

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

**PRELIMINARY RESPONSE BY PATENT OWNER
PURSUANT TO 37 C.F.R § 42.107**

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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.).
2003	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Markman Order, D.I. 96
2004	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Plaintiff's Final Infringement Contentions
2005	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Defendants' Initial Invalidity Contentions
2006	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Defendants' First Supplemental Invalidity Contentions (select portions)
2007	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Complaint
2008	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Plaintiff's Interrogatories to Defendants
2009	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Plaintiff's Requests for Admission
2010	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Plaintiff's Requests for Production

No.	Exhibit Description
2011	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Defendants' Interrogatories to Plaintiff
2012	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Defendants' Requests for Production
2013	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Defendants' Responses to Plaintiff's Request for Production
2014	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Scheduling Order, D.I. 31
2015	<i>Breckenridge Pharmaceutical, Inc. v. Hetero USA Inc. et al.</i> , No. 24-cv-571 (GBW) (D. Del.). Order Resetting Deadlines, D.I. 101
2016	March 11, 2014 Declaration of Dr. Ulrich Brauns

I. INTRODUCTION

Patent Owner, Breckenridge Pharmaceutical, Inc. ("Patent Owner"), respectfully submits this Preliminary Response to the Petition for *Inter Partes* Review ("Petition") filed by MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited ("Petitioner" or "MSN") challenging claims 1-18 of U.S. Patent No. 11,013,729 ("the '729 patent") (EX1001). The Petition fails to establish a reasonable likelihood of prevailing and institution should be denied.

The '729 patent discloses a novel and elegant solution to a well-known and vexing problem in formulating the anticoagulant prodrug dabigatran etexilate ("DE")¹: the prodrug requires an acidic environment to dissolve *in vivo*, but (in its solid form) can degrade by hydrolytic pathways in the presence of moisture, and is sensitive to acid. EX1001 at 2:14-17; 22-25. These properties require that pharmaceutical oral dosage forms with DE be prepared in a manner that both allows for some acid in the formulation but also avoids degradation of DE during storage. *Id.* at 2:4-15.

Prior strategies for preparing oral solid dosage forms of DE included pellets made with layers of excipients that separate the DE from acids in the pellet core, which were

¹ As used herein, "DE" is meant to refer to dabigatran etexilate in its free base form, in addition to a pharmaceutically acceptable salt or polymorph thereof.

then filled into hard capsules. *Id.* at 2:26-44. One embodiment of this formulation approach is the commercial product Pradaxa® disclosed in the Brauns reference (EX1007). *See e.g.*, EX1007 at Fig. 1. The inventors of the '729 patent found the process of preparing layered pellets disclosed in Brauns to be "cumbersome, time consuming and uneconomical." EX1001 at 2:43-44. They also acknowledged alternative tablet formulations in the prior art but noted that the DE in those tablets was highly susceptible to hydrolysis during storage in the presence of humidity. *Id.* at 2:45-54. The inventors noted that these prior formulation strategies were either tedious or technologically demanding or provided compositions unlikely to remain stable over the shelf life of the product. *Id.* at 2:55-58.

After "rigorous experimentation," the inventors of the '729 patent discovered a non-obvious alternative: a two-particle system with the drug DE in one particle and the acid in a separate, protectively coated particle. *Id.* at 2:62-3:2 As the specification explains, this novel formulation approach was found to not only preserve the stability of DE during storage but also allowed for compositions to be more easily and conveniently prepared, as compared to prior dosage forms. *Id.* at 2:58-61. This formulation design also provided for an effective in-vivo release of the active ingredient. *Id.* at 2:62-3:14; *see also id.* at 3:39-42 "The compositions of the present

invention are stable, easy to prepare, and provide the desired in-vitro release of the active.”). And this design also unexpectedly achieved bioequivalence with the prior art single-pellet system formulation, despite employing two distinct particles that produced a faster dissolution profile for DE. EX1002 at 368-70 (May 16, 2016 declaration of Zhengguo Xu).

Now, Petitioner presents a challenge built entirely through the distorting lens of impermissible hindsight. Using the '729 patent as a roadmap, Petitioner scours the prior art for individual components—Brauns for a single-pellet DE oral delivery system, and the inapposite Leane and Sugimoto references for two-particle delivery systems directed to different compounds for altogether different purposes—and improperly stitches them together to reconstruct the claimed invention. This approach ignores the fundamental reality that a person of ordinary skill in the art ("POSA"), looking at the problem prospectively, particularly in view of what Brauns teaches, would have had no reason to abandon Brauns's successful, layered single-pellet design, much less expect that a physically separated two-particle system could reasonably work to achieve the intended function of the claimed invention.

The Petition is fatally flawed and fails to meet the statutory standard for institution for at least three reasons.

