

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited,

Petitioners,

v.

Breckenridge Pharmaceutical, Inc.,

Patent Owner.

U.S. Patent No. 11,013,729

Title: Oral Pharmaceutical Compositions of Dabigatran Etexilate

Case No.: IPR2025-01107

**PETITIONERS' OPPOSITION TO PATENT OWNER'S
REQUEST FOR DISCRETIONARY DENIAL**

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EXHIBIT LIST

Exhibit	Description
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1002	File History of U.S. Appl. No. 14/379,613
1003	File History of U.S. Appl. No. 17/241,793
1004	File History of U.S. Appl. No. 18/356,642
1005	Declaration of Maureen D. Donovan, Ph.D.
1006	Curriculum Vitae of Maureen D. Donovan, Ph.D.
1007	U.S. Patent Publication No. 2006/0183779 (“Brauns”)
1008	File History of U.S. Appl. No. 11/381,890
1009	U.S. Patent Publication No. 2006/0115525 (“Leane”)
1010	U.S. Patent Publication No. 2004/0109890 (“Sugimoto”)
1011	<i>Pharmaceutics: The Science of Dosage Form Design</i> , M.E. Aulton, Ed. (2d. edition 2002) pp. 247-48 (“Aulton”)
1012	K. Lavanya et al., “Pelletization Technology: A Quick Review,” <i>Int’l J. Pharm. Sci. & Res.</i> 2(6):1337-55 (June 2011) (“Lavanya”)
1013	Reserved
1014	FDA Approved Label for Pradaxa (October 2010)
1015	J. Stangier, “Clinical Pharmacokinetics and Pharmacodynamics of the Oral Direct Thrombin Inhibitor Dabigatran Etexilate,” <i>Clin. Pharmacokinet.</i> 47(5):285-95 (2008) (“Stangier”)
1016	FDA Guidance for Industry: Dissolution Testing of Immediate Release Solid Oral Dosage Forms (August 1997)
1017	FDA Dissolution Methods for Dabigatran Etexilate Mesylate (09/22/2011)
1018	Australian Public Assessment Report for Dabigatran etexilate mesylate (May 2011)
1019	FDA Paragraph IV Patent Certifications (06/15/2020)
1020	USPTO Assignments for U.S. Appl. No. 14/379,613
1021	U.S. Patent Publication No. 2008/0069891 (“Habib”)
1022	International Patent App. Pub. No. WO 2012/001156 A2 (“Krka”)
1023	Remington, <i>The Science and Practice of Pharmacy</i> , 21st Ed. (2006) (“Remington”)
1024	Steward Memorandum, Interim Processes for PTAB Workload Management (March 26, 2025)

I. INTRODUCTION

Petitioners oppose Patent Owner's request for discretionary denial.¹ Discretionary denial is not warranted under 35 U.S.C. § 314(a) and the *Fintiv* framework, or under 35 U.S.C. § 325(d) and the *Advanced Bionics* framework.² Nor is denial warranted based on the factors set forth in the March 2025 Interim Processes for PTAB Workload Management ("March 2025 Memorandum"). See Ex. 1024.

First, the *Fintiv* factors weigh decisively against discretionary denial. The claims of the '729 patent challenged in this petition are not involved in any other AIA proceedings. Moreover, contrary to Patent Owner's suggestion, the invalidity challenges raised in the instant Petition have not been—and may never be—adjudicated in the parallel litigation in *Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc.*, No. 24-cv-571 (GBW) (D. Del.) (the "*Hetero* Litigation").

¹ Patent Owner's Request for Discretionary Denial, dated August 13, 2025, Paper 7, is referred to as "Req. ____."

² Patent Owner's Request also cites 35 U.S.C. § 312(a)(3) as allegedly supporting discretionary denial in this case. Req. at 3, 6, 19. Patent Owner, however, has failed to cite any authority supporting the applicability of Section 312(a)(3) to discretionary denial of an IPR institution. The only case Patent Owner cites is *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016). Req. at 19. *Intelligent Bio-Systems*, however, involved the Board's discretion to exclude an improper reply brief filed during an instituted IPR. See *Intelligent Bio-Sys.*, 821 F.3d at 1370 (finding "the Board did not abuse its discretion in finding that IBS's reply brief and accompanying declaration were improper").

Importantly, Petitioners are not parties to the *Hetero* Litigation and have no affiliation with the *Hetero* Litigation defendants. Indeed, they are market competitors. This distinction significantly diminishes the *Hetero* Litigation's relevance under multiple *Fintiv* factors. Indisputably, the evidence Petitioners rely on to challenge the validity of the '729 patent may not be presented in the *Hetero* Litigation. Discretionary denial in this case would also undermine the goals of efficiency, fairness, and patent quality, while exposing Petitioners to future enforcements. The Board should therefore decline to exercise its discretion under Section 314(a).

Second, institution is also supported under Section 325(d). The Petition presents obviousness arguments that are materially distinct from those discussed during prosecution. Of the three prior art references cited in support of the obviousness grounds in the Petition—Brauns (Ex. 1007), Leane (Ex. 1009), and Sugimoto (Ex. 1010)—only Brauns was relied upon by the Examiner as a basis for rejection. Leane was not before the Patent Office, and Sugimoto, though cited in an IDS,³ was not used by the Examiner as a basis for rejection.

³ The Petition's statement that "Sugimoto was not cited as prior art during prosecution of the '729 patent" is an inadvertent error. Pet. at 31. Sugimoto was cited in an IDS during prosecution of the '729 Patent. However, this error does not detract from the Petition or the analysis under Section 325(d) because, as discussed herein, the Examiner materially erred by not raising an objection in view of Sugimoto.

As the Petition demonstrates, the Examiner materially erred by failing to reject the claims in view of Brauns and Sugimoto. Sugimoto discloses a two-particle system that, just like the composition claimed in the '729 patent, was designed to *enhance* the dissolution of an active substance at the desired site—achieving *the same result* as the single-particle system in Brauns. Instead, the Examiner repeatedly rejected the pending claims in view of Brauns and *Habib*. But as noted by the Board on appeal from the Examiner's rejection, Habib's composition was intended to “*inhibit* dissolution of the drug,” i.e., “*the opposite result*” compared to increasing bioavailability taught in Brauns. Pet. at 20-21 (citing Ex. 1002 at 87-88). Thus, Sugimoto is in no way “duplicative” of Habib, as Patent Owner claims.

Further, contrary to Patent Owner's assertion, Leane is not cumulative of Sugimoto or any other reference that was before the Examiner during prosecution of the '729 patent. Leane discloses a two-particle system designed to enhance the dissolution of chitosan, an excipient that in turn enhances the bioavailability of an active substance at the desired site. Thus, Leane and Sugimoto reinforce the prior art teaching that separating chemically incompatible substances into distinct particles was a “convenient way” to deliver them in a single dose. The Board should decline to exercise its discretion under Section 325(d).

