

Filed on behalf of Patent Owner BRECKENRIDGE PHARMACEUTICAL, INC.

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.

Case No.: IPR2025-01107

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

BRIEF IN SUPPORT OF PATENT OWNER'S REQUEST

FOR DISCRETIONARY DENIAL

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PATENT OWNER’S EXHIBIT LIST

No.	Exhibit Description
2001	March 24, 2025 Chief APJ Boalick Memo: Guidance on USPTO's rescission of "Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation"
2002	Docket Report: <i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.).
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2010	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Plaintiff’s Requests for Production
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I. INTRODUCTION

Patent Owner Breckenridge Pharmaceutical, Inc. (“Patent Owner” or “Breckenridge”) submits this brief in support of discretionary denial of the Petition for *inter partes* review (“IPR”) of U.S. Patent No. 11,013,729 (EX1001, “the ’729 patent”) filed by MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited (collectively “Petitioner”). (Paper 1; “Petition” or “Pet.”). Patent Owner respectfully requests that the Director exercise discretion and deny institution of the Petition pursuant to the Interim Processes for PTAB Workload Management memorandum of March 26, 2025 (“Interim Process Memo”) and the discretionary considerations discussed therein. See EX1024 at 1-3. Patent Owner’s analysis, arguments, and positions presented herein support discretionary denial.

Discretionary denial under 35 U.S.C. § 314(a) is appropriate in view of a co-pending district court litigation (“Parallel Litigation”) involving the same (or substantially the same) invalidity challenges to the ’729 patent. See Pet. at 5 (citing *Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.*, No. 24-cv-571 (GBW) (D. Del.)). The IPR sought by Petitioner would not provide a “true alternative” to the proceedings that are already in an advanced stage in the Parallel Litigation, which is scheduled for trial about three months before the deadline for a Final Written Decision (“FWD”). Significant investments in the Parallel Litigation have already occurred and

will continue to accrue prior to both the institution and FWD deadlines. Neither the merits of the Petition nor any other relevant circumstances are sufficient to outweigh the inefficiencies and redundancies associated with instituting IPR here.

Discretionary denial is also warranted under 35 U.S.C. § 325(d). Institution of IPR here would require duplicative efforts by the Board given the significant prosecution of the '729 patent. The invalidity grounds presented in the Petition are based on the same or substantially the same art presented to the Office during examination, including prior art that formed the basis for rejection of the claims. Moreover, a rejection involving art offered by Petitioner was overturned on appeal without amendment, after which the claims were allowed to issue. In particular, the primary reference applied in the Petition (U.S. 2006/0183779; “Brauns” or “’779 publication”) was cited in support of an obviousness rejection that the Board reversed, and the secondary references combined with Brauns in the Petition were either presented to the Office during examination (U.S. 2004/0109890; “Sugimoto”) or cumulative to those that were (U.S. 2006/0115525; “Leane”).

Neither the references cited in Petitioner’s grounds nor the arguments presented in Petitioner’s substantially duplicative obviousness challenges require the Board to assess patentability in a manner not previously before the Office. Indeed, the Petition fails to present any appropriate new rationale on why a person of ordinary skill in the

art (“POSA”) would have been motivated to modify the Brauns disclosure in the first place, much less to arrive at the ’729 patent claims with a reasonable expectation of success. Reassessment of patentability would impose an unwarranted and unnecessary strain on the resources the Board requires to meet its statutory obligations under 35 U.S.C. § 6(b). EX1024 at 1. Patent Owner’s analysis under *Advanced Bionics* herein also supports discretionary denial.

Further discretionary considerations noted in the Interim Process Memo, including the weakness of Petitioner’s unpatentability challenges and the conclusory opinions of Petitioner’s expert declarant, also support denial here.

II. STATEMENT OF PRECISE RELIEF REQUESTED

Pursuant to 35 U.S.C. §§ 314(a), 325(d), and 312(a)(3), and the Interim Processes Memo, Patent Owner respectfully requests that the Director exercise discretion to deny institution of IPR on the ’729 patent.

III. CLAIM CONSTRUCTION

The Director need not construe any term to determine that institution should be discretionarily denied. Patent Owner reserves the right to contest Petitioner’s implicit or explicit constructions and propose its own during any further proceedings.

IV. THE PETITION DOES NOT ACCURATELY SUMMARIZE THE ORIGINAL PROSECUTION

The prosecution of the ’729 Patent before the Office was extensive and included

an appeal where the Board reversed an obviousness rejection that combined the same or similar prior art and utilized similar arguments to those presented in the Petition. EX1002 at 82-88. In a telling omission, the Petition provides only a cursory summary of that appeal and the Board's ultimate findings. Pet. at 4. Further context is needed for the Director to appropriately assess discretionary denial here.

The Examiner had rejected the pending claims during prosecution, including for anticipation by Brauns and obviousness over Brauns in combination with a secondary reference disclosing two particle formulation designs. EX1002 at 216-233, 260-277, 325-338, 387-402, 456-469, 491-504. The Examiner maintained (similar to Petitioner here) that it would have been obvious to formulate the composition taught by Brauns "as two distinct particles as [Habib] teaches [a] pharmaceutical composition [that] comprise[s] two distinct types of particles, one of which includes a pharmaceutical agent," and Brauns "teaches the need for spatial separation of the organic acid and the active substance." EX1002 at 152.

On appeal, the Board generally considered a single issue - whether "the preponderance of evidence of record support[s] Examiner's conclusion that the cited prior art renders obvious the claimed compositions[.]" EX1002 at 86. The Board was persuaded by Patent Owner's (then Appellant's) submissions and arguments and found the Examiner to have failed to present a proper *prima facie* case of obviousness. *Id.* at

87. Patent Owner’s arguments included that 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 the claims under review.” EX1002 at 86-87.

The Petition recasts the record by suggesting that the “sole issue” in that appeal 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 question on appeal, however, was whether a “preponderance of evidence of record support Examiner’s conclusion that the cited prior art renders obvious the claimed compositions[.]” EX1002 at 84-86. In assessing that issue, the Board agreed with Appellant’s (Patent Owner’s) position that “[o]ne of skill in the art could not reasonably predict that the single layered particles of [Brauns] could be separated to form a composition’ of two distinct particles as recited in Appellant’s claims.” *Id.* at 87. Petitioner’s interpretation of the Board’s careful review and decision is inaccurate and misleading. *See* Section V.B (§ 325(d) analysis).