First, Petitioner's entire case is an exercise in impermissible hindsight. The primary reference in each ground, Brauns, teaches the necessity of its specific, layered single-pellet structure to create an "acidic microenvironment" for dissolution *in vivo*, a point Dr. Brauns specifically made in a Declaration during the prosecution of his patent. EX2016 at ¶ 13. A POSA would have understood Brauns's teachings to mean that close proximity between the acid and the drug in a layered pellet configuration, separated only by a specific insulating layer, was essential. Petitioner's proposal to completely separate the drug and acid into different particles runs directly contrary to this teaching.

Second, Petitioner fails to articulate sufficient and credible motivation to combine the references. The secondary references, Leane (EX1009) and Sugimoto (EX1010), address completely different problems—enhancing chitosan bioadhesion and taste-masking in orally disintegrating tablets, respectively. Neither reference suggests a solution to the specific formulation challenges with DE that the inventors recognized. Nor do they speak to any benefits of a two-particle system over a layered single-pellet system generally. As such, Petitioner fails to provide any reasonable basis that would have guided a POSA to completely change the integrated system of Brauns while maintaining its therapeutic function. These are essentially the same fundamental flaws that led the Board to reject the Examiner's combination of Brauns and Habib

during prosecution.

Third, Petitioner offers no evidence for a reasonable expectation of success. Given Brauns's explicit teaching that its integrated layered structure was the key to success, the Petitioner fails to articulate a basis as to why a POSA would have reasonably expected that separating the acid and drug into distinct particles would create the necessary acidic conditions *in vivo* and would maintain the necessary dissolution and subsequent bioavailability of DE. The '729 patent's discovery that a two-particle system could not only work but also provide bioequivalence was entirely unexpected.

For these reasons, and the others set forth below, Petitioner fails to show a reasonable likelihood that it will prevail. Institution of IPR should be denied.

II. THE '729 PATENT AND ITS PROSECUTION HISTORY

The Petition attempts to invalidate the '729 patent by repackaging arguments that this Board has already considered and rejected. The '729 patent provides a non-obvious solution to challenges of formulating DE—an active ingredient that requires an acidic environment to dissolve yet is unstable upon direct contact with acid. The prior art, represented by Brauns, taught that a single-pellet delivery system with an insulating layer was a solution to that problem. The inventors of the '729 patent took a completely different path, discovering that a two-particle system—with DE in a first particle and a

protectively coated acid in a second particle—not only solved the stability and manufacturing problems the inventor’s recognized with the Brauns’ system, but also unexpectedly achieved faster initial dissolution and bioequivalence.

This invention was subjected to a long and thorough examination, culminating in an appeal to this very Board. The Board, after full consideration, reversed the Examiner's obviousness rejection, finding that the prior art did not provide the necessary motivation for a skilled artisan to abandon the integrated, single-pellet design of Brauns in favor of the '729 patent's novel two-particle system. EX1002 at 86-87. The Petition's rehashed arguments, supported by cumulative prior art that was considered during prosecution and conclusory expert opinion that parrots the legal argument, do not warrant a different conclusion.

A. The Board Has Already Found No Motivation to Modify Brauns’ Successful Single-Pellet System

The prosecution history of the '729 patent confirms the non-obviousness of the invention. The Examiner repeatedly rejected the claims as obvious over Brauns in view of Habib. EX1002 at 148, 219, 265, 327, 391, 500. The Examiner's theory was that a POSA would be motivated to modify the single-pellet composition of Brauns into a two-particle system as taught by Habib. EX1002 at 152-54, 224-28, 269-74, 330-31, 393-97, 503. This is the same essential argument Petitioner now makes, merely

substituting the inapposite references Leane and Sugimoto for Habib.

After numerous rejections, the applicants appealed to the PTAB. EX1002 at 173. In a decision directly relevant here, the Board reversed the Examiner's final rejection. EX1002 at 83-88. The Board found "that [the] 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.

III. CLAIM CONSTRUCTION

Petitioner proposes constructions for three terms or phrases: "particles," "a protective coating layer," and the transitional phrase "consisting of." Pet. at 6-8. For the purposes of this Preliminary Response, and to focus on the substantive failings of the Petition's obviousness grounds, Patent Owner does not contest Petitioner's proposed constructions.

Petitioner's proposed construction for "particles" is taken directly from the '729 patent's explicit definition. Pet. at 7 (citing EX1001 at 8:62-66). Similarly, its proposed construction for "a protective coating layer" is based on the patent's definition and consistent with statements made during prosecution. Pet. at 7-8 (citing EX1001 at 5:39-43; EX1002 at 137). Finally, Petitioner's interpretation of "consisting of" as a closed-ended transitional phrase accords with its plain and ordinary meaning in patent law. Pet.

at 8.

No further construction is necessary to resolve the issues at this stage and Patent Owner reserves the right to challenge or present alternative constructions in the event of institution. As set forth in detail below, even under Petitioner's own constructions, the Petition fails to establish a reasonable likelihood that any challenged claim is unpatentable.

