

THE PTAB REVIEW

November 2016

New Testimonial Evidence with Preliminary Responses: Panacea or Placebo?

Just over three years ago, during a keynote speech at the AIPLA annual meeting, the Patent Trial and Appeal Board (PTAB) was criticized as a patent “death squad” by then Chief Judge Randall Rader of the U.S. Court of Appeals for the Federal Circuit. At this year’s AIPLA meeting, new PTAB Chief Judge David P. Ruschke was still defending against that impression. Chief Judge Ruschke highlighted—as he has repeatedly throughout his short tenure—a rule change that went into effect on May 2, 2016, shortly before his appointment. The rule allows patent owners to submit new expert testimony with their preliminary responses. Previously, only the petitioner could present testimony that was new (i.e., created for the proceeding) in the petition stage. Patent owners expressed concern that this asymmetry favored petitioners. As Chief Judge Ruschke has explained, the change was “certainly in response to what the stakeholders were asking for.”

Chief Judge Ruschke has argued that the highlighted change “is having an effect” because patent owners are taking advantage of the opportunity to present such evidence. But practitioners are still asking whether such an effect is illusory or substantive. In particular, what impact, if any, could such testimony actually have on an institution decision?

Wilson Sonsini Goodrich & Rosati conducted an informal survey of the roughly two dozen institution decisions mentioning preliminary response testimony—out of nearly 500 institution decisions entered in the first few months under the new rules—in order to assess whether the filing of new testimonial evidence with a preliminary response had any meaningful impact on the PTAB’s decision whether to institute trial. Based on our review, we found that—consistent with practitioner expectations and with a few exceptions—new testimonial evidence submitted with preliminary responses has had little substantive impact on institution decisions.

By way of background, the rules originally adopted by the U.S. Patent and Trademark Office (USPTO) prohibited patent owners from submitting any new testimonial evidence with a preliminary response. 37 CFR §§ 42.107(c), 207(c) (August 14, 2012). For example, a patent owner could not submit expert testimony newly developed for the preliminary response to rebut testimony submitted with the petition. Among other things, this limitation was consistent with the inability to cross-examine witnesses prior to institution, and the role of the preliminary response in challenging whether the threshold requirements for institution had been met, as compared to the more complete presentation of evidence allowed with the patent owner response following institution. *See* 77 Fed. Reg. 48,689 (August 14, 2012) (comparing statutory authority for preliminary response and response with respect to new testimonial evidence). In essence, the proceedings were designed such that a patent owner’s preliminary response was more akin to a request for “summary judgment” identifying the lack of basis to proceed to the trial stage, rather than as an opportunity to conduct a mini trial before the trial stage.

As of May 2, 2016, however, the rules were amended to allow patent owners to file new testimonial evidence with a preliminary response. 37 CFR §§ 42.108(c), 208(c) (April 1, 2016). But the rules were also amended to minimize the impact of any such evidence, making clear that the PTAB will resolve any issues of material fact created by testimony submitted with a preliminary response in favor of the petitioner. *Id.* In other words, patent owners can now submit new testimonial evidence with a preliminary response, but consistent with the summary judgment-like nature of the preliminary proceedings, that evidence will only be given effect in the institution decision in the rare instance where there is no genuine issue of material fact.

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As expected, in the majority of cases reviewed, the submission of testimony with the preliminary response had no apparent effect. While assessing a limited sample size, our review found that there was no meaningful difference in the rate of institution based on whether or not new testimonial evidence was submitted with the patent owner's preliminary response. There was actually a slightly higher rate of institution when testimonial evidence was submitted (50 percent institution on all claims) compared to instances where no such evidence was submitted (45 percent institution on all claims).

In roughly half of the cases where a patent owner filed new testimonial evidence at the preliminary response stage, the PTAB did not even acknowledge that testimony was filed, but simply ignored it.