II. THE PETITION ACCURATELY SUMMARIZES THE ORIGINAL PROSECUTION

The Petition provides an accurate summary of the prosecution of the '729 patent. *See* Pet. at 13-21. Patent Owner raises only one dispute, asserting that the Petition incorrectly suggests “that the ‘sole issue’” on appeal from the Examiner’s rejection in view of Brauns and Habib “was ‘whether a POSA would have viewed a two-particle system as a viable alternative to the one-particle system of Brauns.’” Req. at 5 (citing Pet. at 26). Patent Owner’s assertions are incorrect.

The selective quoting Patent Owner presents appears in the following excerpt in the Petition:

As noted above, Brauns was the primary reference cited by the PTO during prosecution of the '729 patent, and applicants ultimately overcame the Examiner’s obviousness rejections over Brauns in view of Habib based on the PTAB’s finding that Habib would not have sufficiently motivated a POSA to modify Brauns to develop a composition with the “two distinct types of particles,” as required by the claims of the '729 patent. In doing so, the PTAB found that all of the claim limitations had been addressed, and the sole issue was whether a POSA would have viewed a two-particle system as a viable alternative to the one-particle system of Brauns.

Pet. at 26. The above summary of the PTAB findings in the Petition is consistent with the quotes below from the PTAB decision.

We are persuaded by Appellant’s argument and agree that Examiner has not articulated a sufficient rationale for combining the two particle composition taught in Habib to modify the single particle composition taught in Brauns.

See Ex. 1002 at 87.

In view of these teachings, Examiner has not sufficiently explained why a skilled artisan would be motivated to combine Habib with Brauns to achieve a composition with the “two distinct types of particles” recited in Appellant’s claims. For this reason, Examiner has not met the burden to establish a *prima facie* showing of obviousness. Accordingly, the rejection is not supported by the preponderance of the evidence and we, therefore, reverse.

See id. at 88.

Notably, the Board did not take any issue with the Examiner’s finding that a combination of Brauns and Habib disclosed the limitations of the pending claim. There is nothing “inaccurate” or “misleading” in the Petition’s summary of the ’729 patent’s prosecution history.

III. DISCRETIONARY DENIAL IS UNWARRANTED UNDER SECTION 314(a)

In determining whether to exercise discretion to deny institution in view of a parallel proceeding under 35 U.S.C. § 314(a), the Board developed a framework that includes consideration of six factors (the “*Fintiv* factors”). *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 5-6 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv*”). They include: (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. *Id.* at 6.

“These factors relate to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding.” *Id.* In evaluating the *Fintiv* factors, the Board does not sum up the total number of factors in favor of institution versus those against. Rather, it takes “a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review,” recognizing that “there is some overlap among these factors” and that “[s]ome facts may be relevant to more than one factor.” *Id.* More recently, the Acting Director issued the March 2025 Memorandum identifying additional exemplary discretionary criteria that may be considered and stating that parties are “permitted to address all relevant considerations.” Ex. 1024 at 2.

As set forth below, the *Fintiv* factors are all either neutral or favor institution in this case. Moreover, the Petition’s strong merits, the parties’ settled expectations, the public’s economic interests, and efficiency considerations all further favor institution.

A. Factor 1: Whether the *Hetero* Litigation May Be Stayed Weighs in Favor of Institution.

Patent Owner correctly points out that neither party to the *Hetero* Litigation has filed a motion to stay pending the outcome of an IPR on the '729 patent, and that the district court has not considered a stay in the *Hetero* Litigation. *See* Req. at 7. Under these circumstances, the Board generally “decline[s] to infer . . . how the District Court would rule should a stay be requested by the parties in the parallel case.” *See Hulu, LLC v. SITO Mobile, Ltd.*, IPR2021-00298, Paper 11, at 10-11 (PTAB May 19, 2021) (quoting *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15, at 12 (PTAB May 13, 2020) (informative)). Thus, factor 1 is, at a minimum, neutral.

But the analysis of factor 1 does not end there. Petitioners are not parties to the *Hetero* Litigation and have no relationship or affiliation with the defendants in that case. This critical distinction significantly limits the relevance of the *Hetero* Litigation under factor 1. Indeed, in recent decisions, the Board has determined that “factor [1] weighs strongly against exercising our discretion to deny institution” where Petitioner was “not a party to the [district court] litigation” and “[n]o evidence of a significant relationship between [district court litigant] and Petitioner exists.” *Bose Corp. v. Koss Corp.*, IPR2021-00680, Paper 15, at 13-14 (PTAB Oct. 13, 2021); *see also Owens Corning Roofing & Asphalt, LLC v. Kirsch Rsch. & Dev., LLC*, IPR2020-01389, Paper 11, at 11 (PTAB Feb. 18, 2021) (determining *Fintiv*

factors 1 and 2 weighed “strongly in favor of institution” where the petitioner was not alleged to be a party to parallel litigation scheduled for trial prior to the projected Final Written Decision deadline but was instead a defendant in a separate litigation that did not have a set trial date). The same reasoning applies here.

The cases cited by Patent Owner do not support discretionary denial. For example, Patent Owner cites *Sand Revolution II LLC v. Continental Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24, at 7 (PTAB June 16, 2020). *See* Req. at 8. First, the petitioner in *Sand Revolution II LLC* was the defendant in the parallel district court litigation brought by the patent owner. *Sand Revolution II LLC*, Paper 24, at 3-4. In any event, the Board in *Sand Revolution II LLC* found *Fintiv* factor 1 neutral, and on balance it declined to discretionarily deny institution. *Id.* at 7 (“we do not find that this factor weighs in favor of either exercising or not exercising discretion to deny institution under 35 U.S.C. § 314(a).”); *id.* at 2-3 (finding “the application of discretion to deny under 35 U.S.C. § 314(a) is not warranted when we apply the [*Fintiv*] factors”).

Thus, *Fintiv* factor 1 weighs strongly in favor of institution.

B. Factor 2: The Proximity of the Trial Date in the *Hetero* Litigation and the Board’s Projected Statutory Deadline Weigh in Favor of Institution.

Fintiv factor 2 looks to the “proximity of the court’s trial date to the Board’s projected statutory deadline.” *Fintiv*, Paper 11, at 9. As the Board has further explained, “[t]his 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.” *Bose Corp.*, Paper 15, at 15.

Here, the Board’s final written decision is anticipated by December 25, 2026, while the jury trial in the *Hetero* Litigation is currently scheduled to begin on October 6, 2026. The Scheduling Order in the *Hetero* Litigation was entered on November 6, 2024 (Ex. 2002 at 10, Dkt. 31), and has since been modified at least three times at the parties’ request. *Id.* at 11 (Dkt. 40), and Feb. 10, 2025 Order; *see also id.* at 13 (Dkt. 75 and 76), 16 (Dkt. 101). Assuming the trial date remains unchanged—for example, not postponed due to a joint request from the parties—the district court trial may begin approximately two and a half months before the Board issues its final decision. However, this timing proximity carries limited weight. *See, e.g., Bose Corp.*, Paper 15, at 15 (determining that the efficiency and system integrity concerns that animate “the *Fintiv* analysis are present but not strong” where the

district court trial date was scheduled to start “approximately five months before the [Board’s] final decision”).

