

How New Testimonial Evidence Affects IPR Institution

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It has been two years since the introduction of a rule change that permits patent owners to submit new testimonial evidence (NTE) in support of a preliminary response to an inter partes review petition. To assess the prevalence and value of NTE, we analyzed more than 300 IPR proceedings involving patents in the biotechnology and chemical arts having a preliminary response due on or after May 2, 2016 (the effective date of the rule change). Our study shows that the submission of NTE did not reduce overall institution rates.

In this article we present the results from our analysis and offer several reasons, gleaned from a review of the institution decisions, to account for the overall lack of impact of NTE on institution rates. We also highlight factors for patent owners to consider when deciding whether or not to submit NTE with a preliminary response.

The use of NTE — whether from fact or expert witnesses — was introduced, among other things, to help level a playing field perceived to be tilted in favor of petitioners.[1] But the rule change allowing reliance on NTE to support a preliminary response was implemented with a major caveat: Genuine issues of material fact created by NTE are resolved in favor of the petitioner for purposes of institution.[2] In practice, although the U.S. Patent and Trademark Office reports a steady decrease in institution rate for IPRs, including during the last two years since the implementation of the rule change,[3] our data indicate that NTE has not been a significant contributing factor to the lower institution rates.

Our analysis focuses on IPRs for patents classified by the PTO under Technology Center 1600 (Biotechnology and Organic Chemistry). This narrowed the scope of our study to 340 proceedings that form the basis of our analysis. As shown in Figure 1, patent owners submitted a preliminary response in 268 (79 percent) of the 340 proceedings. A further breakdown shows that in 162 (48 percent) of those proceedings preliminary responses were submitted without NTE and 106 (31 percent) with NTE. For the remaining 72 proceedings (21 percent), patent owners chose not to submit a preliminary response at all. Thus, as these data show, patent owners in this field have been selective and have not blindly embraced the use of



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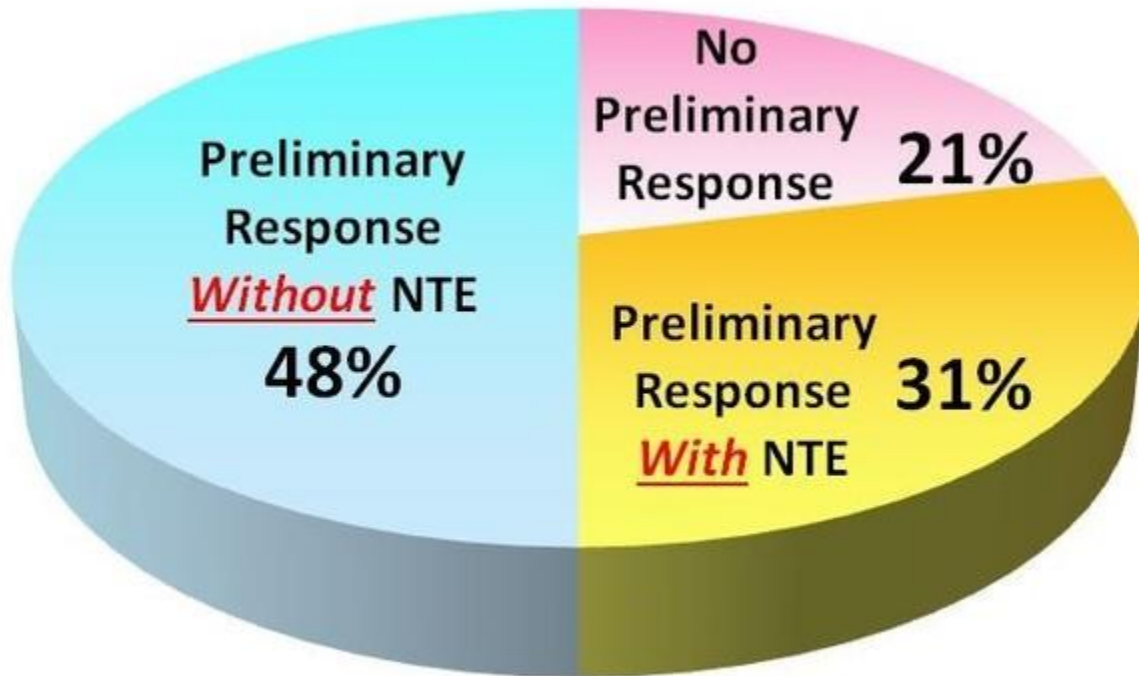
Melissa Gibson



