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Mail Stop Comments-Patents  
Director of the United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
Attn: Vice Chief Administrative Patent Scott C. Weidenfeller

Re: Request for Comments on Discretion to Institute Trials  
Before the Patent Trial and Appeal Board  
85 Fed. Reg. 66,502 (Oct. 20, 2020)  
Docket No. PTO-C-2020-0055

Dear Vice Chief Judge Weidenfeller:

We submit this comment on behalf of Mylan Pharmaceuticals Inc. (“Mylan”), a Viatrix company. Mylan commends the U.S. Patent and Trademark Office (“PTO” or “Office”) 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 also appreciates the opportunity to provide this submission in response to the Agency’s *Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board*, 85 Fed. Reg. 66,502 (Oct. 20, 2020) (“Request”).

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 provide patients the earliest possible access to more affordable medicines by successfully challenging improperly granted patents in district court litigations and through *inter partes* reviews (“IPR”) before the Patent Trial and Appeal Board (“PTAB” or “Board”).

In enacting the AIA, Congress sought to improve patent quality, promote innovation, and reduce the number of improperly granted patents deterring or blocking competition. In the life sciences industry, weak patents that do not actually claim a novel, innovative invention, can nonetheless delay generic or biosimilar competition for many years. AIA proceedings offer an efficient and streamlined process for generic and biosimilar applicants to challenge these weak patents more efficiently, which increases the likelihood of narrowing the patents, claims, or issues in any parallel district court litigation brought under the Hatch-Waxman Act or the Biologics Price Competition and Innovation Act (BPCIA). Ultimately, since these

administrative reviews operate within a strict, statutorily mandated timeframe, this can, and does, expedite the introduction of life-saving medicines.

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

### **INTRODUCTION**

According to the PTO, the PTAB has discretion under 35 U.S.C. § 314(a)<sup>1</sup> to deny review of an IPR petition that otherwise satisfies the relevant statutory institution standard. Request, 85 Fed. Reg. at 66,503; *see General Plastic Indus. Co. v. Canon Kabushiki Kaisha*, No. IPR2016–01357, 2017 WL 3917706, at \*8 (P.T.A.B. Sept. 6, 2017) (precedential) (“§ 314(a) recites ‘may not’ when referring to authorization for *inter partes* review, and does not specify any particular circumstance in which review must be authorized. That means institution of review is committed to the Director’s discretion, which, in turn, has been delegated to the Board.”). Under this purported authority, the PTAB weighs several factors to determine whether it should institute review when the same patent has been challenged in concurrent proceedings before the PTO or other tribunals, in an attempt to balance the goals of the AIA with the potential abuse of the review process. *See* Request, 85 Fed. Reg. at 66,503-04 (“The case-specific analysis the Office has developed attempt to balance Congress’s intent for AIA proceedings to be ‘quick and cost-effective alternatives to litigation,’ on the one hand, with ‘the importance of quiet title to patent owners to ensure continued investment resources,’ on the other hand.”).

These factors are currently set forth in various precedential and informative decisions including: (1) *Apple Inc. v. Fintiv, Inc. (Fintiv I)*, No. IPR2020-00019, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020) (precedential), which summarizes the non-exclusive factors the PTAB will apply to determine whether institution should be denied based on a parallel litigation in U.S. district courts or the International Trade Commission (“ITC”) and (2) *General Plastic* which lists the non-exclusive factors the PTAB will apply to determine whether institution should be denied based on an earlier or concurrent proceeding before the PTO. Request, 85 Fed. Reg. at 66,5504. The PTO seeks comments on the PTAB’s use of the so-called *Fintiv* and *General Plastic* factors to further determine whether it should engage in rulemaking to promulgate these considerations into its regulations. *Id.* at 66506.

For the reasons set forth below, Mylan believes the PTO has far exceeded its statutory authority by using the *Fintiv* factors to deny institution based on parallel litigation in other tribunals. Moreover, these factors have been inconsistently applied, resulting in unpredictable and unfair outcomes that only serve to insulate weak patents from review before a specialized tribunal. Mylan is further concerned that through *General Plastic* and its progeny, the

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<sup>1</sup> Unless otherwise noted, reference in this comment to statutory sections pertaining to IPRs, including institution of review under §314(a) and management of multiple proceedings before the PTO under 35 U.S.C. § 315(a), also encompasses the corresponding statutory sections related to post-grant reviews (“PGR”), including institution of review under 35 U.S.C. § 324(a) and management of multiple proceedings before the PTO under 35 U.S.C. § 325(a).

PTAB will continue to impermissibly expand the scope of its purported discretionary authority to such an extent that it forecloses an accused infringer's access to a quick and efficient administrative procedure to challenge weak patents. Accordingly, Mylan believes that any decision denying institution under 35 U.S.C. § 314(a) based on *Fintiv*, *General Plastics*, or other non-statutory factors should, and indeed must, be subject to appellate review since, for the reasons discussed herein, the PTAB is acting outside the scope of its statutory limits when exercising this so-called discretionary denial authority. *See Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131, 2141-42 (2016) (holding § 314(d) does not preclude appellate review of cases where the PTAB has engaged in "shenanigans" such as depriving parties of due process or when the agency "act[s] outside its statutory limits."); *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) ("[i]f a party believes the Patent Office has engaged in 'shenanigans' by exceeding its statutory bounds, judicial review remains available consistent with the Administrative Procedure Act, which directs courts to set aside agency action 'not in accordance with law' or 'in excess of statutory jurisdiction, authority, or limitations.'") (quoting *Cuozzo*, 136 S. Ct. at 1359; 5 U.S.C. §§ 706(2)(A), (C)).<sup>2</sup>

These legitimate concerns are evident in the PTAB's year-after-year declining institution rates, which are caused in part by the PTAB's increasing exercise of its asserted discretion under § 314(a). (*See* United States Patent and Trademark Office, Trial Statistics IPR, PGR, CBM (Sept. 2020), at 6 (although the number of petitions filed each year has varied, institution rates have dropped from 87% in 2013 to 56% in 2020); *see also* Unified Patents, *PTAB Procedural Denials and the Rise of § 314* (May 13, 2020) ("In 2016, by the most conservative count, just 5 petitions were denied under the Board's § 314(a) authority; in 2017, it was 15; by 2018, it was 45; and in 2019, it was 75. It is set to be more than double that in 2020."); Josh Landau, Patent Progress, *Changes Reducing IPR Institution Rate Have Increased Litigation Frequency and Cost* (Nov. 25, 2020) ("Fundamentally, discretionary denial has harmed the patent ecosystem, reversing the positive changes observed in patent litigation frequency and cost. The changes even appear to have increased the cost of IPR itself.")<sup>3</sup> Because the PTAB's increasing use of its so-called discretionary denial authority undermines Congressional intent and the very purpose of IPR, the PTO should not incorporate the *Fintiv* and *General Plastic* factors into any regulations.<sup>4</sup>

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<sup>2</sup> To the extent that appellate review of these discretionary denials is barred under §314(d) (which, again, Mylan believes are appealable), the absence of such review weighs decidedly in favor of the PTAB (i) narrowly (and rarely) exercising such discretion, and (ii) refraining from further expanding the scope of any such discretion through "precedential" decisions. Without checks or balances that appellate review provides, there is nothing to prevent the PTAB from applying its discretion inconsistently or indiscriminately, thus foreclosing reasonable access to agency review.