Moreover, none of Patent Owner’s cited cases support discretionary denial of the instant Petition. Req. at 10. For example, the parties in *NXP USA, Inc. v. Impinj, Inc.* were involved in a district court litigation. See IPR2021-01556, Paper 10, at 3, 7 (PTAB Apr. 21, 2022). Further, the petitioner in *NXP USA* did not address *Fintiv* or Section 314(a) in its petition. *Id.* at 6. Even assuming that *NXP USA* is relevant, the Board found factor 2 only “weighs **somewhat** in favor of discretionary denial.” *Id.* at 8 (emphasis added). Similarly, the parties in *Cisco Systems, Inc. v. Portsmouth Network Corp.* were involved in a district court litigation. IPR2024-00503, Paper 7, at 2 (PTAB Aug. 6, 2024). And again, the Board found factor 2 “weighs **only slightly** in favor of discretionary denial,” and on balance still decided to institute the petition. *Id.* at 12, 16-17. And the patent owner in *EClinicalWorks, LLC v. Decapolis LLC* had filed infringement actions not only against the petitioner, but also against 14 other parties. IPR2022-00229, Paper 10, at 2-4 (PTAB Apr. 13, 2022). Here, too, the Board found factor 2 “weighs **somewhat** in favor of denial.” *Id.* at 9 (emphasis added).

On the other hand, when addressing a similar scenario, i.e., where petitioners are *not* parties to the parallel litigation, the Board has concluded that *Fintiv* factor 2

“weighed strongly against exercising [] discretion to deny institution.” *Bose Corp.*, Paper 15, at 15. The same reasoning applies here. Thus, *Fintiv* factor 2 weighs strongly in favor of institution.

C. Factor 3: Investment in the *Hetero* Litigation Supports Institution.

The parties in the *Hetero* Litigation have invested time and resources in the district court litigation. Req. at 11-12. But substantial work remains, including completion of fact discovery (November 21, 2025) and expert discovery (March 30, 2026), and briefing on dispositive and *Daubert* motions (May 31, 2026). *See Hulu*, Paper 11, at 13; *see also Arthrex, Inc., v. Medshape, Inc.*, IPR2025-00053, Paper 11, at 10-11 (PTAB Apr. 25, 2025) (finding factor 3 *marginally* favored denial where “work remains in the Parallel Proceeding [between petitioner and patent owner], including fact discovery, expert discovery, and dispositive motion practice.”) (emphasis added).

But again, the analysis does not end there. This is because Petitioners acted diligently in filing this Petition *before* being sued by Patent Owner. *See Fintiv*, Paper 11, at 11 (“[i]f the evidence shows that the petitioner filed the petition expeditiously . . . this fact has weighed against exercising the authority to deny institution.”). Thus, this fact supports instituting trial in the instant petition.

Petitioners’ diligence also distinguishes the present case from those cited by Patent Owner. *See* Req. at 12-14. For example, the petitioner in *10x Genomics, Inc. v. President & Fellows of Harvard College* not only waited “until exactly one year after it was served with the counterclaim for infringement of the [challenged] Patent and nine months after receiving the initial infringement contentions,” but also failed to provide any explanation for the delay. IPR2023-01299, Paper 15, at 18-19 (PTAB Mar. 7, 2024). Similarly, the petitioner in *Nokia of America Corp., et al. v. Pegasus Wireless Innovation LLC* delayed filing its petition until seven months after petitioner was served infringement contentions in the parallel litigation, and five months after petitioner served its invalidity contentions, but did not explain the delay in filing the petition. IPR2025-00036, Paper 14, at 12 (PTAB Apr. 25, 2025).

Thus, factor 3 supports institution in this case.

D. Factor 4: Overlap Between the *Hetero* Litigation and the Petition Strongly Favors Institution.

Patent Owner contends that the validity issues in the *Hetero* Litigation present “significant overlap.” Req. at 14-15. Not so. First, Defendants’ First Supplemental Invalidity Contentions in the *Hetero* Litigation do not disclose Leane, which forms the basis in combination with Brauns for Ground 1 in this Petition. Second, the Brauns and Sugimoto combination, presented as Ground 2 in this Petition, appears to be just one out of six or more obviousness combinations asserted in the

Defendants' Contentions, served on February 14, 2025. *Id.* at 15. And Brauns and Sugimoto are the only overlapping prior art Patent Owner identifies out of the eleven (11) prior art references in Defendants' Contentions. Notably, Defendants in the *Hetero* Litigation appear to advance several additional invalidity positions based on Section 112. *See* Ex. 2006 at 53-57. Thus, it remains unclear—and is certainly not guaranteed—that the specific invalidity challenges raised in this Petition will reach a decision in the *Hetero* Litigation. Indeed, the fact that Petitioners are not parties to the *Hetero* Litigation strongly suggests that the two proceedings will proceed independently and will rely on different evidentiary records.

More importantly, Patent Owner has not asserted claims 8 and 9 of the '729 patent against the *Hetero* Litigation defendants, so that litigation cannot possibly resolve all claims at issue in this proceeding. Further, even if one or more of the claims asserted in the *Hetero* Litigation reach trial, they will be adjudicated under a different legal standard than the claims challenged here. *See ParkerVision, Inc. v. Qualcomm Inc.*, 116 F.4th 1345, 1362 (Fed. Cir. 2024) (“In the IPR proceedings, Qualcomm’s burden of proof was only a preponderance of the evidence. Accordingly, Qualcomm proved the capabilities of the prior art apparatus by a preponderance of the evidence. To prevail on its invalidity contentions in the district court, however, Qualcomm must meet a higher burden: clear and convincing

evidence.”) (internal citations omitted). Under similar circumstances, the Board has previously declined to exercise its discretion to deny institution. *See 3Shape A/S and 3 Shape Inc., v. Align Tech., Inc.*, IPR2020-00223, Paper 12, at 34 (PTAB May 26, 2020) (deciding to institute trial despite the fact that “the projected statutory deadline for a final written decision in this proceeding is after the date when the ITC Investigation would conclude,” finding *inter alia* that “[t]he ITC Investigation will not address the validity of claims 3, 4, 6, 21, 22, and 26 and, for those claims that are addressed, the ITC will apply a more stringent standard than applied in an inter partes review.”).

While this factor already strongly weighs in favor of institution, Petitioners further stipulate that they will not pursue the Grounds raised, or that could have been reasonably raised, in this Petition in a parallel district court litigation should this Petition proceed to a final written decision. *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12, at 18-19 (PTAB Dec. 1, 2020) (precedential). This *Sotera* stipulation eliminates any risk of duplication or conflicting decisions. *Id.* Further, the *Sotera* stipulation distinguishes the cases relied on by Patent Owner. *See* Req. at 16 (citing *Samsung Display Co., Ltd., v. Pictiva Displays Int’l Ltd.*, IPR2024-00855, Paper 12, at 11 (PTAB Nov. 19, 2024) (explaining that petitioner “has not filed any stipulation regarding the use of the references that it has raised or could

have reasonably raised in the district court”); *see id.* at 17 (citing *Sand Revolution II LLC*, Paper 24, at 12 n.5 (PTAB June 16, 2020) (“Notably, Petitioner stipulates only that it will not pursue, in district court, the ‘same grounds’ presented in the Petition in this case.”)).

