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Mail Stop Patent Board  
Director of the United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
Attn: Acting Deputy Chief Administrative Patent Judge Jacqueline Wright Bonilla or  
Vice Chief Administrative Patent Judge Michael Tierney  
PTAB Request for Comments 2018

Re: Request for Comments on Motion to Amend Practice and Procedures in Trial  
Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board  
83 Fed. Reg. 54,319 (Oct. 29, 2018)  
Docket No. PTO-P-2018-0062

Dear Judges Bonilla and Tierney:

We submit this comment on behalf of Mylan Pharmaceuticals Inc. (“Mylan”), who commends the U.S. Patent and Trademark Office (“PTO” or “Agency”) on its continued commitment to ensuring U.S. patent quality and enhancing the post-grant review proceedings created by Congress under the America Invents Act (“AIA”). Mylan appreciates the opportunity to provide comments to the Agency in response to the Agency’s *Request for Comments on Motion to Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board*.

Mylan is one of the largest generic and specialty pharmaceutical manufacturers in the world. It is dedicated to providing greater public access to high-quality medicines by bringing lower-priced drugs and biologics to the market. Mylan has fought tirelessly to bring patients the earliest possible access to more affordable medicines. In approximately the last five (5) years alone, Mylan’s patent challenges in district courts and through *inter partes* review (“IPR”) have allowed consumers to benefit from earlier access to generic competition for more than \$35 billion of annual costs of branded drug products. To do so, Mylan has erased more than 285 years of life from improperly granted patent claims that would otherwise have continued to block lower-priced competition.

Mylan thanks the PTO for considering these comments and would welcome any further dialogue or opportunity to assist the PTO in this matter.

## INTRODUCTION

The PTO's proposed amendment process ("Proposal") is directed to motions to amend challenged claims in IPR, post-grant review ("PGR"), and covered business method ("CBM") proceedings (collectively, "AIA Proceedings"), and specifically proposes an "amendment process that would involve a preliminary non-binding decision by the Board that provides information to the parties regarding the merits of a motion to amend, and an opportunity for a patent owner to revise its motion to amend thereafter." *Request for Comments on Motion To Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 54,319, 54,319 (Oct. 29, 2018). Additionally, the PTO seeks comments regarding a proposed pilot program for implementing the new amendment process. *Id.* Finally, the PTO "seeks input regarding whether the Office should continue to allocate the burden of persuasion regarding patentability of substitute claims" on the petitioner. *Id.*; *id.* at 54,321.

Currently, a patent holder whose patent has been challenged in an AIA Proceeding may file a single motion to amend, in which it can: (1) cancel any challenged claim or (2) propose substitute claims to replace the challenged claims. 35 U.S.C. § 316(d); *id.* § 326(d); 37 C.F.R. § 42.121(a); *id.* § 42.221(a). In the event a patentee wishes to file a subsequent motion to amend, it must seek prior authorization from the Patent Trial and Appeal Board ("PTAB" or "Board") and show good cause for why a second motion to amend should be allowed. 35 U.S.C. § 316(d)(2); *id.* § 326(d)(2); 37 C.F.R. § 42.121(c); *id.* § 42.221(c). Under the current framework, a motion to amend must be filed no later than the time period for filing a patent owner response, or three months after a trial is instituted. 37 C.F.R. § 42.121(a)(1); *id.* § 42.221(a)(1); *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Moreover, each AIA Proceeding must be completed within one year of institution, which may only be extended by six months for good cause. 35 U.S.C. § 316(a)(11); *id.* § 326(a)(11).

The Proposal introduces a new non-binding preliminary decision on the patent owner's motion to amend—to be issued well before the record on the original challenged claims is complete; a second chance for the patent owner to propose all new substitute claims; and up to four (4) additional filings (*i.e.*, the patent owner's revised motion to amend, petitioner opposition, patent owner reply, and petitioner surreply), all within a condensed four (4)-month timeframe.

For the reasons discussed below, the PTO should maintain its current motion-to-amend practice, which is consistent with the plain language of the relevant statutes and the framework for AIA Proceedings as a whole. Congress' principle purpose in crafting new AIA proceedings was to "improve patent quality by expanding the role of third parties to the patent examination process, *creating a streamlined first-window, postgrant review to quickly challenge and weed out patents that never should have been issued in the first place.*" 157 CONG. REC. S5347, S5354 (daily ed. Sept. 7, 2011) (statement of Sen. Leahy) (emphasis added); *see also id.* at S5375 (statement of Dr. Michael W. McConnell) (as with the previous post-issuance reexamination proceedings, Congress created "a mechanism for removing patents that should never have been granted by the PTO because they did not meet the requirements for a valid

patent set by Congress in the Patent Act”). A sudden shift to the current amendment process proposed by the PTO is fundamentally at odds with the stated purpose of creating an efficient patent examination mechanism to reassess earlier patentability decisions. The PTO has offered no sufficient justification for departing from its well-settled practice and Congressional intent; nor is the Proposal “fair” or “balanced,” as alleged in the request for comment. The Proposal also decouples the AIA Proceeding from the amendment process and shifts the Board’s (and the parties’) focus from the prior patentability decision to the patent owner’s proposed amended claims—claims that may never even issue in a contingent system. Consequently, for these reasons, and those set forth below, if the Proposal is implemented through a pilot program with no proposed end date, and without the benefit of formal rulemaking, the PTO’s actions would be arbitrary and capricious. Additionally, Mylan believes the PTO should engage in formal rulemaking in order to properly allocate the burden of persuasion for proposed substitute claims solely to the patent owner.

