abbvie

June 20, 2023

The Honorable Kathi Vidal
Director
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

RE: Docket No. PTO-P-2020-0022: Advance Notice of Proposed Rulemaking on Changes Under Consideration to Discretionary Institution Practices, Petition Word-Count Limits, and Settlement Practices for America Invents Act Trial Proceedings Before the Patent Trial and Appeal Board

Dear Director Vidal:

AbbVie appreciates the opportunity to respond to the USPTO's Advance Notice of Proposed Rulemaking on Changes Under Consideration to Discretionary Institution Practices, Petition Word-Count Limits, and Settlement Practices for America Invents Act Trial Proceedings Before the Patent Trial and Appeal Board (ANPRM). AbbVie is a global, research-based biopharmaceutical company. Since our launch in 2013, we have invested about $60 billion in research to discover, develop and deliver new medicines. Today, we employ approximately 50,000 people around the world. Our mission is to discover and deliver innovative medicines and products that solve serious health issues and enhance people's lives today and address the medical challenges of tomorrow.

AbbVie supports the ANPRM's stated purpose of better aligning the practices of the Patent Trial and Appeal Board (PTAB) with the USPTO's mission to promote and protect innovation and investments in innovation.[1] We encourage the UPSTO to propose clear rules that will promote certainty and predictability in the patent system, facilitate efficient resolution of patentability disputes, and deter abuse.

AbbVie invests in highly risky research and development efforts that yield life-changing biopharmaceutical products but often fail. And even successful innovations generally require many years and millions of dollars of investments. Without reliable and predictable intellectual property rights, these investments simply would not be viable. Therefore, we have a vested interest in fully vetting our patent claims during the examination process and defending their validity against subsequent challenges. We are confident in our inventions, and we place our trust in the U.S. patent system to fulfill the founders' vision of "securing for limited times to … inventors the exclusive right to their … discoveries."[2] When Congress passed the AIA and created PTAB trial proceedings, it recognized the importance of providing confidence in patent rights to enable ongoing investments in tomorrow's technological revolutions and medical advances.[3] Subjecting

[1] ANPRM, 88 Fed. Reg. 24,503 (Apr. 21, 2023).

[2] U.S. Const. art. I, § 8, cl. 8 ("the Intellectual Property Clause").

[3] *See* H.R. Rep. No. 112-98, pt. 1, at 48 (2011) (recognizing "the importance of quiet title to patent owners to ensure continued investment resources").

Google Exhibit 1093
Google v. Mullen

the same patent claims to multiple or overlapping challenges undermines this confidence, deters investment, invites gamesmanship, imposes undue burdens on patent owners and the USPTO, and also raises the question of whether the USPTO would be able to "secure" the patent right to the inventors as required by the US Constitution.[4]

Accordingly, AbbVie supports efforts to more closely align PTAB proceedings with the congressional intent of "establish[ing] a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs."[5] To that end, we offer the following targeted comments on certain proposals discussed in the ANPRM.

1. Mandatory *Sotera* Stipulations Provide a Clear and Predictable Approach to Parallel Proceedings

Forcing patent owners to defend the patentability of their claims in PTAB trial proceedings in parallel with validity challenges in district court or ITC litigation imposes undue burdens, duplicates costs, and increases the risk of inconsistent results. That is true in Hatch-Waxman litigation, as courts are particularly unlikely to stay such litigation pending IPR or PGR proceedings.[6] As such, patent owners engaged in 271(e) litigation often face parallel validity challenges in multiple forums absent a discretionary denial at the PTAB under the existing *Fintiv* framework.[7]

AbbVie strongly supports the ANPRM's suggestion that a mandatory *Sotera* stipulation requirement could replace the existing *Fintiv* framework for evaluating parallel litigation or serve as "a necessary but not sufficient basis for institution" in the face of parallel proceedings in district court or the ITC.[8] As properly recognized in the ANPRM, a *Sotera* stipulation, which prevents a

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[4] The Intellectual Property Clause empowers Congress to promote the progress of useful arts by "securing" for limited times to inventors the exclusive right to their discoveries. The only other place the word "secure" is used in the original U.S. Constitution is in the Preamble ("We the People of the United States, in Order to … secure the Blessings of Liberty to ourselves and our Posterity, do ordain and establish this Constitution of the United States of America"). The meaning of the word "secure" has not significantly changed since the founding of our nation. If a granted patent can be readily and repeatedly reviewed by the USPTO for error or mistake, even during a parallel litigation where the patent is asserted and the same error or mistake is challenged, the granted patent would be anything but "secured."

[5] H.R. Rep. No. 112-98, pt. 1, at 40; *see also* 37 C.F.R. § 42.1(b) (providing that the rules governing PTAB trial proceedings "shall be construed to secure the just, speedy, and inexpensive resolution of every proceeding").