<sup>3</sup> [https://www.uspto.gov/sites/default/files/documents/trial\\_statistics\\_20200930.pdf](https://www.uspto.gov/sites/default/files/documents/trial_statistics_20200930.pdf);  
<https://www.unifiedpatents.com/insights/2020/5/13/ptab-procedural-denial-and-the-rise-of-314>;  
<https://www.patentprogress.org/2020/11/25/changes-reducing-ipr-institution-rate-have-increased-litigation-frequency-and-cost/>.

<sup>4</sup> Though not expressly included as a question in the Request for Comments, Mylan submits that the *Fintiv* and *General Plastic* factors are substantive rules that impermissibly and adversely

## DISCUSSION

Mylan provides the following responses to the presented questions regarding the PTAB's discretion to institute trial as it relates to proceedings in other tribunals and serial petitions.

### PARALLEL PROCEEDINGS IN OTHER TRIBUNALS

***Question: Should the Office promulgate a rule with a case-specific analysis, such as generally outlined in *Fintiv* and its progeny, 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?***

No. While Mylan commends the PTO for its interest in promoting consistency and fairness through rulemaking, the PTO should not promulgate any regulations codifying the case-specific analysis outlined in *Fintiv*, for at least two reasons. First, any such regulations would exceed the PTO's statutory authority and second, because of the flaws in the *Fintiv* decision, such rulemaking would result in inconsistent outcomes, encourage gamesmanship, and contravene Congress's clear intent to create the IPR pathway as alternative forum for challenging patent validity. *See e.g.*, 157 CONG. REC. S1352 (daily ed. Mar. 8, 2011) (statement of Sen. Udall) (recognizing administrative review proceedings before the PTO "are intended to serve as a less-expensive alternative to courtroom litigation and provide additional access to the expertise of the Patent Office on questions of patentability," indeed it is "often the preferred method of examination because a panel of experts is more likely to reach the correct decision on a technical question compared to a jury composed of laypeople.").

As an initial matter, Mylan is alarmed by the continual broadening of the PTO's so-called discretionary denial authority under § 314(a) with respect to parallel proceedings in other tribunals. The PTAB first articulated its new policy in *NHK Spring Co. v. Intri-Plex Technologies, Inc.*, No. IPR2018-00752, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018) (precedential), a case involving a petitioner's use of the same prior art reference and arguments used to reject claims during prosecution. Although the *NHK Spring* panel concluded there was independent basis to deny institution under § 325(d), in an expansive and unprecedented move to broaden the PTAB's discretion, the panel also denied institution under § 314(a) based on the status of the parallel district court litigation. *Id.* at \*7 ("the advanced state of the district court proceeding [jury trial set to begin six months before the PTAB's statutory deadline] is an *additional factor* that weighs in favor of denying the Petition under § 314(a)") (emphasis added).<sup>5</sup>

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impacts the rights and interests of IPR petitioners by permitting the PTAB to deny substantive review based on parallel PTO proceedings or litigation in other tribunals. Accordingly, the PTO should not be permitted to adopt and continue to apply these rules through a unilateral, internal process by designating them as "precedential" and affording no opportunity for public comment. *See* 5 U.S.C. § 553(b), (c); 35 U.S.C. §§ 2(b)(2), 316(a).

<sup>5</sup> Notably, following the PTAB's denial of institution, the district court ultimately extended the trial date an additional eight (8) months before the parties settled and dismissed the suit. Order,

So expansive and unprecedented in fact, that other PTAB panels and judges have later questioned whether § 314(a) can operate as an independent basis to support discretionary denial. *See e.g., Samsung Elecs. Co. v. Immersion Corp.*, No. IPR2018-01499, 2018 WL 7515967, at \*8 (P.T.A.B. Mar. 6, 2018) (declining to rely solely on § 314(a) to deny institution because, unlike *NHK Spring*, there was no independent reason for denial of the present case under 35 U.S.C. § 325(d)); *Ericsson Inc. v. Intellectual Ventures II LLC*, No. IPR2018-01689, 2019 WL 1751243, at \*24 (P.T.A.B. Apr. 16, 2019) (“it is unclear whether considerations under 35 U.S.C. § 314(a) alone would have supported discretionary denial of the petition in that case”); *Cisco Sys., Inc. v. Ramot at Tel Aviv Univ. Ltd.*, No. IPR2020-00122, 2020 WL 2511246, at \*8 (P.T.A.B. May 15, 2020) (Crumbley, ALJ, dissenting) (“[T]he panel in *NHK Spring* found that this ‘advanced stage’ of the proceeding was only enough to counsel for the denial of institution as an *additional factor* in connection with its decision to deny under 35 U.S.C. § 325(d). Here, by contrast, the majority concludes that similar facts are sufficient to counsel for denial *on their own*. This is a significant broadening of the rationale of *NHK Spring*, and should not subsume a measured examination of the stage of the litigation.”)(emphasis added).

Nonetheless, in *Fintiv*, the PTAB double downed on its independent authority to deny institution under § 316(a) by identifying six non-exclusive factors the PTAB should consider in determining whether institution should be denied based on parallel proceedings in other tribunals. *Fintiv I*, 2020 WL 2126495, at \*2-3; *see also Apple Inc. v. Fintiv, Inc. (Fintiv II)*, No. IPR2020-00019, 2020 WL 2486683, at \*4 (P.T.A.B. May 13, 2020) (“considerations of efficiency and fairness . . . can serve as an independent reason to apply discretion to deny institution” under § 314(a)).