IV. LEGAL STANDARDS

An *inter partes* review may be instituted only if the Petition demonstrates “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged.” 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.108(c). A petition must demonstrate unpatentability by a preponderance of the evidence. *In re Magnum Oil Tools Int’l, Ltd.* 829 F.3d 1364, 1375 (Fed. Cir. 2016) (quoting 35 U.S.C. § 316(e)).

Each of Petitioners grounds challenge the patentability of the ’729 patent claims using an obviousness rationale. Pet. at 6. A patent claim is obvious “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the subject matter pertains.” Pre-AIA 35 U.S.C. § 103. However, patentability under obviousness “shall not be negated

by the manner in which the invention was made.” *Id.*

In a properly formulated multi-reference obviousness ground, where a patent challenger identifies a primary reference that allegedly discloses some (but not all) limitations of the claims, the challenger must also identify which limitations are missing from the primary reference and where they can be found in the secondary reference. *See, e.g., Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) (providing that identifying the differences between the prior art and the claims is a required step in the obviousness analysis). The challenger must also explain why a POSA would have modified the primary reference to incorporate the teachings of the secondary reference. *See Virtek Vision Int’l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 888 (Fed. Cir. 2024).

A patent claim composed of several elements is not obvious merely by demonstrating that each element was, independently known in the prior art. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007); *see also id.* at 418-19 (“inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known”). Instead, “obviousness requires the additional showing that a [POSA] would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention” *Unigene Labs., Inc. v. Apotex, Inc.*,

655 F.3d 1352, 1360 (Fed. Cir. 2011). In this sense, obviousness “requires finding that [a POSA] would have been motivated to combine or modify the teachings in the prior art *and* would have had a reasonable expectation of success in doing so.” *Regents of the Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286, 1291 (Fed. Cir. 2018); *Intelligent Bio-Sys. v. Illumina Cambridge Ltd.*, 821 F.3d 1359 at 1367–68; *see also, e.g., 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).

The requirement for a reasonable expectation of success relates not only to the expectation that prior art elements are capable of being physically combined, but also that the combination would have worked for its intended purpose. *See DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F. 3d 1314, 1326 (Fed. Cir. 2009) (citing *KSR*, 550 U.S. at 1739-40). An “inference of nonobviousness is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined ... known elements.” *Id.* A reference may be said to “teach away” from a claimed invention when “a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken

by the applicant." *Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325, 1332 (Fed. Cir. 2008); *see also Chemours Company FC, LLC v. Daikin Industries*, 4 F.4th 1370, 1376-77 (Fed. Cir. 2021) (rejecting the Board's obviousness finding, which "appears to have ignored the express disclosure in Kaulbach that teaches away from the claimed invention and relied on teachings from other references that were not concerned with the particular problems Kaulbach sought to solve").

The Supreme Court has made clear that an obviousness analysis must be expansive, flexible, and grounded in the record evidence, guarding against the "subtle but powerful attraction of hindsight." *KSR*, 550 U.S. at 421; *see also Ortho-McNeil Pharmaceuticals v. Mylan Labs.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008) (retracing the path of the inventor with hindsight and discounting the number and complexity of alternatives is always inappropriate for an obviousness test). While the teaching/suggestion/motivation (TSM) test can no longer be applied rigidly when assessing obviousness, the Federal Circuit continues to use a "flexible TSM test" as a primary guarantor against hindsight analysis. *Id.* at 1364-65 (citing *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007)).

Defects in establishing a ground of unpatentability in a petition are not curable during trial since the petition cannot be corrected or enhanced during trial. *See Sirona*

Dental Sys. GmbH v. Institut Straumann AG, 892 F.3d 1349, 1356 (Fed. Cir. 2018). The Board makes its determination regarding institution based on what the petition actually presents and not what it could have reasonably contained had it been drafted differently. *See also In re Magnum Oil Tools International*, 829 F.3d at 1364, 1381 (holding that the Board is not “free to adopt arguments on behalf of petitioners that could have been, but were not, raised by the petitioner during [a post-grant proceeding]”). The Board cannot “deviate from the grounds in the petition and raise its own” theories of invalidity. *Sirona Dental*, 892 F.3d at 1356.

V. THE PETITION FAILS TO ESTABLISH A REASONABLE LIKELIHOOD OF PREVAILING FOR ANY CLAIM CHALLENGED

For the multiple reasons set forth herein, Petitioner falls short of carrying its burden of establishing a reasonable likelihood of prevailing to show that even the broadest of the claims challenged in Grounds 1 and 2 are obvious. Institution of IPR should therefore be denied.

