

Comments of the Pharmaceutical Research and Manufacturers of America in Response to the USPTO’s Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board (Docket No. PTO-C-2020-0055)

December 3, 2020

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) appreciates the opportunity to submit comments in response to the United States Patent and Trademark Office (“USPTO” or “Office”) Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board (“PTAB” or “Board”).¹

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. The U.S. biopharmaceutical industry supports about 4 million jobs across the economy, with more than 800,000 employees across companies working every day to research and develop new treatments and cures for patients. Since 2000, PhRMA member companies have invested nearly \$1 trillion in the search for new treatments and cures, including an estimated \$83 billion in 2019 alone.² While medicines developed by the industry have produced large improvements in health across a broad range of diseases, they come with significant risks and costs for the industry, as developing one new medicine takes over a decade and costs an average of \$2.6 billion.

Intellectual property 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 intellectual property 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 intellectual property protections domestically and internationally.

Bringing new and improved life-saving and life-improving products to people is the driving mission of our member companies. Because intellectual property is critical to carrying out this mission, PhRMA members appreciate the efforts of the USPTO to revisit its rules and practices regarding trial proceedings under the America Invents Act (“AIA”) before the PTAB and the opportunity to offer PhRMA’s perspective on these proceedings. PhRMA has provided comments in response to prior notices and appreciates the modifications made to the regulations and to the PTAB Consolidated Trial Practice Guide. PhRMA also appreciates the efforts made by the PTAB to provide guidance to Administrative Patent Judges and foster greater consistency in decisions through designating opinions as precedential or informative. Below are comments in response to questions raised in the Notice.

¹ 85 Fed. Reg. 66502-06 (October 20, 2020).

² 2020 PhRMA Annual Membership Survey, *available at* https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_Membership_Survey_2020.pdf.

I. PhRMA Supports the Promulgation of a Rule Using a Case-Specific Analysis for Deciding Whether to Institute a Petition on Claims that have Previously been Challenged in Another Petition

PhRMA supports the promulgation of a rule with a case-specific analysis, such as generally outlined in *Generic Plastic*³, *Valve I*⁴, *Valve II*⁵, and their progeny, for deciding whether to institute a petition on claims that have previously been challenged in another petition (“serial petitions”).

Serial petitions have the potential to be harassing, create uncertainty, and increase the cost of defending a patent owner’s property rights. They also frustrate the patent owner’s right to enjoy quiet title of its intellectual property. The USPTO has recognized that serial petitions are of great concern to patent holders,⁶ and the PTAB has enumerated factors in the precedential *General Plastic* decision that should be considered in determining whether to institute serial petitions for instances in which the same petitioner files multiple petitions against the same patent. The Office has stated that the PTAB “will also take into account whether the same or substantially the same prior art or arguments were previously presented to the Office” when determining whether to institute a serial petition.⁷

³ See *General Plastic Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19, at 16 (PTAB Sept. 6, 2017) (precedential) (providing nonexhaustive factors for the PTAB to consider when deciding whether to exercise discretion to deny a serial IPR petition, including: “1. whether the same petitioner previously filed a petition directed to the same claims of the same patent; 2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it; 3. whether at the time of filing of the second petition the petitioner had already received a patent owner’s preliminary response to the first petition or received the Board’s decision on whether to institute review in the first petition; 4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition; 5. whether the petitioner provides an adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent; 6. the finite resources of the Board; and 7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review”); see also PTAB Consolidated Trial Practice Guide, at 56-58 (Nov. 2019), available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf?MURL=> (reviewing *General Plastic* factors and explaining how they are to be applied).

⁴ See *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00062, Paper 11, at 9-10, IPR2019-00063, Paper 13, at 9-10, IPR2019-00084, Paper 13, at 9-10 (PTAB Apr. 2, 2019) (precedential) (explaining that “[w]hen different petitioners challenge the same patent, [the PTAB] consider[s] any relationship between those petitioners while weighing the *General Plastic* factors” and after concluding that such a relationship exists, weighs this relationship in favor of denial of institution).

⁵ See *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00064, Paper 10, at 9-11, IPR2019-00065, Paper 10, at 9-11, IPR2019-00085, Paper 10, at 9-11 (PTAB May 1, 2019) (precedential) (also explaining that “[w]hen different petitioners challenge the same patent, [the PTAB] consider[s] any relationship between those petitioners while weighing the *General Plastic* factors” and after concluding that such a relationship exists, weighs this relationship in favor of denial of institution).