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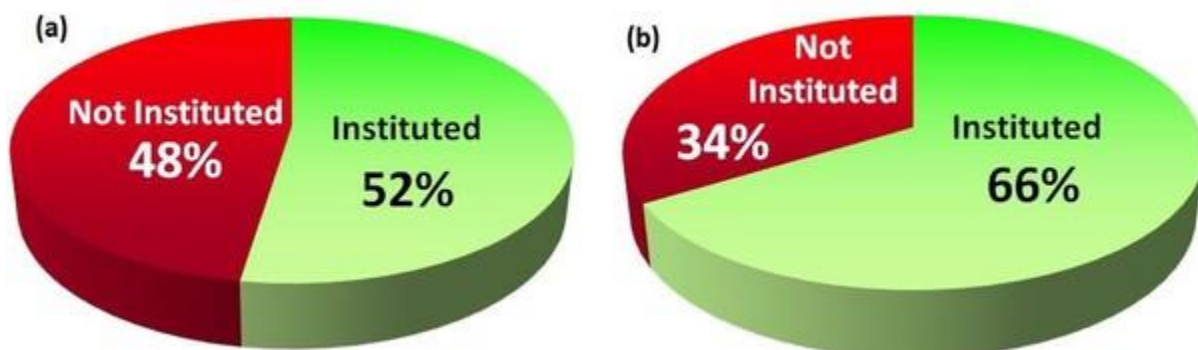
NTE to support their preliminary responses.

Figure 1: Percentage of Patent Owners Filing a Preliminary Response Without NTE, With NTE, or No Preliminary Response at All



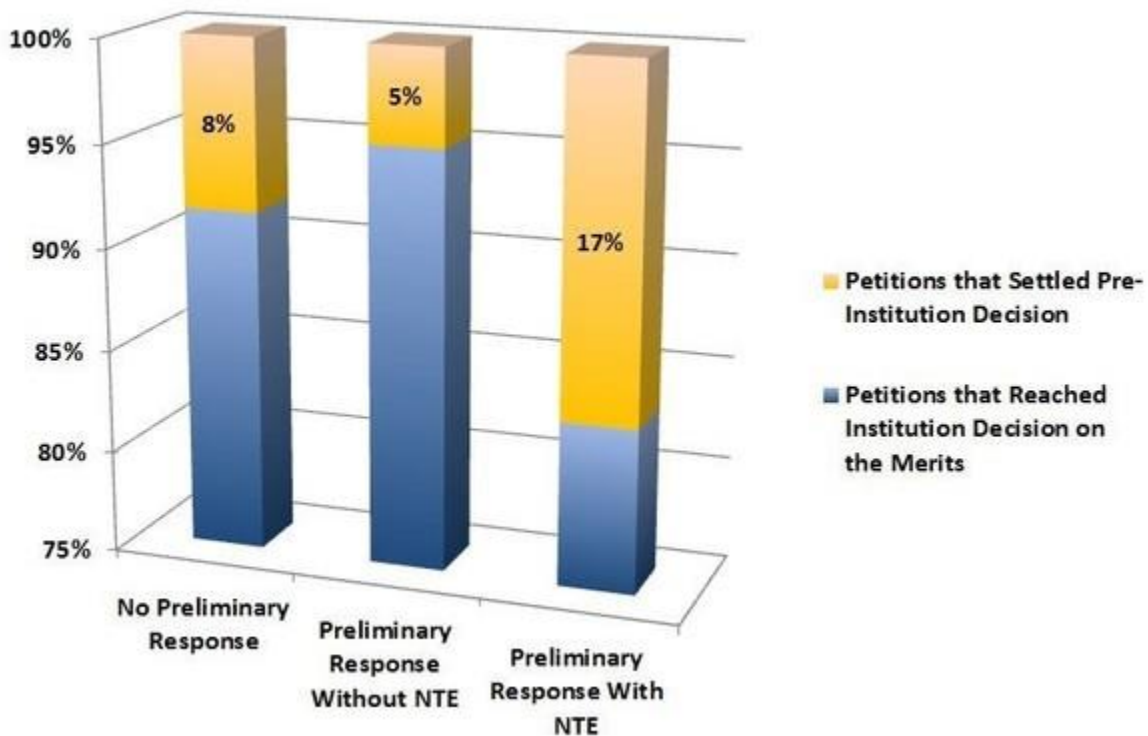
To focus on the effect of NTE, we compared the institution rates between proceedings where patent owners submitted NTE in support of their preliminary response and those where no NTE was submitted. For this comparison, we excluded proceedings that were denied institution based on procedural grounds and those that settled before institution.[4] Instead, we only included proceedings that were decided on the merits. The analysis reveals that — in the aggregate — patent owners fared worse when relying on NTE. As shown in Figure 2, the institution rate was 52 percent (75 out of 143 proceedings) when no NTE was submitted (Figure 2(a)), compared to 66 percent (55 out of 83 proceedings) when NTE was submitted (Figure 2(b)). Although not shown in the figures, the institution rate was 100 percent for proceedings where no preliminary response was filed by patent owner.