[6] *See, e.g.*, The Sedona Conference Working Group 10 on Patent Litigation Best Practices (WG10), *Commentary on Patent Litigation Best Practices: Biopharma Litigation Chapter* 34 (Oct. 2021), https://thesedonaconference.org/sites/default/files/publications/WG10_Patent_Lit_Best_Practices_Biopharma_Chapter_October_2021_public_comment.pdf ("In the Hatch-Waxman context, there is generally a strong incentive to deny a stay request pending IPR/PGR, because courts are disinclined to allow the litigation to extend beyond the 30-month regulatory stay and hence increase the likelihood of an at-risk launch, which may lead to preliminary injunction proceedings."); *see also id.* at 36 ("To date, in the absence of the agreement of the parties, courts have yet to extend the 30-month regulatory stay in light of a pending IPR or PGR").

[7] *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15, at 7-8 (PTAB May 13, 2020) (precedential) (providing factors for evaluating whether efficiency and the integrity of the patent system are best served by discretionarily denying institution in view of parallel proceedings).

[8] ANPRM, 88 Fed. Reg. at 24,516; *see also See Sotera Wireless, Inc.* v. *Masimo Corp.,* IPR2020-01019, Paper 12, at 18-19 (PTAB Dec. 1, 2020) (precedential) (determining that the petitioner's stipulation not to pursue "any ground

petitioner from using any reference or relying on any ground that reasonably could have been raised (even if was not actually raised) in an IPR, "effectively minimizes concerns related to the overlapping issues and duplicative efforts that may [otherwise] result."[9] Thus, requiring all petitioners to file such stipulations is an elegant solution that prevents PTAB trial proceedings from becoming parallel proceedings rather than the "quick and cost-effective ***alternatives*** to litigation" envisioned by Congress.[10] We see no reason not to apply this requirement to both IPR and PGR proceedings.

For similar reasons, AbbVie would also support a mandatory stipulation regarding multiple proceedings within the USPTO. For example, the ANPRM suggests the possibility of "requiring petitioners to file a stipulation that neither they nor their privy or real parties have filed post-grant proceedings ... as to any of the challenge claims; and that if their post-grant proceeding is instituted, neither they nor their privy or real parties in interest, will challenge any of the challenged claims in a subsequent post-grant proceeding."[11] Making such stipulations mandatory would help ensure that AIA trial proceedings are not "used as tools for harassment … through repeated litigation and administrative attacks on the validity of a patent."[12]

2. The "Compelling Merits" Standard Is Unclear and Unnecessary

AbbVie urges the USPTO to retract the "compelling merits" standard introduced last year as an exception to discretionary denials under *Fintiv*.[13] In our view, this standard is unclear, promotes inconsistent and undesirable results, and should not serve as an exception to any of the discretionary denial frameworks, much less all of them as contemplated in the ANPRM.[14]

We disagree with this standard for several reasons. *First*, permitting any new, USPTO-created standard to outweigh all of the other discretionary considerations within the authority granted by Congress is poor policy. *Second*, the definition of "compelling merits" remains largely ambiguous, imprecise, and difficult to understand. We have not been able to identify any judicial decision that would help shed light on the contours of this proposed standard. The ANPRM attempts to clarify that "compelling merits" is a higher standard than the familiar preponderance of the evidence standard, but fails to explain how it compares to the clear and convincing evidence

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raised or that could have been reasonably raised in an IPR" "mitigates any concerns of duplicative efforts … as well as concerns of potentially conflicting decision," and that this stipulation "ensures that an *inter partes* review is a 'true alternative' to the district court proceeding").

[9] ANPRM, 88 Fed. Reg. at 24,515.

[10] H.R. Rep. No. 112-98, pt. 1, at 48 (emphasis added);

[11] ANPRM, 88 Fed. Reg. at 24,517.

[12] H.R. Rep. No. 112-98, pt. 1, at 48.

[13] *See* Director's Memorandum Regarding Interim Procedure for Discretionary Denials in AIA Post-grant Proceedings with Parallel District Court Litigation (June 21, 2022), https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf.

[14] *See* ANPRM, 88 Fed. Reg. at 24,508 (noting that "the Office is considering whether the compelling merits standard should apply as an exception to all of the bases for discretionary denial").

standard applied in district court validity litigation.[15] *Third*, imposing a higher (but imprecisely defined) standard than § 314(a)'s "reasonable likelihood" threshold standard for institution could promote inconsistency in application. *Fourth*, a new exception to discretionary denials is not necessary. As discussed above, for example, a *Sotera* stipulation provides a more elegant solution to effectively address parallel district court or ITC proceedings. We suggest omitting the "compelling merits" standard from any proposed rules.