Most commonly in cases where such new testimonial evidence is mentioned in an institution decision at all, the PTAB resolved disputed issues in favor of the petitioner, as expressly provided by the rules. A typical scenario is one in which the witnesses for both parties dispute whether a prior art feature satisfies a claim limitation, leading to a genuine issue of material fact resolved against the patent owner on institution. For example:

- *Pungkuk EDM Wire Manuf. Co. v. Seong*, No. IPR2016-00762, Paper 15 at 10 (PTAB September 8, 2016) (“[F]or purposes of the present decision only, we must resolve the dispute . . . in Petitioner’s favor and accept the statement by Petitioner’s declarant.”)
- *WhatsApp Inc. v. Triplay, Inc.*, No. IPR2016-00718, Paper 17 at 15-16 (PTAB September 8, 2016) (“Because it would be premature for us to weigh the declarants’ testimony before either declarant is deposed, we decline the request.”)
- *Interactive Brokers LLC v. Chart Trading Dev., LLC*, No. CBM2016-00038, Paper 14 at 8 (PTAB August 23, 2016) (“Dr. Molokhia’s testimony . . . constitutes a genuine issue of material fact that will be viewed in the light most favorable to Petitioner at this stage of the proceeding for purposes of instituting a proceeding.”)
- *Coherus Biosci., Inc. v. Abbvie Biotech. Ltd.*, No. IPR2016-00188, Paper 8 at 14, 18 (PTAB June 13, 2016) (“Patent Owner’s arguments in this regard, at best, create genuine issues of material fact We find these factual disputes best resolved during trial when we are able to assess Petitioner’s and Patent Owner’s evidence and arguments upon review of the entire record.”)

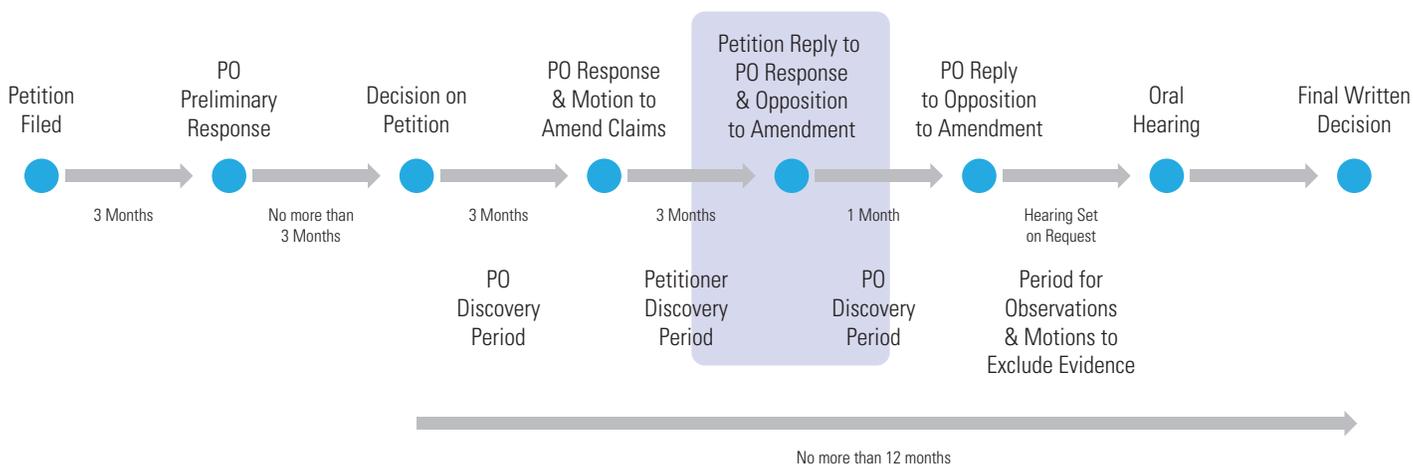
In fact, there have been very few instances in which testimonial evidence with a preliminary response has been credited by the PTAB as leading to denial of institution. One example is found in *Arris Group, Inc., et al. v. Mobile Telecomms. Techs., LLC*, No. IPR2015-00765, Paper 12 (PTAB September 21, 2016), in which the PTAB denied institution on the basis of testimonial evidence submitted with the preliminary response. There, the claims included a negative limitation, namely that a claimed plurality of carrier signals not include redundant information. The petition cited to a portion of the prior art that did not explicitly describe the signals as being non-redundant, but instead simply stated that “individual carriers are each modulated with one part of the digital data.” This argument had gained institution in previous IPR proceedings regarding the patent at issue (all of which settled immediately following institution). This time, however, the patent owner submitted evidence, including testimony from an expert, that the prior art procedures relied upon in fact included substantial redundancy. The PTAB found such evidence persuasive and denied institution on that basis. This is, in fact, the sort of issue that would be ripe for summary judgment, where the petitioner essentially relied on the absence of contrary evidence to meet a limitation, and due to the nature of negative limitations, the patent owner was able to prove the deficiency in the petition by submitting evidence, including new testimonial evidence.