Thus, factor 4 strongly favors institution.

E. Factor 5: The Fact That Petitioners Are Not Parties to the *Hetero* Litigation Strongly Favors Institution.

There is no dispute that Petitioners are not parties in the *Hetero* Litigation. As the Board explained in *Fintiv*, “[i]f a petitioner is unrelated to a defendant in an earlier court proceeding, the Board has weighed this fact *against exercising discretion* to deny institution under NHK.” *Fintiv*, Paper 11, at 13-14 (emphasis added). More recently, the Board has repeatedly reiterated that factor 5 favors institution when the petitioner is not a party to a parallel district court litigation. *See, e.g., Savant Techs. LLC v. Feit Elec. Co.*, IPR2024-01357, Paper 17, at 14-15 (PTAB Mar. 5, 2025) (finding *Fintiv* factor 5 favors institution when petitioner is not a party to a litigation expected to go to trial about three months before the statutory deadline for final written decision); *Posco Co., Ltd. v. Arcelormittal*, IPR2025-00370, Paper 10, at 2 (PTAB Jun. 25, 2025); *Multi-Color Corp. v. Brook & Whittle Ltd.*, PGR2025-00025, Paper 10, at 2 (PTAB Jul. 16, 2025) (referring the petition to the Board finding certain “factors counsel against discretionary denial,” including the

fact that petitioner is not a party to two district court proceedings regarding the challenged patent, and represents that it has no substantive relationship with any defendant in the district court proceedings); *CSPC Megalith Biopharmaceutical Co., Ltd. v. Shanghai Miracogen Inc.*, IPR2025-00685, Paper 9, at 2 (PTAB Jul. 31, 2025) (referring the petition to the Board, finding *inter alia* “**the parties** are not involved in parallel proceeding involving the challenged patent”) (emphasis added); *Charles River Lab ’ys, Inc. v. Seikagaku Corp.*, IPR2025-00440, Paper 9, at 2 (PTAB Jul. 10, 2025) (referring the petition to the Board finding, *inter alia*, “Patent Owner and Petitioner are not engaged in a parallel Litigation.”); *CSPC Pharm. Grp. Ltd., et al. v. IPSEN Biopharm Ltd.*, IPR2025-00505, Paper 11, at 2 (PTAB Jul. 16, 2025) (same).

Patent Owner has failed to cite any cases in which the Board exercised discretion and denied instituting a petition when the petitioner was not a party to the parallel district court litigation. *See* Req. at 17-18. Instead, Patent Owner cites inapposite cases in which the petitioner was a party to the parallel district court litigation. *See Shenzhen Root Tech. v. Chiaro Tech. Ltd. d/b/a Elvie*, IPR2024-01296, Paper 9, at 20 (PTAB Feb. 25, 2025) (“The parties are the same in both this *inter partes* proceeding and in the Shenzhen Root case.”); *BOE Tech. Grp. Co., Ltd. v. Optronix Scis. LLC*, IPR2024-01130, Paper 16, at 13 (PTAB Jan. 27, 2025) (“It is

undisputed that the parties here are the same parties in the parallel district-court litigation.”). More notably, although the same parties in the parallel district court litigation were involved in the petition, the Board instituted trial in *BOE Technology*, finding factor 5 “neutral or weigh[ing] slightly in favor of not exercising discretionary denial.” *BOE Technology*, Paper 16, at 14.

Moreover, this Petition aligns with the objectives of the AIA, which seeks to promote efficient resolution of patent validity to avoid future litigation. Patent Owner may assert the ’729 patent beyond the *Hetero* Litigation. Because Petitioners are not parties to the *Hetero* Litigation, Petitioners have no opportunity to challenge the patent’s validity in that forum. Indeed, the *Hetero* Litigation may not resolve potential litigation against Petitioners. If the Board were to exercise its discretion under Section 314(a) and deny institution, Petitioners would be unfairly deprived of the opportunity to challenge the ’729 patent under the AIA. Such a denial would effectively shield the ’729 patent from scrutiny by Petitioners based on litigation against unrelated parties. Additionally, the parties in the *Hetero* Litigation may settle before any judicial determination on the validity of the ’729 patent, leaving Petitioners exposed to future enforcement and at a competitive disadvantage. Denying institution under these circumstances would be unfair and contrary to

public policy. *See Fintiv*, Paper 11, at 5 (explaining that factors aim to “balance efficiency, fairness, and patent quality.”).

Thus, factor 5 strongly weighs in favor of institution.

F. Factor 6: Other Circumstances That Impact the Board’s Exercise of Discretion, Including the Merits, Favor Institution.

Under Board precedent, the Director should consider the compelling-merits factor only if the first five *Fintiv* factors favor discretionary denial. *See, e.g., CommScope Techs. LLC v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23, at 4-5 (PTAB Feb. 27, 2023) (precedential). As discussed above, the first five *Fintiv* factors weigh against discretionary denial, and therefore, consideration of factor 6 is not necessary. Nevertheless, as discussed below, other considerations, including the Petition’s merits, reliance on expert testimony, the parties’ settled expectations, and public interest, favor institution.

1. The Petition Presents Two Compelling Obviousness Grounds.

The compelling merits of this Petition further reinforce the case for institution and outweigh any potential concerns under factors 1 through 5. *See Ericsson Inc. v. Active Wireless Techs. LLC.*, IPR2024-00951, Paper 12, at 15, 21 (PTAB Dec. 11, 2024) (instituting trial despite finding *Fintiv* factors 1-5 favor denial because the petition presented compelling merits).

As discussed in the Petition, the '729 patent claims a pharmaceutical composition containing dabigatran etexilate with a pharmaceutically acceptable organic acid, wherein the dabigatran etexilate and the organic acid are in separate particles, and the acid-containing particles have a protective coating. Pet. at 1; *see also* Ex. 1001 at 9 (Claim 1).

The Petition also presents the known properties of dabigatran etexilate. Pet. at 9. For example, it was known that (i) dabigatran etexilate dissolves relatively well in water at low acidic pH levels, while being “virtually insoluble” at pH levels above 5, (ii) tartaric acid improves dabigatran etexilate’s bioavailability by increasing its solubility independently of gastric pH and preventing malabsorption, and (iii) dabigatran etexilate is prone to chemical degradation and polymorphic form transformation in an acidic environment. *Id.*

During prosecution of the '729 patent, the pending claims were repeatedly rejected over Brauns in view of Habib. Pet. at 13-20.

Brauns discloses a dabigatran etexilate mesylate dosage form with suitable dissolution, bioavailability, and stability. Pet. at 23, 34-35. The dosage form described in Brauns comprises a layered pellet structure with an insulating layer that spatially separates the organic acid core from the dabigatran etexilate layer prior to administration. *Id.* This structure increases the stability of the finished drug product

before ingestion, while allowing the organic acid to dissolve after administration, thereby creating an acidic environment in the stomach in which dabigatran etexilate can dissolve independently of the stomach's pH. *Id.*

Habib discloses an “abuse resistant drug formulation” comprising two particles wherein the first particle comprises an API and the second particle comprises a fat/wax material present in an amount *sufficient to inhibit the dissolution of the API from the first particle*, e.g., if a capsule containing those particles is crushed, dissolved, or injected. Ex. 1002 at 87; *see also* Pet. at 15-16.

