

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Padagis US LLC,
Petitioner

v.

Neurelis, Inc.,
Patent Owner

Case No. IPR2025-00464
Patent No. 8,895,546

PATENT OWNER'S RESPONSE

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2003	Preliminary Invalidity Contentions served in <i>Neurelis, Inc. v. Padagis LLC</i> , 1:24-cv-00562 (D. Del. Dec. 20, 2024)
2004	Markman Order entered in <i>Gilead Sciences, Inc. v. Lupin Ltd.</i> , 1:22-cv-00615-MN, D.I. 280 (D. Del. Feb. 21, 2025)
2005	Markman Order entered in <i>Spinal Generations, LLC v. Depuy Synthes, Inc.</i> , 1:22-cv-01368 (MN), D.I. 147 (D. Del. Oct. 16, 2024)
2006	Orange Book Listing for U.S. Patent No. 8,895,546
2007	Declaration of Nicholas A. Peppas, Sc.D., dated December 6, 2018 in <i>Aquestive Therapeutics, Inc. v. Hale Biopharma Ventures, LLC</i> , IPR2019-00451, Exhibit 1041 (Jan. 29, 2019)
2008	Declaration of Daniel P. Wermeling, Pharm.D., dated January 27, 2020 in <i>Aquestive Therapeutics, Inc. v. Hale Biopharma Ventures, LLC</i> , IPR2019-00451, Exhibit 1150 (Jan. 28, 2020)
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2010	NOT USED
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2012	NOT USED

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2028	NOT USED
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2030	Written joint research agreement, titled “Master Service Agreement” (7 pages), between Particle Sciences, Inc. and Questcor Pharmaceuticals, Inc., dated April 1, 2007 [FILED UNDER SEAL]
2031	Asset Purchase Agreement between Hale BioPharma Ventures, LLC and Questcor Pharmaceuticals, Inc., dated June 27, 2008 [FILED UNDER SEAL]
2032	H.R. Rep. No. 108-425 (2004)
2033	150 Cong. Rec. S7520-05 (2004)

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2034	Non-disclosure Agreement between Aegis Therapeutics, LLC and Questcor Pharmaceuticals, Inc., dated August 15, 2005 [FILED UNDER SEAL]
2035	Confidentiality Agreement between Particle Sciences, Inc. and Questcor Pharmaceuticals, Inc., dated January 19, 2007 [FILED UNDER SEAL]
2036	Email between Questcor Pharmaceuticals, Inc. and Aegis Therapeutics, LLC, dated February 15, 2007 [FILED UNDER SEAL]
2037	Quote No. QCR 135 between Particle Sciences, Inc. and Questcor Pharmaceuticals, Inc., dated March 28, 2007 [FILED UNDER SEAL]
2038	QSC-002 Project Email Thread between Aegis Therapeutics, LLC and Questcor Pharmaceuticals, Inc., dated March 26, 2007
2039	Redline Comparison between U.S. Patent No. 11,793,786 and U.S. Patent No. 11,241,414
2040	QC and PSI Agreement between Particle Sciences, Inc. and Questcor Pharmaceuticals, Inc., dated April 2, 2008 [FILED UNDER SEAL]
2041	Letter Agreement, with Term Sheet between Neurelis, Inc. and Aegis Therapeutics, LLC, dated August 28, 2007 [FILED UNDER SEAL]
2042	Supply Agreement Neurelis, Inc. and Aegis Therapeutics, LLC, dated May 22, 2008 [FILED UNDER SEAL]
2043	License Agreement Neurelis, Inc. and Aegis Therapeutics, LLC, dated May 22, 2008 [FILED UNDER SEAL]
2044	Transmittal Notice of Intravail from Aegis Therapeutics, dated October 2, 2008 [FILED UNDER SEAL]

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2045	Declaration of Steven Cartt [FILED UNDER SEAL]
2046	Declaration of Dr. Mark Mitchnick [FILED UNDER SEAL]
2047	Declaration of David Hale
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2061	David Ward, <i>Optimizing Nasal Products for Systemic Delivery</i> , 106 ONDRUGDELIVERY 56 (2020) (“Ward-2020”)
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2066	M. Molero-Monfort et al., <i>Retention-activity Relationship Studies of Benzodiazepines by Micellar Liquid Chromatography</i> , 13 BIOMED. CHROMATOGRAPHY 394 (1999) (“Molero-Monfort-1999”)
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2068	Neurelis Patent Family Tree
2069	Declaration of Mareen Donovan, Ph.D. in Support of Defendants' Responsive Claim Construction Brief, <i>Neurelis, Inc. v. Padagis LLC et al.</i> , 1:24-cv-562, D.I. 88-28 (D. Del. August 22, 2025) ("Donovan-CC Decl.")
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2072	Declaration of Dr. Marc Brown regarding U.S. Patent No. 8,895,546
2073	NOT USED
2074	NOT USED
2075	Statutory Disclaimer for Claims 1-16 and 18-21 of '546 Patent
2076	Patent Owner Response, dated November 5, 2019 in <i>Aquestive Therapeutics, Inc. v. Neurelis, Inc.</i> , IPR2019-00451

TABLE OF CHALLENGED CLAIMS

Claim Element	Claim Language from '546 Patent
1. **	1. A pharmaceutical solution for nasal administration consisting of: (a) a benzodiazepine drug; (b) one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w); (c) ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w); and (d) an alkyl glycoside.
15**	15. The pharmaceutical solution of claim 1, wherein the alkyl glycoside is present in pharmaceutical solution in a concentration of at least about 0.01% (w/w).
16**	16. The pharmaceutical solution of claim 15, wherein the alkyl glycoside is present in the pharmaceutical solution in an amount of 0.01% to 1% (w/w).
17	17. The solution of claim 1, consisting of diazepam, vitamin E, ethanol, benzyl alcohol and dodecyl maltoside.
22	22. The solution of claim 16, wherein the alkyl glycoside is dodecyl maltoside

** Claims 1, 15, and 16 have been statutorily disclaimed. They are only included herein to show their limitations that are included within Claims 17 and 22.

I. INTRODUCTION

Neurelis, Inc. (“Neurelis” or “Patent Owner”) submits this Patent Owner Response to the Petition for IPR (“Petition” or “Pet.”) filed by Padagis (“Petitioner”), challenging claims 17 and 22 of U.S. Patent No. 8,895,546 (“’546 Patent”) (EX1001) as obvious over one combination: Gwozdz-PCT (EX1009)¹ with Meezan (EX1010).² This Response is supported by the declarations of Dr. Marc Brown (EX2072) and three of the ’546 Patent inventors: Cartt, Mitchnick, and Maggio (EX2045-EX2047).

“The inventor’s own path itself never leads to a conclusion of obviousness; that is hindsight.” *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012). Petitioner’s choice to follow this path pervades its Petition.

First, Padagis asserts that Gwozdz-PCT, the principal reference, is prior art only under 35 U.S.C. §102(e) (pre-AIA). Pet. at 39. Gwozdz-PCT purports to trace priority to a provisional application (61/040,281) filed March 28, 2008, but the ’546 Patent also traces its disclosure to a provisional application (61/040,558) filed March 28, 2008. The two provisional applications were filed the same day by a joint

¹ To distinguish the reference from the inventor, EX1009 is referred to as “Gwozdz-PCT.”