### **DISCUSSION**

The Proposal listed seventeen (17) questions, reproduced below, to which the PTO is soliciting responses from the public. Mylan provides its responses to each question in turn.

#### ***1. Should the Office modify its current practice to implement the proposal summarized above and presented in part in Appendix A1? Why or why not?***

The PTO should not modify its current practice and certainly not in order to implement the current Proposal. Doing so would frustrate the underlying purpose of the AIA, which was to provide a quick and efficient administrative procedure to weed out patents that should never have issued in the first place. *See, e.g.*, 157 CONG. REC. S1036-37 (daily ed. Mar. 1, 2011) (statement of Sen. Klobuchar); 157 CONG. REC. H4220, H4425 (daily ed. June 22, 2011) (statement of Rep. Goodlatte). IPR is an especially important tool for knocking out unpatentable claims that unnecessarily delay access to more affordable medicines. The Proposal threatens to undermine the effectiveness of this critical tool in several ways:

*First*, the Proposal lacks an adequate explanation, let alone an actual justification, for departing from the current motion to amend practice—a practice that fits within the contours of the governing statute, and is already working. The relevant statutory framework provides for one—and only one—motion to amend by right. 35 U.S.C. § 316(d); *id.* § 326(d). Yet, as the PTO recognized, despite already having an absolute right to amend, patent owners have filed motions to amend in only about 10% of completed AIA trials. *Proposed Motion to Amend Practice*, 83 Fed. Reg. at 54,321. Some of these motions have been successful, though the majority have not. *Id.* But the fact that patent owners have not managed to put forth patentable substitute claims, or otherwise met the statutory and regulatory requirements for a motion to amend, does not mean that the PTO should give them multiple shots on goal. Nevertheless, this low success rate seems to be the *only* reason offered by the PTO to modify its practice, despite the absence of *any* evidence that the current procedure is to blame for the low success rate.

Simply put, the current method is not broken, and does not need fixing. The PTO has not offered any empirical evidence that connects the low number of motions to amend filed, let alone granted, with the current amendment procedure. Indeed, according to the PTO's Motion to Amend Study, the number of motions to amend increased in the last year—even under the current system. *Proposed Motion to Amend Practice*, 83 Fed. Reg. at 54,321. Further, *nothing* in the statute has changed, and the PTO is not simultaneously changing or relaxing the requirements for motions to amend that would necessitate additional guidance on how to meet these requirements. There is no reason to assume that patent owners were not already making their best cases for patentable substitute claims, nor will a preliminary decision turn unpatentable claims into patentable ones. The fact is, there are *numerous* reasons that likely account for the low number of motions filed in the first place—reasons that are likely completely unrelated to the amendment procedure itself. For example, patent owners may be hesitant to narrow claims to such an extent that doing so would decrease their chances of success against accused infringers. Moreover, uncertainty regarding the status of claims that a patent owner has moved to amend; fear of intervening rights; or strong invalidating prior art all provide legitimate reasons, unrelated to the procedure itself, that a patent owner may be hesitant to amend its patent claims. Patent owners already have an opportunity to propose claims as narrow as the law will allow—there is no reason to believe that an early preliminary decision will entice patent owners to narrow the scope of their claims to such an extent that they would no longer capture subject matter that the original broad claims were meant to cover just because a second opportunity to amend exists.

*Second*, far from making the motion to amend process “fair and balanced for all parties,” the Proposal seems geared solely toward incentivizing motions to amend by giving the patent owner multiple opportunities to propose substitute claims for challenged claims. All at the expense of the petitioner who, under the Proposal: 1) would have a more condensed time frame to respond; 2) would not have the benefit of the patent owner's response before it was forced to oppose the patent owner's first motion to amend; and, 3) would be forced to conduct additional prior art searches with each phase of the proceeding and within a more limited period of time, including with respect to potentially *two* sets of substitute claims. Moreover, by forcing the petitioner to file its opposition to the patent owner's motion to amend before it receives the patent owner response, the petitioner may be at risk of making arguments (and construing claims) in its opposition in a way that may not be useful, or worse, conflict with, those arguments it may wish to make in its reply. Again, this new proposed process flies in the face of the purpose of AIA Proceedings, which is to provide an opportunity to reexamine the patentability of already issued claims and finds no support in the statute. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016). Patent owners already have a right to amend that they rarely exercise, likely for reasons unrelated to the amendment procedure, as discussed above. In these circumstances, incentivizing patent owners to file more motions is not only unnecessary, but threatens to take the teeth out of, and wildly unbalance, a process that is already working as intended.