V. THE DIRECTOR SHOULD EXERCISE DISCRETION TO DENY INSTITUTION

The facts and circumstances here warrant denying review under one or more of §§ 314(a), 325(d), and 312(a)(3).

A. The Director should use discretion under § 314(a) to deny the Petition under *Fintiv*.

The advanced state of the Parallel Litigation related to the '729 patent supports discretionary denial under 35 U.S.C. § 314(a). As explained below, *Fintiv* factors 1-4 and 6 either strongly favor or at the very least favor discretionary denial. Factor 5 is at a minimum neutral. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (“*Fintiv*”) (articulating six nonexclusive factors for determining whether to institute an AIA post-grant proceeding where there is parallel litigation). Neither the merits of Petitioner’s challenge nor any other considerations under factor 6 support the conclusion that institution of IPR would reflect an efficient use of the Board’s resources.

On March 24, 2025, Chief APJ Boalick issued a memorandum clarifying how the Board will assess discretionary denial in view of parallel district court litigation (“*Fintiv* Memo”) after restoration of prior policy requiring application of the *Fintiv* and *Sotera* precedent. *Fintiv* Memo (EX2001) at 1; *see also Fintiv*, IPR2020-00019, Paper 11 (P.T.A.B. May 13, 2020); *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 (P.T.A.B. Dec. 1, 2020) (“*Sotera*”). The *Fintiv* Memo stated that “the factors

considered in the exercise of discretion are part of a balanced assessment of all the relevant circumstances in the case, including the strength of the merits.” EX2001 at 3. In effect, compelling merits or a timely-filed *Sotera* stipulation will no longer be dispositive in making a *Fintiv* assessment.

Petitioner asks the Board and Patent Owner to expend substantial time and resources addressing patentability challenges to the ’729 patent that are the same (or substantially the same) as the invalidity positions taken by the Defendants in the Parallel Litigation. That litigation is well underway, and trial is scheduled to occur well before issuance of a FWD by the Board.

1. *Fintiv* Factor 1 - The District Court is unlikely to grant a stay.

Fintiv Factor 1 asks whether the district court in a parallel litigation has granted a stay or evidence exists that one may be granted if a proceeding is instituted. *Fintiv*, IPR2020-00019, Paper 11 at 6. “A district court stay of the litigation pending resolution of the PTAB trial allays concerns about inefficiency and duplication of efforts.” *Id.* at 6. As explained below, Factor 1 weighs in favor of discretionary denial.

First, Petitioner is not a party to the Parallel Litigation and may not request a stay in the District of Delaware.

Second, the District Court has not entered a stay in the Parallel Litigation, and neither party to that litigation has filed a motion to stay pending the outcome of an IPR

on the '729 patent. *Sand Revolution II LLC v. Continental Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24 at 7 (PTAB June 16, 2020) (explaining Board will not predict how the district court will proceed were a motion to be filed for deadlines and procedures in the district court action). Because Petitioner is a non-party, a request for a stay prior to the institution deadline on or about December 25, 2025 is unlikely and at the very least unpredictable. Moreover, in Delaware, a motion to stay a case before determination of institution of an IPR is considered premature and would most likely be denied outright. *See IOENGINE, LLC v. PayPal Holdings, Inc.*, 2019 WL 3943058, at *6-7 (D. Del. Aug. 21, 2019).

Third, the District Court is unlikely to grant a stay given the advanced stage of the Parallel Litigation. That case between direct competitors has been pending for over fifteen (15) months and has progressed significantly. *See generally* EX2002. In the two months since the Petition was filed on June 6, 2025, the District Court has issued a *Markman* order (EX2003) and Patent Owner has served its final infringement contentions (EX2004). The Defendants' initial (EX2005) and supplemental (EX2006) invalidity contentions were served on December 16, 2024 and February 14, 2024, and its final invalidity contentions are due to be served on August 14, 2025. Under these circumstances, a stay is unlikely. *See Tigo Energy Inc. v. SMA Solar Tech. Am. LLC*, 2024 WL 1637511, at *2-3 (D. Del. Apr. 16, 2024) (denying stay motion because fact

discovery is substantially underway, claim construction briefing is complete, and parties are direct competitors).

There is also another patent at issue in the Parallel Litigation that is not subject to any potential IPR proceedings (*see* EX2007 at 1-2), and Defendants there have asserted invalidity defenses beyond the scope Petitioner’s obviousness grounds. *N. Atl. Imports, LLC v. LoCo-Crazy Good Cookers, Inc.*, 2024 WL 4827250, at *3-4 (D. Del. Nov. 19, 2024) (denying stay motion pending IPR outcome because IPR outcome would simplify only “some portion of the issues for trial”); *see also PureWick Corp. v. Sage Prods., LLC*, 1:19-cv-1508-MN (D. Del. May 4, 2021) (minute entry denying partial motion to stay case where IPR was instituted on one patent and three patents were not the subject of IPRs). This includes alternative primary and secondary references to allege obviousness, and additional defenses under Section 112. *See, e.g.*, EX2006 at 15-19 (asserting obviousness of claim 1 over Brauns (i.e., ’779 publication) in view of “the ’220 publication[,]” i.e., U.S. 2003/0195220), 33-37 (asserting obviousness of claim 1 over “the PRADAXA 2010 Label and the ’322 publication[,]” i.e., WO 2009/118322, in combination with further references), 53-56 (asserting invalidity for lack or written description and enablement), 56 (asserting invalidity for indefiniteness). As such, this non-party Petition will not simplify the Parallel Litigation in a manner that warrants a stay.

Fintiv Factor 1 clearly weighs in favor of denying the Petition.

2. *Fintiv* Factor 2 - Trial is scheduled almost three months before the statutory deadline for FWD.

Fintiv Factor 2 considers the proximity of the district court’s trial date to the Board’s projected statutory deadline for a FWD. *Fintiv*, IPR2020-00019, Paper 11 at 6. As explained below, this factor weighs in favor of discretionary denial.