² As will be discussed below, Neurelis filed a statutory disclaimer, such that only Claims 17 and 22 remain in the ’546 Patent.

research group because they disclosed different inventions, which is why Petitioner does not (and cannot) assert any anticipation grounds. But regardless of whether Gwozdz-PCT qualifies as §102(e) prior art, it is not available for obviousness under 35 U.S.C. §103(c)(2), as it was developed under a joint research agreement.

The common and overlapping inventors between the '546 Patent and the asserted prior art are shown below:

'546 Patent (EX1001)	Inventors: Steve Cartt , Hillsborough, CA (US); David Medeiros , Sparks, NV (US); Garry Thomas Gwozdz , Jim Thorpe, PA (US); Andrew Loxley , Brussels (BE); Mark Mitchnick , East Hampton, NY (US); David F. Hale , San Diego, CA (US); Edward T. Maggio , San Diego, CA (US)
WO2009/120933 Gwozdz-PCT (EX1009)	Inventors; and Inventors/Applicants (<i>for US only</i>): GWOZDZ, Garry, Thomas [US/US]; 329 South Main Street, Nazareth, PA 18064 (US). LOXLEY, Andrew [GB/US]; 126 Market Street, #5, Philadelphia, PA 19106 (US). MITCHNICK, Mark [US/US]; 80 Three Mile Harbor Drive, East Hampton, NY 11937 (US).
US2006/0046962 Meezan (EX1010)	Inventors: Elias Meezan , Birmingham, AL (US); Dennis J. Pillion , Hoover, AL (US); Edward T. Maggio , San Diego, CA (US)

Nevertheless, Petitioner would have the Board ignore the Section 103(c)(2) safe harbor, and then modify Gwozdz-PCT with Meezan to reconstruct the challenged claims by re-tracing the steps of the '546 Patent inventors. This tactic is

improper. “What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art,” not the path the inventors forged. *Millenium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1367 (Fed. Cir. 2017) (quoting *Otsuka*, 678 F.3d at 1296).

Second, the putative prior art here provides no tracks that a POSA would have followed to the claimed inventions as there would have been no motivation to combine Gwozdz-PCT and Meezan, absent Petitioner’s hindsight perspective on the inventors’ own work. A POSA viewing Meezan at the priority date, rather than with hindsight, would have understood it to disclose legions of alkyl glycosides of varying alkyl-chain lengths, glycoside content, and various other structural characteristics. Yet, each of the remaining claims of the ’546 Patent is limited to one specific chain length—“dodecyl maltoside”—which has 12 carbons in the alkyl moiety. For a POSA to have chosen dodecyl (12-carbon) maltoside—absent hindsight—would have required an incredible stroke of fortune. *See In re Kuban*, 561 F.3d 1351, 1359 (Fed. Cir. 2009) (“where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness”).

Moreover, Gwozdz-PCT discloses a complete solution for the problem it was addressing. Rather than supply any motivation to combine, Petitioner uses the ’546 Patent itself to identify the problem, solves the identified problem with Gwozdz-

PCT, and then adds Meezan solely because the '546 claims require an additional ingredient that Meezan purportedly discloses (but, in fact, does not). Such hindsight cannot serve as a basis for invalidity.

Lastly, as an end-around the substantive deficiencies with its invalidity argument, Petitioner contends that Neurelis should be unable to defend the '546 Patent on account of collateral estoppel. But the '546 Patent was not the subject of any prior judicial proceeding. The only prior proceeding, IPR2019-00451 ("451 IPR"), concerned Patent No. 9,763,876 ("876 Patent"). This is a different patent with different patent claims and different issues of patentability.

II. THE '546 PATENT AND THE CHALLENGED CLAIMS

A. STATUTORY DISCLAIMER UNDER 35 U.S.C. §253

Neurelis has statutorily disclaimed Claims 1-16 and 18-21 of the '546 Patent to simplify issues in this IPR. *See* 35 U.S.C. § 253.

Doc Code: STAT.DISCLMR
Document Description: Statutory Disclaimers per Manual of Patent Examining Procedure(MPEP) 1490

PTO/SB/43 (11-23)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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DISCLAIMER IN A PATENT UNDER 37 CFR 1.321(a)	
Name of Patentee Neurelis, Inc.	Docket Number (optional) 148570-004321
Patent Number 8,895,546	Date Patent Issued November 25, 2014
Title of Invention ADMINISTRATION OF BENZODIAZEPINE COMPOSITIONS	
Patentee hereby disclaims:	
☒ the following complete claim(s) in the above-identified patent: <u>1-16, 18-21</u> .	
☐ the terminal part of the term of the above-identified patent beginning on the date: _____.	

EX2075 (statutory disclaimer). Neurelis does not statutorily disclaim Claims 17 and 22 of the '546 Patent.

Claims 1-16 and 18-21 are removed from this IPR proceeding. Consequently, in its final written decision, the Board should not address disclaimed Claims 1-16 and 18-21. *See Intel Corp. v. VLSI Tech. LLC*, IPR2018-01040, Paper 36, 16 (PTAB Feb. 12, 2020) (“Consistent with other Board decisions in which some, but not all, challenged claims have been disclaimed after institution, we address the patentability only of the remaining claims.” (collecting decisions)); *Axonics, Inc. v. Medtronic, Inc.*, IPR2020-00680, Paper 45 at 2-4 (P.T.A.B. Sept. 22, 2021) (addressing only non-disclaimed claims in final written decision when statutory disclaimer was filed after institution).

Neurelis does not seek an adverse judgment as to disclaimed Claims 1-16 and 18-21. An adverse judgment is not appropriate, because Claims 17 and 22 remain in the '546 Patent—there are “remaining claim[s] in the trial.” *See* 37 C.F.R. §42.73(b)(2). Nor does Neurelis concede that the subject matter of disclaimed Claims 1-16 and 18-21 is in the prior art, or that the disclaimed claims are unpatentable. “Disclaimed claims are treated as if they never existed, and disclaimer does not legally constitute an admission that the subject of the disclaimer appears in the prior art.” *Raytheon Techs. Corp. v. Gen. Elec. Co.*, 993 F.3d 1374, 1379 n. 4 (Fed. Cir. 2021); *see Gunn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) (“A statutory

disclaimer under 35 U.S.C. § 253 has the effect of canceling the claims from the patent and the patent is viewed as though the disclaimed claims had never existed in the patent.”). Rather, Neurelis disclaimed the claims solely to streamline the case.

B. PROSECUTION HISTORY

The ’546 Patent issued from Application 13/495,942, (“the ’942 Application”) that ultimately claims priority to the ’558 Provisional (filed March 28, 2008). When filing the ’942 Application, Neurelis submitted the art on which this Petition relies, including the record from the 451 IPR. EX1002 at 157-162.