The applicant appealed the Examiner's rejection to the Board. Pet. at 20. On appeal, the applicant argued that the “Examiner has not presented a sufficient prima facie showing because Brauns describes only a single, layered particle composition that achieves an acidic microenvironment through ‘immediate diffusion’ of the acid layer into the active substance layer and there is no motivation or suggestion in the cited references to change that composition to the ‘two distinct types of particles’ recited in Appellant's claims.” Ex. 1002 at 87-88. The Board found “that Examiner has not articulated a sufficient rationale for combining the two particle composition taught in Habib to modify the single particle composition taught in Brauns.” *Id.* at 87. The Board noted “Brauns teaches that an advantage of the ‘spatial separation of the organic acid and active substance by the insulating layer’ in its layered particle

composition is that it increases bioavailability by facilitating the creation of ‘an acid microclimate in which the active substance can dissolve’ when acid from the core diffuses into the drug layer.” *Id.*; Pet. at 20-21. However, the Board found that Habib’s composition was intended to “*inhibit* dissolution of the drug,” i.e., “*the opposite result*” compared to increasing bioavailability taught in Brauns. Ex. 1002 at 87-88 (emphasis added); Pet. at 20-21. Accordingly, the Board reversed the Examiner’s rejection, finding that “Examiner has not sufficiently explained why a skilled artisan would be motivated to combine Habib with Brauns to achieve a composition with the ‘two distinct types of particles’ recited in Appellant’s claims.” Ex. 1002 at 88.

As discussed in the Petition, prior art not used by the Examiner as a basis for rejection or before the Board on appeal would have motivated a POSA to prepare the claimed two-particle system to spatially separate the organic acid from dabigatran etexilate prior to administration, thus increasing the stability of the finished drug product, while allowing the organic acid to dissolve after administration to create an acidic environment in the stomach enabling dabigatran etexilate to dissolve independently of the stomach pH. Pet. at 35-37.

Patent Owner asserts “the Petition fails to articulate a proper and sufficient basis (supported by evidence) to modify Brauns in the first place, much less to do so

to achieve the claimed invention with a reasonable expectation of success.” Req. at 21. Patent Owner’s argument lacks any merit. Indeed, the Petition clearly sets forth several motivations to modify the Brauns teachings in view of Leane (Ground 1) or Sugimoto (Ground 2), and explains why a POSA would have reasonably expected to successfully prepare the composition claimed in the ’729 patent. Pet. at 34-37 (citing Ex. 1005 ¶¶ 184-96).

First, the Petition explains that a POSA would have been motivated to design around Brauns’s pending claims, which had been allowed by the PTO at that time. *Id.* at 35. Patent Owner criticizes the Petition for allegedly lacking authority or evidentiary basis for this statement. Patent Owner’s assertion is incorrect. The Petition cites the prosecution history of Brauns showing the pending claims had been allowed at the time, as well as citing the Donovan Declaration explaining a POSA’s motivation. Pet. at 35 (citing Ex. 1005 ¶ 188, and Ex. 1008 at 55, 127, 173). Further, it is well settled that a fact finder “should consider a range of real-world facts to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue,” and that a motivation to combine can be found explicitly or implicitly in the prior art references themselves, in market forces, in design incentives, or in “any need or problem known in the field of endeavor at

the time of invention and addressed by the patent.” *Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1359 (Fed. Cir. 2017).

Second, the Petition explains that a POSA would have been motivated to explore alternative methods for spatially separating tartaric acid from dabigatran etexilate that were different from Brauns’s multilayered pellet structure. This is because, in practice, forming an intact insulating layer—necessary for ensuring storage stability and durability of the drug product—was challenging. Pet. at 35 (citing Ex. 1005 ¶¶ 190, Ex. 1022 at 5). In particular, the Petition cites Exhibit 1022, which discloses challenges encountered when preparing a multilayered pellet structure as taught in Brauns:

“The formulations . . . contain a tartaric acid crystal core, [which] increases the dissolution rate of dabigatran by modifying the pH of the microenvironment when the pellet is dissolved. On the other hand, dabigatran etexilate is unstable in the presence of tartaric acid; therefore, an isolating layer between the tartaric acid core and API (Active Pharmaceutical Ingredient) layer has to be applied. ***This is particularly tricky since the tartaric acid cores are produced by powder layering of tartaric acid dust onto tartaric acid crystals. The cores produced by such a process are only quasi-spherical and it is very difficult to avoid the formation of satellites which cause defects in the isolating layer. The so-called satellites are small particles adhering to the outside of the otherwise rounded pellets and detracting from the otherwise spherical geometry of the pellets. These lead to impaired storage stability and hence durability of the finished product.***”

Ex. 1022 at 5 (emphasis added).

Third, the Petition explains that “preparing distinct particles (e.g., pellets) was known as a ‘convenient way’ to separate chemically incompatible substances that needed to be delivered in a single dose.” Pet. at 35 (citing Donovan Decl. ¶ 191, which in turn cites Ex. 1012 at 2, 16-17).

Fourth, the Petition explains that prior art discloses successful applications of two-particle systems containing an organic acid in separate coated particles, which improved the solubility of a pH-dependent material while controlling when—or at what rate—the material with pH-dependent solubility encounters the organic acid. Pet. at 36-37 (citing Ex. 1005 ¶¶ 193-96, which in turn cites specific paragraphs from Leane and Sugimoto). The Petition further explains that a POSA would have been motivated to combine the teachings of Brauns with Leane, or with Sugimoto, because all these prior art references aim to solve the same problem: improving the dissolution of a material having pH-dependent solubility in the digestive tract while controlling the timing or rate at which the acid comes into contact with the material. Pet. at 37 (citing Ex. 1005 ¶¶ 187, 193-94, 196).

Finally, the Petition explains that a POSA would have had a reasonable expectation of success in combining Brauns with either Leane or Sugimoto, as each reference teaches similar solutions, namely, incorporating an organic acid in the drug formulation while spatially separating the organic acid from a compound with pH-

dependent solubility and acid incompatibility until the preparation reaches the intended site of dissolution. Pet. at 37. Further, these approaches yield a similar and predictable outcome: increased dissolution of the compound having pH-dependent solubility at the desired site, while avoiding contact between the organic acid and the acid-incompatible compound before the drug product reaches its desired site of action. Pet. at 37 (citing Ex. 1005 ¶¶ 187, 193-94, 196).

Thus, the Petition presents ample evidence supporting a POSA's motivation to modify the teachings of Brauns in view of Leane (Ground 1) or Sugimoto (Ground 2) to arrive at the claimed invention. Neither the Examiner nor the Board previously discussed the evidence presented in the instant Petition when evaluating the patentability of the '729 patent.