Simply put, Mylan maintains that the PTAB has no discretionary authority to deny institution under § 314(a) based solely on proceedings in other tribunals. But even if the PTAB were to have that discretion, it should not, and indeed cannot, exercise any purported discretion based on the *Fintiv* factors. These factors are speculative, unpredictable, and have been inconsistently applied, resulting in outcomes contrary to the PTO’s stated goal of administrative efficiency. Thus, for the reasons set forth below, the PTO should not promulgate any regulations based on the case-specific analysis as outlined in *Fintiv* and its progeny.

**A. PTAB Has No Authority Under § 314(a) to Deny Institution Based Solely on Proceedings in Other Tribunals.**

Section 314(a) does not authorize the PTAB to deny institution of an otherwise-meritorious IPR petition based solely on the advanced state, or even the existence of, parallel proceedings in other tribunals. Far from an affirmative grant of such authority, the plain language of § 314(a) limits the Director’s discretion to whether “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged,” provided that the petition otherwise meets the statutory requirements under 35 U.S.C. §311 and subject to any patent

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*Intri-Plex Techs., Inc. v. NHK Int’l Corp.*, No. 17-cv-01097 (N.D. Cal. Aug. 7, 2019), ECF No. 254 (rescheduling trial for November 2019); Order, *Intri-Plex Techs., Inc. v. NHK Int’l Corp.*, No. 17-cv-01097 (N.D. Cal. Oct. 21, 2019), ECF No. 267 (dismissing suit with prejudice following settlement).

owner response pursuant to 35 U.S.C. § 313. Section 314(a) thus requires a substantive analysis of the asserted grounds of unpatentability, and does not otherwise grant the PTAB authority to consider alternative *non*-statutory grounds for denying institution, let alone justify denial based solely only on parallel proceedings, regardless of so-called efficiency or fairness factors.

Furthermore, under § 315, Congress has already expressly contemplated and specified how parallel proceedings should be accounted for or otherwise affect a pending petition. There can be no doubt that Congress not only was aware of the possibility of parallel litigation, but, refused to close the PTAB doors to an accused infringer because of it.

*First*, Congress unambiguously contemplated and enabled the possibility of parallel proceedings by ascribing a one-year period after service of a U.S. district court or ITC complaint for an accused infringer to file an IPR. 35 U.S.C. § 315(b); *see Thryv, Inc. v. Click-To-Call Techs., LP*, 140 S. Ct. 1367, 1374-1375 (2020) (function of statutory window is “to minimize,” not eliminate, the overlap between IPR and patent-infringement litigation). This express statutory window is *unqualified* and specifically accounts for any potential overlap between a timely filed IPR petition and a parallel litigation. Congress easily could have, but chose not to, require the accused infringer to make a showing that its petition was filed before an advanced stage of litigation or contains different grounds, arguments, or evidence than presented in the parallel proceeding.

*Second*, when it wanted to, Congress knew how to explicitly limit IPR based on parallel proceedings. More specifically, under § 315(a), Congress only barred PTAB review in the limited circumstance where the petitioner or real party in interest files a civil action challenging the validity of the patent before filing the IPR petition. 35 U.S.C. § 315(a)(1). Likewise, Congress only compelled a stay of parallel litigation when the petitioner or real party in interest filed a civil action challenging the validity of the patent on or after filing an IPR. 35 U.S.C. § 315(a)(2) (significantly, this provision only mandates stay of the civil action, not the PTAB proceeding). Congress also expressly omitted invalidity counterclaims brought by the accused infringer from the scope of any such bar or mandatory stay. 35 U.S.C. § 315(a)(3). The fact that Congress chose to bar or stay parallel litigation if it is initiated by the petitioner, but not when it is initiated by the patent owner, is significant particularly because of the unqualified one-year period to allow an accused infringer to file an IPR. At bottom, Congress was well aware of the potential for parallel proceedings, and made deliberate policy choices on how to account for them in the IPR framework. *See e.g., Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2146 (2016) (“This possibility, however, has long been present in our patent system, which provides different tracks—one in the Patent Office and one in the courts—for the review and adjudication of patent claims. . . . These different evidentiary burdens mean that *the possibility of inconsistent results is inherent to Congress’s regulatory design.*”) (emphasis added). That Congress chose not to grant the PTAB discretion to deny institution solely based on such proceedings speaks volumes. The PTO has no authority to ignore, much less change, those deliberate Congressional choices.

*Third*, while Congress granted the PTAB discretion under § 315(d) to stay, transfer, consolidate, or terminate parallel proceedings involving the same patent before the PTO, there is no analogous grant of authority with respect to parallel proceedings in other tribunals. 35 U.S.C. § 315(d). This Congressional silence recognizes the value of preserving an accused infringer’s

access to the PTAB's expertise when an accused infringer "truly believes that the patent being asserted is invalid," and the "important[ance] for it to have an avenue to request the PTO to take another look at the patent in order to better inform the district court of the patent's validity." 157 CONG. REC. H4425-26 (daily ed. June 22, 2011) (statement of Rep. Goodlatte).

*Fourth*, while Congress expressly estops an accused infringer, following an unfavorable final written decision, from asserting the same grounds that were raised or could have reasonably been raised in another PTO action, district court action, or ITC proceedings, there is no parallel provision based on a district court or ITC validity decision. 35 U.S.C. §§ 315(e), 325(e). This is a deliberate legislative choice because that bar existed under the pre-AIA *inter partes* reexamination scheme that IPR was intended to replace. 35 U.S.C. § 317(b) (2011) ("once a final decision has been entered against a party in a civil action . . . that the party has not sustained its burden of proving the invalidity of patent claim in suit or if a final decision in an *inter partes* reexamination proceeding instituted by a third-party requester is favorable to the patentability of any original or proposed amended or new claim of the patent, *then neither that party nor its privies may thereafter request an inter partes reexamination of any such patent claim on the basis of issues that the party or its privies raised or could have raised in such civil action or inter partes reexamination proceeding.*") (emphasis added).