A. The Petition is Built on an Impermissible Hindsight Reconstruction of the Invention

Petitioner's obviousness challenges rest entirely on an impermissible hindsight reconstruction of the '729 patent and its claims to two-particle system. *See Dropworks, Inc. v. Bio-Rad Laboratories*, IPR2021-00212, Paper 7 at 13-14 (P.T.A.B. June 1, 2021) (denying institution because Petitioner used impermissible hindsight).

Using the claimed invention as a roadmap in an attempt to arrive at the claimed invention, Petitioner pieces together disparate elements from prior art references that address different problems, with different goals, and that teach away from the claimed solution. Petitioner’s argument begins with a discussion of Boehringer Ingelheim’s layered single-pellet DE delivery system Pradaxa® having a DE layer separated from a tartaric acid core by an insulating layer. Pet. at 1-2, 9-10. The Petition then identifies Rubicon Research Private Limited (“Rubicon”) as a generic company “developing a generic version of Pradaxa® in 2011-2012, [where] formulators at Rubicon designed around the Pradaxa® oral capsule formulation by placing the dabigatran etexilate mesylate and tartaric acid in separate pellets in the capsule.” Pet. at 2-3.

But Rubicon’s efforts to allegedly “design around” Pradaxa® were not disclosed in the prior art and therefore not available to a POSA. Indeed, the Petitioner admittedly recognizes that Rubicon’s two-particle DE delivery system formed the basis for the very patent they now challenge in the Petition. *Id.* at 3 (Indian patent application to Rubicon “served as a priority document for a PCT Appl. No. PCT/EP2013/053426 that entered national phase in the United States and eventually issued as the ’729 patent”).² Relying

² The Rubicon inventors assigned the application for the ’729 patent (U.S. 14/796,613) to Laboratorios Del Dr. Esteve S.A. on August 26, 2014. *See* USPTO Assignment Database

on the file history of the '729 patent itself, Petitioner then creates a façade using prior art rejections from the patent examiner to construct the inventor's two-particle solution by combining Boehringer Ingelheim's Pradaxa[®] patent ("Brauns") with alternative references alleged to disclose two-particle systems for controlling pH-dependent solubility ("Sugimoto" and "Leane"). *Id.*

Petitioner's use of the '729 patent and its prosecution history to set the stage for its obviousness grounds is the epitome of impermissible hindsight; a basis by which the Board has previously denied institution. *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570 (Fed. Cir. 1996) ("invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made"); *see also STMicroelectronics v. Trustees of Purdue University*, IPR2022-00252, Paper 13 at 20 (P.T.A.B. June 22, 2022) (denying institution because Petitioner's obviousness combination "appears to be driven ... by an exercise of impermissible hindsight reconstruction" and is therefore "flawed)).

The Petition starts with the '729 patent's solution—a two-particle system—and

at Reel/frame 035424/0104 (assignment recorded April 16, 2015). After a series of assignment transfers, Patent Owner Breckenridge assumed ownership of the '729 patent on February 8, 2022. *See id.* at Reel/frame 058976/0891 (assignment recorded February 10, 2022).

then works backward, thus limiting the expanse of available prior art to references that Petitioner can force to fit their pre-determined template. *See KSR*, 550 U.S. at 421 (warning against "the distortion caused by hindsight bias"). This is not a permissible obviousness analysis. *See Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1367 (Fed. Cir. 2017) ("However, making weight of the method [patentee] used in finding the invention is beside the point. The last sentence of 35 U.S.C. § 103, with great clarity, excludes such methodology in stating that '(p)atentability shall not be negated by the manner in which the invention was made.'" (alteration in original) (quoting *In re Kratz*, 592 F.2d 1169, 1175 (C.C.P.A. 1979))). The proper inquiry is what a POSA, viewing the prior art *at the time of the invention* and without the benefit of the '729 patent's disclosure, would have been motivated to do.

At the time of the invention, Brauns had already provided a state-of-the-art solution for formulating the acid-labile, pH-dependent drug DE with a layered single - pellet delivery system. EX1007 at Fig. 1. Brauns taught that its specific architecture—an acid core, a separating insulating layer, and a drug layer—was advantageous for creating an "acid microclimate in which the active substance can dissolve" in the body while ensuring the "durability of the finished product." EX1007 at ¶¶ [0011], [0013]. As such, Brauns had already provided a formulation that addressed the issues with DE

identified in the Petition, e.g., its “virtual insolub[ility]” at pH levels higher than 5 and its propensity chemical degradation in an acidic environment (*see* Pet. at 9), with an insulating layer that protects DE from degradation until it is administered, after which the organic acid assists with dissolution and uptake of the drug. *Id*; *see also id.* at FIG. 1 (illustrating the layered single-pellet formulation of Brauns).