⁶ See USPTO Chat with the Chief (Oct. 24, 2017), available at https://www.uspto.gov/sites/default/files/documents/Chat_with_the_Chief_Boardside_Chat_Multiple_Petition_Study_20171024.pdf.

⁷ PTAB Consolidated Trial Practice Guide, *supra* note 3, at 55.

Although the *General Plastic* decision is helpful in situations when the same petitioner files multiple petitions, the USPTO should ensure that any potential rulemaking directs the PTAB to also use its discretion to address the relationship between petitioners when multiple parties file petitions against the same patent, often on the same or very similar art that was previously presented, as has been instructed by other precedential decisions including *Valve I* and *Valve II*. Moreover, in order to avoid potential harassment of patent owners, the USPTO should ensure that any rulemaking instructs the PTAB to consider the total number of petitions filed against the challenged patent when deciding whether to institute review, and, even if the petitioners are not related, whether these petitioners have any related matters in common.

PhRMA appreciates the USPTO's clarification that the *General Plastic* factors for denying serial petitions are not exclusive and that "[t]here may be other reasons besides the 'follow-on' petition context where the 'effect...on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete the proceedings,' 35 U.S.C. § 316(b), favors denying a petition even though some claims meet the threshold standards for institution under 35 U.S.C. §§ 314(a), and 324(a)."⁸ Further, with respect to determining whether to grant or deny a petition under 35 U.S.C. § 325(d), PhRMA appreciates the USPTO's clarification of its application of the nonexclusive *Becton-Dickinson* factors⁹, which the PTAB applies when considering whether art is the same or substantially the same as art presented during a prior proceeding. PhRMA also appreciates the USPTO's explanation that relevant factors can also include other proceedings related to the same patent, either at the Office, in district courts, or the ITC.¹⁰ PhRMA therefore supports the use of a case-by-case analysis to review the underlying facts in the many situations in which serial petitions may arise.

Promulgation of rules by the USPTO under the Administrative Procedure Act ("APA") is appropriate because of the discretion given to the USPTO by Congress.¹¹ Moreover, while PhRMA believes designating opinions through the Precedential Opinion Panel is an appropriate

⁸ *Id.* at 58.

⁹ See *Becton, Dickenson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, at 17-18 (PTAB Dec. 15, 2017) (applying the following factors when determining whether to exercise discretion under 325(d): "(a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or a Patent Owner distinguishes the prior art; (e) whether a petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments"); see also PTAB Consolidated Trial Practice Guide, *supra* note 3, at 62-63 (reviewing PTAB guidance on serial petitions).

¹⁰ See PTAB Consolidated Trial Practice Guide, *supra* note 3, at 58.

¹¹ See 35 U.S.C. §§ 314(a) and 324(a) (granting the Director the authority to deny PTAB petitions), 316(b) (instructing the Director to consider, when prescribing regulations, the effects to the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter), and 325(d) (granting authority to deny a petition if the same or substantially the same prior art or arguments were previously submitted to the Office).

process, promulgating rules through the rulemaking process provides greater certainty, predictability, and advanced notice to stakeholders and the public. Rules creating a case-based analysis of serial petitions would also promote fairness by ensuring that petitioners do not automatically receive multiple attempts at invalidating a patent. It would also reduce burden and expense for the USPTO which may otherwise be forced to review patents that have already been the subject of a PTAB proceeding. Finally, it eliminates the expense to patent owners of having to defend a patent in multiple PTAB proceedings at the same time or over a potentially extensive period of time and furthers the opportunity to have quiet title over already challenged patents.

II. PhRMA Supports the Promulgation of a Rule with a Case-Specific Analysis for Deciding Whether to Institute More than One Petition Filed at or about the Same Time on the Same Patent

PhRMA supports the promulgation of a rule with a case-specific analysis, such as generally outlined in the Consolidated Trial Practice Guide, for deciding whether to institute more than one petition filed at or about the same time on the same patent (“parallel petitions”).

The USPTO, in its Consolidated Trial Practice Guide, explains that parallel petitions “may place a substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns.”¹² PhRMA agrees that like serial petitions, parallel petitions have the potential to be harassing, create uncertainty, and increase the cost of defending a patent owner’s property rights.

PhRMA recognizes that there may be situations in which a petitioner believes it would need to file parallel petitions. However, PhRMA agrees with the USPTO that incidences in which parallel petitions are warranted are limited and that “multiple petitions by a petitioner are not necessary in the vast majority of cases.”¹³ Indeed, “a substantial majority of patents have been challenged with a single petition.”¹⁴ Those scenarios in which parallel petitions are filed by a petitioner would therefore be best served by applying a case-specific analysis to the facts of those situations.

