

**Comments of the Pharmaceutical Research and Manufacturers of America in Response 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 (Docket No. PTO-P-2020-0022)**

**June 20, 2023**

**I. Introduction**

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments in response to the United States Patent and Trademark Office’s (USPTO) 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, 88 Fed. Reg. 24,503 (Apr. 21, 2023) (“the Notice”).

PhRMA represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA’s member companies have invested more than \$1.1 trillion in the search for new treatments and cures, including \$102.3 billion in 2021 alone. The biopharmaceutical industry is committed to working every day to discover and develop new treatments and cures for patients battling serious and life-threatening diseases such as heart disease, cancer, Alzheimer’s, and, most recently, COVID-19, while also anticipating and preparing for the next pandemic. These new treatments and cures are made possible by the American system of intellectual property (IP) protections.

IP protections are essential for biopharmaceuticals given the costly, lengthy and risky process for discovering, developing, and obtaining FDA approval for medicines. It is important that the USPTO maintain the IP protections afforded by the Patent Act in order to foster research and development of innovations that benefit patients. PhRMA appreciates the work of the USPTO in providing incentives for innovation in biopharmaceuticals and other sectors, including its ongoing work to provide leadership to improve IP protections domestically and internationally.

As the Office contemplates broad regulatory changes to America Invents Act (AIA) trial proceedings before the Patent Trial and Appeal Board (PTAB), PhRMA urges the Office to evaluate potential proposals through the lens of the following principles.

**A. The Importance of Clarity and Predictability**

The Notice contemplates the potential for broad changes across nearly all types of discretionary denials at the PTAB, which would displace a significant body of precedent upon which petitioners, patent owners, and the Board rely every day. PhRMA encourages the prioritization of clear rule proposals that will promote predictable results.

Many of the potential proposals in the Notice include mutually exclusive alternatives and definitions, as well as multiple variations on rules and exceptions. The Notice also invites yet further proposals. As a result, it is difficult to discern not only the contours of any potential rules,

but also the Office’s ultimate regulatory direction in this space. The lack of clarity makes it challenging to provide productive comments at this stage, but PhRMA has endeavored to provide productive feedback on the potential proposals discussed in the Notice and looks forward to additional opportunities to engage with the USPTO on this important topic.

## **B. The Importance of Promoting Fair and Efficient Adjudication**

Congress intended the AIA to promote streamlined and cost-effective adjudication of patentability disputes and to discourage abusive and inefficient patent challenges. Adjudicating overlapping challenges, abusive serial challenges, redundant challenges, and parallel challenges in multiple forums does not promote the goals of the AIA or the integrity of the patent system. Patent challengers (and related parties) should be held to a “single bite at the apple” to promote efficiency, fairness, and finality, as well as the patent owner’s right to enjoy quiet title of its IP.<sup>1</sup> Consistent with the goals of the AIA, patent challengers should be incentivized to bring their best art and arguments in a single challenge in a single forum.

## **C. The Importance of Case-Specific Analyses**

Congress sought to create an alternative to district court litigation when enacting the AIA and creating PTAB proceedings. In many cases where there is already ongoing district court litigation on patents challenged in a PTAB petition, the litigation is stayed or the PTAB proceeding is resolved long before the district court comes to a conclusion. However, patents covering biopharmaceutical inventions are distinct because they are also subject to established statutory frameworks that set timelines and procedures for patent disputes in order to allow generic and biosimilar products to reach the market efficiently. The institution of a PTAB proceeding can subvert the Hatch-Waxman framework and other statutory frameworks, including the BPCIA, when the challenged patent is also subject to one of these frameworks.

Congress also granted broad discretion to the Board at the institution phase to police abuse. PhRMA suggests that the Office retain the statutory authority granted by Congress to reject petitions filed for purposes that run counter to the goals of the AIA, the interests of fairness and efficiency, and the reputation and integrity of the Office and the U.S. patent system.

## **II. PhRMA Suggests Not Adopting the “Compelling Merits” Standard**

PhRMA urges the Office *not* to adopt “compelling merits” as an independent exception to any of the bases for discretionary denial. The standard is not well-understood, and misapplication could swallow the potential discretionary denial rules. The interests of predictability, finality, efficiency, and fairness would be undermined by a rule that permits an imprecise measuring of the merits to override any competing factors weighing against institution, such as the burdens imposed on the parties and the Office, the possibility of gamesmanship, and the need for finality.