Patent Owner then alleges that the Petition does not address the "declaration testimony from the inventor of Brauns, who attested (during prosecution of Brauns) that '[a]n acid core layer, and insulating layer and an active substance layer are necessary components' of the single particle invention, as they provide an acidic microenvironment in close proximity of the active substance layer and the organic acid layer." Req. at 23-24.

Patent Owner's argument misinterprets the declaration testimony from the inventor of Brauns. The cited testimony in Brauns's prosecution states that the

different layers in the single-particle system in Brauns “are necessary components” *of the single particle invention*. Ex. 1002 at 194 (Brauns Decl. ¶ 19). More specifically, the Brauns inventor declared:

The present formulation was designed to accommodate the specific and unique properties of the prodrug, dabigatran etexilate, ***an acid core layer, an insulating layer and an active substance layer are necessary components of this invention***. For example, the acid core layer provides the low-pH microenvironment once the formulation enters the stomach. The insulating layer first acts as a protective layer between the acid core and active substance layer on storage but then permits the diffusion of acid to the active substance layer immediately in passage through the stomach. The active substance layer provides the correct dosage of prodrug.

Id. (emphasis added). Nothing in the cited testimony suggests that the acid core layer, the insulating layer, and the active substance layer are also “necessary” in ***a two-particle composition***. As discussed in the Petition, a POSA would have understood that in a two-particle system, the acid can be spatially separated from the acid-sensitive component during manufacturing or storage, while still creating an acidic environment post-administration to enhance dissolution of the acid-sensitive component at the desired site of action. Pet. at 27-28 (citing Ex. 1009 ¶¶ [0015]-[0016], [0022], [0044], [0058]-[0059]), 31 (citing Ex. 1010 ¶¶ [0001], [0008]-[0009], [0013], [0077]-[0084]).

Patent Owner’s argument regarding reasonable expectation of success is similarly meritless. Req. at 24-25. Patent Owner argues “[t]he Petition does not point

to any salient teaching in Leane or Sugimoto about how to formulate dabigatran etexilate and an organic acid into separate particles.” *Id.* To the contrary, the Petition cites specific paragraphs in both Leane and Sugimoto teaching how to prepare separate particles of an organic acid and a drug substance, such as dabigatran etexilate. *See* Pet. at 39-40 (explaining Leane discloses a composition comprising drug compound agglomerates and organic acid agglomerates, citing, e.g., Ex. 1009 ¶¶ [0058]-[0059]); *see also id.* at 46-50 (explaining Brauns and Leane teachings regarding methods for preparing the disclosed agglomerates); Pet. at 52-53 (explaining Sugimoto discloses compositions comprising drug compound granules and organic acid granules and methods of preparing same, citing, e.g., Ex. 1010 ¶¶ [0013], [0024]-[0025], [0131]-[0132]).

Finally, Patent Owner’s argument that the Petition and the Donovan Declaration present “the same conclusory assertions on obviousness” lacks any merit. Req. at 26. Both the Petition and the Donovan Declaration present evidence supporting the two obviousness grounds presented, including (i) the scope and content of the prior art (Pet. at 34-62 and Ex. 1005 ¶¶ 97-181, discussing the disclosures of Brauns, Leane, and Sugimoto); (ii) the differences between the prior art and the claims (Pet. at 21-34 and Donovan Decl. ¶¶ 97-181, discussing motivation to combine and reasonable expectation of success, and presenting an element-by-

element analysis comparing the '729 patent claims with the relevant prior art disclosures); (iii) the level of ordinary skill in the pertinent art (Pet. at 21 and Donovan Decl. ¶¶ 18-20); and (iv) secondary considerations (Pet. at 62-68 and Donovan Decl. ¶¶ 274-93, rebutting the alleged unexpected results presented in three declarations submitted during prosecution of the '729 patent). *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). Each *Graham* factor discussed in the Petition and the Donovan Declaration is supported by citations to the relevant disclosures in prior art. The Donovan Declaration further presents an overview of the relevant technology known to a POSA as of the claimed priority date, which provides the necessary context to understand the claims of the '729 patent and the prior art. Ex. 1005 ¶¶ 65-96.

Thus, *Fintiv* factor 6 supports institution.

2. Petitioners' Reliance on Expert Testimony Favors Institution.

As the Board recently confirmed in *Irhythm Technologies, Inc. v. Welch Allyn, Inc.*, IPR2025-00363, Paper 10, at 2-3 (PTAB June 6, 2025), reliance on expert testimony is proper where the expert provides technical context and supports the Petition's element-by-element mapping of the prior art to the claim limitations. This is exactly what Petitioners have done in the instant Petition. Dr. Donovan's expert testimony confirms that the Petition accurately interprets the cited prior art and

appropriately applies the teachings of prior art references to the challenged claims. As the Board has found before, this type of expert testimony follows regulations requiring disclosure of underlying facts in expert testimony. *GD Energy Prods., LLC v. Kerr Mach. Co.*, PGR2025-00031, Paper 11, at 2 (PTAB June 25, 2025) (denying patent owner’s request for discretionary denial finding petitioners’ reliance on expert testimony was in compliance with regulations requiring disclosure of “underlying facts or data”); *see also* 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”).

Patent Owner argues that the Petition “relies on Dr. Donovan’s conclusory testimony as a crutch to supply claim limitations missing from the combinations of Brauns and Leane (or Sumitomo).” Req. at 29. This argument is without any merit. To support its argument, Patent Owner cites the Petition at page 39 and refers to the first phrase of the first sentence in Section (c) regarding Element 1.3 (“Element 1.3 is obvious over Brauns in view of Leane”). *Id.* However, Patent Owner ignores the rest of this section, which not only provides citations to specific disclosures in Leane (¶ [0059]) and the known properties of dabigatran etexilate (discussed in Section V.A.1 of the Petition) but also explains how a POSA would have understood the cited prior art teachings as compared with Element 1.3, as explained by Dr. Donovan

in paragraphs 203 through 205 of her declaration. *See also id.* at 52-53 (citing ¶¶ [0013], [0024], and [0131] of Sugimoto, and the known properties of dabigatran etexilate (discussed in Section V.A.1 of the Petition), as well as the Donovan Declaration). Thus, Dr. Donovan’s declaration and the Petition’s citations thereto do not support discretionary denial. *See Cambridge Indus. USA, Inc. v. Applied Optoelectronics, Inc.*, IPR2025-00434, Paper 11, at 2 (PTAB June 26, 2025) (denying patent owner’s request for discretionary denial where patent owner failed to identify any portions of the expert testimony that suggested petitioner used its expert to fill gaps in the prior art).

Even if certain portions of the Donovan Declaration were consistent with the Petition’s arguments, that would not be sufficient to give it “little or no weight” as Patent Owner contends. *See* Req. at 26-27. Patent Owner relies on *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 12 (PTAB Feb. 10, 2023) (“*Xerox*”). But the Board in *Xerox* found the expert declaration supporting the petition “sets forth Petitioner’s conclusory assertions [regarding inherent disclosure or the obviousness of a missing element] as though they are facts, rather than setting forth facts and evidence in support of Petitioner’s assertions.” *Xerox* at 5. That is not the case here. As discussed above, Petitioners do not rely on the Donovan Declaration to support any inherent disclosure in the prior art or to support the obviousness of an element

not disclosed in the prior art. Further, Dr. Donovan cites explicit disclosures in the prior art of the ground for every limitation of the challenged claims of the '729 patent and provides reasoned analysis for motivation to combine the prior art of the ground and reasonable expectation of success. *See, e.g.*, Ex. 1005 ¶¶ 199-214 (discussing the differences between claim 1 and Brauns in view of Leane), ¶¶ 182-97 (discussing motivation to combine and reasonable expectation of success).