Trial by jury in the Parallel Litigation is scheduled to commence on October 6, 2026 (EX2014 at ¶ 21), nearly *three months* before the statutory deadline for issuance of a FWD on December 25, 2026. This is *longer* than differentials the Board has previously found to support denial under Factor 2. *See, e.g., Nxp Usa, Inc. v. Impinj, Inc.*, IPR2021-01556, Paper 10 at 7-8 (PTAB Apr. 21, 2022) (finding Factor 2 favored denial because trial date was set two months before FWD deadline); *Cisco Sys., Inc. v. Portsmouth Network Corp.*, IPR2024-00503, Paper 7 at 11-13 (PTAB Aug. 6, 2024) (same); *Fintiv*, IPR2020-00019 Paper 15 at 13 (PTAB May 13, 2020) (same); *EClinicalWorks, LLC v. Decapolis LLC*, IPR2022-00229, Paper 10 at 9 (PTAB Apr. 13, 2022) (one-to-two-month differential); *see also generally Fintiv*, IPR2020-00019, Paper 11 at 9 (“[i]f the [district] court’s trial date is earlier than the projected statutory deadline, the Board generally has weighed this fact in favor of exercising authority to deny institution”).

Further, the amount of work that the parties to the Parallel Litigation will incur prior to the statutory deadline for FWD is extensive and includes fact witness depositions and expert discovery, followed by substantial pretrial filings before commencement of a jury trial. *See e.g.*, EX2014 at ¶¶ 19-20; EX2015 at 2. There is no good reason to force Patent Owner to spend time and resources both in the Parallel Litigation and in this proceeding when the Parallel Litigation will resolve invalidity issues months before the Board. *See also* Section V.A.4 (*infra*) (Factor 4 describing significant overlap of issues).

Fintiv Factor 2 clearly weighs in favor of denying this Petition.

3. *Fintiv* Factor 3 - The Court and the parties have expended significant efforts in the litigation.

Fintiv Factor 3 considers investment in the parallel proceeding by the district court and the parties, including “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.” *Fintiv*, IPR2020-00019, Paper 11 at 9. As explained below, Factor 3 weighs substantially in favor of discretionary denial.

The Parallel Litigation was initiated on May 10, 2024. EX2007 at 1, 13. Since that time, both parties to the litigation have spent considerable time and resources and will continue to invest significant time and resources prior to a potential institution

decision on or around December 25, 2025. To date, Patent Owner has served four sets of interrogatories, four sets of document requests, and seventeen requests for admission on the Defendants. *See e.g.*, EX2008, EX2009, EX2010; *see also* EX2002 (docket entries 19, 28, 76, 90). Patent Owner has also responded to Defendants' document requests and interrogatories, and has substantially completed document production, producing approximately 6,000 documents to Defendants. *See* EX2002 (docket entries 29, 72, 79, 87, 97, 104, 105, 107, 108). Patent Owner has also served final infringement contentions. EX2004. Similarly, Defendants have produced documents, served written discovery, responded to discovery requests, and served initial and supplemental invalidity contentions. *See e.g.*, EX2011, EX2012, EX2013, EX2005, EX2006; *see also* EX2002 (docket entries 22, 34, 37, 41, 42, 48, 62, 77, 80, 86, 89). Both parties also filed claim construction briefs, a *Markman* hearing was held on May 15, 2025, and a *Markman* order issued on June 26, 2025. *See* EX2002 (docket entries 54, 69, 73, 96); EX2003. The parties have also agreed to a deadline for Defendants' to serve their final invalidity contentions tomorrow, August 14, 2025.

The efforts expended in the Parallel Litigation are greater than (or at the very least similar to) those in other cases in which the Board has favored discretionary denial. *See e.g.*, *10x Genomics, Inc. v. President & Fellows of Harvard Coll.*, IPR2023-01299, Paper 15 at 18 (PTAB Mar. 7, 2024) (finding factor 3 favors denial because parties had

“exchanged initial and supplemental infringement and invalidity contentions, completed claim construction briefing and held a claim construction hearing” but were still in fact discovery); *Nokia of Am. Corp., et al. v. Pegasus Wireless Innovation LLC*, IPR2025-00036, Paper 14 at 12 (PTAB Apr. 25, 2025) (same finding when *Markman* hearing was held, and “the parties have exchanged [preliminary] invalidity contentions”); *Arthrex, Inc., v. Medshape, Inc.*, IPR2025-00053, Paper 11 at 10-12 (PTAB Apr. 25, 2025) (same finding even when fact discovery recently opened and no deposition had taken place but parties exchanged infringement and invalidity contentions, claim construction briefing, and held a *Markman* hearing before institution decision).

The district court itself has also invested time and resources in the Parallel Litigation, including a *Markman* hearing and subsequent order, and the resolution of multiple discovery disputes. EX2003; *see also* EX2002 (docket entries 45, 60, 71, 93-94, 102). The district court’s investment weighs in favor of denying the Petition. *See 10x Genomics*, IPR2023-01299, Paper 15 at 18 (“Even more significantly, the district court has invested substantial resources in the parallel proceeding. The district court has held a claim construction hearing and issued its Claim Construction Order on February 1, 2024.”). By the time the Board decides whether to institute this Petition, the parties to the Parallel Litigation will have also completed fact discovery (November 21, 2025)

and served the opening round of expert reports (December 22, 2025). EX2015 at 2.

The above-described efforts, along with the additional fact and expert discovery efforts to be completed before the institution deadline, are undoubtedly extensive. To allow the IPR proceeding to continue in the face of substantial investment in the Parallel Litigation would be unnecessarily duplicate and thus an inefficient use of Patent Owner and Board resources. *See Zhuhai Cosmx Batter Co., Ltd. v. Ningde Ampere Technology Limited*, IPR2023-00587, Paper 12 at 14 (P.T.A.B. Sept. 12, 2023) (finding this factor “heavily favors denial” where the parallel litigation had advanced beyond fact discovery to the completion of initial reports).

Fintiv Factor 3 clearly weighs in favor of denying this Petition.

4. *Fintiv* Factor 4 - There is significant overlap of issues.

Fintiv Factor 4 assesses the overlap between the issues raised in the Petition and in the Parallel Litigation and considers “inefficiency and the possibility of conflicting decisions.” *Fintiv*, IPR2020-00019, Paper 11 at 12 (“if the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial”). *Id.* There is significant overlap here: the same issues and the same (or substantially the same) prior art concerning substantially the same claims of the ’729 patent will have to be considered and decided in the Parallel Litigation where no Defendant is the same party as Petitioner.