Since its introduction, the “compelling merits” standard has resisted precise definition. Unlike the “preponderance of the evidence” or “clear and convincing evidence” standards, which benefit from rich jurisprudential histories and widespread understanding among the bar and

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<sup>1</sup> 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,” and noting that AIA trial proceedings “are not to be used as tools for harassment or a means to prevent market entry through repeated litigation and administrative attacks on the validity of a patent.”).

stakeholders, the “compelling merits” standard was introduced for the first time last year.<sup>2</sup> The Notice indicates that the Office intends “compelling merits” to be higher than the “preponderance of evidence” standard applied at the conclusion of the proceeding, as well as the threshold institution standards,<sup>3</sup> but the exact contours of the standard remain murky.<sup>4</sup> The Notice exacerbates this confusion by using additional vague and imprecise terms in an attempt to define the standard, such as “firm conviction” and “highly likely.”

This uncertainty regarding the standard’s interpretation fosters unpredictable outcomes and may present oversight challenges to ensuring that the Board does not conflate the “compelling merits” exception with the lower statutory thresholds for institution.

Moreover, while consideration of the merits may be appropriate in the context of certain discretionary denial determinations,<sup>5</sup> PhRMA suggests that it should not serve as an absolute exception to any of the discretionary denial frameworks. To the extent the Office proposes retaining the “compelling merits” standard, PhRMA supports the Notice’s suggestion that the Board should not reach it until evaluating all other discretionary denial issues, and that when the patent owner raises factual questions, the Board should view the record in the light most favorable to the patent owner and draw all reasonable inferences in favor of the patent owner.<sup>6</sup>

### **III. PhRMA Supports Using Discretionary Denials to Recognize “Prior Adjudications Upholding Validity”**

PhRMA supports efforts to promote finality regarding an issued patent’s validity, particularly where courts or the PTAB previously have issued “prior final adjudications” as the Notice contemplates. Indeed, ignoring prior validity adjudications and instituting *additional* proceedings cannot be squared with Congress’s intent to provide “quick and cost-effective *alternatives* to litigation.”<sup>7</sup>

According to the Notice, one potential proposal would require the Board to deny institution of IPR petitions where prior final adjudications upheld the validity of claims that “substantially overlap” the challenged claims, subject to an exception addressed below. PhRMA supports the spirit of this potential proposal, as well as the Notice’s suggestion of expanding its

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<sup>2</sup> 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](https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621.pdf).

<sup>3</sup> See 35 U.S.C. §§ 314(a) (“a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition”), 324(a) (“more likely than not that at least 1 of the claims challenged in the petition is unpatentable”).

<sup>4</sup> See, e.g., Nicholas Matich, *Vidal’s Latest Director Review Decisions Fail to Simplify the ‘Compelling Merits’ Analysis*, IPWatchdog (Mar. 9, 2023), <https://ipwatchdog.com/2023/03/09/vidals-latest-director-review-decisions-fail-simplify-compelling-merits-analysis/id=157472/>.

<sup>5</sup> See *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15, at 8 (PTAB May 13, 2020) (precedential) (providing, as one of the factors to evaluate in the context of parallel proceedings, “other circumstances ... including the merits”).

<sup>6</sup> PhRMA suggests caution in opening the door to pre-institution discovery, which would add further complexity and potential delay to what Congress intended to be a streamlined process.

<sup>7</sup> H.R. Rep. No. 112-98, Part 1, at 48 (emphasis added).

scope to include certain prior *ex parte* reexamination decisions, which present similar policy concerns, and triggering the rule without waiting for the exhaustion of appeals, which can take years. PhRMA would additionally encourage the Office to consider including prior *inter partes* reexamination decisions within the scope of the potential proposal as well. Furthermore, PhRMA also supports the Notice's potential definition of "substantially overlap" to include situations in which at least one of the challenged claims is the same or "substantially the same" (i.e., any differences are not material to patentability) as a previously adjudicated claim.

According to the Notice, the potential proposal includes an exception for when the petitioner: (1) has Article III standing or "intends to pursue commercialization of a product or service in the field of the invention of a challenged claim;" (2) was not a real party in interest (RPI) or privy to the prior challenger (unless the prior challenge was not resolved on the merits); and (3) meets the "compelling merits" test. While PhRMA does not oppose the exception in principle, it merits further refinement, and PhRMA offers several suggestions to that end.

For example, the potential exception expressly incorporates the "compelling merits" standard, which suffers from imprecision as discussed above. Should the Office retain the standard, however, PhRMA is more supportive of using it in this type of context, where demonstrating compelling merits is an element of the petitioner's burden and not an exception that independently overrides a rule. Additionally, the qualification for prior challenges not resolved on the merits is confusing and appears unnecessary in the vast majority of cases because the potential rule itself would apply only to prior "final, appealable decision[s]." PhRMA also suggests using the broader "substantial relationship" definition for the second prong of the potential exception both as a matter of policy and for consistency with other potential proposals discussed in the Notice. PhRMA further notes that determining whether a petitioner "intends to pursue commercialization" could prove difficult and lead to additional pre-institution disputes at odds with the streamlined proceedings envisioned by Congress.