Lastly, any suggestion that the PTO has discretion to deny institution based on non-statutory efficiency and fairness factors simply because the PTO is authorized to promulgate regulations under § 316(a) is deeply flawed. The PTO's rulemaking authority is not *carte blanche* to re-write the governing statute nor otherwise disregard Congressional intent. As set forth above, the one-year time bar under § 315(b) unambiguously reflects Congress' considered judgment that IPR institution can only be barred when the petitioner files more than one year from service of the infringement complaint. The PTAB's discretion is neither warranted nor appropriate where, as here, Congress has directly addressed the precise question at issue by legislating a bright-line rule to determine the effect of a parallel proceeding. Because Congress left absolutely no statutory gap for the PTO to fill, there is no room for agency discretion to change, if not upset, the balance set by Congress. *United States v. Home Concrete & Supply, LLC*, 566 U.S. 478, 487 (2012) ("The fact that a statute is unambiguous means that there is 'no gap for the agency to fill' and thus 'no room for agency discretion.'") (quoting *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 982–83 (2005)). In addition, to the extent the PTO may consider the "[t]he economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete instituted proceedings" when promulgating regulations, the PTO's rulemaking authority is still limited to the enumerated aspects of AIA proceedings identified under § 316(a). 35 U.S.C. § 316(a)-(b). While this section authorizes the PTO to "set[] forth the standards for showing of sufficient grounds to institute a review under section 314(a)" or establish "the relationship of [IPR] review to other [PTO] proceedings," noticeably absent is any authority, much less directive, to consider whether instituting an IPR would result in duplicative proceedings in other tribunals. 35 U.S.C. § 316(a). Moreover, as discussed in the next section, the interest of the economy cannot possibly be served when the *Fintiv* factors are inconsistently applied or continue to evolve after a petition is filed, making it impossible for accused infringers to decide if, when, and on what grounds it should petition for PTAB review. Likewise, when the discretionary factors can be manipulated by the patent owners based on, among other things, the

chosen venue or the timing of certain litigation milestones, this threatens the integrity of the patent system as a whole. Similarly, the finite resources of the PTAB is also no reason to support discretionary denial, since the filing fees due at both the petition and institute stages, are supposed to capture the aggregate cost of conducting the requested review.

For at least these reasons, there is every reason to believe that Congress considered but refused to endow the PTAB with discretion and authority under § 314(a) to deny institution based solely on the status and scope of parallel proceedings, and little reason to believe otherwise. This, alone, is reason enough for the PTO not to promulgate a contrary rule.

**B. *Fintiv* and Its Progeny Provide No Clear Guidance Regarding How the Non-Exhaustive Factors Should Be Weighed or Applied, Resulting in Inconsistent and Unpredictable Outcomes that Undermine IPR and the Patent System.**

Besides the PTAB lacking authority to deny institution based on parallel proceedings, *Fintiv* and its progeny are also deeply flawed, leading to inconsistent decision-making that encourages gamesmanship and contravenes Congress's clear intent to create IPR as an efficient forum for challenging a patent. Because many of the *Fintiv* factors require speculation about the likely course of parallel litigation, including prognosticating about whether a court will grant a stay or amend the case schedule or whether the parties will settle or drop claims and defenses, it often produces inconsistent and unfair outcomes. Moreover, because there is no discernable consensus regarding how these factors may be consistently applied or balanced against each other, any regulation codifying the *Fintiv* factors could be used to justify virtually any conclusion, which only serves to undermine the IPR pathway and the patent system as a whole. The section below discusses each of the six factors and some of the inconsistent, if not absurd, outcomes that have resulted in the mere seven months since the PTAB designated *Fintiv* as precedential.

○ **Factor 1: Whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted**

Under this factor, the PTAB considers whether a stay has been granted or may be granted in the future. *Fintiv I*, 2020 WL 2126495, at \*3-4. The PTAB strictly applies this factor and routinely declines to speculate as to the likelihood of a stay where none has been requested. See e.g., *Supercell Oy v. Gree, Inc.*, No. IPR2020-000215, 2020 WL 3092613, at \*4 (P.T.A.B. June 10, 2020) (“[W]e determine that the least speculative course of action is to focus on the record in this case, which is silent as to whether the district court has granted a stay, or has commented on the possibility of a stay in this case.”). But even where a district court has expressed a willingness to reconsider a motion to stay request following an institution decision, the PTAB has declined to apply this factor in favor of institution. See e.g., *Cisco*, 2020 WL 2511246, at \*3 (even where the district court has an “established practice” to reconsider a motion to stay if the review is instituted, the PTAB “decline[s] to speculate how the district court would rule on another stay request. A judge determines whether to grant a stay based on the facts in each case.”). This means, for all practical purposes, the only way this factor favors institution is if the petitioner obtains a pre-institution stay, which are routinely denied as premature. Accordingly, this factor is preordained to weigh against institution.

In addition, *Fintiv* and its progeny disregard the obvious tension and overlap between this and other factors such that the district court's refusal to grant a pre-institution stay may be outcome determinative, despite the petitioner's best efforts to balance opposing interests. District courts typically consider the stage of the district court proceeding and whether a stay will simplify the issues—both of which implicate other *Fintiv* factors—in deciding whether to stay a litigation pending IPR. More specifically, factor 4 considers facts relevant to the overall investment in the parallel litigation and factor 5 considers the overlap of issues between the two proceedings.

This tension puts the petitioner in the difficult, if not impossible position, of trying to predict the appropriate time to move for a stay and decide how many overlapping grounds it should include in its petition at the outset to increase the chances of a stay. The earlier the defendant files its motion to stay the district court action, the more likely the district court may deny the motion as premature since the PTAB has not instituted review. *Supercell OY v. Gree, Inc.*, No. PGR2020-00041, 2020 WL 5519314, at \*5 (P.T.A.B. Sept. 14, 2020) (observing “legitimate reasons may lead a party not to file a motion to stay a parallel proceeding prior to the Board’s institution decision, including because such a motion may be viewed as premature”). But the later the defendant waits to file the motion, the less likely a district court will stay the case if it has invested significant resources, which also favors denial of institution under *Fintiv* factor 4. *See e.g., Cisco*, 2020 WL 2511246, at \*3 (majority concluding that the district court would be less inclined reconsider granting a stay after it conducted a *Markman* hearing). Likewise, the more overlap between the two proceedings, the more likely the district court will grant a motion to stay, but also the more likely the PTAB will deny review under factor 5 if a stay is not granted. *See id.* at \*7. This demonstrates the folly of basing an institution decision on an ill-advised factor that requires the petitioner to speculate about the likely course of parallel litigation at the time it files its petition.

○ **Factor 2: Proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision**

Under this factor, the PTAB bases an institution decision on the possibility of a district court trial prior to the projected statutory deadline for a final written decision. *Fintiv I*, 2020 WL 2126495, at \*3-4; *Google LLC v. Parus Holdings, Inc.*, No. IPR2020-00847, 2020 WL 6166339, at \*6 (P.T.A.B. Oct. 21, 2020) (“This proximity inquiry is a proxy for the likelihood that the trial court will reach a decision on validity issues before the Board reaches a final written decision.”). The PTAB considers whether the district court’s trial date (as of the schedule entered at the institution date) is earlier than the projected statutory deadline, and often declines to speculate on whether the trial date may later be subsequently extended.