3. The Office Should Adhere More Closely to the Plain Language and Congressional Intent of 35 U.S.C. § 325(d)

We welcome efforts to clarify the scope and applicability of § 325(d), which provides that the Director may reject an *ex parte* reexamination request, IPR petition, or PGR petition if "the same or substantially the same prior art or arguments previously were presented to the Office." This discretion provides an important safeguard against duplicative patentability challenges. We fully support the ANPRM's proposed clarification that § 325(d) applies to ***any*** prior proceedings "involving the challenged patent or a ***related*** patent or application,"[16] particularly references or arguments previously presented in any parent, child, or other related patent or application. However, the ANPRM also suggests that the USPTO is considering limiting the application of § 325(d) in several other material ways that would supersede already unduly restrictive precedent.[17] AbbVie has concerns regarding many aspects of these proposals. For example, we disagree with the proposal of "limiting the application of [§ 325(d)] to situations in which the Office previously ***addressed*** the prior art or arguments."[18]

Instead of redefining or revising rules for determining whether art or arguments previously were explicitly "considered," "addressed," or "evaluated" on the record, we urge the USPTO to consider a different approach that more closely aligns with the statute's plain language. On its face, § 325(d) permits discretionary denial where the art or arguments "were ***presented*** to the Office."[19] In other words, if the applicant, examiner, patent owner, or a challenger presented the same or substantially the same art or arguments to the Office during any prior proceeding, the PTAB should be empowered to deny institution, regardless of whether the Office issued an express articulation of reasons to reject the art or arguments. That approach comports with not only the plain language of the statute, but also congressional intent.[20] For example, Senator Kyl explained that—unlike the prior statute governing *inter partes* reexamination—the AIA resolves a problem with those

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[15] *See id.*

[16] *Id.* at 24,512 (emphasis added).

[17] *See, e.g.*, *Becton, Dickinson & Co.* v. *B. Braun Melsungen AG,* IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (precedential as to section III.C.5, first paragraph); *Advanced Bionics, LLC* v. *Med-El Elektromedizinische Geräte GmbH,* IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential).

[18] ANPRM, 88 Fed. Reg. at 24,512 (emphasis added).

[19] 35 U.S.C. § 325(d) (emphasis added).

[20] *See, e.g.*, H.R. Rep. No. 112-98, pt. 1, at 76 (noting that § 325(d) permits the USPTO to "decline requests for repeated proceedings on the same question"); 157 Cong. Rec. S1042 (daily ed. Mar. 1, 2011) (statement of Sen. Kyl) (noting that § 325(d) "allows the Patent Office to reject any request for a proceeding … if the same or substantially the same prior art or arguments previously were presented to the Office with respect to that patent").

previous proceedings. In particular, he noted that "[t]he Office has generally declined to apply estoppel … to an issue that is raised in a request for inter partes reexamination if the request was not granted with respect to that issue," but that under § 325(d), "the Office could nevertheless refuse a subsequent request … with respect to such an issue, even if it raises a substantial new question of patentability, because the issue previously was presented to the Office in the petition for inter partes or post-grant review."[21] Senator Kyl thus directly addressed the situation in which art or arguments were ***presented*** to the Office but not expressly ***addressed***. That approach respects the efforts of patent applicants who present the best-known art to the examiner with the expectation that it will be considered prior to the Office allowing patent claims.

Assuming that the same or substantially the same art or arguments were previously presented to the Office, petitioners should bear a higher burden to overcome this presumption of finality. We support the use of the current "material error" standard, which the ANPRM appears to support, to address factual issues such as anticipation or written description or the underlying factual inquiries for other legal questions.[22] For obviousness, enablement, or other issues for which the ultimate determination is a question of law, we urge the Office to require the petitioner to show that the previous determination by the examiner or Office conflicts with a clearly established Federal Circuit precedent or an unambiguous controlling statute. This approach would promote further clarity and predictability and avoid reweighing previously presented evidence as a basis for initiating post-grant proceedings.

We also suggest adopting the potential proposal discussed in the ANPRM for handling situations in which a patent owner raises factual questions that cannot be resolved at institution, such as objective indicia of non-obviousness. In particular, we agree that—in this context—"the Office should adopt a test whereby (1) the record will be viewed in the light most favorable to the patent owner and (2) the Board will draw all reasonable inferences in favor of patent owner."[23]

More generally, we urge the USPTO to consider clarifying many of the potential proposals discussed in the ANPRM, including language such as "intends to pursue commercialization," "exceptional circumstances," and disclosure requirements that potentially incorporate the notoriously difficult-to-understand "beneficial ownership" concept.

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[21] 157 Cong. Rec. S1376 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl).

[22] *Compare* ANPRM, 88 Fed. Reg. at 24,512 ("It will not be considered material error if reasonable minds can disagree regarding the purported treatment of the art or arguments."), *with Advanced Bionics*, IPR2019-01469, Paper 6, at 8-9 ("If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.").

[23] *Id.*

AbbVie appreciates the opportunity to submit comments. We look forward to continued dialogue with the agency and other stakeholders on these issues. If you require further clarification on any of the comments provided above, please do not hesitate to contact us.

Respectfully submitted,

AbbVie Inc.
1 North Waukegan Road
North Chicago, Illinois 60064