*Third*, by significantly increasing the potential number of filings and by introducing a new preliminary decision early in the AIA proceeding, the Proposal seriously threatens to derail the critical timelines imposed by Congress, not to mention the very purpose of

the AIA as a whole. To ensure that AIA Proceedings would be conducted within a predictable timeline, Congress imposed a strict statutory timeframe wherein each proceeding must be completed within one year of institution, which may only be extended by six months for good cause. 35 U.S.C. § 316(a)(11); *id.* § 326(a)(11). Given these time constraints, the PTO is already pressed to complete AIA examinations within the prescribed time period. In fact, the PTO has previously recognized that additional briefing regarding motions to amend would be “incompatible” with the prescribed schedule for AIA Proceedings. *Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board*, 80 Fed. Reg. 50,720, 50,724 (proposed Aug. 20, 2015). The Proposal completely ignores these concerns, however, adding costly, resource-intensive briefing requirements for both the patent owner and the petitioner, triggering up to four (4) additional filings (i.e., revised motion to amend, petitioner opposition, patent owner reply, petitioner sur-reply), all within a condensed four (4)-month time frame. The Proposal also imposes additional demands on an already overwhelmed Board, who will have to issue not just one but two written decisions. And while the preliminary decision called for in the Proposal is non-binding, it is safe to assume that, even so, it will be well-considered and based on a thorough examination of all the arguments and evidence submitted to the Board—all of which is also incompatible with the already tight time constraints.

Furthermore, the additional costs associated with the added briefing and discovery needed would “frustrate the purpose” of AIA proceedings as an alternative route to challenging patents. H.R. REP. NO. 112-98, pt. 1, at 48 (2011). According to a 2015 American Intellectual Property Law Association (“AIPLA”) Economic Survey, the median cost of an IPR through a PTAB hearing was \$275,000, while the average cost of patent infringement litigation, with \$1-\$10 million at risk, is closer to \$1 million through the end of discovery and \$2 million through final disposition. AIPLA 2015 REPORT OF THE ECONOMY SURVEY 37, 43 (2015). The PTO has previously recognized that adding additional discovery or briefing to the process would result in increased costs and could “negatively impact the ability of the Office to meet the statutory requirements” of AIA Proceedings. *August 2015 Proposed Amendments*, 80 Fed. Reg. at 50,725; *see also Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board*, 81 Fed. Reg. 18,750, 18,758 (Apr. 1, 2016) (recognizing “[b]ecause Congress intended AIA proceedings to be a quick and cost-effective alternative to litigation, the statute provides only limited discovery in trial proceedings before the Office”). Additional briefing could disincentivize the filing of petitions due to the increased costs, which threatens the usefulness of AIA proceedings as an effective administrative procedure to weed out patents that should never have issued in the first place.

*Fourth*, the Proposal effectively decouples the current AIA Proceedings from the procedure to amend claims by switching the focus of the proceedings to the potential patentability of the proposed substitute claims instead of the patentability of the challenged claims and the “earlier administrative grant of a patent.” *Cuozzo*, 136 S. Ct. at 2144. Under the current procedure, both the Board and the parties focus first and foremost on the patentability of the challenged claims in a petition—exactly as they should. *See Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1370, 1373 (2018) (IPR is “reconsideration of the Government’s decision to grant a public franchise” and evolved from Congress’ creation of “administrative processes [such as ex parte and inter partes reexam] that authorize the PTO to

reconsider and cancel patent claims that were wrongly issued.”). For instance, if the Board deems the challenged claims patentable, it may never even reach a decision on the patentability of the claims that were the subject of the motion to amend—that question becomes moot. Moreover, under the existing schedule, regardless of the timing of the patent owner’s motion to amend, the petitioner will always have the benefit of having received the patent owner’s response prior to filing its opposition to the motion to amend. In contrast, under the Proposal, before the Board even considers the claims challenged in a petition, it is tasked with reviewing both parties’ initial arguments and supporting prior art with respect to the patent owner’s proposed substitute claims—something the Board is not tasked with doing under the current procedure until it issues its final written decision, if at all. Moreover, as noted above, the petitioner is forced to respond to the patent owner’s motion to amend before it has even seen the patent owner response.

*Fifth*, the Proposal forces the Board to issue a written decision on proposed substitute claims—however preliminary—that is not based on a full record and that could impact the question of patentability of the *challenged* claims—claims that have not themselves been construed and for which testimony has not been examined. More specifically, whether binding or not, any preliminary determination on a patent owner’s motion to amend would necessarily require the Board to construe claims and likely opine on at least some of the same prior art applicable to the original claims at issue in the IPR. Yet, the preliminary determination would not have the benefit of the full trial proceeding, including the petitioner reply, or any discovery of declarants, including cross-examination. This hampers the ability of the Board to do its job and prejudices the parties—particularly the petitioner, who is forced to oppose the motion to amend in a condensed time frame and before receiving the patent owner response—all of which places practical limitations on the petitioner’s ability to submit an opposition that is as well-supported and complete as it is permitted to do now.