*First*, this factor ignores the reality that schedules entered early in district court cases are not fixed and are frequently modified and extended during litigation. *See e.g., Precision Planting, LLC v. Deere & Co.*, No. IPR2019-01044, 2019 WL 6481776, at \*6 (P.T.A.B. Dec. 2, 2019) (a district court trial date is often a moving target because courts routinely “extend or accelerate deadlines and modify case schedules for myriad reasons.”). Indeed, in some jurisdictions, courts simply enter a “Trial Readiness” date early on in the litigation, and wait to evaluate or set a pretrial schedule as that readiness date approaches. This often means that the trial

date could be several months *after* the readiness date—yet this earlier date could be used to deny institution, despite being a poor proxy for the likelihood of a district court decision before a final written decision. Moreover, a scheduled trial date far from guarantees a final judgement in any specified timeframe since post-trial events can take many more months, even years, to resolve. *Sand Revolution II, LLC v. Cont’l Intermodal Grp. (Sand Revolution I)*, No. IPR2019-01393, 2020 WL 581790, at \*8 (P.T.A.B. February 5, 2020) (DeFranco, ALJ, dissenting) (“[T]hat a jury trial may occur in the district court before any Final Decision would be due here does not guarantee the entry of final judgment by the district court before the time of any Final Decision on our part, as the district court litigation may still need to continue with a damages trial and post-trial motions.”). Thus, a patent owner is incentivized to game the system by accelerating the district court schedule at the start of the litigation only to later request extensions or slow the progress of the litigation after institution is denied.

*Second*, this factor effectively requires a petitioner to file its IPR at least 18 months before any trial is scheduled in a parallel proceeding—which may be impossible in so-called “rocket docket” venues where the scheduled trial date may come sooner than the statutory deadline even if the accused infringer files a petition shortly after suit. *See e.g.*, R. Tata, ‘*Rocket Docket*’ *Justifies Its Name for 11<sup>th</sup> Straight Year*, LAW360 (Jun. 10, 2019) (identifying three district court venues where the median time to trial was less than 18 months); B. Eakin, *West Texas Judge Says He Can Move Faster Than PTAB*, LAW360, (Nov. 27, 2019) (citing local rules for U.S. District Judge Alan D. Albright who schedules trial around 12-14 months after case management conference).<sup>6</sup> Indeed, the PTAB has strictly applied this factor even when the scheduled trial date was less than 18 months after patent issuance. *Supercell Oy v. Gree, Inc.*, No. IPR2020-00310, 2020 WL 3368960, at \*5 (P.T.A.B. June 18, 2020) (this factor weighed against institution even though the petitioned patent issued on May 14, 2019, the Eastern District of Texas trial date was scheduled for October 5, 2020 (16 months and 21 days after patent issuance), and the statutory final written decision deadline was June 2021).<sup>7</sup> This would, for all practical purposes, foreclose an IPR option when an accused infringer is sued in a venue with a compressed litigation schedule. This factor can also promote unequal and unfair outcomes depending on where the accused infringer is subject to suit under the relevant venue rules. Defendants who can be sued in faster jurisdictions may be disadvantaged by having a shorter period to petition for IPR compared to other defendants who are only subject to venue in slower jurisdictions. There simply is no basis in the statute to support, or to otherwise believe that Congress could possibly have contemplated or intended, such disparate results based on a factor that is not within the control of the petitioner. Furthermore, because the average time to trial can vary significantly by jurisdiction, this factor only encourages forum shopping to try to insulate patents from IPR challenges.

*Third*, and just as critically, this factor also truncates the ability of a petitioner to make full use of the one-year window Congress expressly provided to allow the accused infringer

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<sup>6</sup> <https://www.law360.com/articles/1167066/-rocket-docket-justifies-its-name-for-11th-straight-year>; <https://www.law360.com/articles/1224105/west-texas-judge-says-he-can-move-faster-than-ptab>.

<sup>7</sup> By the time of the PTAB’s institution determination, the trial date had been extended two months, but this did not change the Board’s analysis or the weight given this factor against institution.

to have “a reasonable opportunity to identify and understand the patent claims that are relevant to the litigation.” *See* 157 CONG. REC. S5429 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl). Indeed, the pressure to act immediately forces defendants either to forgo an IPR altogether, or else hastily file an IPR, potentially reducing the quality of the petition, given the compressed period to search for prior art, retain experts, draft and file the petition and supporting declarations. Moreover, Congress’s decision to key the 1-year time bar off of service of the complaint, as opposed to another litigation milestone, reflects the implicit benefit of selecting a time marker that is fixed early in the litigation, not subject to change once other actions have occurred, and does not vary depending on the venue. The PTAB should not supplant this express statutory period with one of its own that does nothing more than introduce uncertainty and the opportunity for gamesmanship.

*Fourth*, compounding the disparate treatment, the PTAB has inconsistently applied this factor when it comes to (1) the delta between the trial date and projected statutory deadline and (2) the weight afforded this factor if the trial date is uncertain. For example, consider just a few of the representative examples below evidencing the disparate outcomes based on similar facts:

- *Fintiv II*, 2020 WL 2486683, at \*5 (“Because the currently scheduled District Court trial is scheduled to begin two months before our deadline to reach a final decision, this factor weighs somewhat in favor of discretionary denial in this case” even in spite of evidence of previous trial date extensions and potential pandemic related complications) (emphasis added);
- *Sand Revolution II, LLC v. Con’l Intermodal Grp. (Sand Revolution II)*, No. IPR2019-01393, 2020 WL 3273334, at \*4 (P.T.A.B. June 16, 2020) (finding factor “weighs marginally in favor of not exercising discretion” even though jury trial was currently scheduled to begin four months before the final decision deadline given other evidence that the trial date is uncertain based upon, among other things, previous extensions and pandemic related complications) (emphasis added);
- *Apple Inc. v. Parus Holdings, Inc.*, No. IPR2020-00687, 2020 WL 5665773, at \*6 (P.T.A.B. Sept. 23, 2020) (viewing “this factor as neutral” since court had not scheduled trial date yet, even though if trial was held during the range of proposed dates, this predicted timeline would be approximately two months before the final written decision deadline) (emphasis added); and
- *Google LLC v. Parus Holdings, Inc. (Google)*, No. IPR2020-00846, 2020 WL 6164613, at \*6 (P.T.A.B. Oct. 21, 2020) (finding this “factor is, at best, neutral” where the trial is scheduled to begin three months before the final decision and there was some evidence that further delays are possible) (emphasis added).