Indeed, a Declaration under 37 C.F.R. § 1.132 by Dr. Ulrich Brauns (hereinafter “the Declaration”) was submitted and made of record as evidence during prosecution of the ’729 patent to support an amendment filed on April 16, 2018. EX1002 at 293-303. Brauns is the first named inventor of the Brauns reference, and the Declaration further emphasizes, from the inventor’s perspective, the importance of using a layered single-pellet DE delivery system. The Declaration explained why single layered particles were critical to his invention, as follows:

13. It was hypothesized that some patient stomachs were more basic because of normal variability, by disease, or co-medication with drugs that increase gastric pH. That is, if the gastric environment of the patient is not sufficiently acidic, the prodrug (dabigatran etexilate mesylate) does not dissolve sufficiently to ensure adequate bioavailability. This was not expected but only detected during formulation development. To solve this problem, the formulation itself was re-design to a) act as an acidic microenvironment while in the stomach in order to quickly dissolve the majority of the prodrug prior to entering the small intestine; b) be stable before entering GI (Gastro Intestinal) tract for storage purposes; and c) work well for the entire patient population, meaning that bioavailability would be consistent and high for the entire patient population. This solution to the

problem was not easy given the unique structure of dabigatran etexilate salt and the resulting solution to the problem, that is providing the particular form of pharmaceutical preparation as claimed, which forms the subject matter of this invention.

EX2016 at ¶ 13. The Declaration also explained the necessity of layered single-pellets and their different components:

19. 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. at ¶ 19.

Accordingly, inventor Brauns taught a POSA that a layered single-pellet having an acid core and an DE active substance layer, separated with an insulating layer, were necessary components of the invention as set forth in his patent application. As shown in the excerpts above, inventor Brauns explained that the acid core layer provides the low-pH microenvironment once the formulation enters the stomach that is needed to dissolve the prodrug DE and ensure adequate bioavailability for a broad patient population. Inventor Brauns further elaborates on the distinct functions of the insulating layer in his single-pellet formulation: firstly, as a protective layer between the acid core

and active substance on storage; and secondly, permitting the diffusion of the acid substance layer immediately in passage through the stomach.

As such, Brauns explains that the spatial separation within a single particle of the acid from the active ingredient is required for storage, but the single particle with both the acid and active ingredient is also necessary to affect an “immediate” diffusion of acid into the active substance layer when the formulation reaches the stomach. To achieve this immediate diffusion, Brauns explains that the active substance layer and the acid layer must be in the same particle. Thus, Brauns identified this single particle configuration as a necessary configuration, since it was the only way that Brauns and, in turn, the cited Brauns publication achieved the immediate dissolution *in vivo* of the claimed invention.

There is no disclosure, or suggestion, of any configuration other than a layered single-pellet in Brauns for achieving the goal of an improved formulation. And there is no teaching, much less a suggestion of successfully formulating DE mesylate in any configuration other than a single layered particle. Petitioner has not established that a POSA would have bucked the knowledge that, at the time the '729 patent was filed, a layered single-pellet formulation with an organic acid and DE isolated in separated layers was required to solve the problems associated with DE and provide an improved

dosage form. As such, a POSA reading and considering Brauns at the time of the '729 patent invention would have concluded that a layered single pellet delivery system was necessary to achieve the advantages described in Brauns.

Petitioner ignores these fundamental teachings and statements and instead uses the '729 patent as a blueprint to argue that a POSA would have abandoned Brauns' integrated system in favor of a physically separated, two-particle system. This hindsight-driven approach cherry-picks teachings from unrelated fields—chitosan-based drug delivery (Leane) and taste-masked ODTs (Sugimoto)—that happen to involve two-particle systems, while ignoring the stark differences in purpose, function, and design considerations. Such a "pick and choose" analysis, divorced from the perspective of a POSA facing the actual problem, is legally improper and cannot support a finding of obviousness. *See Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012).

The Petitioner's impermissible use of the '729 patent and problems the inventors recognized with layered single-pellet DE delivery systems also sidesteps alternative one-particle solutions disclosed in prior art relied upon in the Petition itself. *See* EX1001 at 2:45-3:14 (inventors recognized problems with single-pellet DE delivery systems and solved them with two-particle delivery system that is "stable, easy and convenient to

prepare, [and] provide the desired release profile and bioavailability”). The Technology Overview section of the Petition points to WO 2012/001156 (EX1022; (“Kroselj”)) to support that DE was known to be prone to chemical degradation and polymorphic form transformation in an acidic environment and then explains that these problems provided the basis for the insulating layer Pradaxa® drug product. Pet. at 9. However, the Petition conveniently ignores the art-recognized problems associated with Pradaxa® identified in Kroselj that were solved without a two-particle delivery system.