Defendants in the Parallel Litigation have identified eleven (11) prior art references they intend to rely upon to support invalidity. *See* EX2006 at 3-4. Notably, two of those references are heavily relied upon by Defendants in support of their obviousness defenses: Brauns and Sugimoto. EX2006 at 5 (summary of Brauns), 8 (summary of Sugimoto), 15-32 (contending obviousness of asserted claims 1-7 and 10-18 of the '729 patent over Brauns in combination with Sugimoto and general knowledge in the art). These same two references form the basis for obviousness grounds presented in the Petition. Brauns serves as the primary reference in both obviousness grounds, and Sugimoto serves as a secondary reference in Ground 2. *See* Pet. at 6, 21-26 (summary of Brauns), 31-34 (summary of Sugimoto), 37-51 (Ground 1 – Brauns primary reference), 51-62 (Ground 2 – Brauns in view of Sugimoto).

Petitioner has also acknowledged that the Leane reference is being used as a secondary reference in combination with Brauns (Ground 1) for essentially the same reasons as Sugimoto is being used as a secondary reference (Ground 2). Specifically, Petitioner asserts that “claims 1-18 are *prima facie* obvious over Brauns in view of *either* Leane or Sugimoto” because “both Leane and Sugimoto are directed to pharmaceutical dosage forms in which an organic acid is used to assist with the dissolution of a material having pH-dependent solubility—in Leane, chitosan, and in Sugimoto, a weakly basic drug.” Pet. at 63; *see also id.* at 37 (Brauns, Leane, and

Sugimoto are each allegedly attempting to solve the same problem and teaching similar solutions with a similar predictable outcome). As Sugimoto and Leane are being used for essentially the same purpose, Petitioner's combination of Brauns and Leane in Ground 1 is not substantively distinguishable from the Brauns and Sugimoto defense presented in the Parallel Litigation.

Additionally, both the District Court and the Board would need to determine the validity/patentability of sixteen (16) of the eighteen (18) total claims in the '729 patent. Issued claims 1-7 and 10-18 are currently asserted in the Parallel Litigation, and the Defendants have asserted obviousness defenses to all of those claims. While the Petition asserts challenges to all 18 issued claims, Petitioner's obviousness challenges to dependent claims 8 and 9 address subsidiary process limitations beyond those in asserted process claims 6 and 7. *See* Pet. at 45-50, 58-90. And though Patent Owner does not assert these dependent claims in the Parallel Litigation, Petitioner's treatment of these claims does not detract from the substantial overlap of issues between the two proceedings. *See Samsung Display et al. v. Pictiva Displays Int'l Ltd.*, IPR2024-00855, Paper 12 at 11 (P.T.A.B. Nov. 19, 2024) ("the Petition is based on the same prior art references, presently asserted against the same patent claims, as the District Court action, raising the specter of significant overlap and duplication of efforts"). Indeed, Petitioner's analysis identifies claims 8 and 9 as "product-by-process" and contends that

they are invalid for the same reasons as product claim 2. Pet. at 45-46, 58.

Nor is this Petition a “true alternative” to District Court litigation. *See Sand Revolution II*, Paper 24 at 12, n.5 (P.T.A.B. June 16, 2020) (informative). The District Court will have to resolve substantially the same issues regardless of the outcome before the Board. Indeed, the Defendants in the Parallel Litigation are raising the same obviousness defense as Ground 2 in the Petition, and the art and arguments presented in Ground 1 are essentially cumulative to that obviousness defense. Pet. at 37, 62-63 (use of Sugimoto and Leane for the same purpose in combination with Brauns). For these reasons, inefficient and duplicative efforts between the district court and the Board cannot be avoided, whether by stipulation or otherwise. Indeed, Petitioner cannot file a *Sotera* stipulation in the District Court as they are not a party to the Parallel Litigation.

Fintiv Factor 4 substantially weighs in favor of denying this Petition.

5. *Fintiv* Factor 5 - The Petitioner is different from the Defendants in the Parallel Litigation.

Factor 5 is neutral as the Defendants in Parallel Litigation and the Petitioner here are different parties despite their apparent, and perhaps common, interest to challenge the '729 patent. *Shenzhen Root Technology v. Chiaro Technology Ltd. d/b/a Elvie*, IPR2024-01296, Paper 9 at 19-20 (P.T.A.B. Feb. 25, 2025). Nonetheless, even if the Director were to find this factor to weigh somewhat against denial, it would not tip the

balance towards institution because the combination of other *Fintiv* factors substantially favors discretionary denial. See e.g., *BOE Technology Group Co., Ltd. v. Optronics Sciences LLC*, IPR2024-01130, Paper 16 at 13 (P.T.A.B. Jan. 27, 2025) (“The parties being the same ‘could weigh either in favor of, or against, exercising discretion to deny institution, depending on which tribunal is likely to address the challenged patent first.’”) (quoting *Carrier Fire & Security Americas Corp. v. Sentrilock, LLC*, IPR2021-00665, Paper 12 at 13–14 (P.T.A.B. Sept. 16, 2021)).

6. *Fintiv* Factor 6 - The merits of the Petition are lacking, and other discretionary factors support denial.

The merits of a Petition may form part of a balanced assessment of all the relevant circumstances applicable under *Fintiv*. EX2001 at 3.

a) *The Merits of the Petition do not Outweigh the Substantial Circumstances Favoring Discretionary Denial*

It is settled law that “the burden of proving a proposition of unpatentability” is borne by (and remains at all times with) the Petitioner. 35 U.S.C. §§ 314(a), 316(e); *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016). The Board’s rules further specify that a petition must include “[a] full statement of the reasons for the relief requested, including a detailed explanation of the significance of the evidence including material facts, and the governing law, rules, and precedent[,]” and must specify “where each element of [each challenged] claim is found in the prior art patents

or printed publications relied upon [and] the relevance of the evidence to the challenge raised.” 37 C.F.R. § 42.22(a)(2); *see also* 37 C.F.R. §§ 42.104(b)(4)-(5) (a petition for *inter partes* review must identify how the construed claim is unpatentable under the statutory grounds on which the petitioner challenges the claims).

A petitioner must “articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness” — “mere conclusory statements” will not suffice. *Magnum Oil*, 829 F.3d at 1380. Indeed, “[i]t is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify ‘with particularity’ the ‘evidence that supports the grounds for the challenge to each claim.’” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (quoting 35 U.S.C. § 312(a)(3)).