Thus, for all the reasons listed above, this factor unfairly weighs against institution by failing to consider the likelihood, if not certainty, of post-institution changes to the litigation schedule. Moreover, the inconsistent application of this factor is manifest, making it difficult for the

petitioner to predict how the PTAB would weigh this factor, which complicates the decision whether to expend resources to file an IPR in the first instance.

- **Factor 3: Investment in the parallel proceeding by the court and the parties**

Under this factor, the PTAB considers “the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision” and the diligence of the petitioner in filing the petition. *Fintiv I*, 2020 WL 2126495, at \*4. With respect to the parties’ and the district court’s investment, the PTAB advises that “district court claim construction orders may indicate that the court and the parties have invested sufficient time in the parallel proceeding to favor denial.” *Id.* With respect to the petitioner’s diligence, “notwithstanding that a defendant has one year to file a petition,” the PTAB considers the timing of when the petitioner becomes aware of the claims being asserted compared to the timing of the patent owner response to the petitioner’s invalidity contentions in the parallel proceedings as landmarks delineating when a petitioner has acted “expeditiously.” *Id.* at \*5.

*First*, the PTAB exceeds its authority and undermines Congress’s clear intention to provide an unqualified one-year period for an accused infringer to challenge the patentability of a patent by requiring the petitioner to also prove it acted “expeditiously,” despite filing its petition within the proscribed statutory window. *See* 35 U.S.C. § 315(b). This extra-statutory requirement forces petitioners to forgo the one-year statutory period Congress deemed necessary to determine whether to file an IPR and the opportunity to “identify and understand” the relevant patent claims and prior art. 157 CONG. REC. S5429 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl) (rejecting a proposal for a shorter time bar (six months) reasoning that the longer period was necessary given the challenge of determining “in the first few months of the litigation which claims will be relevant and how those claims are alleged to read on the defendant’s products.”). This effectively renders the one-year window meaningless, because the PTAB can deny instituting an otherwise timely-filed and meritorious petition on non-statutory grounds.

*Second*, as with other factors, the PTAB has disparately applied this factor in different cases, resulting in a range of outcomes for the acceptable time period to file the petition in relation to other litigation milestones.

- *Cisco*, 2020 WL 2511246, at \*4 (finding this factor weighed “somewhat in favor of discretionary denial” because the completion of claim construction hearing and *Markman* hearing (no terms construed by Court yet) at the time of the institution decision, despite evidence that petitioner diligently filed petition less than five months into the statutory period and less than two months after receiving the Patent Owner’s infringement contentions and before it served its invalidity contentions);
- *Vmware, Inc. v. Intellectual Ventures I LLC*, No. IPR2020-00470, 2020 WL 4873198, at \*8 (P.T.A.B. Aug. 18, 2020) (finding this factor neutral even though Court completed *Markman* hearing and issued a claim construction order at time of institution decision, but also finding the timing of the petition reasonable because

the petitioner filed less than four weeks after serving its initial invalidity contentions and nearly six months before the statutory deadline);

- *HP Inc. v. Neodron Ltd.*, No. IPR2020-00459, 2020 WL 5519487, at \*17-18 (P.T.A.B. Sept. 14, 2020) (finding this factor weighed “*somewhat against denying institution*” even though parties completed claim construction briefing and Court held *Markman* hearing because petitioner acted diligently by filing its petition nearly five months before the statutory deadline and approximately two months after the patent owner served its preliminary infringement contentions and two weeks prior to the petitioner’s service of preliminary invalidity contentions); and
- *SMIC, Americas v. Innovative Foundry Techs., LLC*, No. IPR2020-00786, 2020 WL 5902835, at \*9 (P.T.A.B. Oct. 5, 2020) (finding this factor *weighed against exercising discretion* even though at the time of the institution decision the parties had completed claim construction discovery and briefing and the court had already held its *Markman* hearing, the panel also noted that petitioner acted expeditiously by filing its petition within one week of receiving patent owner’s infringement contentions).

*Third*, considering whether claims have been construed by the district court is also contrary to the PTAB’s own regulations, which contemplate that an IPR may proceed after a district court has construed the claims and the PTAB may consider this previous construction of the disputed terms. 37 C.F.R. § 42.100(b) (“Any prior claim construction determination concerning a term of the claim in a civil action, or a proceeding before the International Trade Commission, that is timely made of record in the *inter partes* review proceeding will be considered.”).

- **Factor 4: Overlap between the issues raised in the petition and in the parallel proceeding**

Under this factor, whether “the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding” favors denial. *Fintiv I*, at 2020 WL 2126495 at \*5-6. But even when the PTAB would be the first tribunal to assess the patentability of non-overlapping claims or defenses, it “may still be inefficient to proceed because the district court may resolve validity of enough overlapping claims to resolve key issues in the petition.” *Id.* at \*6; *HP*, 2020 WL 5519487, at \*18 (giving no weight to the unasserted claims that are challenged in the petition because the petitioner did not identify any prejudice associated with not instituting trial on the non-overlapping claims); *Apple Inc. v. Maxell, Ltd.*, No. IPR2020-00409, 2020 WL 4680047, at \*4-5 (P.T.A.B. Aug. 11, 2020) (finding this factor favored discretionary denial even though the petition challenged all six patent claims compared to the one claim at issue in the parallel litigation, based on different prior art and motivation to combine).

*First*, this factor incorrectly assumes that the asserted claims and patents in parallel litigation are fixed and cannot be changed after suit is filed. As is often the situation, the patent owner may reduce the number of asserted claims and patents in the parallel litigation as the case

progresses and the trial date approaches. If this reduction occurs after the PTAB declines to institute review, then there is a real possibility that the unasserted claims and patents would be left unchallenged. This also encourages gamesmanship because factor may cause the patent owner to assert as many patents as possible in their complaint to increase the “overlap” with the IPR, only to later drop patents and claims once IPR is no longer a viable pathway.

*Second*, as Administrative Law Judge Crumbley observed, this factor must be weighed in light of the reasonable belief that “significant overlap between the issues in the proceedings makes it more likely that the district court will grant a motion to stay,” *Cisco*, 2020 WL 2511246, at \*8 (cautioning against “interpret[ing] this *Fintiv* factor so strictly that it creates a presumption that both cases will move forward concurrently”). As such, the overlap between the two proceedings actually favors institution because it will ultimately simplify and efficiently resolve patent validity issues through estoppel. *Id.* at \*9 (reasoning that if the district court litigation is stayed and “all challenged claims are found unpatentable, then there is nothing left for the district court to decide on the question of infringement,” while if one or more claims are upheld, then the estoppel provision under § 315(e)(2) will constrain the invalidity arguments that can be raised before the court, likely leaving only the question of infringement).