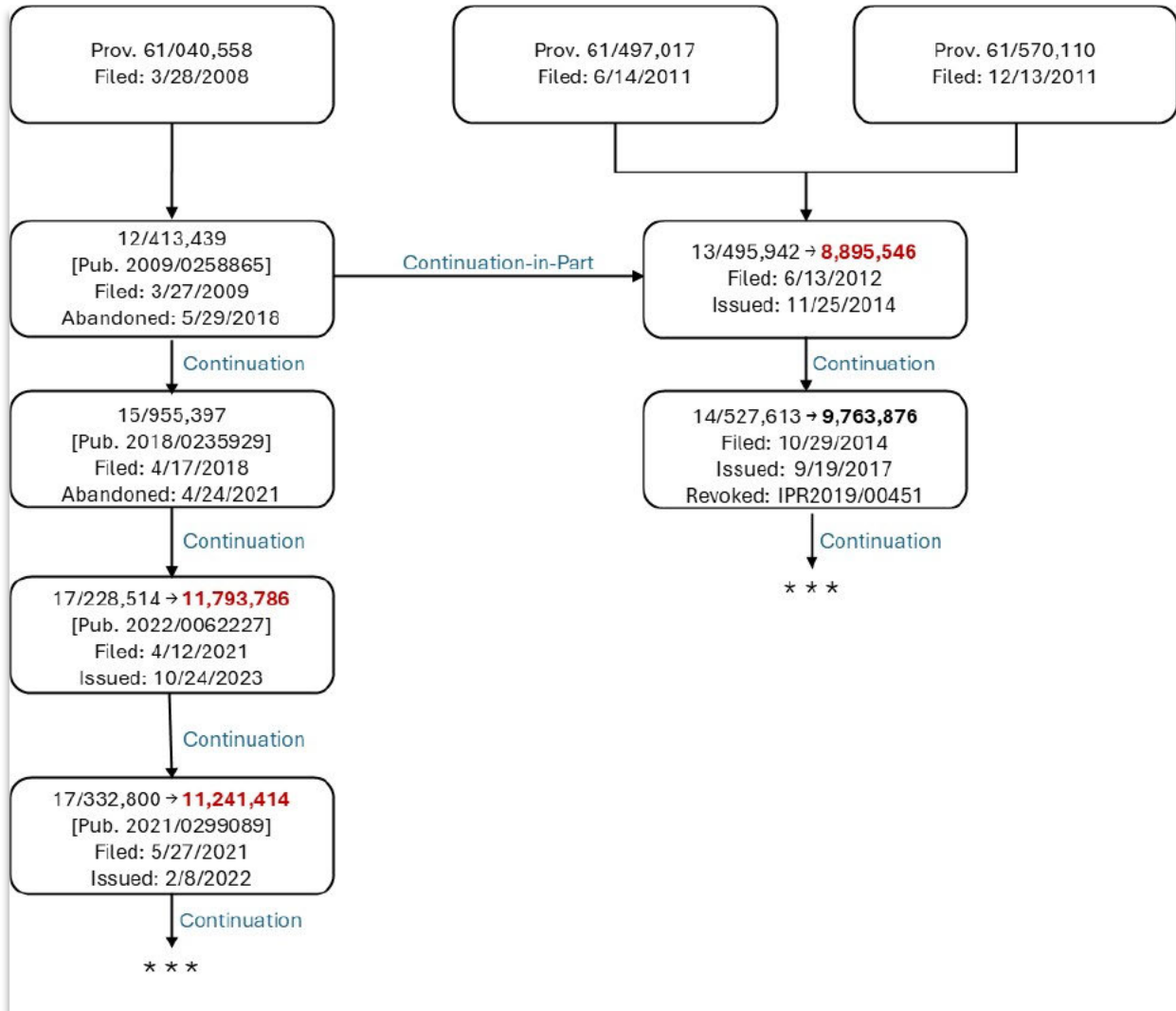
C. THE CLAIMED INVENTION

The ’546 Patent provides a pharmaceutical solution containing both tocopherols or tocotrienols (e.g., vitamin E) and alcohols (e.g., ethanol and benzyl alcohol), which readily dissolve diazepam while maintaining appropriate viscosity. EX1001, 37:50-60.

The ’546 Patent claims Valtoco®, a pharmaceutical solution of diazepam that an acquaintance or family member of a patient can administer to treat acute bouts of seizure clusters. EX1001 at 21:38-44. Valtoco® was approved in January 2020 and awarded Orphan Drug Exclusivity because it possesses clinical superiority and provides “a major contribution to patient care.” 21 C.F.R. §316.3(b)(3)(iii); EX2001 at 4; EX2072 ¶¶114-117.

D. FAMILY TREE

A summary of relevant patents and applications is shown below, with those challenged by Padagis in red.



EX2068.

III. LEVEL OF ORDINARY SKILL

A person of ordinary skill in the art (“POSA”) has the following qualifications:

[T]he skilled artisan holds a Master's degree with many years of experience, or a Ph.D. or Pharm.D degree with several years of experience or its equivalent experience in the field of pharmaceutical research and development. The skilled artisan would have knowledge of benzodiazepine structure and function, including physiochemical characteristics of benzodiazepines generally. The skilled artisan would further have knowledge and practical experience developing and working with intranasal formulations, including knowledge of the physiology and anatomy of the nasal cavity and methods of administering drugs intranasally. The skilled artisan also would have knowledge concerning clinical aspects of bioavailability, tolerability, and patient acceptability of intranasal formulations and the difficulty of administering drugs by other routes during an event like a seizure.

EX2072 ¶¶61-62.

IV. CLAIM CONSTRUCTION

“[W]hen a petitioner takes alternative [claim construction] positions before the Board and a district court, that petitioner should, at a minimum, explain why alternative positions are warranted.” *Revvo Techs., Inc. v. Cerebrum Sensor Techs., Inc.*, IPR2025-00632, Paper 20 at 3-4 (P.T.A.B. Nov. 3, 2025) (precedential). Gamesmanship “does not further the Office’s goal of ‘providing greater predictability and certainty in the patent system.’” *Id.* at 4. Here, Petitioner’s obviousness challenge requires applying a construction of the “consisting of” language that directly contradicts Petitioner’s construction in district court. Petitioner contends in district court that the claims preclude even trace amounts of water, yet here relies on aqueous embodiments of both Gwozdz-PCT and Meezan to argue obviousness.

A. PETITIONER’S DISTRICT COURT POSITION FOR “CONSISTING OF”

Claims 17 and 22 (through their dependency from previous claim 1) recite, “A pharmaceutical solution for nasal administration consisting of” several ingredients. In district court, the parties dispute what “consisting of” means:

Term	Neurelis’s Position	Padagis’s Construction
A pharmaceutical solution for nasal administration consisting of	No construction necessary; the scope of “consisting of” is established by law.	“a pharmaceutical solution for nasal administration containing only those elements set forth in the claim and excluding anything else, particularly excluding water and oil” Otherwise indefinite.

EX2050 (Joint-CC Br.) at 27. Although Petitioner *now* contends in IPR that “consisting of” needs no construction, Petitioner in district court asserts that it means “excluding anything else, particularly excluding water and oil”; the claims cannot include embodiments having even “trace impurities” of water or oil. *Id.* at 27, 46. If the claims are construed to allow any amount of water or oil, Petitioner contends the claims are indefinite because a POSA could not reasonably ascertain their scope. *Id.* at 53-57.