#### **IV. PhRMA Supports a Case-Specific Approach to Limiting Abusive and Inefficient Serial Petitions**

PhRMA supports efforts to limit repetitive and redundant challenges to the same patent, which invite gamesmanship, impede finality, and impose undue burdens on patent owners and the Office. For that reason, PhRMA has previously supported the promulgation of a rule providing for case-specific analysis for deciding whether to institute review on claims that previously have been challenged in another petition, such as generally outlined in *General Plastic*, *Valve I*, and *Valve II*.<sup>8</sup>

The Notice suggests potentially replacing *General Plastic* and its progeny with a rule that the Board would deny any serial IPR or PGR petition filed by the same petitioner or related parties subject to two exceptions: earlier petitions not resolved on the merits and "exceptional

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<sup>8</sup> See PhRMA, Comments on the USPTO's Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board (Docket No. PTO-C-2020-0055) at 2 (Dec. 3, 2020) ("2020 PhRMA Comments") (citing *General Plastic Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19, at 16 (PTAB Sept. 6, 2017) (precedential); *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00062, Paper 11, at 9-10 (PTAB Apr. 2, 2019) (precedential) ("*Valve I*"); *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00064, Paper 10, at 9-11 (PTAB May 1, 2019) (precedential) ("*Valve II*").

circumstances.” PhRMA in principle supports limiting serial petitions filed by the same petitioner or related parties but notes that inefficient serial petitions can be filed by parties having no relationship to the initial petitioner, and serial petitions can also be abusive or otherwise inappropriate despite an earlier discretionary denial. Therefore, PhRMA suggests that the Office should exercise its discretion broadly to deny petitions filed by any party that pose the risk of duplicative or inefficient proceedings or would serve to harass a patent owner that has already successfully defended the patentability of the challenged claims at least during original examination and has already received at least one post-grant challenge to those claims. Likewise, PhRMA suggests retaining flexibility to address abusive serial petitions regardless of how those prior challenges were resolved.

To the extent the Office proposes a rule limited to certain petitioners, PhRMA supports the Notice’s suggestion that such a rule should encompass not only the same petitioner and its RPIs or privies, but also any party with a “significant relationship” to that petitioner,<sup>9</sup> or a party who previously joined the prior instituted proceeding.<sup>10</sup> PhRMA also supports expanding any such rule to include petitioners with a “substantial relationship” to the initial petitioner as defined in the Notice, which indicates that the potential “substantial relationship” definition would expand the party relationship concepts currently applied in the discretionary denial context and “would be broadly construed” to include “others that are significantly related” to the initial petitioner. PhRMA further supports the Notice’s suggestion that “substantial relationship” should additionally include “those involved in a membership organization, where the organization files IPRs or PGRs,” as well as “instances in which entities may pool their resources to challenge a patent,” such as “where multiple entities are defending infringement claims in district court litigation, or have related interests in challenging the patentability.” Excluding the former invites mischief, and excluding the latter ignores the realities of litigation in the context of Hatch-Waxman and BPCIA cases, which frequently involve multiple patent challengers simultaneously advancing overlapping invalidity claims.

PhRMA suggests clarifying that “resolved for reasons not materially related to the merits” does *not* include petitions denied for failure to meet the institution standard on the merits, such as the “reasonable likelihood” standard of 314(a), or petitions discretionarily denied upon a finding that the petition did not meet the “compelling merits” (or similar) standard. In those cases, the petitioner should not benefit from a second bite at the apple when it initially failed to meet even these threshold requirements.

As with the potential prior-adjudication proposal, PhRMA suggests applying the potential new serial-petition proposal not only in cases where “at least one overlapping claim” was previously challenged, but also where the challenged claims “substantially overlap” the previously challenged claims as defined in the Notice and as potentially applied in the prior-adjudication proposal discussed above. Furthermore, while the Notice expressly references only prior IPR, PGR, or CBM petitions, PhRMA suggests expanding the rule to include prior reexamination proceedings as well, as inefficient and abusive serial challenges are not limited to petitions following previous AIA trials.

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<sup>9</sup> See *Valve I*, IPR2019-00062, Paper 11, at 9-10.

<sup>10</sup> See *Valve II*, IPR2019-00064, Paper 10, at 9-11.

According to the Notice, “exceptional circumstances” may include situations in which: (a) a patentee changes the scope of the claims through amendment or a proposed claim construction; (b) the petitioner reasonably could not have known of or found the prior art; or (c) the petitioner raises a new statutory challenge and has a “justifiable explanation” for why it was not raised before. PhRMA suggests at least two clarifications. First, PhRMA suggests clarifying that offering a new claim construction does not necessarily “change” the scope of the claims. To reduce disputes about what qualifies as a “change” in scope, PhRMA suggests limiting this exception to changes in scope via claim amendments. Second, PhRMA suggests clarifying what is meant by a “justifiable explanation” and at minimum clarifying that such an explanation will not excuse additional arguments under the same statutory challenge (e.g., new § 103 arguments when the prior petition also relied on obviousness). Additionally, PhRMA notes that determining whether a petitioner “reasonably could not have known of or found” particular prior art poses another difficult inquiry likely to lead to unpredictable results.