*Sixth*, allowing the patent owner a second opportunity to amend its claims may result in fewer petitions overall due to the uncertain estoppel risks. Under the estoppel provision of 35 U.S.C. § 315(e) (and also § 325(e)), a petitioner could potentially face estoppel arguments with respect to multiple patentability issues raised in a patent owner’s motion to amend (or revised motion to amend) that it could not have anticipated prior to the filing of its IPR petition. *See Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1310 (Fed. Cir. 2017) (“Where the petitioner bears the burden, it is logical to estop the petitioner from raising that ground in the future, whether related to originally challenged claims or entered amended claims.”). This runs counter to the purpose of these proceedings and could result in fewer petitions due to this added risk. *See Patent Quality Improvement: Post-Grant Opposition: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 108th Cong. 16 (2004) (statement of James A. Toupin, General Counsel, U.S. Patent and Trademark Office) (explaining that the new post-grant proceedings were “designed to be more efficient than litigation while preserving enough of the full participation according to parties in litigation that challengers will be able to risk being able to be bound by the result”). A petitioner cannot be expected to anticipate whether (or how) a patentee may amend its claims when it files its petition—let alone how the patent owner may revise its claims a second time.

In sum, the Proposal finds no support in the statute and offers no clear benefit to the parties or the Board, yet, without question, it will add additional burdens on the parties and the Board, will prejudice the petitioner, and runs contrary to the purpose of the AIA Proceedings as a whole.

***2. Please provide comments on any aspect of the proposed amendment process, including, but not limited to, the content of the papers provided by the parties and the Office and the timing of those papers during an AIA trial.***

As explained above, Mylan does not believe that any part of the PTO's proposed amendment process should be implemented. However, if the Proposal were implemented, as an initial matter, and at the very least, the filing deadline for the petitioner's opposition should be moved back so that the petitioner has sufficient time to respond and has the benefit of reviewing the patent owner response prior to filing. Under the Proposal, the petitioner has just six (6) weeks after receiving the patent owner's motion to amend to oppose that motion, at which time the petitioner would not have received the patent owner response. *Request for Comments*, 83 Fed. Reg. at 54,325 (Appendix A1). Thus, the petitioner would be required to conduct prior art searches and address potentially new patentability arguments on an incomplete record—without understanding how the patent owner planned to support its patentability arguments with respect to the *original* claims, including for example, any claim construction positions the patent owner planned to take. As a result, under the current Proposal, the petitioner could be forced into making arguments and seeking a claim construction with respect to the substitute claims that could hurt it later in its reply. Moreover, six weeks is simply not sufficient, especially given that, currently, the petitioner has the burden of persuasion regarding patentability. Thus, at the very least, the petitioner should be afforded the three (3)-month period it previously enjoyed to assess any new patentability issues or run any new prior art searches, just as the patent owner still has three (3) months to submit its response.

*Second*, if the PTO were to implement its two (2)-staged motion to amend process, given the strain such additional briefing and discovery would put on the proceedings, a patent owner who chooses to engage in the motion to amend process should be limited to proceeding with the amended claims on a non-contingent basis and deemed to have conceded the unpatentability of all originally-challenged claims. If the parties and the Board were otherwise forced to proceed on a contingent basis, there is significant risk that the statutory one (1)-year deadline could not be met, and the petitioner would be severely prejudiced. By way of example, under the PTO's proposed timeline, the parties would be forced to simultaneously engage in discovery on the original claims, any substitute claims, and potentially a *second set* of revised substitute claims, effectively forcing the parties to present respective cases on up to three (3) pending sets of claims. This would likely result in not only delays in the already tight schedule to complete AIA Proceedings, but could also result in the petitioner not having sufficient time to take necessary discovery on its main arguments relevant to the original claims. Ignoring the time pressures surrounding this procedure and the imbalance to the parties would be arbitrary, at best.

*Third*, any proposed change to the amendment procedure should at the very least limit the number of substitute claims that may be introduced by the patent owner—this is absent from the current Proposal. Without such limitation, the patent owner could introduce hundreds

of substitute claims, and in some cases more than one set of those claims, resulting in a significant burden on the petitioner and the Board. This is particularly so if the burden of persuasion continues to rest with the petitioner to show that any amended claims are not patentable, since new prior art searches will take considerable time and resources. Unless some limitations are imposed, the Congressional deadline for completing these proceedings could be in jeopardy.

*Fourth*, and finally, if the PTO's goal here truly is to "provide an improved amendment practice in AIA trials in a manner that is fair and balanced for all parties," the patent owner should not be permitted to submit a brand new set of revised amended claims in response to the preliminary decision—it places the petitioner back at square one in terms of preparing and supporting any arguments against patentability and forces the Board to review and examine an entirely new set of substitute claims in its final written decision. *Proposed Motion to Amend Practice*, 83 Fed. Reg. at 54,320. Thus, *if* any preliminary decision is to be issued, given that it would be issued on an incomplete record and without the benefit of fully developed arguments or claim construction positions, it should be limited to addressing (1) any procedural reasons the motion to amend was denied, (2) whether the claims improperly enlarge the scope of the patent, and (3) whether the patent owner presents an unreasonable number of substitute claims. This would prevent the patent owner from putting forth all new substitute claims in its revised motion to amend. It also ensures that any substantive analysis of the patentability of any substitute claims would be reserved for consideration upon a fully developed record. *See Aqua Prods.*, 872 F.3d at 1325 (finding "[t]he Board must base its patentability determinations on the entirety of the record before it"); *id.* ("That final substantive decision must be based on *the entirety* of the record. Basic principles of administrative law compel this conclusion" (emphasis in original)). Limiting the scope of the preliminary decision in this manner further comports with the governing statutory framework, which provides for only one full motion to amend as of right.