In support of its construction, Petitioner provided a declaration from Dr. Donovan—the same expert supporting its petition—stating that “the ‘consisting of’ transition language does not allow for the inclusion of small amounts of water.” EX2069 (Donovan-CC Decl.) ¶26. She continued that “even very small amounts of

water” should not be considered “an ‘impurity ordinarily associated’ with the claimed solution,” and is thus excluded from the claims—even water “less than about 0.1%.” *Id.* ¶¶26, 33. She proposes that if the claims allow some water—even as trace impurities—“a POSA cannot reasonably ascertain what is within the scope of the invention, and what is outside the scope of the invention, and the claims are indefinite.” *Id.* ¶50; *see* EX2050 (Joint-CC Br.) at 55-56; EX2069 (Donovan-CC Decl.) ¶¶53, 57.

B. PETITIONER’S CONFLICTING PTAB POSITION FOR “CONSISTING OF”

Meanwhile in this forum, Petitioner’s contentions directly contradict its position in district court in multiple ways. First, Petitioner does not propose here that “consisting of” requires construction. Indeed, Petitioner fails to prove (or even address) whether the formulations of Gwozdz-PCT (EX1009) and Meezan (EX1010) have water, whether trace amounts or otherwise. But as discussed below every prior art formulation on which Petitioner relies does, in fact, contain some amount water. *See infra* §IX.A.1. Worse yet, Petitioner affirmatively relies on at least one embodiment of Gwozdz-PCT that is in an aqueous solution (i.e., explicitly including water). *See infra* §IX.B.4.b. Petitioner nowhere explains or justifies this inconsistency.

Second, Petitioner contends the claims are indefinite in district court, but here contends that a POSA can understand their scope when asserting obviousness.

When a petitioner argues indefiniteness in district court but not before the PTAB, it “is *required* to explain why those different positions are warranted.” *Tesla, Inc. v. Intellectual Ventures II LLC*, IPR2025-00340, Paper 18 at 3 (P.T.A.B. Nov. 5, 2025) (Director Review, informative) (internal citations omitted); *see Cambridge Mobile Telematics, Inc. v. Sfara, Inc.*, IPR2024-00952, Paper 12 at 8 (P.T.A.B. Dec. 13, 2024) (informative) (petitioner required to explain the inconsistency in claim-construction positions).

Petitioner wholly ignores its district court claim construction to advance its contradictory obviousness arguments here.

V. THE ASSERTED GROUND AND ASSERTED REFERENCES

Petitioner asserts that the challenged claims would have been obvious over the combination of two references:

Reference	Asserted Status
WO2009/120933 Gwozdz-PCT (EX1009)	§102(e)(1) (pre-AIA)
US2006/0046962 Meezan (EX1010)	§102(b) (pre-AIA)

Pet. at 22-23.

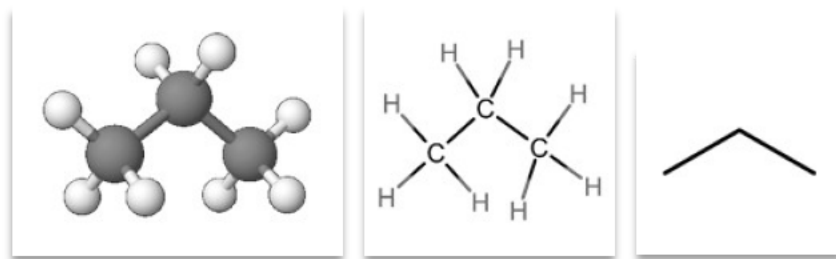
VI. TECHNICAL BACKGROUND

Dr. Brown provides a tutorial, excerpted below, covering aspects of organic chemistry and pharmaceutical formulations relevant to this dispute. EX2072 ¶¶63-

103; EX2049 (Dr. Brown's CV). Dr. Brown also discusses benzodiazepines, including diazepam. *Id.* ¶¶104-113 (citing EX2062-EX2067, EX2071).

A. ALKANES

Alkanes are a type of hydrocarbon compound that are made entirely of carbon (C) and hydrogen (H) atoms, and in which all the carbon-carbon bonds are single bonds. A three-carbon alkane is propane (C_3H_8). It can be depicted in three-dimensional fashion, in short-hand fashion, or in skeletal fashion:



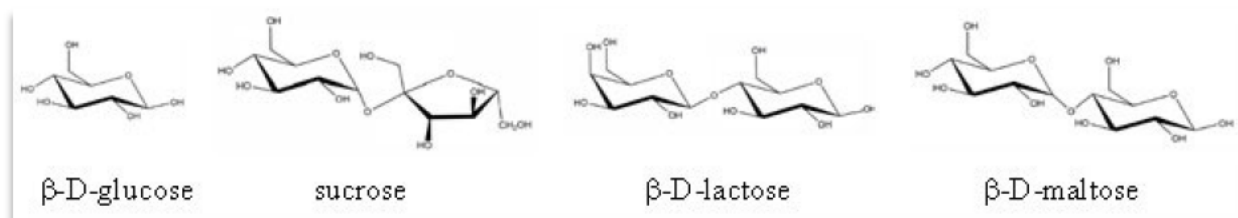
EX2072 ¶¶64-68 (referencing EX2051-EX2052).

When an alkane is not a standalone molecule, but is instead bonded to another chemically distinct portion of a molecule (often called a *moiety*), the “group name is derived by replacing the *-ane* of the corresponding alkane by the suffix *-yl*.”³ EX2051 at 10. For example, dodecane (12 -carbons) becomes “dodecyl.” EX2072 ¶73.

³ Chemical bonding of an alkyl group to another moiety also results in the possibility of additional structural isomers, depending on which position of a given alkane bonds with the other moiety. EX2072 ¶73.

B. SACCHARIDES AND GLYCOSIDES

One category of carbohydrates is commonly called “sugars,” or “saccharides.” A simple sugar molecule with one unit (monosaccharide) has the chemical formula of $C_6H_{12}O_6$ (e.g., glucose). Exemplary disaccharides (two sugar units) include sucrose, lactose, and maltose:



EX2051 at 13-15; EX2072 ¶¶74-75.

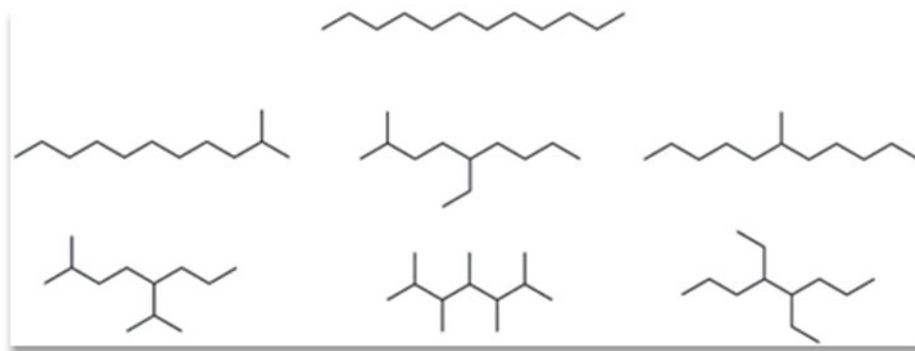
When a saccharide is chemically connected to another chemically distinct moiety, the resulting molecule is often termed a “*glycoside*.” For example, when connected to another moiety maltose becomes “maltoside.” A glycoside has two main parts: the sugar part, which is typically a cyclic monosaccharide; and the non-sugar part, which can be an organic molecule, like an alkane. EX2051 at 13-15; EX2072 ¶¶76-81.