As with serial petitions, the promulgation of rules by the USPTO under the APA to require a case-specific analysis on the facts of situations in which parallel petitions are filed is appropriate, allowable in view of the discretion provided to the USPTO, and would result in greater certainty to patent owners and other stakeholders by creating standards by which parallel petitions would be assessed via the rulemaking process.

Rulemaking on the discretion to deny parallel petitions would also promote fairness by creating a gatekeeper function that would prevent petitioners from automatically receiving

¹² PTAB Consolidated Trial Practice Guide, *supra* note 3, at 59.

¹³ *Id.*

¹⁴ *Id.* (explaining that it should be rare that two petitions by a petitioner may be needed, and “unlikely that circumstances will arise where three or more petitions by a petitioner with respect to a particular patent will be appropriate”).

multiple concurrent attempts at invalidating a patent, and would reduce the burden and expense for the USPTO which would otherwise be forced to oversee multiple simultaneous proceedings. It would also reduce the expense to patent owners of having to defend a patent in multiple PTAB proceedings concurrently.

III. PhRMA Supports the Promulgation of a Rule with a Case-Specific Analysis for Deciding Whether to Institute a Petition on a Patent that is or has been Subject to Other Proceedings in a U.S. District Court or the ITC

PhRMA supports the promulgation of a rule with a case-specific analysis for deciding whether to institute a petition on a patent that is or has been subject to other proceedings in a U.S. district court or the ITC. PhRMA therefore supports the incorporation of the *NHK-Fintiv*¹⁵ factors into any future rulemaking.

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.

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 in district court 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 generics work to expedite proceedings to meet that 30-month goal, as do the district courts. Thus, courts rarely stay Hatch-Waxman litigation, and PTAB proceedings become duplicative to those cases that are already

¹⁵ See *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15, at 7-8 (PTAB May 13, 2020) (precedential) (providing factors the PTAB will take to determine whether efficiency and integrity of the patent system are best served by denying or instituting 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 that impact the Board’s exercise of discretion, including the merits”); see also *Supercell OY v. Gree, Inc.*, PGR2020-00039, Paper 14, at 26-27, PGR2020-00041, Paper 14, at 24-25 (PTAB Sept. 14, 2020) (applying the *NHK-Fintiv* factors to deny petitions for post grant review).

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.¹⁶

The *NHK-Fintiv* factors are appropriate to incorporate into a rule. In the Hatch-Waxman context, they support the use of discretion when another statutory framework would be subverted or frustrated by the institution of a PTAB proceeding, and indeed have already been applied to support the denial of a petition challenging a patent involved in a Hatch-Waxman litigation.¹⁷ The USPTO should therefore recognize the applicability of the *NHK-Fintiv* factors to an analysis of whether institution on a petition may subvert an existing statutory framework, such as Hatch-Waxman.

Promulgation of these rules by the USPTO under the APA is appropriate here as well because of the discretion given to the USPTO by Congress. Rulemaking directing the PTAB to consider the *NHK-Fintiv* factors and thereafter to use its discretion to deny a PTAB petition based on these factors 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 venue in which they would need to defend their patents and promote fairness by supporting that these patent challenges be litigated through established statutory frameworks.

¹⁶ 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.”)

¹⁷ See *Mylan Labs. Ltd. v. Janssen Pharmaceutica NV*, IPR2020-00440, Paper 17, at 12-25 (PTAB Sept. 16, 2020) (applying the *NHK-Fintiv* factors to find in favor of denial of an IPR petition challenging a patent involved in Hatch-Waxman litigation for reasons including that the district court was unlikely to stay in part due to the Hatch-Waxman statutory 30-month stay of generic approval, the district court trial date would occur before the PTAB’s Final Written Decision deadline, and the two proceedings overlapped in issues, asserted prior art, and involved parties). The factual bases for supporting denial of institution considered in *Mylan v. Janssen* are common in Hatch-Waxman cases.

IV. Conclusion

PhRMA appreciates the USPTO's efforts to revisit its rules and practice regarding trial proceedings under the AIA before the PTAB and the opportunity to offer its perspective on these proceedings. PhRMA and its member companies are committed to helping the USPTO find solutions to the many challenges it faces today and in the years to come.

Respectfully submitted,

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