***3. How does the timeline in Appendix A1 impact the parties' abilities to present their respective cases? If changes to the timeline are warranted, what specific changes are needed and why?***

As discussed above, under the current Proposal, the petitioner would be required to respond to the patentability and appropriateness of proposed substitute claims without the benefit of having reviewed the patent owner response. Thus, the petitioner would be required to conduct prior art searches and address potentially new patentability arguments on an incomplete record—without the benefit of the patent owner's arguments regarding patentability of the original claims, including for example, the patent owner's claim construction positions. At the very least then, *if* a new motion to amend procedure is adopted, the petitioner should be afforded three (3) months to oppose the motion, to allow the petitioner the benefit of having reviewed the patent owner response, and also to provide additional time for any necessary additional prior art searches. In fact, the current amendment procedure—which offers the petitioner three (3) months to oppose any motion to amend—was adopted by the PTO with the understanding that it needed to account for the lack of further examination of substitute claims by the Agency, while also adhering to the structural limitations of AIA Proceedings:

The Board does not conduct a prior art search to evaluate the patentability of the proposed substitute claims, and any such requirement would be impractical given the statutory structure of AIA proceedings. If a motion to amend is granted, the substitute claims become part of an issued patent, without any further examination by the Office. Because of this constraint, the Office has set forth rules for motions to amend that account for the absence of an independent examination by the Office where a prior art search is performed as would be done during prosecution, reexamination, or reissue.

*August 2015 Proposed Amendments to the Rules*, 80 Fed. Reg. at 50,724.

Additionally, the decoupling of the proposed amendment procedure from the rest of the proceedings gives the patent owner an opportunity to engage in discovery regarding its amended claims that the petitioner does not have. Specifically, under the proposed timeline, the patent owner submits its motion to amend and the petitioner submits its opposition, before the petitioner has an opportunity to engage in discovery of the patent owner and its potential deponents. Conversely, the patent owner is able to engage in discovery of the petitioner both before and after submission of its motion to amend and prior to the submission of its patent owner response. Such an imbalance threatens the very framework of AIA Proceedings that sought to carefully balance the rights of third parties and patent owners in an effort to promote a healthier patent system. *See* 152 CONG. REC. 16,834, 16,998 (Aug. 6, 2006) (statement of Sen. Leahy) (recognizing “the delicate balance we have struck in the post-grant review process” and the desire to “make certain that the procedure is both efficient and effective at thwarting some strategic behavior in patent litigation and at promoting a healthier body of existing patents”).

***4. If the Office implements this proposal, should the Board prepare a preliminary decision in every proceeding where a patent owner files a motion to amend that proposes substitute claims?***

If the PTO begins issuing preliminary decisions, it should do so in all cases. Uncertainty as to whether the parties would be subjected to the PTO’s preliminary decision and two-staged amendment practice, with its accompanying accelerated timelines, would make planning and strategy more difficult and complex. As discussed below, however, even if there is a presumption that a preliminary decision will be made, the parties should be allowed to opt out of the two-staged amendment procedure and proceed with a single motion to amend with no early preliminary decision, if jointly agreed upon.

***5. What information should a preliminary decision include to provide the most assistance to the parties in presenting their case? For example, is there certain information that may be particularly useful as the parties consider arguments and evidence to present in their papers, how issues may be narrowed for presentation to the Board, and/or whether to discuss a settlement?***

As discussed above, to the extent the PTO engages in providing preliminary decisions, any preliminary decision should be limited to addressing (1) any procedural reasons

for denial of a motion to amend, (2) whether the claims improperly enlarge the scope of the patent, and/or (3) whether the patent owner presents an unreasonable number of substitute claims. Any substantive analysis of the patentability of any substitute claims should be reserved for consideration upon a fully developed record. *See Aqua Prods.*, 872 F.3d at 1325.

***6. If the Office implements this proposal, should there be any limits on the substance of the claims that may be proposed in the revised motion to amend? For example, should patent owners be permitted only to add limitations to, or otherwise narrow the scope of, the claims proposed in the originally-filed motion to amend?***

If the PTO were to implement its Proposal, any patent owner filing a revised motion to amend should only be permitted to address the issues raised in the preliminary response. And as discussed above, to the extent the PTO engages in providing preliminary decisions, any preliminary decision should be limited to addressing (1) any procedural reasons for denial of a motion to amend, (2) whether the claims improperly enlarge the scope of the patent, and/or (3) whether the patent owner presents an unreasonable number of substitute claims. In such a case, there would be *no* new substitute claims submitted as part of the patent owner's revised motion to amend. That said, the patent owner would still be permitted to respond to any objections raised under 35 U.S.C. §§ 316(d)(3) or 326(d)(3) and explain why the original substitute claims did "not enlarge the scope of the claims of the patent or introduce new matter."

***7. What is the most effective way for parties and the Office to use declaration testimony during the procedure discussed above? For example, how and when should parties rely on declaration testimony? When should cross-examination of declaration witnesses take place, if at all, in the process? At what stage of briefing should a party be able to rely on cross-examination (deposition transcripts) testimony of a witness?***

If the patent owner intends to rely upon declaration testimony in support of its motion to amend, then such declarant(s) should be made immediately available to the petitioner for deposition following submission of the motion to amend. This allows the petitioner to use cross-examination testimony in its opposition and the Board to rely on such cross-examination testimony in providing its preliminary decision.