Kroselj points to problems with the “powder layering method” used during the production of Pradaxa® which created tartaric acid “satellites which cause defects in the isolating layer ... [and] lead to the impaired storage stability and hence durability of the finished product.” EX1022 at 3-5 (also noting that the powder layering methods utilized in the prior art “is a very complicated and long process” that can create tartaric acid cores that “may not be sufficiently firm for further processing”). The Kroselj inventors addressed these problems not with a two-particle system, but by the provision of single-pellet “solid oral dosage form of [DE], in particular [DE] methanesulfonate, ... produced by suspension/solution layering of tartaric acid onto spherical cores, such as neutral cores comprised of sucrose, microcrystalline cellulose and starch, or tartaric acid pellets, followed by an isolating layer and the layer comprising the active

pharmaceutical ingredient[,] where [o]ptionally an overcoat can be applied.” *Id.* at 8 (also noting the “surprising” discovery that [DE] methanesulfonate pellets can ... be prepared according to a much simplified and technologically less demanding process than powder layering of tartaric acid crystals with tartaric acid dust “).

Accordingly, the Petition alleges art-recognized problems associated with the layered single-pellet Pradaxa[®] delivery system in an attempt to arrive at the claimed invention, while ignoring alternative solutions to those problems without the need for a two-particle DE delivery system. *See Ortho-McNeil Pharms.*, 520 F.3d at 1364 (retracing the path of the inventor with hindsight and discounting the number and complexity of alternatives is always inappropriate for an obviousness test). Petitioner’s use of two-particle delivery systems disclosed in Sugimoto and Leane that are unrelated to the goals of DE delivery systems ignores alternative solutions. It is not permissible to use the ’729 patent disclosure to arrive at the specific solution discovered by the inventors, when alternative solutions were available for the POSA to consider. *Dropworks, Inc.*, IPR2021-00212, Paper 7 at 13 (citing *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998) (“[d]etermination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention”)).

Petitioner fails to meet their burden in establishing that a POSA, faced with problems of formulating the single-pellet DE delivery systems like Pradaxa[®], would have modified without impermissible hindsight the single-pellet system of Brauns based upon the cited two-particle systems disclosed in Leane or Sugimoto. For these reasons alone, the Petition fails to establish a reasonable likelihood of prevailing, and its request for institution should be denied.

As detailed further below, even if a POSA were to find a proper motivation to combine Brauns with either Leane or Sugimoto, which is not provided in the Petition, they would have had no reasonable expectation of success in preparing and achieving the advantages of the two-particle DE delivery systems claimed in the '729 patent.

B. The Petition Fails to Establish a Proper Motivation to Combine Brauns with Leane or Sugimoto

A legally sufficient obviousness case requires not just that the individual elements existed in the prior art, but that a POSA would have had a specific reason to select and combine them in the manner claimed. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007). Petitioner fails to meet this requirement.

The entirety of Petitioner's motivation argument from the Petition is the following:

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 meet the requisite burden of establishing that a POSA would have been motivated to abandon Brauns' successful layered single-pellet design. The inapposite teachings of Leane and Sugimoto provide no reason to do so. *Chemours Company*, 4 F.4th at 1376-77.

Petitioner's premise that a POSA would have been motivated to "design around" Brauns by creating a two-particle system is both without authority and without merit. Pet. at 3, 35. Even if a POSA was aware of manufacturing challenges with Brauns' insulating layer (Pet. at 10), the logical path forward would have been to *improve* that layer or find alternative methods to create the integrated pellet—not to discard the entire successful design principle of an "acid microclimate" created by a layered single-pellet structure. EX1007 at ¶ [0011]. Indeed, as explained in Section V.A above, that is exactly

what Kroselj did to address perceived issues with the powder layering process used to prepare the Pradaxa[®] composition as described in Brauns.

Moreover, Brauns *teaches away* from a simple mixture of drug and acid particles by emphasizing the need for "spatial separation *of the organic acid and active substance by the insulating layer*." EX1007, ¶ [0011] (emphasis added). This teaching would have discouraged a POSA from pursuing a two-particle system, which would have been seen as risking the very microclimate that Brauns identified as critical for DE dissolution. *See DePuy Spine*, 567 F. 3d at 1326; *Ricoh Co.*, 550 F.3d at 1332.

During prosecution of the '729 patent, the Board correctly recognized this lack of motivation when it reversed the rejection over Brauns in view of Habib, noting it was "not clear why one of ordinary skill in the art would have considered Habib's ... formulations to be relevant to the layered particle compositions 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").

The same logic applies here. Petitioner simply has not explained why a POSA

would have been motivated to depart from Brauns' integrated solution based on the disparate teachings of Leane or Sugimoto. *See Chemours Company*, 4 F.4th at 1376-77.

C. Leane and Sugimoto Are Inapposite Prior Art and Do Not Remedy the Petition's Deficiencies

The secondary references cited by Petitioner fail to provide the missing motivation because they are directed at solving entirely different technical problems.