As the Board has instructed time and again, a petition for *inter partes* review must tell a story; mere conclusory attorney argument or conclusory statements from an expert are not sufficient to carry the burden of demonstrating unpatentability. Indeed, petitions have been routinely denied under 35 U.S.C. § 314(a) from the 2013 outset of *inter partes* review for failure to meet Office regulatory requirements. *See, e.g., Zetec, Inc. v. Westinghouse Electric Company. LLC*, IPR2014-00384, Paper 10 at 12 (P.T.A.B. July 23, 2014) (denying institution on obviousness grounds supported by perfunctory assertions); *Lake Cable LLC v. Windy City Wire, Cable & Tech. Prods. LLC et al.*,

IPR2013-00528, Paper 11 (P.T.A.B. February 19, 2014) at 19 (denying institution on obviousness grounds because petition did not articulate an adequate reason why a POSA would have modified reference to meet a claim limitation). The Board has also denied petitions for failing to properly apply the *Graham* factors in an obviousness analysis. *See, e.g., Samsung Electronics Co., Ltd. v. Poer2B Inc.*, IPR2022-01378, Paper 12 at 15 (P.T.A.B. Mar. 15, 2023) (citing *Graham*, 383 U.S. at 17 (denying institution because the Board could not “ascertain the difference between the claimed invention and the asserted prior art, as required”)); *NJOY, LLC v. JUUL Labs, Inc.*, IPR2024-00536, Paper 17 (P.T.A.B. Aug. 12, 2024) (denying institution where petitioner did not show a reasonable expectation of success in combining the asserted references); *Honeywell Int’l Inc. v. DSM IP Assets, B.V.*, IPR2024-00493, Paper 7 (P.T.A.B. Aug. 21, 2024) (same).

Both of Petitioner’s invalidity grounds present an obviousness challenge to all claims of the ’729 patent. “A party that petitions the Board for a determination of obviousness must show that ‘a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.’” *Apotex Inc. v. Wyeth LLC*, IPR2014-00115, Paper 94, slip op. at 11 (P.T.A.B. Apr. 20, 2015) (quoting *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed.

Cir. 2009)).

The Petition includes a section on the “Motivation to Combine the Prior Art” that states simply “Brauns and Leane (Ground 1) and Brauns and Sugimoto (Ground 2) render claims 1-18 obvious because when combined, they teach each and every element of the claims.” Pet. at 34. Notwithstanding the legal inaccuracies of that statement, 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. 35 U.S.C. § 103 (obviousness assesses whether the “differences between the claimed invention and the prior art are such that the claimed invention *as a whole* would have been obvious to a [POSA]” without consideration of “the manner in which the invention was made”) (*emphasis added*); *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct 1721, 1731 (2007) (patent claim composed of several elements is not obvious merely by demonstrating that each element was, independently, known in the prior art; also noting the importance of identifying a reason that would have prompted a POSA to combine the elements as the new invention does).

In both Grounds 1 and 2, Petitioner bases the entirety of its arguments on the conclusory and overly simplistic proposition that a POSA would have been motivated:

. . . to design a dabigatran etexilate oral dosage form that retained the advantageous properties of Brauns’ preparation but differed structurally from its layered pellets, for example, to design around Brauns’ pending claims that

had been allowed by the PTO at that time. Ex. 1005, ¶188; Ex. 1008, pp. 55, 127, 173. Further, a POSA would have been motivated to look for alternative ways of spatially separating the tartaric acid from dabigatran etexilate to Brauns' multilayered pellet structure because, in practice, it was known to be difficult to prepare an intact insulating layer, which was required for storage stability and durability of the finished product. Ex. 1005, ¶190; Ex. 1022, p. 5.

Pet. at 35. Petitioner does not meaningfully explain with supporting evidence why a POSA would have been motivated to modify Brauns to arrive at the claimed compositions in the first place. *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (“obviousness concerns whether a skilled artisan not only could have made but would have been motivated to make the combinations or modifications of prior art to arrive at the claimed invention”). Clearly, Petitioner's proposition is made in hindsight.

Moreover, Petitioner's assertion that a POSA would have been motivated to design around Brauns's pending claims is without authority. Pet. at 35. It also lacks a proper evidentiary basis. Indeed, the Petition merely cites to claims that were pending before the Office during prosecution of Brauns without any discussion of their limitations or how a POSA would have designed around them. Pet. at 35 (citing EX 1008 at 55, 127, 173). Petitioner's citation to a corresponding expert declaration provides no further explanation. EX1005, ¶188 (simply noting that “a POSA would have understood that the Patent Office has allowed the claims in Brauns ... [to a]

multilayer structure with an organic acid core and a dabigatran etexilate layer”).

Petitioner’s assertion that “a POSA would have been motivated to look for alternative ways of spatially separating the tartaric acid from dabigatran etexilate to Braun’s multilayered pellet structure” is similarly deficient. Pet. at 35. Here, Petitioner relies on another reference (WO 2012/001156; EX1022) to allege that problems existed in the Brauns multilayer configuration due to “difficult[ies] to prepare an intact insulating layer.” *Id.* (citing EX1022 at 5). Again, neither the Petition nor Petitioner’s expert discuss any such difficulties with any particularity, much less explain why a POSA would have been motivated to moderate them in view of the Brauns disclosure itself. *Id.* (citing EX1005 at 190). Petitioner also fails to tie this purported ancillary issue into a justifiable basis to modify Brauns in a manner leading to the claimed inventions. *See* Pet. at 35-36 (simply noting 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”).

Petitioner’s failure is particularly acute in the face of the evidence already weighed by the Office and the Board. *See* Section V.B (*infra*). Indeed, Petitioner’s grounds do not remedy the Examiner’s failure to present a proper *prima facie* case as the Board determined on appeal, or adequately address 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.” EX1002 at 189-194, ¶¶ 13 and 19. Accordingly, modifying the invention of Brauns by using two distinct types of particles rather than a single layered pellet would have destroyed the necessary functions of the components of the Brauns invention. EX1002 at 189-194. The Brauns inventor’s explanation of his own patent document helps establish how a POSA reading Brauns would interpret its disclosure and scope. Obviousness combinations that ignore the teachings of an inventor in a reference and undermine those teachings are not proper. *DePuy Spine Inc. v. Medtronic Sofamor Danek Inc.*, 567 F.3d 1314 (Fed. Cir. 2009) (finding the prior art’s teachings undermine the very reason being preferred as to why a POSA would have combined the known elements).