*Third*, even in instances where a petitioner stipulates they will not pursue overlapping grounds in district court litigation if the IPR is instituted, the PTAB has only weighed this factor “marginally in favor of not exercising discretion to deny institution.” *Sand Revolution II*, 2020 WL 3273334, at \*5 n. 5 (observing that a broader stipulation, which, in effect, is a stipulation not to raise any 35 U.S.C. §§ 102 or 103 invalidity grounds in the district court, even if those grounds are not included in the pending petition, “might have tipped this factor more conclusively in [the petitioner’s] favor”). But this, once again, puts the petitioner in a difficult position: include all available grounds in its petition at the outset, thereby increasing the chances the PTAB denies institution if the district court does not stay the litigation prior to institution, or otherwise risk waiving its right to an IPR altogether and losing the benefit of having an expert panel of judges adjudicate its claims.

Moreover, different panels have considered the effect of the stipulation differently when it comes to multi-defendant litigations involving unrelated parties. *Compare SMIC*, 2020 WL 5902835, at \*10 (finding that the proposed stipulation would not mitigate the overlap where the petitioner provided no evidence “that it has the authority to make such a stipulation as to all of the defendants in the parallel litigation”), *with Google*, 2020 WL 6164613, at \*8 (“Patent Owner does not explain persuasively why we should preclude Petitioner from raising its challenges here based on the speculation that unrelated parties in litigation might later raise those same challenges,” despite the patent owner’s assertion that the other co-defendants have asserted the same art as in the petitioner’s petition).

- **Factor 5: Whether the petitioner and the defendant in the parallel proceeding are the same party**

While this factor plainly suggests that the PTAB only considers whether the petitioner and the defendant are the same or related parties, *Fintiv* actually instructs weighing this

factor against institution “[e]ven when a petitioner is unrelated to a defendant . . . if the issues are the same as, or substantially similar to, those already or about to be litigated, or other circumstances weigh against redoing the work of another tribunal, the Board may, nonetheless, exercise the authority to deny institution.” *Fintiv I*, 2020 WL 2126495, at \*6.

*First*, this factor defies logic and common sense. If this factor weighs against institution, then it automatically penalizes a petitioner for simply being a defendant in a district court proceeding. *See Cisco*, 2020 WL 2511246, at \*9 (Crumbley, ALJ, dissenting) (“In cases such as the one at hand, where the parties are the same, the factor is neutral. To hold otherwise—that the factor weighs in favor of denial if the parties are the same—would, in effect, tip the scales against a petitioner merely for being a defendant in the district court. But I see no basis for such a presumption, either in the text of the statute or in the intent of Congress in passing it.”). This factor has no place in any analysis because the petitioner’s status as a defendant in parallel litigation something Congress *expressly* permitted by creating a one-year window for an accused infringer to petition for PTAB review. To the extent it does, at best, it should only be neutral or otherwise weigh in favor of institution if the petitioner or defendant is not the same party. *Id.*

*Second*, this factor, once again, ignores the realities of litigation particularly with respect to unrelated defendants and the potential for litigation outcomes completely outside the control of the petitioner. For one, unrelated parties could have different motivations and litigation strategies to challenging the asserted patent (e.g., different non-infringement defenses, asserted claims, litigation styles, etc.). Moreover, under this factor, the PTAB does not consider what would happen if the unrelated defendant in the parallel litigation settles or drops invalidity grounds or claims after the PTAB denies institution. *See Fintiv I*, 2020 WL 2126495, at \*6 (acknowledging that a parallel proceeding may settle or fail to resolve the patentability question). Thus, it is fundamentally unfair for the PTAB to deny an accused infringer access to PTAB review simply because the patent has also been asserted against another defendant—particularly when two or more district courts may freely adjudicate the same or substantially similar invalidity issues regarding the same patent against different defendants. Such a result is “contrary to the goal of providing district court litigants an alternative venue to resolve questions of patentability.” *Cisco*, 2020 WL 2511246, at \*9 (Crumbley, ALJ, dissenting).

○ **Factor 6: Other circumstances that impact the Board’s exercise of discretion, including the merits**

Under this catchall factor, the PTAB considers “if the merits of a ground raised in the petition seem particularly strong on the preliminary record, this fact has favored institution,” but “if the merits of the grounds raised in the petition are a closer call, then this fact has favored denying institution when other factors favoring denial are present.” *Fintiv I*, 2020 WL 2126495, at \*6. Indeed, even when the strength of the merits and “factor 6 weigh[s] toward institution, [the PTAB] would still deny institution because of the significant weight of the other *Fintiv* factors against institution.” *Google LLC v. Personalized Media Commc’ns*, No. IPR2020-00720, 2020 WL 6530766, at \*4 (P.T.A.B. Nov. 5, 2020).

Thus, despite Congress's clear directive that only a merits assessment should be considered as part of any determination under § 314(a), under *Finitiv* and its progeny, institution of a bulletproof petition that otherwise complies with the statutory requirements can still be outweighed by other non-statutory factors. 35 U.S.C. § 314(a) (the PTAB "may not authorize an *inter partes* review to be instituted unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition"). This is the very definition of unreasoned decision-making, and it certainly should not be codified in rules.

***Question: Alternatively, in deciding whether to institute a petition on a patent that is or has been subject to other proceedings in district court or the ITC, should the Office (a) altogether disregard such other proceedings, or (b) altogether decline to institute if the patent that is or has been subject to such other proceedings, unless the district court or the ITC has indicated that it will stay the action?***

The PTAB should altogether disregard any district court or ITC proceeding(s) in deciding whether to institute review that otherwise complies with the procedural and statutory timing requirements and meets the institution threshold. This, of course, still permits the PTAB to consider information from the parallel proceeding for the purpose of PTAB's merit-based assessment of whether there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims.

For the reasons set forth above with respect to the previous question, Mylan does not believe the PTAB has any authority to deny institution based on the existence or "advance stage" of proceedings in other tribunals. Through the 1-year time bar, estoppel, and other express provisions in § 315, Congress has already considered and accounted for the effect of parallel proceedings in other tribunals. The PTAB has no discretion, much less authority, to supplant this careful consideration with its own non-statutory grounds for denying institution.