Finally, the Notice also suggests the possibility of denying *any* serial petition, regardless of petitioner’s relationship to the prior petitioner, *unless* the petition meets the “compelling merits” test. PhRMA disagrees with this approach for the reasons explained above. For example, a meritorious petition may nonetheless conflict with considerations of efficiency, fairness, and finality.

#### **V. Rulemaking Regarding Section 325(d) Is Not Necessary**

In principle, PhRMA supports efforts to clarify the application of § 325(d) when evaluating whether “the same or substantially the same prior art or arguments previously were presented to the Office.” The Office has provided significant guidance regarding this inquiry through precedential PTAB opinions.<sup>11</sup> At this time, PhRMA is unaware of any widespread or significant requests to modify the status quo, much less any evidence supporting the narrowing provisions proposed in the Notice. Accordingly, PhRMA suggests that rulemaking is unnecessary in the Section 325(d) context.

Furthermore, the Notice suggests potentially “superseding” *Becton Dickinson, Advanced Bionics*, and their progeny with proposals that would significantly and unduly limit § 325(d). For example, one aspect of the potential proposal would limit § 325(d) to “previously *addressed*” art or arguments, meaning that the Office must have evaluated them and articulated its consideration in the record. PhRMA does not support this limitation of § 325(d). The statute provides that the Board may reject art or arguments previously “*presented* to the Office,” which is a broader and more appropriate standard reflecting the reality that, for example, examiners should not need to expressly discuss every reference considered during the course of prosecution, particularly where multiple references include similar teachings.<sup>12</sup>

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<sup>11</sup> 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 Gerate GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential).

<sup>12</sup> PhRMA agrees, however, that upon a showing that “the same or substantially the same prior art or arguments previously were presented to the Office,” § 325(d), petitioners must establish “material error” by the Office. Errors should *not* be considered “material” if reasonable minds can disagree. See *Advanced Bionics*, IPR2019-01469, Paper

As an additional example, the Notice suggests the possibility of unduly limiting “substantially the same” art to art containing the *same* teaching, which invites petitioners to locate art using slightly different language to convey similar information.<sup>13</sup> The Notice further suggests the possibility of limiting § 325(d) to parent or other related applications that “contain or contained substantially the same limitations” and suggests that “substantially the same” may require such a high degree of similarity that the claims would be subject to obviousness-type double patenting rejections. This too would unduly limit the statute, as very different limitations may be subject to challenges based on the same art, for example.

PhRMA does agree with the proposed clarification that § 325(d) applies to *any* prior proceeding, including prosecution, reissue, reexamination, and AIA trials involving the challenged patent or related patents or applications. PhRMA strongly disagrees, however, with the alternative suggestion that § 325(d) should be limited to art or arguments addressed solely in the context of the challenged patent itself to the exclusion of any parent or other related application, which would severely undermine the purpose of the statute, particularly for child applications with identical disclosures or similar claim terms. Furthermore, to the extent the Office is considering expanding the scope of § 325(d) to “non-related applications,” as additionally suggested in the Notice, the Office should clarify the scope of relevant applications.

#### **VI. PhRMA Supports Limiting Parallel Petitions by the Same Petitioners or Those with Substantial Relationships Rather Than Permitting Jumbo, Fee-Based Petitions**

PhRMA supports efforts to limit multiple parallel challenges to the same patent, which facilitate gamesmanship and impose undue burdens on patent owners and the Office. For that reason, PhRMA previously has supported the promulgation of a rule with a case-specific analysis, such as generally outlined in the Consolidated Trial Practice Guide.<sup>14</sup>

The Notice contemplates a potential rule in which the Board would not institute parallel petitions filed by the same petitioner or a petitioner with a “substantial relationship” absent a showing of “good cause.” PhRMA supports this approach in principle and agrees with the Board’s current guidance that one petition challenging a patent should be sufficient in most situations.<sup>15</sup>

PhRMA suggests a flexible, case-specific test for “good cause.” Not all of the factors identified in the Notice would be appropriate in this context.<sup>16</sup> For example, PhRMA is unaware

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6, at 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.”).

<sup>13</sup> In addition, the Notice does not attempt to define “substantially the same” arguments.

<sup>14</sup> See 2020 PhRMA Comments at 4.