C. ALKYL GLYCOSIDE

An “alkyl glycoside” represents a molecule in which an alkane (alkyl moiety) is bonded to a sugar moiety. An “alkyl glycoside” represents a broad genus of potential chemical compounds, including accounting for the following variations:

- The saccharide or glycoside moiety (e.g., single-unit sugars such as glucose, fructose, and galactose, or two-unit sugars such as maltose, etc.);
- The stereochemistry of the saccharide or glycoside (e.g., D or L);
- The anomeric structure of the saccharide or glycoside (e.g., α or β);
- Substitution of heteroatoms (e.g., sulphur) in the saccharide or glycoside;
- The alkyl chain (its size and its isomeric structure, i.e., the number of carbon atoms, and whether they are linear or branched);
- Which carbon of the alkyl chain is connected to the glycoside or saccharide moiety; and
- The linking chemistry between the moieties (e.g., glycosidic, thioglycosidic, ester, ureide, amide, etc.).

EX2072 ¶80. One subgenus of alkyl glycosides is “dodecyl maltoside.” The “dodecyl” refers to the alkyl group having twelve carbons, and it is bonded to a maltose (maltoside). A handful of the 355 isomers of dodecane ($C_{12}H_{26}$) include:



EX2072 ¶¶78-81.

VII. GWOZDZ-PCT (EX1009) IS NOT §102(e) PRIOR ART

“In an *inter partes* review, the burden of persuasion is on the petitioner to prove ‘unpatentability by a preponderance of the evidence,’ 35 U.S.C. § 316(e), and that burden never shifts to the patentee.” *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). This rule “necessarily requires the reference patent document first to be qualified as prior art.” *Intelligent Wellhead Sys., Inc. v. Downing Wellhead Equip., LLC*, IPR2024-00256, Paper 11 at 10-11 (P.T.A.B. June 5, 2024). “The burden to make this showing thus falls squarely on Petitioner.” *Id.* at 12. Petitioner cannot meet its burden to demonstrate that Gwozdz-PCT (EX1009) qualifies as prior art.

First, every named inventor on Gwozdz-PCT (Gwozdz, Loxley, and Mitchnick) is also a named inventor on the ’546 Patent. Petitioner has not even addressed (much less demonstrated) the “by another” requirement of Section 102(e). *See, e.g., Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1358 (Fed. Cir. 2019) (describing factors to analyze Section 102(e)); *Google LLC v. IPA Techs. Inc.*, 34 F.4th 1081, 1085 (Fed. Cir. 2022) (applying *Duncan* to an obviousness challenge).

Second, for Gwozdz-PCT to achieve a §102(e) (pre-AIA) prior art date to the 61/040,281 provisional, two requirements must be met. First, Petitioner must demonstrate that the provisional provides written-description support for at least one

claim. *See Dynamic Drinkware*, 800 F.3d 1375, 1382 (Fed. Cir. 2015). Second, “the cited content” relied on to support the unpatentability analysis must also be “adequately supported by the written description of the provisional application.” *In re Riggs*, 131 F.4th 1377, 1384-85 (Fed. Cir. 2025). Both factors are required.

Petitioner fails to meet the second factor. Petitioner asserts that “a motivation existed to combine the teachings of Meezan related to alkyl glycosides with the pharmaceutical solutions described in Gwozdz.” Pet. at 26. The basis is that “Gwozdz teaches that the pharmaceutical solutions ... may further incorporate additional pharmaceutically acceptable additives, including ... ‘penetration enhancers’ ... to improve the efficacy.” Pet. at 26-27 (citing EX1009, 10:12-16); *see* Pet. at 30, 44; EX2070 (Donovan Tr.) at 78:22-79:6. As the Board explained, however:

Petitioner did not establish that Gwozdz’s disclosure of “penetration enhancers” finds support in the Gwozdz Provisional. Pet. 22. Conversely, Patent Owner shows that the phrase is absent in the Gwozdz Provisional. Prelim. Resp. 20-21.

Paper 13 at 18-19. This omission can be seen by comparing identical paragraphs from the two documents.

10 solubilizing agent such as Cremophor. Such pharmaceutical compositions may further contain other pharmaceutically acceptable additives such as, but not limited to, acidifying, alkalizing, buffering, chelating, complexing and solubilizing agents, antioxidants and antimicrobial 15 preservatives, humectants, suspending and/or viscosity modifying agents, tonicity and wetting or other biocompatible materials.	EX1064, 10:10-17
10 compositions may further contain other pharmaceutically acceptable additives such as, but not limited to, acidifying, alkalizing, buffering, chelating, complexing and solubilizing agents, antioxidants and antimicrobial 15 preservatives, penetration enhancers, humectants, suspending and/or viscosity modifying agents, tonicity and wetting or other biocompatible materials.	EX1009, 10:10-17

There is no disclosure of “penetration enhancers” in Gwozdz-Provisional (EX1064); EX2072 ¶156.

Third, Gwozdz-PCT is unavailable to be used as an asserted reference in an IPR proceeding, which is limited to “prior art consisting of patents or printed publications.” 35 U.S.C. §311(b). Gwozdz-PCT is not a patent, and Section 311(b) does not include “patent applications” under the available grounds. It is also not a “printed publication” in the sense that “before the critical date the reference must have been sufficiently accessible to the public interested in the art.” *See Constant v.*

Advanced Micro-Devices, Inc., 848 F.2d 1560, 1568 (Fed. Cir. 1988). Gwozdz-PCT published on October 1, 2009, which is after the '546 Patent's critical date.⁴

VIII. GWOZDZ-PCT IS NOT AVAILABLE IN AN OBVIOUSNESS COMBINATION UNDER 35 U.S.C. §103(C)(2)

The only prior art basis Petitioner asserts for Gwozdz-PCT is that it qualifies under 35 U.S.C. §102(e). Pet. at 22. Indeed, Gwozdz-PCT was filed March 27, 2009 (EX1009), and Petitioner does not dispute that the challenged claims of the '546 Patent have priority to the first non-provisional, 12/413,439, filed March 27, 2009. Pet. at 12, 16. Thus, Petitioner does not contend that Gwozdz-PCT published early enough to qualify for any prior art provision *other* than Section 102(e).

Section 102(e) prior art is precluded, however, from being used in an obviousness combination under 35 U.S.C. § 103(c), because the inventions claimed in the '546 Patent resulted from a qualifying joint research agreement (JRA) that was in effect when the inventions were made, the inventions were developed within the scope of that agreement, and the patent is in the process of being properly amended to disclose the parties to the agreement.