Leane is focused on enhancing drug absorption by using the bioadhesive polymer chitosan. EX1009 at ¶ [0005]. The purpose of Leane's formulation is to dissolve the chitosan in the intestine to leverage its bioadhesive properties. *Id.* at ¶¶ [0012], [0016]. The acid agglomerates in Leane are merely a tool to achieve chitosan dissolution. Petitioner has not reasonably established that to improve a DE formulation a POSA would have had a reason to turn to a reference concerning the dissolution mechanics of a bioadhesive polymer. The challenges of formulating chitosan are not the challenges of formulating DE, an acid-labile drug.

Sugimoto is directed to orally disintegrating tablets (ODTs) and the problem of taste-masking. EX1010, Abstract. The goal of an ODT is to disintegrate rapidly *in the oral cavity* without an unpleasant taste. *Id.* at ¶ [0001]. Sugimoto's use of coated acid granules is to prevent contact between the drug and acid in the mouth. *Id.* at ¶¶ [0024]-

[0025]. This is a completely different context from a capsule formulation designed to be swallowed whole and release its contents in the stomach. Petitioner has not established, as required, that a POSA concerned with the gastric dissolution and stability of DE in a capsule would look to a taste-masking technology for ODTs for a solution.

These references are classic examples of inapposite art that do not cure the fundamental lack of motivation to modify Brauns.

D. The Petition Fails to Establish a Reasonable Expectation of Success

Even if a POSA were inexplicably motivated to combine these references, there would not have been a reasonable expectation of success. Pharmaceutical formulation is a notoriously unpredictable art. *See In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). Given Brauns' teachings and statements that its integrated, layered structure was necessary to create the required "acid microclimate," Petitioner has not established, as required, that a POSA would have reasonably expected that physically separating DE and acid into distinct particles would work for its intended purpose. *See DePuy Spine*, 567 F. 3d at 1326; *Ricoh Co.*, 550 F.3d at 1332. Indeed, the Petition fails to address Brauns' own statements (EX 2016) or provide any basis for how a POSA could have predicted that, in a mixture of separate particles, the acid particles and DE particles would disperse similarly in gastric fluid, to provide a localized acidic environment

needed for DE to dissolve before being swept away to higher pH regions of the GI tract where it is insoluble. The fact that the '729 patent's two-particle system not only worked but provided *faster* initial dissolution and was bioequivalent to the integrated Brauns formulation was a surprising and unexpected result. EX1001 at 14:30-16:6; EX1002 at 439-45. Petitioner's conclusory assertion of a reasonable expectation of success ignores the significant scientific hurdles and the unpredictability inherent in such a drastic reformulation, which the '729 inventors overcame.

E. Rebuttal of the Asserted Grounds

Petitioner's specific grounds for rejection are each fatally flawed for the reasons outlined above and for the additional reasons below.

1. Ground 1: Claims 1-18 Would Not Have Been Obvious Over Brauns in View of Leane

Petitioner's combination of Brauns and Leane fails because Leane is not reasonably pertinent to DE formulations. Leane addresses the problem of dissolving the basic polymer chitosan to enable its bioadhesive properties. EX1009 at ¶ [0011]. Leane's entire technical disclosure, including its discussion of acid agglomerates and coatings, is framed around the specific properties of chitosan and its interaction with the intestinal environment. *Id.* at ¶¶ [0012]-[0016], [0041].

The Petition does not establish, as required, that a POSA would have considered

Leane's teachings on chitosan dissolution to be transferable to the distinct problem of formulating DE. DE is not the polymer chitosan; it is a small-molecule prodrug with unique stability, solubility, and bioavailability characteristics. Petitioner provides nothing to support the contention that Leane would give a POSA a reasonable expectation that separating DE and tartaric acid into two different particles, as Leane does for its components, would result in a stable, effective, and bioequivalent formulation. Leane's dissolution data (Figs. 1 & 3) is specific to chitosan and provides no predictable information about how DE would behave in a similar system. The proposed combination is a classic hindsight-driven amalgamation of references that a POSA would have had no reason to pursue.

Petitioner's flawed combination extends to its element-by-element mapping, which improperly equates functionally distinct features. For example, Petitioner contends that Leane's "coated ... pellets" EX1009 at ¶¶ [0081]-[0082] satisfy the "protective coating layer" limitation. Pet. at 39-40. But the coating in Leane is designed to "provide a short delay in dissolution" to allow chitosan particles to disperse before the acid dissolves. EX1009 at ¶ [0044]. Its function is temporal control for a specific interaction with chitosan. In contrast, the claimed protective layer must prevent physical contact and chemical interaction between DE and the acid during storage *and* facilitate

the creation of a dissolution microenvironment in the stomach. Petitioner has not established that a POSA would have reasonably expected Leane's coating, developed for a different purpose with a different substance, to successfully perform these distinct functions for DE.