Moreover, Petitioner does not meaningfully explain with supporting evidence why a POSA would have reasonably expected success in arriving at the claimed inventions of the ’729 patent by modifying Brauns with either Leane or Sugimoto, including a failure to address why a POSA would have reasonably expected to “retain[] the advantageous properties of Brauns’ preparation” as Petitioner’s motivational statements require. Pet. at 35. Indeed, The 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 to achieve the “similar and predictable outcome” of “increased dissolution of the compound with pH dependent solubility when the drug product reached its desired site of action while avoiding contact between the acid and the compound with pH dependent solubility before the drug product reached its desired site of action.” Pet. at 37. Outside of this bare assertion, the Petition fails to explain (with appropriate supporting evidence) why or how the POSA would have accomplished the claimed two particle design without using hindsight to guide the way. *NJOY, LLC*, IPR2024-00536, Paper 17 at 10; *Honeywell Int’l Inc*, IPR2024-00493, Paper 7 at 9.

Dr. Donovan’s testimony provides no remedy for this critical failure in the Petition. See Pet. at 37 (purportedly citing EX1005 at ¶¶ 187, 193-194, 196 to support expectation of success). Instead, the Petition’s citations to the Donovan declaration describe Brauns as providing one purported “solution to a problem posed by the conflicting chemical properties of dabigatran etexilate” (EX1005 at ¶ 187), while Leane allegedly solved a “problem posed by the conflicting chemical properties of chitosan” (*id.* at ¶ 194) and Sugimoto allegedly addressed the “conflicting properties of drug substances that need acidic but also have unpleasant taste in the mouth” (*id.* at ¶ 194). The cited testimony is cursory and provides no evidentiary support for any expectation, much less a reasonable one, that the combination of Brauns with either Leane or

Sugimoto would have provided a solution to the problem Petitioner alleges to be associated with Brauns.

For these reasons alone, the Petition fails to present a challenge sufficient to shift the balance of Patent Owner's *Fintiv* analysis toward institution of the Petition. Indeed, Patent Owner's overview on the merits herein combined with the additional details in the forthcoming POPR tend to further favor denial.

*b) The Donovan Declaration Substantially Repeats the
Conclusory Arguments of the Petition Without Substantial
Explanation or Additional Evidence*

The Interim Process Memo provides that a *Fintiv* analysis may address the extent of a petition's reliance on expert testimony. EX1024 at 2. As explained in the merits section, the Petition fails to address obviousness under a proper *Graham* analysis, including a failure to provide any substantial factual basis or rational underpinning to support how a POSA would have been motivated to achieve the inventions of the challenged claims with a reasonable expectation of success. Petitioner's largely conclusory assertions on obviousness rely heavily on the say-so of its expert. There are significant problems with Petitioner's approach.

First, the Donovan Declaration makes many of the same conclusory assertions on obviousness as those presented in the Petition. As the Board has made clear, an expert declaration that merely parrots the petition without providing additional technical

detail, analysis, or evidentiary support is entitled to little if any weight. See *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 12 at 2, 5 (P.T.A.B. Feb. 10, 2023) (“Board was correct in giving little weight to Petitioner’s expert because the expert declaration merely offered conclusory assertions ... and repeated, *verbatim*, Petitioner’s conclusory arguments”). A comparison of the Petition’s assertions with the passages from the Donovan Declaration cited for support establish that the same is true here.

To begin, the Petition cites to the Donovan Declaration to support its proposed construction for two terms appearing the ’729 patent claims. See Pet. at 6-8 (citing EX1005 at ¶¶ 54-61 to support proposed constructions for “particles” and “a protective coating layer”). The cited passages from the Donovan Declaration state that a “POSA would have understood” the terms “particles” and “a protective coating layer” to mean the same thing as Petitioner’s proposed definitions (EX1005 at ¶¶ 56, 61), and Dr. Donovan’s analysis repeats the arguments presented in the Petition essentially *verbatim*. See Pet. at 7 (proposal for “particles”) and 7-8 (proposal for “a protective coating layer”); cf. EX1005 at ¶¶ 54-56 (same arguments for “particles” without more) and ¶¶ 57-61 (same arguments for “a protective coating layer” without more).

Outside of a brief technology overview in Section V.A and Petitioner’s definition of a POSA in Section VI, the Petition primarily cites to the Donovan Declaration to support an alleged motivation to combine the prior art to arrive at the inventions claimed

with a reasonable expectation of success. See Pet. at Section VIII.A (citing EX1005 at ¶¶ 184-188, 190-196). But again, the cited portions of the Donovan Declaration present the same general and conclusory assertions as the Petition without more. Indeed, Dr. Donovan summarizes the same disclosures from Brauns (see EX1005 at ¶¶ 184-186), Leane (*id.* at ¶¶ 184-186) and Sugimoto (*id.* at ¶ 196) and repeats the same bare assertions on motivation and reasonable expectation of success provided in the Petition. See Pet. at 35-36; *cf.* EX1005 at ¶¶ 187-192 (discussing general motivations identical to the Petition); Pet. at 36-37; *cf.* EX1005 at ¶¶ 193-197 (repeating the same “alternative solutions” provided by Leane and Sugimoto). Citations to the Donovan Declaration to support disclosure of claim elements are similarly repetitive. See, *e.g.*, Pet. at 37-41 (discussion on elements of independent claim 1); *cf.* EX1005 at ¶¶ 199-214 (same general discussion without more); Pet. at 41-43 (discussion on elements of independent claims 11-16); *cf.* EX1005 at ¶¶ 215-221 (same general discussion without more).

Second, 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. The Federal Circuit has made clear that the *ipse dixit* of an expert is not sufficient to support obviousness challenges at the PTAB. See, *e.g.*, *TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352 (Fed. Cir. 2019) (reversing PTAB obviousness finding regarding motivation to combine

based only on conclusory expert testimony as not supported by substantial evidence).

Third, instead of using expert testimony for helpful context or explaining terms of art, Petitioner relies on Dr. Donovan's conclusory testimony as a crutch to supply claim limitations missing from the combinations of Brauns and Leane (or Sumitomo). *See, e.g.*, Pet. at 39 (citing EX1005 at ¶¶ 203-205) ("Element 1.3 is obvious over Brauns in view of Leane"); EX1005 at ¶¶ 203-205 ("[i]t is my opinion that the combination of Brauns in view of Leane renders obvious this element, which require that the 'the first type of particles is free from organic acids and inorganic acids.'"). But again, Dr. Donovan's testimony simply echoes arguments in the Petition and is therefore not helpful to any determination of obviousness or non-obviousness by the Board. It also fails to explain with sufficient details how any proposed modification to Brauns is supposed to work. *See Personal Web Techs.*, 848 F.3d at 994 ("[A] clear, evidence-supported account of the contemplated workings of the combination is a *prerequisite* to adequately explaining and supporting a conclusion that a relevant skilled artisan would have been motivated to make the combination and reasonably expect success in doing so.") (*emphasis added*).