⁴ The Federal Circuit “conclude[d] that §§311(b) and 102(e)(1) permit IPR challenges based upon published patent applications.” *Lynk Labs, Inc. v. Samsung Elecs. Co.*, 125 F.4th 1120, 1132 (Fed. Cir. 2025). Lynk Labs has sought *certiorari* from the Supreme Court, so Neurelis includes the argument to preserve it.

Section 102(e) prior art does not preclude patentability if, at the time the invention was made, the prior art and the claimed invention were deemed to be owned by the same entity or subject to an obligation of assignment to that entity.

This exemption applies when:

- 1) The claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the claimed invention was made;
- 2) The claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
- 3) The application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

35 U.S.C. §103(c)(2)(A)-(C). All three conditions apply here.

As explained in more detail below, Particle Sciences, Inc. (“PSI”) and Questcor Pharmaceuticals, Inc. (“Questcor”) entered into a JRA before the ’546 Patent’s earliest claimed priority date. PSI is the assignee of Gwozdz-PCT, and Questcor is the predecessor-in-interest of the ’546 Patent.⁵ The claimed inventions arose from activities conducted within the scope of that JRA, and the ’546 Patent is in the process of being amended to identify the parties to the JRA. *See* Papers 23,

⁵ Questcor sold its interest in the JRA to Hale BioPharma Ventures (“HBV”) in 2008. *See* EX2047 (Hale Decl.) ¶10. HBV is the predecessor in interest to Neurelis, Inc., the Patent Owner.

26. Thus, Gwozdz-PCT is unavailable for obviousness because it resulted from work under the JRA.

A. FACTOR 1: THE '546 PATENTED INVENTIONS WERE MADE BY OR ON BEHALF OF QUESTCOR AND PSI, WHO WERE PARTIES TO A JRA THAT WAS IN EFFECT BEFORE THE CLAIMED INVENTIONS WERE MADE

A JRA was in effect before the earliest priority date of the '546 Patent. *See* 35 U.S.C. §103(c)(3).

1. Questcor and PSI's Joint Research Agreement

In late 2006, Questcor approached PSI to help with research and development work that resulted in the inventions claimed in the '546 Patent. As part of that process, the parties executed a Master Services Agreement ("MSA"), dated April 1, 2007. EX2030. The MSA formalized Questcor's and PSI's partnership and outlined the scope of collaboration to perform formulation work for the diazepam nasal-spray development program that is the subject of the '546 Patent. EX2030 at 1.

The MSA demonstrates the existence of a JRA under Section 103(c), because it is a written contract executed by two or more parties for the performance of experimental, developmental, or research work in the field of the invention. *See* 35 U.S.C. §103(c)(3) (pre-AIA). Additional documents, communications, and experimental details that were shared between the parties provide further evidence that a JRA existed between Questcor and PSI. *See id.*; EX2032 (H.R. Rep. No. 108-425) at 10 ("Congress does not intend to prescribe the specific form of the agreement

parties must use to benefit from this Act nor to require the writing be contained in a single instrument.”); EX2033 (150 Cong. Rec. S7520-05) at 3 (Sen. Hatch, “The House indicated in its committee report that a joint research agreement may be evidenced by one or more writings.”); EX2035; EX2037; EX2040.

2. The ’558 Provisional Was Filed on March 27, 2008

Almost one year after signing the MSA, Questcor filed the ’558 Provisional pursuant to the terms of the MSA. The ’558 Provisional identifies individuals from Questcor and PSI who worked jointly to develop the inventions disclosed therein. *See generally* EX2045-EX2047 (inventor declarations). Gwozdz-Provisional (61/040,281), filed the same day pursuant to the JRA, identifies the same PSI individuals who worked jointly to develop the inventions disclosed in the ’558 Provisional.

3. Assignment of the JRA to HBV and Subsequently to Neurelis

In June 2008, Questcor transferred all its interest and rights to the JRA and the QSC-002 Project, including the inventions claimed in the ’414 Patent, to HBV pursuant to an Asset Purchase Agreement dated June 27, 2008. *See* EX2031 (APA). The JRA between Questcor and PSI was expressly assigned to HBV. *See id.* at 2

[REDACTED]

(assigning the MSA from Questcor to HBV).

In December 2018 and February 2019, Neurelis was assigned all the QSC-002 Project assets, including the '546 Patent and the patent applications to which it claims priority, as evidenced by assignments recorded in the PTO's assignment database. Reel/Frame Nos. 48211/0840, 48271/0304, 58369/0292, and 58369/0412.

4. The Inventions Were Made by the Parties to the JRA

As elaborated in the declarations of inventors Cartt, Mitchnick, and Hale (EX2045-EX2047), the parties to the JRA each contributed to the formulations that are now claimed in the '546 Patent. All the work was done and performed under the JRA. Even before the '558 Provisional was filed, the parties worked to obtain supplies of and technical knowhow concerning *n*-dodecyl- β -D-maltoside (Ed Maggio at Aegis, Inc.). EX2041 (Letter Agreement); EX2034; EX2036; EX2038; EX2042; EX2044; *see* EX2061 (Ward) at 4 (discussing Intravail). Neurelis ultimately signed that supply and license agreement as part of the diazepam nasal-spray development program under the JRA. EX2043 (License Agreement).

B. FACTOR 2: THE CLAIMED INVENTIONS WERE MADE AS A RESULT OF ACTIVITIES UNDERTAKEN WITHIN THE SCOPE OF THE JRA

The '546 Patent inventions resulted from activities undertaken within the scope of the JRA. As Cartt (Questcor) and Mitchnick (PSI) testified, the MSA governed the development of the diazepam nasal-spray development program. EX2045 ¶19; EX2046 ¶14. This agreement formalized Questcor's engagement of

PSI (along with HBV and Neurelis, as Questcor's successors in interest) to perform formulation work for nasal spray products targeting central nervous system disorders, outlining the scope and purpose of the collaboration as follows:

[REDACTED]

[REDACTED]

[REDACTED]

EX2030 at 1.

After executing the MSA, Questcor and PSI continued to collaborate to develop the claimed invention of the '546 patent. *See generally* EX2045-EX2047. The MSA provided that Questcor retained ownership of all intellectual property for inventions [REDACTED]

[REDACTED]. EX2030 at 3 [REDACTED]; *accord id.* at

1 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *See* EX2030 at 3; *see* EX2045 ¶26.

Pursuant to this arrangement, Questcor and PSI filed two separate patent applications on March 28, 2008. *See* EX2040. These filings became the '558 Provisional (owned by Questcor) and Gwozdz-Provisional (owned by PSI). *See id.*

Shortly thereafter, Questcor assigned the joint research agreement to HBV, [REDACTED]
[REDACTED]. EX2030 at 5. In June 2008, Questcor sold the diazepam nasal-spray project to HBV via an Asset Purchase Agreement, [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]. HBV then continued the collaboration with PSI under the same agreement, ultimately filing the '439 Application to which the '414 Patent claims priority.