Further, the Board does “*not* accord [expert] testimony little or no weight simply because it is verbatim to what Petitioner states in the Petition. The *Xerox* case . . . does not require or indicate otherwise.” *Unified Patents, LLC v. Togail Techs., Ltd.*, IPR2023-00338, Paper 7, at 11 (PTAB Aug. 18, 2023) (emphasis added). “Rather, the critical inquiry is whether a declaration discloses underlying facts or data on which the opinion is based.” *Bizlink Tech., Inc. v. Anderson Power Prods., Inc.*, IPR2024-00687, Paper 7, at 27-28 (PTAB Nov. 22, 2024). As explained above, this is exactly what the Donovan Declaration does. The Declaration discloses, in detail, the underlying facts (e.g., the disclosures in references, the expert’s knowledge and experience, etc.) on which her opinions are based. Thus, it is entitled to its full weight. *See Hum Indus. Tech., Inc. v. Amstead Rail Co.*, IPR2023-00540, Paper 10, at 37 (PTAB Aug. 11, 2023) (“If declaration testimony is supported sufficiently and, in turn, supports contentions in the Petition, we do not give it little

to no weight simply because it is repeated in the Petition[.]”). Indeed, the Board has recognized that it is logical for the petition and the expert declaration to be similar, as the expert declaration supports the invalidity grounds in the petition. *Hum Indus. Tech.*, IPR2023-00540, Paper 10, at 37 (finding overlap results from the petition citing the expert declaration without any deviation from the matters to which the expert testifies).

Further, Patent Owner’s reliance on *TQ Delta, LLC v. Cisco Systems, Inc.*, 942 F.3d 1352 (Fed. Cir. 2019) (“*TQ Delta*”), is misplaced. In *TQ Delta*, the Federal Circuit explained that the petition and the supporting expert declaration relied on two sentences from a prior art patent specification that provided “no express discussion of, nor any connection to” the element at issue. *TQ Delta*, 924 F.3d at 1362. Patent Owner cites this case to support its assertion that the “Petitioner’s citations to the Donovan Declaration provide no evidentiary basis to support a POSA’s alleged knowledge and motivation to combine Brauns with either secondary reference with a reasonable expectation of success.” Req. at 28-29. Patent Owner’s assertion is without any merit. The Donovan Declaration cites the known properties of dabigatran etexilate, and disclosures in Brauns, the Brauns’s prosecution history, Sugimoto, Leane, Exhibit 1022, and Exhibit 1012, to support her opinions on

motivation to combine and reasonable expectation of success. *See* Ex. 1005 ¶¶ 182-97.

Thus, Dr. Donovan's declaration and the Petition's citations thereto do not support discretionary denial.

3. Patent Owner Does Not Have Strong Settled Expectations in the '729 Patent.

The Board may consider the "settled expectations of the parties, such as the length of time the claims have been in force," as a factor for discretionary denial. *See* Ex. 1024 (March 2025 Memorandum) at 2. The '729 patent issued in May 2021. The Board has previously found that patents that have been in force for the same or longer amounts of time do not support a strong settled expectation from patent owners. *See, e.g., Cambridge Indus. USA, Inc. v. Applied Optoelectronics, Inc.*, IPR2025-00434, Paper 11, at 2 (PTAB June 26, 2025) (denying patent owner's request for discretionary denial, finding patent owner did not have strong settled expectations that favor discretionary denial as to patents issued in 2020 and 2019); *MIM Software Inc. v. Progenics Pharms., Inc.*, IPR2025-00630, Paper 12, at 2 (PTAB July 24, 2025) (referring the petition to the Board, finding *inter alia* that Patent Owner did not have strong settled expectations that favor discretionary denial as to patents issued in 2020, 2022, and 2024); *CSPC Megalith Biopharmaceutical Co., Ltd. v. Shanghai Miracogen Inc.*, IPR2025-00685, Paper 9, at 2 (PTAB July 31,

2025) (referring the petition to the Board, finding *inter alia* that Patent Owner did not have strong settled expectations that favor discretionary denial as to the patent issued in 2020); *Amazon.com, Inc., et al. v. Soundclear Techs. LLC*, IPR2025-00565, Paper 11, at 2 (PTAB July 10, 2025) (referring the petition to the Board, finding *inter alia* that Patent Owner did not have strong settled expectations that favor discretionary denial as to the patent issued in 2021).

Further, “[e]arly challenges favor robust, predictable patent rights and weigh against discretionary denial.” *Ajinomoto Co., Inc. v. Abtis Co., Ltd.*, IPR2025-00283, Paper 13, at 2 (PTAB July 2, 2025). Petitioners’ early challenge here weighs in favor of institution.

4. Institution Would Be an Efficient Use of the Board’s Resources.

Considerations of efficiency also weigh against exercising discretionary denial. The ’729 patent has only a relatively small number of claims (18), and the Petition challenges all of them. Further, the Petition presents a limited number of Grounds and prior art references challenging those claims. Specifically, both Grounds 1 (Brauns and Leane) and 2 (Brauns and Sugimoto) assert only two-reference combinations to challenge all the claims of the Patent. Because the Petition challenges few claims based on a small number of straightforward Grounds, institution of the Petition would be an efficient use of the PTAB’s resources.

5. Public Interest Favors Institution.

Public interest—economic and otherwise—also favors institution. The Supreme Court has explained that “inter partes review helps protect the public’s ‘paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope.’” *Cuozzo Speed Techs. v. Lee*, 79 U.S. 261, 279-280 (2016) (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)). Here, the claims of the ’729 patent will not expire until January 1, 2034, thereby blocking public action and further potential innovation for more than nine years following the expected institution date. Therefore, the public has a significant interest in institution so that the Board can determine the patentability of each claim of the ’729 patent and prevent potentially long-lasting public harm caused by an improvidently granted patent claim remaining in force. The public’s interest would be further advanced by institution because the Petition challenges two claims of the ’729 patent (claims 8 and 9) that are not currently at issue in the *Hetero* Litigation. Thus, by instituting this Petition, the PTAB can act to protect the public from the potential harm of these claims remaining in effect even if all currently asserted claims in the *Hetero* Litigation are adjudicated and the *Hetero* Litigation defendants succeed in invalidating all currently asserted claims in the district court.

