR2016-00945, Paper No. 7 (P.T.A.B. Aug. 2, 2016) [hereinafter Vireo Preliminary Response].

20. See Preliminary Response, LG Elecs., Inc. v. Core Wireless Licensing S.A.R.L., No. IPR2016-00986, Paper No. 11 (P.T.A.B. Aug. 3, 2016); Preliminary Response, Colas Solutions, Inc. v. Blacklidge Emulsions, Inc., No. IPR2016-01031, Paper No. 6 (P.T.A.B. Aug. 12, 2016).

21. See Preliminary Response, Apple Inc. v. Rosetta-Wireless Corp., No. IPR2016-00616, Paper No. 7 (P.T.A.B. May 25, 2016) [hereinafter Rosetta-Wireless Preliminary Response]; Preliminary Response, Apple Inc. v. Personalized Media Commc'ns, LLC, No. IPR2016-00751, Paper No. 7 (P.T.A.B. June 22, 2016); Preliminary Response, Amneal Pharm., LLC v. Purdue Pharma L.P., No. IPR2016-01027, Paper No. 9 (P.T.A.B. Aug. 12, 2016) [hereinafter Purdue Pharma Preliminary Response]; Preliminary Response, Mylan Pharm. Inc. v. Shire Labs., Inc., No. IPR2016-01033, Paper No. 7 (P.T.A.B. Aug. 18, 2016); Preliminary Response, MasterCraft Boat Co. v. Malibu Boats, LLC, No. IPR2016-01057, Paper No. 6 (P.T.A.B. Aug. 23, 2016) [hereinafter Malibu Boats Preliminary Response].

22. See Preliminary Response, LifeWave, Inc. v. Blendermann, No. IPR2016-00571, Paper No. 6 (P.T.A.B. June 8, 2016).

23. See Preliminary Response, Baker Hughes Inc. v. Lubrizol Specialty Prods., Inc., No. IPR2016-00734, Paper No. 8 (P.T.A.B. July 6, 2016); Preliminary Response, ARRIS Grp., Inc. v. Mobile Telecomms. Techs., LLC, No. IPR2016-00765, Paper No. 14 (P.T.A.B. June 27, 2016); Preliminary Response, Polygroup Ltd. (MCO) v. Willis Elec. Co., No. IPR2016-00802, Paper No. 7 (P.T.A.B. Aug. 4, 2016).

24. See Preliminary Response, Gen. Elec. Co. v. Rolls-Royce PLC, No. IPR2016-00528, Paper No. 6 (P.T.A.B. May 9, 2016); Preliminary Response, Fitbit, Inc. v. BodyMedia, Inc., No. IPR2016-00545, Paper No. 6 (P.T.A.B. May 9, 2016); Rosetta-Wireless Preliminary Response, *supra*, note 21; Preliminary Response, Realtime Data LLC v. Oracle Int'l Corp., No. IPR2016-00695, Paper No. 6 (P.T.A.B. June 15, 2016); Preliminary Response, Seabery N. Am. Inc. v. Lincoln Global, Inc., No. IPR2016-00840, Paper No. 9 (P.T.A.B. July 20, 2016).

25. See Preliminary Response, Mohawk Energy Ltd. v. Enventure Global Tech., Inc., No. IPR2016-00954, Paper No. 5 (P.T.A.B. July 29, 2016).

26. See Preliminary Response, Clark Filter, Inc. v. Camfil USA, Inc., No. IPR2016-00982, Paper No. 8 (P.T.A.B. Aug. 4, 2016); Malibu Boats Preliminary Response, *supra* note 21; Preliminary Response, MasterCraft Boat Co. v. Malibu Boats, LLC, No. IPR2016-01058, Paper No. 6 (P.T.A.B. Aug. 23, 2016).

27. See Purdue Pharma Preliminary Response, *supra* note 21; Preliminary Response, Amneal Pharm., LLC v. Purdue Pharma L.P., No. IPR2016-01028, Paper No. 9 (P.T.A.B. Aug. 12, 2016).

28. See Vireo Preliminary Response, *supra* note 19; Preliminary Response, Harvest Trading Grp., Inc. v. Vireo Sys., Inc., No. IPR2016-00947, Paper No. 8 (P.T.A.B. Aug. 3, 2016).

29. 37 C.F.R. § 42.108(c).

30. *See, e.g.*, Mylan Pharm. Inc. v. UCB Pharma GmbH, No. IPR2016-00517, Paper No. 12, at 22 (P.T.A.B. July 20, 2016) (acknowledging the conflicting testimony of the petitioner’s and the patent owner’s respective experts and stating that “[b]ecause, at this stage of the proceedings, Patent Owner’s ‘supporting evidence concerning disputed material facts will be viewed in light most favorable to the petitioner,’ we find, on the present record, that Petitioner has demonstrated a reasonable likelihood that one of ordinary skill in the art would have recognized from the lipophilicity profile of 5-HMT, and/or the Brynne reference, that the 5-HMT would have poor oral bioavailability/absorption”); ASUS Computer Int’l v. Avago Techs. Gen. IP (Singapore) Pte. Ltd., No. IPR2016-00647, Paper No. 7, at 17 (P.T.A.B. Aug. 12, 2016) (“At this preliminary stage, with neither declarant having been cross-examined, we resolve the conflicting declaration testimony in favor of Petitioner, recognizing that Schmidl is not explicit in stating that synchronization signals are multiplexed with data upstream of the IFFT.”).

31. *See* nXn Partners, LLC v. Nissan Chem. Indus., Ltd., No. IPR2016-00694, Paper No. 7, at 18 (P.T.A.B. Aug. 31, 2016) (“[A]s Patent Owner recognizes . . . , there are disagreements between its declarant and Petitioner’s declarant. . . . As [patent owner’s declaration] creates genuine issues of material fact . . . , we view the disputed facts in the light most favorable to Petitioner and determine that Petitioner has established a reasonable likelihood that challenged claim 1 is inherently anticipated by Mita.”).

32. *See* USPTO, PATENT TRIAL AND APPEAL BOARD STATISTICS (Sept. 30, 2016), https://www.uspto.gov/sites/default/files/documents/aia_statistics_september2016A.pdf.