It is also worth noting that new testimonial evidence submitted with a patent owner preliminary response may weigh against the interests of the patent owner, and should be carefully thought through prior to submission. For example, in *Arkema Inc. v. Honeywell Int’l Inc.*, No. PGR2016-00012, Paper 13 (PTAB September 2, 2016), the patent owner argued nonobviousness based on the unpredictability of the art, and submitted new testimonial evidence supporting its assertion of unpredictability. The PTAB then relied on that testimony regarding unpredictability in instituting a post-grant review on enablement and written description.

Ultimately, new testimonial evidence with preliminary responses may have little impact beyond giving the USPTO a talking point to pacify a particularly vocal segment of stakeholders. As far as practitioners are concerned, the change should not fundamentally alter preliminary response practice, which should focus on the arguments most likely to be effective pre-institution. Testimonial evidence may be helpful in the somewhat unique instance where a gap exists in the petitioner’s prima facie case that would otherwise not be apparent but for the submission of testimonial evidence. But testimonial evidence that simply tries to rebut the petitioner’s testimony, as might be done with the patent owner’s response during trial, is unlikely to be successful pre-institution.

Evolving Theories of Unpatentability Raise Red Flags at the PTAB and Federal Circuit

Proceedings before the Patent Trial and Appeal Board (PTAB), including *inter partes* review (IPR), post-grant review (PGR), and covered business method (CBM) review, are highly expedited proceedings for which each party has essentially a single opportunity to present its case. A petitioner makes its unpatentability case in its petition materials. If review is instituted, the trial stage (no longer than 12 months) is dedicated largely to exploring the merits of the petitioner’s unpatentability case as stated in the petition, and the patent owner’s substantive rebuttal to that case (i.e., the patent owner’s response). Besides limited discovery, a petitioner during the trial stage of an instituted proceeding is typically limited to the filing of a reply brief in response to the patent owner’s rebuttal case (see shaded box below). As a result of the compact nature of PTAB proceedings, the Federal Circuit and the PTAB have been forced to consider how to treat argument and evidence that arise late in the procedure—such as, in the petitioner’s reply brief or at oral argument.



The PTAB’s rules and practice guide underscore the limited nature of this petitioner reply:

“A reply may only respond to arguments raised in the corresponding [Patent Owner Response]. § 42.23. While replies can help crystalize issues for decision, a reply that raises a new issue or belatedly presents evidence will not be considered and may be returned. The Board will not attempt to sort proper from improper portions of the reply.” *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48,756, 48,767.

As such, thoroughly developing unpatentability theories and corresponding supporting evidence is of the utmost importance for petitioners seeking success before the PTAB. Recent Federal Circuit decisions confirm the necessity of such an approach.

The Federal Circuit has recently focused its attention on the procedural safeguards that protect the rights of parties involved in proceedings before the PTAB. These procedural safeguards derive from the Administrative Procedure Act (APA), which ensures that parties to an agency proceeding receive notice of the factual and legal matters at issue and have an opportunity to respond with evidence and argument. What constitutes adequate notice and opportunity to respond is well-established in the context of patent examination and reexamination. However, examination is procedurally different from IPR in which, as illustrated above, each party has one opportunity to present its case. As a result, argument and evidence that arise in the procedure, such as in the petitioner’s reply brief or at oral argument, have been met with skepticism by both the Federal Circuit and the PTAB.

“Unlike district court litigation—where parties have greater freedom to revise and develop their arguments over time and in response to newly discovered material—the expedited nature of IPRs bring with it an obligation for petitioners to make their case in their petition...”

— From *Intelligent Bio-Systems, Inc. v. Illumina*

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Consideration of New Argument in Reply Is Discretionary. Pursuant to the PTAB's rules and practice guide, as noted above, petitioners should expect that new argument or evidence first presented in reply will *not* be considered by the PTAB. In *Intelligent Bio-Systems, Inc. v. Illumina, Inc.*, 821 F.3d 1359 (Fed. Cir. 2016), the PTAB refused to consider a petitioner reply brief and accompanying expert declaration from Intelligent Bio-Systems because, among other reasons, it contained new argument and evidence in violation of 37 CFR § 42.23(b). The Federal Circuit affirmed the PTAB's decision saying that "the expedited nature of IPRs bring[s] with it an obligation for petitioners to make their case in their petition to institute."