<sup>15</sup> Consolidated Trial Practice Guide, 59 (Nov. 2019) (“Based on the Board’s experience, one petition should be sufficient to challenge the claims of a patent in most situations. Two or more petitions filed against the same patent at or about the same time ... may place a substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns. In addition, multiple petitions by a petitioner are not necessary in the vast majority of cases.” (internal citation omitted)).

<sup>16</sup> Potential “good cause” factors identified in the Notice include: “(1) whether the patent owner has asserted a large number of claims in the parallel litigation; (2) whether the petitioner is challenging a large number of claims; (3)

of any reason that the “strength of the merits” should justify multiple petitions, particularly because—consistent with current practice—the Notice contemplates five-page petitioner submissions ranking the parallel petitions and explaining the differences between them.<sup>17</sup> In most cases, the parties and the Office benefit when the petitioner’s strongest arguments are presented in a single petition.

The Notice separately suggests the possibility of permitting petitioners to pay additional fees for higher word-count limits. PhRMA strongly *disagrees* with this approach, which would circumvent the parallel petition safeguards, unduly burden patent owners, and unfairly benefit wealthy petitioners. Instead, petitioners should be subject to the parallel petition framework that requires petitioners to establish good cause for multiple petitions and to rank and explain those petitions.<sup>18</sup>

## **VII. PhRMA Supports Mandatory *Sotera* Stipulations and a Case-Specific Approach to Limiting Inefficient Parallel Litigation Proceedings**

PhRMA supports efforts to limit redundant parallel challenges to the same patent, which invite gamesmanship, impede finality, present the risk of inconsistent outcomes, and impose undue burdens on patent owners and the Office. The risks of duplicative parallel proceedings are particularly acute in the biopharmaceutical industry in view of the incentives for expedient district court resolution of Hatch-Waxman lawsuits, which result in courts rarely granting stays in view of PTAB proceedings.

PhRMA also strongly disagrees that the “compelling merits” test should serve as an exception to *Fintiv* or to any potential parallel litigation rule for the reasons articulated above.

### **A. PhRMA Supports a Case-Specific Approach**

PhRMA supports a case-specific discretionary denial analysis for parallel litigation proceedings, such as the factors provided in *Apple v. Fintiv*.<sup>19</sup> While some stakeholders have raised concerns about the accuracy of trial date predictions, those issues have already been

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whether there is a dispute about a priority date requiring arguments under multiple prior art references; (4) whether there are alternative claim constructions that require different prior art references or mutually exclusive grounds; (5) whether the petitioner lacks sufficient information at the time of filing the petition, e.g., the patent owner has not construed the claims or provided specific information as to the allegedly infringed claims; (6) whether there are a large number of claimed embodiments challenged, e.g., composition claims, method of making claims, and method of use claims; (7) the complexity of the technology in the case; and (8) the strength of the merits of the petition.”

<sup>17</sup> PhRMA has no objection to this approach, which includes an opportunity for a patent-owner response.

<sup>18</sup> As recognized in the Notice, this approach more easily allows the Board to deny petitions with non-meritorious theories. Permitting a single, larger petition with a mix of meritorious and non-meritorious arguments would require the Board to institute or deny the entire jumbo petition in view of the Supreme Court’s decision in *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359-60 (2018).

<sup>19</sup> See *Fintiv*, IPR2020-00019, Paper 15, at 7-8 (providing factors to determine whether efficiency and the integrity of the patent system are best served by denying IPR when a patent is or has been subject to another proceeding, including: “1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted; 2. proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision; 3. investment in the parallel proceeding by the court and the parties; 4. overlap between issues raised in the petition and in the parallel proceeding; 5. whether the petitioner and the defendant in the parallel proceeding are the same party; and 6. other circumstances ... including the merits”).

addressed through subsequent Office guidance.<sup>20</sup> Moreover, trial dates tend to be particularly predictable in biopharmaceutical litigation.

Accordingly, should the Office jettison the *Fintiv* framework in favor of a single “clear and predictable rule,” PhRMA supports the further potential proposal to consider an “additional factor-based test” consistent with our comments above. Under that potential approach, PhRMA opposes the omission of *Fintiv* factor 1 (the likelihood of a stay). Despite the Notice’s suggestion that it is “difficult to predict a district court’s future actions,” certain types of litigation, such as Hatch-Waxman lawsuits, rarely result in a district court issuing a stay in view of PTAB proceedings. PhRMA also supports in principle the potential expansion of *Fintiv* factor 5 to include not only consideration of whether the petitioner and defendant are the same party, but also consideration of RPIs, privies, and parties that are “substantially related.”

Furthermore, a “clear and predictable rule” focused on the Board’s determination of whether “a trial in the district court is likely to occur before the projected statutory deadline for a final written decision” would better promote the policy goals underlying *Fintiv* than an arbitrary six-month filing safe-harbor for petitioners, which would likely become a *de facto* deadline rushing petitioners while simultaneously foreclosing consideration of legitimate parallel litigation concerns.