The collaborative efforts under the MSA resulted in the filing of both the '558 Provisional and Gwozdz-Provisional on March 28, 2008, and continued through the filing of the '439 Application on March 27, 2009 (an ancestor to the '546 Patent) and Gwozdz-PCT. These filings were direct outcomes of the formulation and development work contemplated by the MSA, as evidenced by the declarations of Cartt, Mitchnick, and Hale, as well as contemporaneous documentation.

Accordingly, the claimed invention was developed squarely within the scope of the JRA, satisfying the second prong of §103(c)(2).

C. FACTOR 3: THE '546 PATENT IS BEING AMENDED TO DISCLOSE THE NAMES OF THE PARTIES TO THE JRA

Pursuant to 37 C.F.R. §1.71(g)(1), the specification may be amended to include the names of the parties to a joint research agreement. Neurelis has requested leave to seek a certificate of correction from the Director to identify Questcor, HBV, and PSI as parties to the joint research agreement underlying the claimed invention. *See* Papers 23, 26. Before the time for Final Written Decision, Neurelis expects that the Director will have granted the request and issued the requested certificate of correction, thus satisfying the third prong of §103(c)(2).

IX. THE CHALLENGED CLAIMS ARE NOT OBVIOUS OVER GWOZDZ-PCT AND MEEZAN

Petitioner's obviousness contentions should be rejected outright, because Petitioner has not "carried its burden to prove that all claimed limitations are disclosed in the prior art." *PAR Pharm.*, 773 F.3d at 1194. Petitioner and Dr. Donovan fail to address the "consisting of" language in the claims, particularly in view of their district court claim constructions. In view of this fundamental hole in the Petition, the Board need not "consider motivation to combine and reasonable expectation of success." *Id.*

A. THE COMBINATION DOES NOT DISCLOSE ALL CLAIM LIMITATIONS

The Director has stated that the USPTO "will enforce and no longer waive the requirement of 37 C.F.R. §42.104(b)(4) (Rule 104(b)(4)) that a petition for inter

partes review (IPR) ‘must specify where each element of the claim is found in the prior art patents or printed publications relied upon.’” *See* Director Memo (7/31/2025), “Enforcement and Non-Waiver of 37 C.F.R. §42.104(b)(4) and permissible uses of general knowledge in *inter partes* reviews.”⁶ Although “expert testimony, common sense, and other ... general knowledge” may have previously sufficed to “supply a missing claim limitation” (*see id.*), the Petition here lacks even that.

1. “consisting of”

According to Petitioner’s claim-construction position in district court, there is no disclosure in Gwozdz-PCT or Meezan meeting any of the ’546 Patent claims, because Gwozdz-PCT and Meezan contain some amount of water.

As detailed above (*supra* §IV), Petitioner and Dr. Donovan advocate in district court that the challenged claims exclude “water and oil.” EX2050 (Joint-CC Br.) at 27; EX2069 (Donovan-CC Decl.) ¶¶26, 33. In fact, Petitioner asserts in district court that the claims exclude *even trace impurities*, such as trace amounts of water. EX2050 (Joint-CC Br.) at 46 (emphasis added). In support of this extreme position, Dr. Donovan opined in district court that the “consisting of” language of the ’546 Patent claims “does not allow for the inclusion of small amounts of water.”

⁶ https://www.uspto.gov/sites/default/files/documents/aapa_memo_final__signed.pdf.

EX2069 (Donovan-CC Decl.) ¶26; *see id.* ¶¶33, 50; EX2070 (Donovan Tr.) at 226:15-21.

Before the Board, however, Petitioner takes a completely different view. *First*, Petitioner relies on Gwozdz-PCT to disclose solutions of diazepam in tocopherols, benzyl alcohol, and ethanol, where the ethanol indisputably contains water. Pet. at 43-44 (citing EX1062 ¶¶147-148; EX1009 at 6:16-19). At the time, it was well-known that even “dehydrated” (200-proof) ethanol is not water-free (EX1038 (USP 26) at 5) and Dr. Donovan agrees. EX2070 at 36:9-25. In the embodiment cited in the Petition, Gwozdz-PCT states that “the ethanol is desirably 180 to 200 proof ethanol, *i.e.*, in the range of 90-100% ethanol.” EX1009 at 6:27-6:29. The remaining percentage of the composition (up to 10%) is almost entirely water. EX2072 ¶¶133-135.

Second, the Petition relies on an embodiment of Gwozdz-PCT discussing “penetration enhancers” as motivation to combine with Meezan. Pet. at 26-27, 30, 44 (citing to EX1009, subsets of 10:9-10:16). The full embodiment, however, states that pharmaceutical solutions with “penetration enhancers” are formulated “for injection by combining the instant pharmaceutical solution with, e.g., saline solution or *water*.” EX1009 at 10:6-8 (emphasis added). Thus, regardless of whether “saline

solution or *water*” is used in the formulation, water is present as an intended ingredient. EX2070 (Donovan Tr.) at 79:3-80:20;⁷ EX2072 ¶136.

Third, the focus of Meezan is combining therapeutic agents “with various surfactants” in aqueous solutions. EX1010 ¶[0003]; *see* Abstract (“surfactant”). Just as every embodiment in Gwozdz-PCT includes water, every example in Meezan involves peptides or proteins that have been dissolved in water. EX2072 ¶¶137-139. Petitioner utterly fails to address how these water-based references somehow result in the ’546 Patent inventions, which—according to Petitioner in district court—exclude every trace of water.

B. THERE WOULD HAVE BEEN NO REASON TO COMBINE GWOZDZ-PCT AND MEEZAN

Even if the Board were to consider motivations to combine, these too fail. Hindsight bias pervades the obviousness analysis, starting with the Petitioner’s use of the ’546 Patent itself as a basis for the motivation to combine. Petitioner takes a reference (Gwozdz-PCT) with no identified need for improvement and then reworks it by adding alkyl glycosides from Meezan. And not just *any* alkyl glycoside, but

⁷ By extracting the “penetration enhancers” language but ignoring the remainder of the embodiment, Petitioner improperly “use[s] hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1998).

the subgenus (dodecyl maltoside), even though Meezan teaches that other alkyl glycosides would be preferable. There would have been no reason to do this, other than hindsight reconstruction, particularly since the two references are directed to different therapeutic agents and different excipients. The “proposed combination remains poorly defined and tainted by hindsight bias.” *See Intel Corp. v. Besang Inc.*, IPR2023-00991, Paper 40 at 36 (P.T.A.B. Dec. 26, 2024).

1. Hindsight pervades the obviousness assertion

In the opening of its Motivation to Combine section, Petitioner cites only the '546 Patent when characterizing a “known problem in the art” as “the inability to administer benzodiazepine drugs (e.g., diazepam) due to the limited solubility of the benzodiazepine drug compounds.” Pet. at 25. Petitioner then concludes, “In view of these shortcomings, a POSA would have been motivated to improve the solubility of benzodiazepine drugs....” Pet. at 25 (emphasis added). Formulating the problem from the challenged patent itself is improper hindsight. *See InTouch Techs., Inc. v. Vgo Commns., Inc.*, 751 F.3d 1327, 1351 (Fed. Cir. 2014) (expert improperly “relied on the [challenged] patent itself as her roadmap for putting what she referred to as pieces of a ‘jigsaw puzzle’ together”).