Furthermore, Petitioner's mapping for the "first type of particles" is a hindsight-driven combination of Brauns' drug layer with Leane's two-particle concept. Brauns teaches an uncoated active substance layer applied over a coated acid core. EX1007 at ¶¶ [0010], [0050]-[0051]. It is clear from Brauns that this uncoated drug layer is only stable because it is physically separated from the acid by the insulating layer *within the same pellet*. There is no teaching in Brauns or Leane to suggest that this same uncoated drug formulation could be simply mixed as a separate particle with a population of acid particles—even coated ones—without causing significant stability issues upon any breach or imperfection of the coating. This is not a predictable "design choice," but a complete reformulation with no reasonable expectation of success.

Because the underlying combination is improper, Petitioner's arguments regarding the dependent claims also fail. The process steps for making a chitosan formulation in Leane (claim 8) or the specific excipients used therein (claims 10, 14) are not interchangeable with the requirements for the claimed capsule formulation. And

for each dependent claim, the Petition fails to explain why a POSA would have simply swapped DE into Leane's chitosan formulation with any expectation of creating a stable, bioequivalent capsule, for the same reasons as the independent claim. Each step of Petitioner's obviousness argument relies on hindsight and ignores the fundamental differences between the cited art and the claimed invention.

2. Ground 2: Claims 1-18 Would Not Have Been Obvious Over Brauns in View of Sugimoto

The combination of Brauns and Sugimoto is even more strained. Sugimoto is directed to a completely different dosage form—an orally disintegrating tablet (ODT)—with a completely different primary objective: taste-masking. EX1010, Abstract. The technical constraints and goals of an ODT that must disintegrate in the mouth are fundamentally different from those of a capsule that is swallowed.

The Petition does not establish that a POSA working on a DE capsule would have looked to Sugimoto for guidance. Sugimoto's use of coated acid granules is to "prevent contact of the drug with the acid ... in the oral cavity," not to engineer a specific dissolution microenvironment in the stomach. EX1010 at ¶¶ [0024]-[0025]. The water-soluble coatings taught by Sugimoto are chosen for their properties in the mouth, and Sugimoto provides no information that would lead a POSA to believe this system would work to achieve the delicate balance of stability and bioavailability required for DE in

the stomach. *Id.* at ¶ [0029]. The bioavailability data in Sugimoto is for a different drug in dogs and is not predictive of success for DE delivery in humans. *Id.* at Fig. 3. Petitioner's reliance on Sugimoto improperly combines references from disparate fields of endeavor to reconstruct the invention.

The ground fails for lack of motivation and lack of a reasonable expectation of success.

The Petition's element-by-element mapping for this ground is similarly defective. Petitioner asserts that Sugimoto's coated acid granules meet the limitations of the '729 patent. Pet. at 53. This ignores the fundamentally different function and context. Sugimoto's coating is specifically described as being "insoluble in alcoholic solvent" (EX1010, Abstract), a property relevant to a specific manufacturing process for ODTs that involves treating the tablets with ethanol vapor. *Id.* at ¶ [0135]. This coating is designed to be stable in saliva for taste-masking (*supra*). Petitioner has provided nothing to support the contention that a POSA would have concluded that a coating designed for this highly specific ODT manufacturing process and oral environment would function as a "protective coating layer" in the highly acidic and aqueous gastric environment to achieve the controlled dissolution needed for dabigatran. The reference provides no teaching that would create a reasonable expectation of success. Moreover,

the entire framework of Sugimoto is incompatible with the problem solved by the '729 patent. Sugimoto's invention is a compressed ODT, requiring specific excipients and compression properties to achieve rapid disintegration in the mouth. EX1010 at ¶¶ [0133]-[0134]. The Petition does not establish that these properties are reasonably pertinent to a multiparticulate capsule formulation designed for gastric release. The Petition fails to explain why a POSA would have been motivated to import granulation and coating technology from the distinct field of ODTs, with its focus on taste-masking and oral disintegration, to solve the gastric dissolution and long-term stability challenges of DE in a capsule.

Because the underlying combination is improper, Petitioner's arguments regarding the dependent claims also fail. The process steps for making an ODT in Sugimoto (claim 8) or the specific excipients used therein (claims 10, 14) are not interchangeable with the requirements for the claimed capsule formulation. And for each dependent claim, the Petition fails to explain why a POSA would have simply swapped DE into Sugimoto's ODT formulation with any expectation of creating a stable, bioequivalent capsule, for the same reasons as the independent claim. Each step of Petitioner's obviousness argument relies on hindsight and ignores the fundamental differences between the cited art and the claimed invention.

VI. CONCLUSION

For the foregoing reasons, Patent Owner, Breckenridge Pharmaceutical, Inc., respectfully requests that the Board deny institution of *inter partes* review.

Dated: September 25, 2025

Respectfully submitted,

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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 Preliminary Response totals 7197 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: September 25, 2025

Manner of service: Electronic mail addressed to:
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Documents served: **PRELIMINARY RESPONSE BY PATENT OWNER
PURSUANT TO 37 C.F.R § 42.107**

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