Figure 2: Institution Rate for Patent Owners Filing a Preliminary Response (a) Without NTE, or (b) With NTE



Although the percentages reflected in Figure 2 are limited to proceedings that reached an institution decision and thus exclude proceedings where the parties reached settlement pre-institution, it is worth noting the effect that NTE had on settlement. As shown in Figure 3, a review of the proceedings that reached settlement before institution indicates that NTE may have had an effect on the outcome. Specifically, cases settled pre-institution 8 percent of the time when no preliminary response was submitted, 5 percent of the time when a preliminary response with no NTE was submitted, and 17 percent of the time when a preliminary response with NTE was submitted. This nontrivial effect on settlement may be an additional factor for patent owners to consider when assessing the value of NTE in support of a preliminary response.

Figure 3: Pre-Institution Settlement Rate for Proceedings in Which Patent Owner Submitted



Not surprisingly, with respect to institution decisions in favor of petitioner, we have found numerous examples where the Patent Trial and Appeal Board instituted proceedings because the opinions proffered by patent owner’s declarant simply raised genuine issues of material fact.[5] In addition, the board tends to grant institution if the challenge raised by patent owner’s NTE is one on which, in the board’s view, the petitioner did not have the initial burden of production. For example, the board is likely to institute a proceeding when the patent owner introduces NTE directed to: secondary considerations of nonobviousness;[6] a challenge as to whether a prior art reference is enabled;[7] or the antedating of a prior art reference.[8] In such cases, the board will generally institute proceedings to allow a full and complete record to be developed post-institution.

On the other hand, NTE can be helpful to demonstrate that a petitioner failed to meet its burden of proof to establish obviousness. In particular, if the patent owner’s NTE persuasively points out a deficiency in petitioner’s obviousness argument, without raising an issue of material fact, the board will generally deny institution. For example, patent owners have argued successfully with the help of NTE that the prior art fails to teach all elements of the claimed invention, that a skilled artisan would not be

motivated to combine the asserted references, or that there was no reasonable expectation of success in combining the prior art.[9]

It is also noteworthy that patent owners have argued successfully, without NTE, that the petitioner failed to provide adequate motivation to combine or reasonable expectation of success by relying solely on attorney argument based on the disclosure in the prior art.[10] Such an approach may seem attractive to patent owners in that it reduces the risk of introducing a genuine issue of material fact through NTE. But in at least one instance, the board has criticized a patent owner for failing to submit expert testimony in support of its preliminary response.[11] In that case, the patent owner argued that the prior art did not disclose the claimed dosing regimen because the calculations conducted by petitioner's expert were erroneously based on linear kinetics rather than on the actual nonlinear kinetics and that, as such, there could be no reasonable expectation of success.[12] The board disagreed and found that without the benefit of expert testimony from patent owner, it could not give petitioner's arguments based on expert testimony less weight than those based on patent owner's attorney argument.[13]

Conclusion

Our review of institution decisions for IPR proceedings involving biopharma patents reveals that patent owners have not blindly embraced the use of NTE to support their preliminary responses — and for good reason. Reliance on NTE at the preliminary stage is not always necessary or even advisable. The use of NTE is least effective when it contributes to the creation of genuine issues of material fact, which the board is required to decide in favor of petitioner for purposes of institution. Thus, simply pitting the testimony from a patent owner's declarant against that of a petitioner's declarant will do little to prevent institution.