The Petition presents nothing more than conclusory assertions from Petitioner's expert, who provides little (if any) additional evidentiary support or rational underpinnings to support Petitioner's obviousness grounds. This additional

consideration under Factor 6 also tends to favor denial.

B. The Director should use discretion to deny the Petition under § 325(d).

“In determining whether to institute or order [an IPR], the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). The Board applies a two-part framework to consider whether to exercise discretion to deny institution under § 325(d), commonly referred to *Advanced Bionics* Part 1 and Part 2:

- (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 [the] 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 (P.T.A.B. Feb. 13, 2020) (“[a]t bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown”).

The Director should deny institution under 35 USC § 325(d) because Petitioner’s references are the same or substantially the same art previously presented to the Office

(*Advanced Bionics* Part 1), and the Petition fails to demonstrate that the Office erred in any material way (*Advanced Bionics* Part 2).

1. Advanced Bionics Part 1

Art previously presented to the Office includes “art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), [or] in the prosecution history of the challenged patent.” *Advanced Bionics*, 2020 WL 740292, at *3.

Again, the Petition presents two obviousness grounds, each of which rely on Brauns as a primary reference. See Pet. at 6. As Petitioner concedes, the Brauns reference was thoroughly considered by the Office, as it was initially applied by the Examiner to reject claims pending during prosecution of the ’729 patent. See Pet. at 13-21 (“[t]he ’613 application was consistently rejected by the Office under, *inter alia*, 35 U.S.C. § 103 as obvious over Brauns in view of Habib”). The Examiner’s obviousness rejection applying Brauns was also considered on appeal where the Board reversed the Examiner and the ’729 claims were subsequently allowed to issue. *Id.* at 20-21. The Brauns reference satisfies *Advanced Bionics* Part 1.

Contrary to Petitioner’s misleading statement, Sugimoto (applied as a secondary reference in Ground 2) was indeed presented to the Examiner. See Pet. at 31; EX1001 at 1 (see field (56) - Sugimoto listed as second reference cited under “U.S. PATENT

DOCUMENTS”). Sugimoto was also considered by the Examiner during prosecution. EX1002 at 376 (Examiner signed 6-1-17 IDS identifying Sugimoto), 388-389 (Examiner acknowledging that 6-1-17 IDS was considered). The Sugimoto reference also satisfies *Advanced Bionics* Part 1. See *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 4 (P.T.A.B. May 19, 2025) (precedential) (citing *Google LLC v. Valtrus Innovations Ltd.*, IPR2022-01197, Paper 18 at 15 (P.T.A.B. June 13, 2023) (“providing a document to the Office in an Information Disclosure Statement is sufficient to satisfy prong one of the *Advanced Bionics* analysis”)).

Leane is cumulative of the art that was before the Office during prosecution, including Sugimoto. See *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17 (P.T.A.B. Dec. 15, 2017) (precedential) (relevant considerations include “the similarities and material differences between the asserted art and the prior art involved during examination” and “the cumulative nature of the asserted art and the prior art evaluated during examination”). The Petitioner relies on Leane for substantially the same reasons as Sugimoto. Both references are applied as secondary references in combination with Brauns for their alleged similar disclosures of “solid oral dosage forms containing an organic acid in separate coated particles improved the solubility of a pH-dependent material while controlling when, or the rate by which, the material encounters the organic acid.” Pet. at 36. Specifically, the Petition

states:

Leane teaches using organic acid particles to improve the dissolution of chitosan, a substance that is soluble only in acidic pH levels, over the pH range found in intestine (5 to excess of 7.5) while controlling the rate of the organic acid dissolution, which was important for rapid chitosan dissolution[, and] ...

Sugimoto similarly teaches solid oral dosage forms containing coated organic acid granules (i.e., particles) and granules containing a drug having pH-dependent solubility kept the drug separated from the acid until the composition reached the stomach and improved the dissolution of the drug independent of the stomach pH, after the drug reached the stomach.

Id. at 36-37. Based on these similar disclosures, Petitioner then argues that “[a] POSA would have readily combined Brauns with *either Leane or Sugimoto* because Brauns, Leane, and Sugimoto are each attempting to solve the same problem of improving dissolution in the digestive tract of a material having pH-dependent solubility while controlling the timing or the rate at which the acid comes into contact with the material.”

Id. The Petitioner also uses the similar teachings of Leane and Sugimoto when arguing for a reasonable expectation of success. *Id.* (“POSA would have had a reasonable expectation of success in combining Brauns with Leane or Sugimoto, because each reference teaches similar solutions ... with similar and predictable outcomes”).

Petitioner’s bases for its IPR challenge rely on Sugimoto and Leane in substantially the same way to argue that it would have been obvious to modify the teachings of Brauns and provide a two-particle system:

The prior art also taught successful applications of the two-particle system. In particular, each of Leane and Sugimoto discloses that solid oral dosage forms containing an organic acid in separate coated particles improved the solubility of a pH-dependent material while controlling when, or the rate by which, the material encounters the organic acid.

Pet. at 36. As such, Leane is substantially the same as art previously presented to the Office and considered by the Examiner. *See Parse Biosciences*, 2023 WL 8789872, at *6 (where Petitioner “relie[d] on Saleh and Song in the alternative for a similar teaching,” the Board determined that “Saleh is cumulative” of Song, which “was before the Examiner”); *Helena Labs. Corp. v. Sebia*, IPR2024-00801, Paper 10 at 12 (P.T.A.B. Oct. 23, 2024) (art is cumulative where “Petitioner relies on both Shihabi and Huang as disclosing” the same teaching and Shihabi was presented during prosecution); *see also Ecto World*, IPR2024-01280, Paper 13 (P.T.A.B. May 19, 2025). The Leane reference also satisfies *Advanced Bionics* Part 1.