The APA Requires an Opportunity to Respond When the Ground of Unpatentability Changes. Petitioners risk vacatur or reversal by the Federal Circuit if the PTAB does rely on a new unpatentability theory or evidence first raised in reply. In *Dell, Inc. v. Accelaron LLC*, 818 F.3d 1293 (Fed. Cir. 2016), the petitioner, Dell, presented evolving theories of unpatentability during the trial about which structure of a prior art embodiment met the claim limitation. Dell pointed to one structure in the petition, another in the reply brief, and yet another at oral argument. The PTAB relied on the structure presented for the first time at oral argument in finding the claim anticipated. The Federal Circuit vacated and remanded the affected part of the PTAB decision, finding that Accelaron was not afforded an opportunity to respond to the new unpatentability theory and, as such, its rights under the APA were violated. On remand from the Federal Circuit (IPR2013-00440, paper number 49), the PTAB chose to disregard both the new reply brief argument and oral hearing argument, rather than allow Accelaron to submit rebuttal evidence. The PTAB ultimately found the claims patentable.

An Opportunity to Respond to New Evidence Submitted in Reply Is Not Absolute. New evidence, however, is not per se improper simply because it is new or provided in reply. In *Genzyme Therapeutic Products, LP v. Biomarin Pharmaceutical, Inc.*, 825 F.3d 1360,1368 (Fed. Cir. 2016), the petitioner's obviousness ground relied on references that contained only *in vitro* experimental data, which the institution decision found predictive for the therapeutic protein claimed in the patents. Patent Owner, Genzyme, argued in response that *in vitro* data was not predictive of success in treating humans. In reply, Biomarin cited prior art that disclosed *in vivo* experiments performed on the same therapeutic protein. The PTAB found the claims obvious and cited to the *in vivo* prior art in support of its findings as to the state of the art. The Federal Circuit found that Genzyme's rights under the APA were not violated because the petitions made reference to the *in vivo* prior art, and therefore Genzyme was on notice that this art might be cited by the PTAB in the final written decision. Biomarin's argument in reply also did not materially depart from the unpatentability theory presented in the petition or adopted in the institution decision. The Federal Circuit reached a similar conclusion in *Belden, Inc. v. Berk-Tek LLC*, 805 F.3d 1064 (Fed. Cir. 2015).

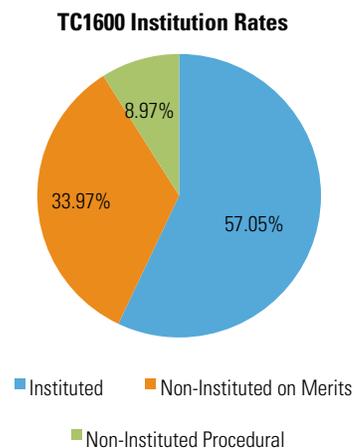
Procedural Rights Under the APA Apply to Petitioners. In *SAS Institute, Inc. v. ComplementSoft, LLC*, 825 F.3d 1341 (Fed. Cir. 2016), the PTAB construed a claim term in the final written decision in a manner that varied significantly from how it was construed in the institution decision. The Federal Circuit agreed with the ultimate construction, but remanded to the PTAB for further proceedings because the petitioner did not have notice of the changed construction and therefore was not in a position to present evidence and argument in response as provided by the APA.

These cases highlight the fact-specific nature of whether evidence submitted in reply is allowable. The Federal Circuit has signaled that the PTAB may simply disregard new argument presented in reply, as provided under the rules, and that decision will be reviewed with deference. Disregarding the evidence is the most efficient option for the PTAB, especially given the Federal Circuit's recent attention to procedural rights under the APA. As such, petitioners should ensure that all arguments and evidence necessary for proving unpatentability are in the petition. Petitioners should recognize that new evidence submitted with reply runs a high risk of not being considered by the PTAB. Conversely, patent owners should bring new arguments in reply to the PTAB's attention and specifically request the appropriate relief.

Are Biotech and Organic Chemistry Inventions More Difficult to Invalidate at the PTAB?