#### **B. The Board Should Consider Whether Institution May Subvert an Existing Statutory Framework**

A case-specific analysis permits the Board to consider the interplay between PTAB proceedings and other existing statutory frameworks. For example, a flexible approach supports the use of discretion when another statutory framework would be subverted or frustrated by the institution of a PTAB proceeding.<sup>21</sup>

Preserving this flexibility is of particular importance in the biopharmaceutical industry. As PhRMA explained in its 2020 comments,<sup>22</sup> the Hatch-Waxman and BPCIA frameworks were created by Congress to provide an opportunity to resolve patent disputes prior to generic or biosimilar market entry, respectively. For example, Hatch-Waxman contemplates litigation in the situation where, in conjunction with filing an application for FDA approval of a generic drug, the generic applicant may challenge the validity of a patent or assert that its product would not infringe the patent. If the patent owner files a timely suit, the Hatch-Waxman framework results in a 30-month stay in the approval of the generic application by the FDA so that the courts can address issues of patent validity and infringement prior to generic marketing. Innovators and

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<sup>20</sup> 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](https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621.pdf).

<sup>21</sup> Indeed, the Federal Circuit has rebuffed efforts to challenge the use of the *Fintiv* factors to deny petitions challenging patents involved in Hatch-Waxman litigation. See *Mylan Lab’ys Ltd. v. Pharmaceutica*, 989 F.3d 1375, 1382-83 (Fed. Cir. 2021) (denying mandamus because, among other things, “Mylan lacks a clear and indisputable right to review of the Patent Office’s determination to apply the *Fintiv* factors” and “Mylan had no right for its petition to be considered without reference to the Teva litigation and no right to an IPR”).

<sup>22</sup> See 2020 PhRMA Comments at 5-6.

generics work to expedite proceedings to meet that 30-month goal, as do the district courts.<sup>23</sup> Thus, courts rarely stay Hatch-Waxman litigation, and PTAB proceedings become duplicative to those cases that are already progressing through the district courts. The BPCIA also created a litigation framework for resolving patent disputes prior to biosimilar launch, with the goal of encouraging an efficient biosimilar market entry. However, the institution of PTAB proceedings simultaneously to a Hatch-Waxman or BPCIA lawsuit subverts these frameworks and the balances struck by Congress, resulting in increased uncertainty, burden, and expense to patent owners, as often they are required to defend their patents in two venues simultaneously, even from challenges by the same parties.<sup>24</sup>

Promulgation of rules preserving the flexibility to consider whether institution on a petition may subvert an existing statutory framework, such as Hatch-Waxman, would reduce the burden and expense for the USPTO and patent owners. Under situations in which a statutory framework applies, these PTAB petitions could be denied with an expectation that these patent disputes will be litigated in the federal courts. Denying a petition based on whether another statutory framework applies would moreover reduce uncertainty for patent owners as to the forum in which they would need to defend their patents and promote fairness by supporting that these patent challenges be litigated through established statutory frameworks.

### **C. PhRMA Supports Mandatory *Sotera* Stipulations**

PhRMA supports in principle the potential proposal to make “a *Sotera* stipulation a necessary but not sufficient basis for institution.” *Sotera* stipulations provide significant benefits for the reasons identified by the Office in the Notice, particularly when they foreclose petitioners from raising any grounds in the parallel proceeding that they reasonably could have raised in their petitions. For that reason, PhRMA disagrees that other, narrower types of stipulations would be sufficient to address concerns regarding duplicative litigation. For example, PhRMA disagrees with the Notice’s alternative suggestions of replacing the potential *Sotera* stipulation requirement with a *Sand Revolution* stipulation or a *Sotera* stipulation that is limited to the specific patent claims challenged in the petition or to the claims asserted at the time the stipulation is filed.

### **D. PGRs Should Not Be Exempt from Potential Parallel Litigation Rules**

PhRMA disagrees that PGR proceedings should be exempted completely from *Fintiv* or any proposed rule permitting discretionary denial in view of parallel litigation. Concerns regarding efficiency and burdens apply similarly in IPR and PGR proceedings, particularly in biopharmaceutical patent cases, which are particularly unlikely to be stayed. While the Notice appears to justify this potential approach by referencing the broader estoppel that applies

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<sup>23</sup> See 21 U.S.C. § 355(j)(5)(B)(iii) (providing for 30-month stay “or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action”).