***8. If a petitioner ceases to participate in an AIA trial and the Board solicits patent examiner assistance regarding a motion to amend, how should the Board weigh an examiner advisory report relative to arguments and evidence provided by a patent owner? What type of assistance or information should a patent examiner provide? Should prior art searches by examiners be limited to those relevant to new limitations added to proposed substitute claims and reasons to combine related to such limitations?***

[No comment.]

***9. Should the Board solicit patent examiner assistance in other circumstances, and if so, what circumstances? For example, should the Board solicit patent examiner assistance***

***when the petitioner remains in the AIA trial but chooses not to oppose the motion to amend?***

No. AIA proceedings are structured to provide a quick and efficient administrative procedure to weed out patents that should never have issued in the first place. *See, e.g.*, 157 CONG. REC. at S1036-37; 157 CONG. REC. at H4425. All determinations thus should be adjudicated by the expert judges of the Board that are tasked, and likely more experienced, with such determinations, not patent examiners that issued such patents in the first instance. In fact, from its very inception, the PTO recognized that revised post-grant review proceedings should be in front of panel of administrative patent judges with “experience in dispute resolution.” *Patent Quality Improvement: Post-Grant Opposition: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 108th Cong. 16 (“The USPTO proposes a review model different from reexamination, namely, a genuinely contested case presided over by a panel of administrative patent judges . . . .”); *id.* (“The USPTO’s proposal is thus designed to put review of the propriety of patent claims that the public regards as important in the hands of senior, legally-qualified officials with experience in dispute resolution.”). The PTO has had the opportunity to involve patent examiners in these proceedings before now and has declined to do so. *See April 2016 Amendments to the Rules*, 81 Fed. Reg. at 18,755. Nothing in the Proposal changes the need to involve judges experienced in dispute resolution—in fact, given the highly complicated structure of the Proposal, it is critical that, if such Proposal were implemented, expert judges are the ones making both the preliminary and final written decisions in AIA Proceedings.

***10. Should a motion to amend filed under the proposed new process be contingent or non-contingent? For purposes of this question, “contingent” means that the Board will provide a final decision on the patentability of a proposed substitute claim only if it determines that a corresponding original claim is unpatentable (as in the current proposal); and “non-contingent” means that the Board will provide a final decision on the patentability of substitute claims in place of determining the patentability of corresponding original claims.***

If a patent owner chooses to engage in the proposed amendment procedure, it should proceed with the amended claims on a non-contingent basis, having made the choice to abandon/cancel all original claims that have been challenged. As noted above, if the PTO were to adopt a two-staged motion to amend process, given the prejudice this would have on the petitioner and the huge negative impact this could have on the ability of the parties and the Board to meet the statutory deadline, any patent owner who chooses to file a motion to amend should be deemed to have conceded the unpatentability of all originally-challenged claims, leaving only the substitute claims at issue and effectively canceling the original claims. In light of this, any amendment process would necessarily be non-contingent.

This is consistent with the statutory framework already in place and the Federal Circuit’s interpretation of the same. Pursuant to 35 U.S.C. §§ 318(a) and 328(a), if the Board issues a final written decision in an AIA Proceeding, it must do so “with respect to the patentability of any patent claim challenged by the petitioner ***and any new claim added.***” And as the Federal Circuit has recognized, “Congress expressly demanded that the Board adjudicate

the patentability of proposed substitute claims under § 318(a),” thus, “the Board must assess patentability of proposed substitute claims on the record of the IPR, even if no petitioner opposes the proposed claims.” *Aqua Prods.*, 872 F.3d at 1349 (Taranto, J., Prost, J., Chen, J., Hughes, J., dissenting and joined in part in other respects by Dyk, J., Reyna, J.); *see also id.* at 1309 (majority opinion) (“the Board must assess the patentability of all claims in the proceeding, including amended claims that have been entered into the proceeding”).

In contrast, if the Proposal were adopted on a contingent basis without limiting the patent owner to its proposed substitute claims, the patent owner would be allowed to have three sets of potentially viable claims in play at the same time (*i.e.*, those at issue in the petition, the first motion to amend, and revised motion to amend). Specifically, under the Proposal, the patent owner potentially has two opportunities to raise new issues of patentability based on amended claims. Conversely, a petitioner must address (and brief, with expert support) new issues of patentability raised by the patent owner, perhaps twice, and in a condensed time period. Further, the petitioner could be subject to estoppel arguments on any new prior art raised that was not contemplated by the petitioner at the time of filing, therefore significantly limiting the petitioner’s defenses in any further proceeding or litigation. Given the significant burden on the petitioner and strain on the already extended resources of the Board, as noted above, if a patent owner chooses to engage in the proposed amendment procedure, it should thus proceed with the amended claims on a non-contingent basis, having made the choice to abandon/cancel all original challenged claims. This would limit the amount of briefing required by both parties, and limit the claims at issue, which gives the petitioner (and the Board) more clarity as to which claims, and which “version” of the claims, are in dispute.