Questions often arise regarding outcomes for *inter partes* review (IPR) challenges to patents issuing from the Patent Office's 1600 Technology Center for Biotechnology and Organic Chemistry (TC1600) relative to other technology centers, such as computers and software. A comparison of IPR outcomes for TC1600 patents versus general Patent Office statistics¹ indicates that IPR petitions for TC1600 patents are instituted less frequently than average but that institution is a significant threshold that frequently leads to cancellation of some or all instituted claims.

As shown in the adjacent graphs, non-joinder institution rates for TC1600 patents of approximately 57 percent are lower than the overall average of 71 percent. Still, more than half of non-joinder IPR institution decisions for TC1600 patents through mid-2016 granted

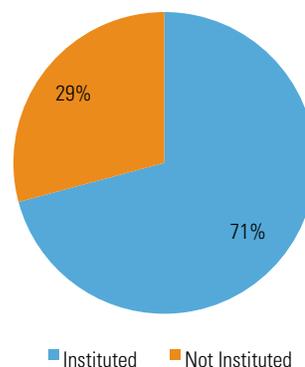


institution. Of the approximately 43 percent of challenges that resulted in a non-institution decision, almost 9 percent of all decisions on institution denied institution based on some procedural issue, as opposed to evaluating the merits of the challenge.

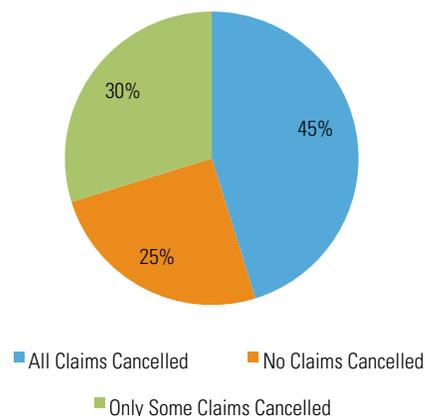
For patents related to therapeutic compounds, questions commonly arise whether institution rates vary depending on if the challenge is to a claimed chemical compound (e.g., structural obviousness) as opposed to claims to formulations or methods of treatment using the compound. A review of non-joinder institution decisions in the 1600 Technology Center through mid-2016 reveals that formulations and methods of treatment patents had institution rates in the low-to-mid sixty percent range, whereas the institution rate for compound patents was approximately 48 percent. In other words, it is harder for a petitioner to achieve institution in a structural obviousness case than in a formulation or method of treatment case, but it is by no means impossible.

Though the PTAB institutes an IPR trial for TC1600 patents less frequently than other patents, our analysis also suggests that final IPR results for TC1600 patents may be comparable to PTAB averages. For TC1600 patents, 25 percent of trials resulted in all challenged claims of the patent being upheld. Coupled with a 43 percent non-institution rate, this means that approximately 57 percent of all IPR challenges for TC1600 patents that reach an institution decision resulted in no claims being cancelled. In comparison, PTO statistics indicate that overall approximately 61 percent of challenged claims are either not instituted in the first place or are subsequently found patentable in a final written decision. Similarly, approximately 45 percent of final written decisions for TC1600 patents found that all claims should be cancelled, compared to Patent Office IPR statistics indicating that approximately 51 percent of instituted claims are found unpatentable in a final written decision. In each case, the chances of survival of claims for TC1600 patents appears to be about average, and the chances for petitioner success appear to improve substantially once the petition clears the initial threshold of institution.

Overall IPR Institution Rate



IPR Trial Outcomes for TC1600 Patents



¹ Patent Office claim outcome data through June 2016 obtained from <https://www.uspto.gov/sites/default/files/documents/2016-6-30%20PTAB.pdf>.

About Our Post-Grant Practice

The professionals in Wilson Sonsini Goodrich & Rosati's post-grant practice are uniquely suited to navigate the complex trial proceedings at the United States Patent and Trademark Office (USPTO). We have extensive experience before the PTAB, representing clients in numerous new trial proceedings and in countless reexaminations and patent interference trials. Our practice includes professionals with decades of experience at the PTAB, including former PTAB personnel. As the needs of a case may require, our team also collaborates with other WSGR professionals, including district court patent litigators and patent prosecutors, with technical doctorates or other advanced technical degrees. Our core team leverages firmwide intellectual property expertise to provide comprehensive IP solutions for clients that cover strategy, prosecution, licensing, enforcement, and defense.

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