<sup>24</sup> See Carlos A. Garcia & Jonathan Stroud, *Ships in the Night*, 68 Am. U. L. Rev. 1111, 1170 (2019) (“Parallel proceedings like [PTAB proceedings] were not contemplated when the Hatch-Waxman Act was passed, do not embody the purposes of the AIA itself, and are not an efficient means of litigating disputes like these that are already cabined and complicated by another set of long-implemented statutory schemes. Instead, they harass the patent owner, increase the litigation costs for all parties, and deter settlements with early aNDA filers.”).

following a final written decision in a PGR proceeding relative to an IPR proceeding, either version of estoppel is less consequential for parallel litigation proceeding on a similar timeline.

#### **E. PhRMA Supports Increased Scrutiny of Petitioners Seeking Joinder**

The Notice also contemplates permitting the Board to consider whether a petitioner seeking joinder “would have been time-barred from filing the petition it seeks to join,” and requiring the Board to evaluate joinder petitions “with respect to the timing of any underlying litigation of the earlier-filed petition.” PhRMA in principle supports these potential proposals, which would promote finality and police gamesmanship, such as attempts to leverage straw petitioners to facilitate otherwise time-barred petitions.

#### **VIII. PhRMA Supports Clear Rules with Appropriate Safeguards to Address Certain Non-Competitive Petitioners**

PhRMA supports efforts to limit institution on filings by non-competitive entities that may serve to shield the actual real parties in interest and privies from statutory estoppel provisions or challenge patent claims that such entities are time-barred from challenging. Such challenges subvert the purpose of the AIA and threaten the integrity of the Office. Thus, PhRMA in principle supports the promulgation of a rule to address such situations. For the reasons explained above, however, PhRMA disagrees with the Notice’s suggestion that a “compelling merits” determination should override the potential rule, such that the Board would institute on a petition regardless of whether the petitioner would otherwise be foreclosed from seeking review.

The Notice suggests a potential proposal that would require the Board to deny IPR or PGR petitions filed by entities that: (1) are for-profit; (2) have not been sued for infringement or threatened with suit sufficient to qualify for declaratory judgment standing; (3) do not have a potentially infringing product on the market or investments in bringing such a product to market; and (4) do not have a “substantial relationship” with an entity that falls outside the scope of (1)-(3). In PhRMA’s view, this potential proposal requires significant modification and clarification.

For example, *non-profit* entities may file petitions presenting the same policy concerns as those articulated in the Notice. Accordingly, PhRMA would expand the scope of the potential rule to eliminate the “for-profit” requirement. In addition, PhRMA notes the likely pre-institution discovery disputes and difficulty in determining the suggested alternative to declaratory judgment standing of whether a petitioner “has a reasonable apprehension of suit based on the prior litigation conduct of the patentee asserting the patent or related patents against similarly situated companies.” And as noted above in connection with the potential “prior adjudication” proposal, determining whether a petitioner has “invested to bring to market” a product or service could also prove difficult and lead to pre-institution disputes and discovery requests.

The Notice acknowledges that “where multiple entities are defending infringement claims in district court litigation, or have related interests in challenging the patentability of patent claims, they may join together to challenge the subject patent claims,” and that this “may advance the Office’s mission and vision.” That particular scenario occurs frequently in the context of Hatch-Waxman and BPCIA lawsuits, as multiple potential generic or biosimilar manufacturers often mount several patent challenges simultaneously. In these situations, it would be efficient and preferable for all such entities to “join together to challenge the subject patent claims before the PTAB.” Otherwise, patent litigation involving several defendants opens the

door for costly and duplicative challenges by parties that share a common “interest[] in challenging the patentability” but fall short of traditional RPI or privity tests. Accordingly, PhRMA suggests including such entities within the scope of the potential “substantial relationship” definition as discussed above, which would subject them to the potential proposals limiting serial and parallel petitions and thereby potentially encourage joinder with earlier petitions.

#### **IX. PhRMA Supports Mandatory “Stipulations on No Multiple Challenges”**

As noted above, PhRMA supports efforts to limit repetitive and redundant challenges to the same patent, which invite gamesmanship, impede finality, and impose undue burdens on patent owners and the Office. Accordingly, PhRMA in principle supports the potential proposal to reduce patent-owner harassment by “requiring petitioners to file a stipulation that neither they nor their privy or real parties [in interest] 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 ....” PhRMA also suggests expanding the definition of “prior post-grant proceedings” to include prior *inter partes* reexaminations, which—while increasingly rare—present the same policy concerns.

Importantly, the requirement of a stipulation “as a condition to not discretionarily denying institution under 35 U.S.C. 314(a)” should not foreclose discretionary denial by the Board in appropriate cases. PhRMA recommends against the Office proposing the potential stipulation requirement as an *exception* to discretionary denials, which could permit institution in situations presenting concerns unrelated to multiple challenges, such as parallel proceedings or considerations under § 325(d). In other words, and consistent with the comments above regarding *Sotera* stipulations, this potential stipulation should be a necessary but not sufficient basis to avoid discretionary denial.