***11. If the Office implements the proposal in which the Board issues a preliminary decision on a motion to amend, as discussed above, should any additional changes be made to the current default trial schedule to accommodate the new practice?***

As noted above, if the Proposal were adopted and implemented on a non-contingent basis, this would reduce the amount of briefing required and the potential sets of claims at issue—the originally challenged claims would be deemed abandoned or cancelled, and no petitioner reply or patent owner surreply would be necessary. However, if the Proposal were adopted and implemented on a contingent basis, as discussed above, the petitioner should be given three (3) months to respond to any motion to amend, so that the petitioner has the benefit of having reviewed the patent owner’s response before having to conduct prior art searches and address new patentability arguments with respect to the patent owner’s motion to amend.

***12. What impact would implementing the proposals above have on small or micro entities who participate as parties in AIA trial proceedings?***

[No comment.]

***13. Should the Office consider additional options for changing the timing and/or the Board’s procedures for handling motions to amend that are not covered by the proposals above? If so, please provide additional options or proposals for the Office to consider, and discuss the advantages or disadvantages of implementation.***

As discussed above, the PTO fails to provide adequate explanation for its departure from the current statutory amendment process, which provides a patent owner whose patent has been challenged in an AIA Proceeding the right to file a single motion to amend, and requires good cause for any further amendment. 35 U.S.C. § 316(d); *id.* § 326(d); 37 C.F.R. § 42.121(a), (c); *id.* § 42.221(a), (c). The Proposal does not provide any rationale for departing from the requirement of good cause for any further amendment, which was proposed as part of the framework of post-grant proceedings long before the statutory language prescribing AIA Proceedings was even finalized. (*See Patent Quality Improvement: Post-Grant Opposition: Hearing Before the Subcomm. On Courts, the Internet, and Intellectual Property of the H. Comm. On the Judiciary*, 108th Cong. 45 (statement of Michael K. Kirk, Executive Director, AIPLA) (“A patent owner would have the right to amend the claims of the patent as a part of the patent owner’s response to the opposition request. Any amended claim could not enlarge or broaden the subject matter claimed in the patent. Subsequent amendments could only be made upon a showing of good cause.”). Thus, any proposal implemented by the PTO should limit the patent owner to one motion to amend by right, with good cause required for anything further, consistent with both the statutory language and the framework of AIA Proceedings. 35 U.S.C. § 316(d); *id.* § 326(d); 37 C.F.R. § 42.121(c); *id.* § 42.221(c).

Moreover, as discussed above, any preliminary determination would not have the benefit of the full trial proceeding, including the patent owner response, or any discovery of declarants, including cross-examination, etc. Therefore, not only would the determination be non-binding, it would be incomplete and could potentially lead to confusion for both parties, particularly if a fully developed record leads to a differing outcome, and thus Mylan would advocate for no preliminary decisions.

As discussed above, neither the Proposal nor current procedure limits the number of claims that may be amended by the patent owner, or the number of substitute claims that may be included in a motion to amend (or revised motion to amend). Any proposed change to the amendment procedure should limit the number of substitute claims that may be introduced by the patent owner for at least the reasons discussed above.

***14. Should the Office consider not proceeding with the pilot program in AIA trials where both parties agree to opt-out of the program?***

Yes. The PTO should allow the parties the opportunity to opt-out of the pilot program and proceed under the current amendment procedure. However, the parties should be given a deadline by which they must agree to opt-out (such as one week after the Institution Decision), so that the parties will know what to expect from a timing and strategy perspective.

***15. Should the Office engage in rulemaking to allocate the burden of persuasion regarding the patentability of proposed substitute claims in a motion to amend as set forth in the Western Digital order? What are the advantages or disadvantages of doing so?***

Mylan believes that the PTO should engage in rulemaking to allocate the burden of persuasion with respect to the patentability of substitute claims; however, that burden should fall on the *patent owner*, not the petitioner, consistent with the PTO’s prior practice.

The rationale behind presumptively patentable substitute claims runs counter to the PTO's practice in examination. As it currently stands under *Western Digital*, "the burden of persuasion will ordinarily lie with the petitioner to show that any proposed substitute claims are unpatentable." *W. Dig. Corp. v. Spex Techs., Inc.*, IPR2018-00082 (P.T.A.B. Apr. 25, 2018) at 4. This decision has no statutory or regulatory basis, however, and such a stark departure from the PTO's prior practice should not occur without the benefit of the formal rulemaking process.

Importantly, such rulemaking would also not conflict with the Federal Circuit's decision in *Aqua Products*. That decision focused heavily on the PTO's failure, to date, to engage in formal rulemaking on this very issue, and the lack of deference to which the PTO's prior practice was entitled as a result. See, e.g., *Aqua Prods.*, 872 F.3d at 1319-22 (majority opinion); *id.* at 1328-34 (Moore, J., Newman, J., O'Malley, J. concurring); *id.* at 1338-40 (Reyna, J., Dyk, J., dissenting). However, nothing in *Aqua Products* prevents the PTO from engaging in this important rulemaking now, or from shifting the burden back to the patent owner, as Congress intended. *Id.* at 1328 (Moore, J., Newman, J., O'Malley, J. concurring); *id.* at 1335, 1341 (Reyna, J., Dyk, J., dissenting, Prost, J., Taranto, J., Chen, J., Hughes, J., dissenting in part). The PTO can—and should—engage in formal rulemaking on this issue pursuant to its promulgating authority under 35 U.S.C. §§ 316(a)(9) and 326(a)(9). This will give the PTO the opportunity to examine the relevant statutory authorities, and solicit comments, after which it can adopt the statutory interpretation most in line with the text and purpose of the AIA: placing the burden of persuasion on the patent owner.