Similarly, the board will generally disregard NTE submitted with a preliminary response in favor of waiting for a fully developed record post-institution for issues that petitioner has not had a chance to address — and for which, in the board's view, petitioner does not have the initial burden of production. These include, for example, secondary considerations of nonobviousness or the antedating of a prior art reference. In such circumstances, patent owners may be well advised to keep NTE close to the vest pre-institution and to focus their efforts on more fruitful forms of attack. A strategy that has proven effective for patent owners is that of exposing weaknesses in a petition either because petitioner's evidence is lacking or it is somehow deficient. As our analysis shows, such attacks do not necessarily require the use of NTE to be successful.

In the end, the decision of whether or not to use NTE in support of a preliminary response involves consideration of multiple factors and may not necessarily be focused solely on preventing institution, but may involve other overarching considerations such as the potential for early settlement. A careful analysis of those strategic considerations is key to maximizing the impact of NTE in IPR proceedings.

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[1] Amendments to the Rules of Practice for Trials before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750 at 18,755 (Apr. 1, 2016).

[2] *Id.* See also 37 C.F.R. §42.108(c).

[3] See USPTO Trial Statistics, Patent Trial and Appeal Board (April 2018) (indicating a steady decrease in institution rate from 87% in fiscal year 2013 to 62% through April of fiscal year 2018).

[4] Procedural grounds include, for example, institutions denied because the Board found a petition redundant of an earlier petition under 35 U.S.C. § 325(d) or time-barred under 35 U.S.C. § 315(b).

[5] See e.g., *Modernatx, Inc. v. Curevac AG*, IPR2017-02194, Paper 9 (PTAB Apr. 18, 2018); *Ambry Genetics Corp. v. The Johns Hopkins University*, IPR2017-02093, Paper 8 (PTAB Mar. 19, 2018).

[6] See, e.g., *UPL Ltd. v. Agrofresh Inc.*, IPR2017-01919, Paper 8 (PTAB Mar. 7, 2018); *Pfizer, Inc. v. Genentech, Inc.*, IPR2017-01488, Paper 34 (PTAB Jan. 11, 2018).

[7] See, e.g., *Sanofi-Aventis U.S. LLC v. Immunex Inc.*, IPR2017-01879, Paper 19 (PTAB Feb. 15, 2018).

[8] See, e.g., *Acrux DDS Pty Ltd. v. Kaken Pharm. Co., Ltd.*, IPR2017-00190, Paper 12 (May 1, 2017).

[9] See, e.g., *Complete Genomics, Inc. v. Illumina Cambridge Ltd.*, IPR2017-02174, Paper 20 (PTAB Apr. 20, 2018), *Mylan Pharms. Inc. v. Shire Lab., Inc.*, IPR2017-00011, Paper 7 (PTAB Apr. 14, 2017), and *Mylan Pharms. Inc. v. AstraZeneca AB*, IPR2016-01325, Paper 11 (PTAB Dec. 14, 2016), respectively.

[10] See, e.g., *Sawai USA, Inc. v. Astellas Pharma Inc.*, IPR2018-00079, Paper 7 (PTAB May 4, 2018); *Hologic, Inc. v. Enzo Life Sci., Inc.*, IPR2018-00019, Paper 17 (PTAB Apr. 18, 2018); *Sandoz Inc. v. AbbVie Biotechnology Ltd.*, IPR2017-01987, Paper 15 (PTAB Mar. 9, 2018).

[11] See *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00805, Paper 13 (PTAB Jul. 27, 2017).

[12] *Id.* at 13.

[13] *Id.* at 15.