#### **SERIAL PETITIONS**

***Question: Should the Office promulgate a rule with a case-specific analysis, such as generally outlined in *General Plastic*, *Valve I*, *Valve II* and their progeny, for deciding whether to institute a petition on claims that have previously been challenged in another petition?***

No. The PTO should not promulgate regulations based on *General Plastic*, *Valve I*, *Valve II* and their progeny as it applies to claims that have been previously challenged in another petition by an unrelated party. Based on overarching concerns about abuse of the review process with repeated attacks on patents, the PTAB explained in *General Plastic* that it has authority under § 314(a) to deny institution of so-called "follow-on" or "serial" petitions seeking review of the same patent claims challenged in a previous PTAB proceeding and set forth seven nonexclusive

factors for the PTAB to consider.<sup>8</sup> Request, 85 Fed. Reg. at 66,504 (citing *General Plastic*, 2017 WL 3917706, at \*7).

The PTAB later broadened the application of the *General Plastic* factors in *Valve Corporation v. Electronic Scripting Products, Inc. (Valve I)*, Nos. IPR2019-00062, -00063, -00084, 2019 WL 1490575, at \*4 (P.T.A.B. Apr. 2, 2019) (precedential), where it denied institution based on an earlier petition filed by the petitioner's co-defendant challenging the same claims. Even though the current petitioner did not file the previous petition, the PTAB determined that the petitioners were "similarly situated" and shared a "significant relationship" because they were both accused of infringement based on the same product. *Id.* at \*5 (where the co-defendant's device incorporated technology licensed from the petitioner). The PTAB explained that application of these factors "is not limited solely to instances when multiple petitions are filed by the same petitioner" and it would consider "*any relationship* between" different petitioners challenging the same patent. *Id.* at \*4 (emphasis added). The following month, the PTAB even further broadened the application of the *General Plastic* factors to another case involving the same parties in *Valve Corporation v. Electronic Scripting Products, Inc. (Valve II)*, No. IPR2019-00064, -00065, 00085, 2019 WL 1965688 (P.T.A.B. May 1, 2019) (precedential). Using similar reasoning from *Valve I*, the PTAB denied institution because the petitioner previously petitioned, and was ultimately joined as a petitioner, to the earlier filed IPR submitted by HTC Corporation and HTC America, Inc. *Id.* at \*1.

Through shifting and incremental adjudications, the PTAB has gone from using the *General Plastic* factors solely with respect to follow-on petitions by the same petitioner to now applying it to petitioners who are unrelated, but are purportedly similarly situated, and share some undefined and ambiguous "significant relationship" with the earlier petitioner. *Valve I*, 2019 WL 1490575, \*5. Depending on how the PTAB continues to apply or broaden this standard in the future, Mylan is concerned the PTAB may find a way to extend *General Plastic*—as patent owners continue to encourage it to do so—to bar different petitioners who share no relationship other than being both accused of infringing the same patent.<sup>9</sup> Such a result would, in effect, automatically

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<sup>8</sup> The *General Plastic* factors include: (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 PTAB'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 PTAB; and (7) the requirement under 35 U.S.C. 316(a)(11) to issue a final determination not later than one year after the date on which the Director notices institution of review." *General Plastic*, 2017 WL 3917706, at \*7.

<sup>9</sup> To date, there is no evidence that the PTAB has applied *General Plastic* in this situation, but patent owners have increasingly encouraged the PTAB to consider doing so under the PTAB's

deny an IPR option to a petitioner who files later in time and would create a perverse incentive to rush to the PTO to file the first IPR. Such a result is fundamentally inconsistent with the purpose and function of the AIA.

***Question: Alternatively, in deciding whether to institute a petition, should the Office (a) altogether disregard whether the claims have previously been challenged in another petition, or (b) altogether decline to institute if the claims have previously been challenged in another petition?***

To the extent that the PTAB considers whether the petitioned claims have been previously challenged, it should be limited to whether the same prior art or arguments have been previously presented in a petition, as Congress directed in 35 U.S.C. § 325(d). Under such circumstances, Congress has authorized the PTAB to determine the manner in which review may proceed, including providing for a stay, transfer, consolidation, or termination of any such proceedings. *Id.*

In view of this authority, the PTO should not adopt a bright-line rule or otherwise automatically decline to institute review simply because the petitioned claims have been previously challenged in another petition. Any such policy would preclude the PTO from instituting review of petitions that challenge the same claims, on any grounds, by any party, even those unrelated to the first petitioner. There is no basis in the AIA to support such a result given Congress's clear intent to only limit certain parties from petitioning for review—e.g., the patent owner or any accused infringer (and their real-parties-in-interest or privies) served with a complaint more than one year from the petition. Implementing a first-to-file policy would also encourage an artificial and chaotic race to the PTAB, which could have a direct effect on the quality of the petition, and prevent “a meaningful opportunity to improve patent quality and restore confidence in the presumption of validity that comes with issued patents in court.” H.R. REP. NO. 112-98, pt. 1, at 48 (2011).

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*Valve I* precedent. See e.g., *Google*, 2020 WL 6164613, at \*10 (finding *General Plastic* weighs in favor of institution since there is “no apparent relationship” between two petitions given they “are accused of infringement based on different, competing products”); *Google LLC v. Uniloc 2017 LLC*, No. IPR2020-00396, 2020 WL 4463086, at \*5 (P.T.A.B. Aug. 3, 2020) (rejecting patent owner argument that even though Google and Samsung are direct competitors who have different products they nonetheless shared an implicit relationship given the close overlap between the petitions); *Mercedes-Benz USA, LLC v. Carucel Invs., L.P.*, No. IPR2019-01404, 2020 WL 374571, at \*3-4 (P.T.A.B. Jan. 22, 2020) (rejecting patent owner argument that Mercedes and Volkswagen are “similarly situated defendants” since they were sued around the same time and both patent litigation cases have been consolidated for discovery and claim construction and both cases involve the same patents, similar infringement theories, and are expected to involve identical claim construction and invalidity issues.).

In conclusion, Mylan respectfully urges the PTO to reconsider the scope of its authority under § 314(a), particularly with respect to the use of the *Fintiv* factors to deny institution based on parallel proceedings in other tribunals, and use of the *General Plastic* factors when it comes to denying institution of an IPR petition challenging patent claims previously challenged by an unrelated party.

Mylan appreciates the opportunity to provide comments on the considerations for instituting AIA trials as it relates to proceedings in other tribunals and serial AIA petitions. 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 PTO to revisit and reassess patents it may have issued in error.

Sincerely,



William A. Rakoczy  
on behalf of Mylan Pharmaceuticals Inc.