Allowing the burden of persuasion to remain with the petitioner effectively means that any proposed substitute claims are *per se* patentable and requires a petitioner to show otherwise. However, given that an IPR is effectively, and is considered to be, a continued examination, the burden to show that a claim is patentable should always rest with the patent owner. The presumption of validity and heightened evidentiary standard in litigation arise from deference to the PTO's specialized expertise. See, e.g., *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007) (holding courts presume validity because "the PTO, in its expertise, has approved the claim"). But deference to administrative expertise is not an issue during initial examination, reexamination, or IPR when the PTO reviews its own work to correct its own mistakes before a patent is the subject of a full infringement and validity proceeding. Indeed, time and time again the PTO has recognized that substitute claims are not subject to an independent examination by the Agency, and thus, not only are they not entitled to deference, but they require a patent owner to affirmatively establish the patentability of the claims. *April 2016 Amendments to the Rules*, 81 Fed. Reg. at 18,754; *August 2015 Proposed Amendments to the Rules*, 80 Fed. Reg. at 50,724. The burden of persuasion should thus fall on the patent owner when filing a motion to amend, in part to account for the lack of examination and prior art search that would normally be performed by the PTO. See *Aqua Prods.*, 872 F.3d at 1340-41 (Reyna, J., Dyk, J., dissenting, Prost, J., Taranto, J., Chen, J., Hughes, J., dissenting in part), 1352 (Taranto, J., Prost, J., Chen, J., Hughes, J., dissenting and joined in part in other respects by Dyk, J., Reyna, J.).

If the burden of persuasion for substitute claims continues to fall on the petitioner, AIA Proceedings will effectively turn into yet another court of validity. This could discourage

would-be patent challengers from initiating AIA proceedings, as the patentee gets the added benefit of authoring substitute claims which are presumed valid, and yet the full scope of defenses is not available to a petitioner as it would be in district court patent challenges. Thus, the PTO should engage in formal rulemaking in order to properly allocate the burden of persuasion for potential substitute claims solely on the patent owner.

***16. If the Office continues to allocate the burden as set forth in the Western Digital order, under what circumstances should the Board itself be able to justify findings of unpatentability? Only if the petitioner withdraws from the proceeding? Or are there situations where the Board itself should be able to justify findings of unpatentability when the petitioner remains in the proceeding? What are the advantages or disadvantages?***

The Board should always be permitted to justify findings of unpatentability, whether asserted by the petitioner or not, and whether or not the petitioner withdraws from the proceeding. *Bosch Auto. Serv. Sols., LLC v. Matal*, 878 F.3d 1027, 1040 (Fed. Cir. 2017), *as amended on reh'g in part* (Mar. 15, 2018). This comports with the PTAB's statutory role as the gatekeeper of patentability:

The Director's important role as a gatekeeper and the Board's authority to proceed in the absence of the parties convinces us that the USPTO is acting as the United States in its role as a superior sovereign to reconsider a prior administrative grant and protect the public interest in keeping patent monopolies "within their legitimate scope."

*Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1329 (Fed. Cir. 2018); *see also Aqua Prods.*, 872 F.3d at 1311 ("[W]here the challenger ceases to participate in the IPR and the Board proceeds to final judgment, *it is the Board* that must justify any finding of unpatentability by reference to the evidence of record in the IPR.") (emphasis in original) (citing *Cuozzo*, 136 S. Ct. at 2144)). Thus, the PTO should always have the option of cancelling claims that should never have been allowed in the first instance.

***17. If the Office adopts the current proposal including a preliminary decision by the Board on a motion to amend, do the answers to questions 15 and 16 change?***

No. Regardless of whether the PTO adopts the Proposal, the PTO should still resolve questions 15 and 16 as discussed above.

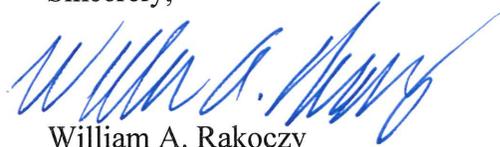
\* \* \*

In conclusion, Mylan respectfully urges the PTO to maintain the current amendment procedure, which was designed, consistent with Congressional intent, to create an efficient and balanced process for reconsidering, and canceling where necessary, patent claims that were wrongly issued.

Mylan appreciates the opportunity to provide comments regarding the proposed amendment procedure, as well as on the potential for rulemaking on the issue of the burden of

persuasion, and appreciates the PTO's consideration of these comments. Mylan supports the PTO's on-going commitment to work with the patent community and industry to ensure that AIA Proceedings continue to be an efficient mechanism that allows the Agency to revisit and reassess patents it may have issued in error.

Sincerely,



William A. Rakoczy  
on behalf of Mylan Pharmaceuticals Inc.