In sum, the art applied in Petitioner’s obviousness grounds was either already before the Office or substantially the same as art already before the Office. *Advanced Bionics* Part 1 is satisfied for each of Brauns, Sugimoto, and Leane.

2. Advanced Bionics Part 2

Under *Advanced Bionics* Part 2, Petitioner carries the burden of demonstrating a material error by the Office. “If a condition in the first part of the framework is satisfied and the petitioner fails to make a showing of material error, the Director generally will

exercise discretion not to institute *inter partes* review.” *Advanced Bionics*, IPR2019-01469, Paper 6 at 8–9. Petitioner’s burden is significant. *Id.* (if “the alleged error is a disagreement with a specific finding of record by the Office, then ordinarily the petitioner’s required showing of material error must overcome persuasively that specific finding of record”); *see also Becton*, IPR2017-01586, Paper 8 at 17–18 (explaining that [*Becton-Dickinson*] factor (e) asks “whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art”). Notably also, “[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” *Advanced Bionics*, IPR2019-01469, Paper 6 at 9.

Petitioner cannot carry its required burden here. Nor can Petitioner remedy or supplant these substantial flaws in the Petition with supplemental information. *See American Well Corporation v. Teladoc Health, Inc.*, IPR2021-00748, Paper 23 at 11 (P.T.A.B. Feb. 28, 2022) (citing *Pacific Marketing Int’l, LLC v. Ignite USA, LLC*, IPR2014-00561, Paper 23 at 3 (P.T.A.B. Dec. 2, 2014) (“the provision for submitting supplemental information is not intended to offer a petitioner a routine avenue for bolstering deficiencies in a petition . . . a petitioner should not expect § 42.123 to present a ‘wait-and-see’ opportunity to supplement a petition after initial comments or arguments have been laid out by a patent owner.”)). For example, Petitioner should not

be allowed to make allegations that the Office purportedly erred in view of Sugimoto where the Petition erroneously states that “Sugimoto was not cited as prior art during prosecution of the ’729 patent.” As explained in the Part I analysis above, Sugimoto was most certainly considered by the Examiner.

Recognizing that it is Petitioner’s burden to prove otherwise, Patent Owner nevertheless submits that the Office did not err in a manner material to patentability when allowing the ’729 claims to issue. As Petitioner notes, the application for the ’729 patent was “consistently rejected by the Office under, *inter alia*, 35 U.S.C. § 103 as obvious over Brauns in view of Habib.” Pet. at 13. The applicant submitted multiple declarations under 37 C.F.R. § 1.132 during prosecution, including those comparing the dissolution and relative bioavailability of dabigatran etexilate in the claimed two-particle formulations and the Brauns single-particle formulation. *Id.* at 13-15; *see specifically id.* at 14-15 (noting from the Tyebi declaration that formulations of the pending claims “exhibit a faster dissolution profile” compared to Brauns which would not have been predicted from Brauns; further noting from the Xi declaration that formulations of the pending claims were “bioequivalent to those of Brauns”).

Nonetheless, even after the applicant amended the claims to their current form and argued, *inter alia*, that a POSA would not have considered modifying Brauns to arrive at the claimed compositions as an identifiable, predictable solution (*see* Pet. at

18-20), the Examiner maintained the rejection over Brauns in view of Habib for the reasons of record. *Id.* at 20. The rejection was reversed on appeal, where the Board agreed with applicant's arguments that "the Examiner had not articulated a sufficient rationale for combining the two-particle composition taught in Habib to modify the single particle composition taught in Brauns." EX1002 at 5; *see also id.* at 6 ("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 [, and therefore] ... has not met the burden to establish a prima facie showing of obviousness").

Moreover, the Petitioner fails to present arguments and facts that warrant reconsideration of prior art, such as Sugimoto, submitted to the Office in an IDS or used by the Examiner. *See* Section V.A.6 (*supra*). As explained above, the Petition provides only a cursory analysis of Sugimoto in the context of obviousness, and fails to support (with appropriate evidence) its basis for modifying Brauns in view of Sugimoto to arrive at the claimed inventions. *See* Section V.A.6.a (*supra*). Indeed, Petitioner's justifications in support the motivation and reasonable expectation of success are based essentially on the conclusory opinions of its expert. *See* Section V.A.6.b (*supra*). Petitioner's undeveloped arguments and cursory expert declarations are insufficient to warrant reconsideration of Sugimoto. *Advanced Bionics*, IPR2019-01469, Paper 6 at 9-

10, n.10) (discussing *Becton Dickinson* factors (e) and (f)); see also *American Well Corporation*, IPR2021-00748, Paper 23 at 11.

This is also not a case where the patent applicant submitted hundreds of references in IDSs for Examiner consideration. Instead, the applicant submitted approximately 35 documents and, therefore, it cannot be said that an undue burden was placed on the Examiner that would have compromised his ability to consider and understand the full context of each document submitted by applicant, including Sugimoto. See *Ecto World*, IPR2024-01280, Paper 13 at 7 (P.T.A.B. May 19, 2025) (noting that discretionary denial is not warranted when IDS presented over 1,000 references), n.3 (but acknowledging that approximately 87% of applications contain 50 or fewer applicant-provided items of information, approximately 77% contain fewer than 25, and only 4% of contain more than 200 applicant-provided items of information).

In sum, after thorough consideration of the disclosures of Brauns and Habib, the Examiner's rationale for combining them, and the arguments and declarations submitted by Appellant, the Board determined that the claims that issued in the '729 patent were not obvious over the cited references. The Examiner accordingly allowed the claims shortly thereafter. EX1002 at 58 (“[p]ursuant to the Patent Board Decision on 01/12/2021, the instant invention is considered novel and unobvious over the closest

prior art”). The extensive prosecution, including the successful appeal, combined with the Examiner’s ability to fully consider the ~35 other documents submitted to the Office, including Sugimoto, further supports that the Office did not materially err in its evaluation of the asserted prior art when determining that the issued claims were patentable. *Cf. Ecto World*, IPR2024-01280, Paper 13 at 7.

VI. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that the Director deny institution of IPR in view of the above discretionary considerations.

Dated: August 13, 2025

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CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

Under the provisions of 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the word count for all portions of the foregoing Patent Owner's Brief in Support of Request for Discretionary Denial totals 9011 words per Microsoft Word, which complies with the requirement of 14,000 words allowed under 37 C.F.R. § 42.24(d).

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CERTIFICATE OF SERVICE

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

Date of service: August 13, 2025

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