The Notice suggests an exception to this potential proposal “where a petitioner can establish exceptional circumstances.” PhRMA urges the Office to provide more details regarding any proposed “exceptional circumstances” exception. For example, PhRMA disagrees that a potential exception in this context should be as broad as the “exceptional circumstances” suggested in the context of the potential serial-petition proposal. And as explained in the context of the potential serial petition proposal above, PhRMA suggests clarifying that offering a new claim construction does not necessarily broaden or alter the scope of the claims; therefore, PhRMA suggests limiting this potential exception to broadening claim amendments.

#### **X. PhRMA Does Not Oppose Separate Discretionary Denial Briefing, but Discretionary Denials Should Not Require New Patent Owner Disclosures**

PhRMA does not oppose the Notice’s potential proposals to permit separate briefing on discretionary denials or the Board’s ability to raise discretionary denial issues *sua sponte*.

PhRMA strongly disagrees with the Notice’s suggestion that discretionary denials potentially should be conditioned on patent owners disclosing additional information regarding patent ownership, government funding, third-party litigation funding support, or any stake any party has in the outcome of the AIA proceeding or any parallel proceedings on the challenged claims. Disclosing government funding is not necessary because patent owners are already

required to disclose this information in the patent itself.<sup>25</sup> And the Office has not articulated a sufficient justification for compelling disclosure of the remaining information. More specifically, the Office has not justified this additional burden on patent owners, which could discourage discretionary denial requests at the expense of fairness, finality, and adjudicatory efficiency. This concern is particularly acute in view of the incredibly broad disclosure requirements under consideration, including information related solely to separate district court proceedings.

For the same reasons, PhRMA opposes the Notice's suggestion of a similar potential disclosure requirement proposal embedded in the "substantial relationship" definition, which would require patent owners and petitioners to disclose any ownership interests in the parties,<sup>26</sup> any government funding related to the patent, and third-party litigation funding support, and any stake any party has in the outcome of the trial or parallel proceedings.

On the other hand, requiring additional information regarding "entities having a substantial relationship" *with petitioners* would inform the Board's assessment of RPI and privity issues and would be essential to the Board's application of the potential serial and parallel petition proposals impacting petitioners having "substantial relationships" with each other.

#### **XI. The USPTO Should Not Promulgate New Rules Regarding Settlement Agreements in the Context of Discretionary Denial Rulemaking**

PhRMA suggests that potential regulatory changes expanding existing statutory requirements regarding the submission of settlement agreements would be better addressed in a separate process, as this issue does not relate to discretionary denials and merits more fulsome vetting. To the extent the Office moves forward with a proposed rule requiring the submission of pre-institution settlement agreements, however, PhRMA suggests clarifying the confidentiality provisions related to the submission of all settlement agreements in connection with 37 C.F.R. § 42.74(c) and 35 U.S.C. §§ 135(e), 317(b), and 327(b).

For example, the Office could clarify what constitutes "good cause" for the disclosure of a settlement agreement submitted as "business confidential information."<sup>27</sup> The "good cause" requirement should be construed narrowly to prevent non-parties from accessing sensitive information that could harm the parties if made public.<sup>28</sup> The Office could also clarify that the

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<sup>25</sup> See 37 C.F.R. § 401.14(f)(4) (requiring the inclusion "within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, 'This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention'").

<sup>26</sup> This potential proposal references the SEC's definition of "beneficial ownership." PhRMA notes that this is a complex legal inquiry unfamiliar to many patent practitioners and likely unfamiliar to the Board as well.

<sup>27</sup> The statutory standard for "good cause" has not yet been clarified by the Office. See, e.g., David McCombs, Eugene Goryunov & Brooke Cohen, *Terminating an IPR: File Your Settlement Agreement Without Concern—At Least For Now*, IPWatchdog (Apr. 19, 2022), <https://ipwatchdog.com/2022/04/19/terminating-ipr-file-settlement-agreement-without-concern-least-now/>.

<sup>28</sup> By way of comparison, confidential settlement agreements submitted to the DOJ or FTC pursuant to the Medicare Modernization Act are exempted from FOIA and may not be made public, "except as may be relevant to any administrative or judicial action or proceeding." 21 U.S.C. § 355 Note, at § 1114.

parties are entitled to notification if the PTAB is considering a request for access to a confidential settlement agreement.

## **XII. Conclusion**

PhRMA appreciates the USPTO's efforts to revise and clarify its rules regarding trial proceedings under the AIA before the PTAB, as well as the opportunity to offer its perspective on these proceedings. PhRMA and its member companies are committed to contributing to the dialogue between the USPTO and stakeholders on these and other important patent issues.

Respectfully submitted,

/s/

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/s/

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