Compelling economic interests favor institution for yet another reason. Patent Owner is aggressively asserting the '729 patent, as evidenced by the *Hetero* Litigation. Petitioners filed this Petition *before* getting sued by Patent Owner in a district court litigation. One of the main purposes of the AIA proceedings is to provide an efficient and cost-effective mechanism to resolve patentability issues outside costly litigation. *See, e.g., Gen. Plastic Indus. Co. v. Canon Kabushiki Kushida*, IPR2016-01357, Paper 19, at 16-17 (PTAB Sep. 6, 2017) (“[W]e recognize that an objective of the AIA is to provide an effective and efficient alternative to district court litigation.”). It is in the public interest to discourage Patent Owner from leveraging a district court litigation against *different* parties to insulate a questionable patent from the PTAB review. Otherwise, parties like Petitioners are forced to incur significant costs defending against patent infringement allegations or pursuing declaratory judgment in district courts. A discretionary denial in these circumstances would undermine the main purpose of the AIA proceedings and is thus contrary to the public interest.

IV. DISCRETIONARY DENIAL IS UNWARRANTED UNDER 35 U.S.C. § 325(d)

In determining whether to discretionarily deny a petition under Section 325(d), the Patent Office policy requires a determination of “(1) whether the same or substantially the same art previously was presented to the Office or whether the

same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, at 8 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*”).

The instant Petition presents obviousness arguments that are materially distinct from the obviousness combinations discussed during prosecution. Of the three prior art references cited in support of the obviousness grounds in this Petition, the Examiner relied on only one—Brauns (Ex. 1007)—as a basis for rejection. Another reference, Sugimoto (Ex. 1010), was cited in an IDS but was not used by the Examiner as a basis for rejection. The third reference, Leane (Ex. 1009), was not before the Patent Office at all.

A. The Brauns and Sugimoto Combination (Ground 2) Satisfies the *Advanced Bionics* Test

Patent Owner relies heavily on Brauns to argue discretionary denial is warranted under Section 325(d). Req. at 2, 31. But the Examiner never considered Brauns in combination with Sugimoto as a basis for rejection. As the Acting Director recently explained, “a petitioner may argue that it satisfies the second part of *Advanced Bionics* because the asserted prior art was not a basis for rejection during

examination, is not substantially the same as prior art the Examiner applied, and includes specific teachings that impact patentability of the challenged claims.” *Ecto World, LLC, et al. v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13, at 5 (PTAB May 19, 2025) (precedential) (quotes omitted).

That is exactly the case here with respect to the Brauns and Sugimoto combination presented in Ground 2. Indeed, Patent Owner fails to present any analysis showing the Sugimoto teachings discussed in the Petition are cumulative of *any* reference discussed during the prosecution. This is fatal to Patent Owner’s Section 325(d) arguments as to Ground 2.

Further, the Examiner materially erred by not discussing the relevant teachings of Sugimoto and not rejecting the claims for the reasons presented in Ground 2. Instead, the Examiner repeatedly cited a combination of Brauns and Habib. Pet. at 13-15. However, as noted by the Board, Habib’s composition was intended to “*inhibit* dissolution of the drug,” i.e., “*the opposite result*” compared to increasing bioavailability taught in Brauns. Pet. at 20-21 (citing Ex. 1002 at 87-88 (emphasis added)). Thus, the Examiner materially erred during prosecution of the ’729 patent by failing to reject the claims in view of Brauns and Sugimoto, the latter of which discloses a two-particle system designed to *enhance* the dissolution of an

active substance at the desired site—achieving *the same result* as the single-particle system described in Brauns.

As discussed in the Petition, Sugimoto teaches preparing a composition containing two distinct particles: drug-containing particles and coated organic acid-containing particles. Pet. at 32-34 (citing Ex. 1010 ¶¶[0131]-[0133] (Example 1); *see also id.* ¶¶ [0136]-[0152] (Examples 2-4)). Sugimoto also discloses comparative reference compositions without acid-containing particles. Pet. at 33 (citing Ex. 1010 ¶¶[0161]-[0163] (Reference Examples 5-6)). Sugimoto further discloses results from *in vitro* dissolution testing and *in vivo* bioavailability studies comparing Example 1 and Reference Example 6, demonstrating that the two-particle compositions of Example 1 had a higher dissolution rate and increased bioavailability compared to Reference Example 6. Pet. at 33 (citing Ex. 1010 ¶¶[0178]-[0186]). In sum, Sugimoto teaches compositions comprising two distinct particles—one comprising an active ingredient and another comprising an acid—resulting in an enhanced dissolution rate and increased bioavailability relative to compositions without an acid.

Therefore, a discretionary denial is not warranted as to Ground 2 because the Petition explains how the Examiner materially erred by not considering the relevant teachings of Sugimoto in combination with Brauns and not issuing a rejection based

on this combination. *See, e.g., Skullcandy, Inc. v. Earin AB*, IPR2025-00690, Paper 9, at 2 (PTAB July 31, 2025) (referring the petition to the Board, finding “Petitioner appears to show a material error by the Office, and it is an appropriate use of Board resources to review the potential error.”); *Amazon.com, Inc., et al. v. Soundclear Techs. LLC*, IPR2025-00565, Paper 11, at 2 (PTAB July 10, 2025) (referring the petition to the Board, finding, *inter alia*, “Petitioner persuasively argues that the Office erred in a manner material to the patentability of the challenged claims with respect to the previously presented prior art.”); *Microsoft Corp. v. Partec Cluster Competence Ctr. GmbH*, IPR2025-00318, Paper 9, at 2 (PTAB June 12, 2025) (referring the petition to the Board, finding petitioner provided persuasive evidence that the Office erred in a manner material to the patentability of the challenged claims).

B. The Brauns and Leane Combination (Ground 1) Satisfies the *Advanced Bionics* Test.

As discussed above, Leane was not before the Patent Office during prosecution of the ’729 patent. Thus, the combination of Brauns in view of Leane satisfies *Advanced Bionics* part 1. *See Advanced Bionics*, Paper 6, at 8.

Patent Owner’s sole argument with respect to Leane is that Leane is cumulative of Sugimoto. Req. at 32-34. As an initial matter, and as discussed above, Patent Owner fails to make any meaningful analysis of how Sugimoto teachings

discussed in the Petition are cumulative of any reference discussed during the prosecution. For the same reasons, Patent Owner has not demonstrated that Leane is cumulative of any prior art reference discussed during the prosecution.

Further, contrary to Patent Owner's assertions, Leane is not cumulative of Sugimoto. Instead, Leane demonstrates that the claimed two-particle compositions were employed in prior art by not one, but two independent groups—Sugimoto and Leane—as a solution to improve the dissolution of acid-sensitive materials that nonetheless need an acidic environment to dissolve. Leane thus reinforces the prior art teaching in Exhibit 1012 that preparing two distinct particles was a “convenient way” to separate chemically incompatible substances that needed to be delivered in a single dose. Pet. at 10 (citing Ex. 1012 at 2), 35. Thus, a discretionary denial under Section 325(d) is not warranted as to the combination of Brauns and Leane presented in Ground 1.

Respectfully submitted,

Date: September 25, 2025

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CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. § 42.6(e)(4), that service was made on Counsel for Patent Owner as detailed below:

Date of service: September 25, 2025

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Documents served PETITIONERS' OPPOSITION TO PATENT OWNER'S
REQUEST FOR DISCRETIONARY DENIAL

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