Petitioner asserts that “Gwozdz[-PCT] provides guidance regarding how to solubilize poorly water-soluble compounds (such as diazepam).” Pet. at 26. Identifying no deficiency in Gwozdz-PCT, Dr. Donovan then asserts that “a POSA

would have also looked to additional references for guidance regarding additive compositions to improve the efficacy of the pharmaceutical solutions of Gwozdz.” EX1062 ¶¶97-98. Relying on Dr. Donovan, Petitioner asserts that Gwozdz-PCT states that “additional pharmaceutically acceptable additives” can be used, Meezan has additives in it, so “a POSA was motivated to apply the teachings of Meezan related to alkyl glycosides to the pharmaceutical solutions of Gwozdz[-PCT].” Pet. at 27.

But Gwozdz-PCT does not describe any deficiencies with solubility or bioavailability or any other need for improvement once a therapeutic agent (including diazepam) is dissolved in the tocopherol and alcohol solvent system it discloses. *See* EX2070 at 58:4-14 (Gwozdz solves the problem of limited solubility of diazepam); EX2072 ¶¶141-144, 160-161. Nor does the Petition identify any such shortcomings or reasons why Gwozdz-PCT needs modification. Petitioner has failed to demonstrate that its “[f]ormulation of the problem was derived directly from the prior art, rather than from the challenged claims.” *Purdue Pharma L.P. v. Depomed, Inc.*, 643 F. App’x 960, 966 (Fed. Cir. 2010) (rejecting obviousness assertions for improper hindsight).

Elsewhere Petitioner asserts that solubility of diazepam for intranasal applications *was already solved* in the art. The Petition relies on a Florida Emergency Medical Services guide to assert that a POSA would have known that a

solution of diazepam could have been administered intranasally in sufficient doses to be therapeutically effective. Pet. at 20-21; EX1062 ¶76 (discussing EX1019); EX2070 at 255:4-256:1 (stating the intranasal dose was “effective”). Dr. Donovan states that benzodiazepines had been studied and recommended for intranasal delivery, and the “medical literature is replete with examples.” EX1062 ¶¶60-61, 72-77. Thus, the very “problem” identified as the basis to combine Gwozdz-PCT and Meezan was either not a problem at all (because it had been solved), or it was not known in the prior art. EX2072 ¶144. Either way, there would have been no reason to combine Gwozdz-PCT and Meezan, absent hindsight.

2. The Petition does not identify any reason to modify Gwozdz-PCT

Even if one pretends that the Petition derived the “known problem” of limited solubility of diazepam from the prior art, rather than the ’546 Patent (Pet. at 25), Gwozdz-PCT states that it solves the problem. There would have been no need or reason to modify Gwozdz-PCT with additional excipients from Meezan.

Gwozdz-PCT states that its formulation was successful, without any identified deficiencies. Gwozdz-states that its formulation is “less irritating to the skin and/or mucous membranes,” “provides a higher loading of therapeutic agent,” and “provides for improved ability to dissolve hydrophilic and lipophilic therapeutic

agents,” such as diazepam. EX1009, 5:4-5:7, 9:19-10:2. Gwozdz-PCT does not identify any need for improvement. EX2072 ¶¶145-146.

Petitioner asserts that “while Gwozdz was focused on pharmaceutical solutions developed to improve the solubility of drugs with solubility issues,” Meezan presented a distinct approach of utilizing compounds that increase the absorption and bioavailability of drug compounds. Pet. at 27. This is pure hindsight, because Gwozdz-PCT states that it already succeeded in “providing increased bioavailability of the therapeutic agent.” EX1009, 7:5-8; *see* 4:34-5:2, 5:30-31, 8:30-31. Furthermore, Petitioner contends that, once diazepam was made sufficiently soluble (as in Gwozdz-PCT), improved bioavailability inherently followed: “It was well-known that benzodiazepines have sufficient lipophilic character to readily cross biologic membranes [citing EX1027].” Pet. at 18; *see* EX1062 ¶65. Thus, absent hindsight, a POSA would not have considered Meezan to improve Gwozdz-PCT. EX2072 ¶¶147-153.

In summary, even if a POSA *could* have modified the formulation of Gwozdz-PCT, that does not mean the POSA *would* have done so. *See Virtek Vision Int’l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 886-87 (Fed. Cir. 2024) (“[O]bviousness 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.”); *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359

(Fed. Cir. 2020) (“The obviousness inquiry does not merely ask whether a skilled artisan could combine the references, but instead asks whether ‘they would have been motivated to do so.’”). The Petition fails to prove that a POSA would have been motivated to make the identified modifications that are predicates to obviousness.

3. Interactions with other excipients

Before making the modification Petitioner proposes to Gwozdz-PCT, there would need to be a reason for doing so. EX2072 ¶154. Petitioner has not provided any such reason, and its analysis on motivations to combine “should be made explicit.” *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). The Petition does not even cite to *KSR*, let alone provide any of the exemplary rationales to support obviousness. *See* M.P.E.P. §2143(I) (“Examples of Rationales under *KSR*”).

a. Ethanol and benzyl alcohol

The specific alcohols (ethanol and benzyl alcohol) recited in the claims provide additional reasons that, absent hindsight, a POSITA would not have modified the formulation of Gwozdz-PCT to include Meezan:

1. A pharmaceutical solution for nasal administration consisting of:

- (a) a benzodiazepine drug;
- (b) one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w);
- (c) **ethanol and benzyl alcohol in a combined amount** from about 10% to about 70% (w/w); and
- (d) an alkyl glycoside.

17. The solution of claim 1, consisting of diazepam, vitamin E, ethanol, benzyl alcohol and dodecyl maltoside.

1. A pharmaceutical solution for nasal administration consisting of:

- (a) a benzodiazepine drug;
- (b) one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w);
- (c) **ethanol and benzyl alcohol in a combined amount** from about 10% to about 70% (w/w); and
- (d) an alkyl glycoside.

15. The pharmaceutical solution of claim 1, wherein the alkyl glycoside is present in pharmaceutical solution in a concentration of at least about 0.01% (w/w).

16. The pharmaceutical solution of claim 15, wherein the alkyl glycoside is present in the pharmaceutical solution in an amount of 0.01% to 1% (w/w).

22. The solution of claim 16, wherein the alkyl glycoside is dodecyl maltoside.

Petitioner asserts that a POSA would have been motivated to include benzyl alcohol in the formulation of Gwozdz-PCT, because “a POSA would also know that benzyl alcohol provides other advantageous properties to the formulation, including its function as an antimicrobial preservative.” Pet. at 32 (citing EX1016 at 9). Yet the monograph Petitioner cites states that the “antimicrobial activity [of benzyl alcohol] is reduced in the presence of nonionic surfactants,” and that “Ethanol is inactivated in the presence of nonionic surfactants.” EX1016 at 10, 14. Thus, Petitioner’s proposed modification of Gwozdz-PCT by including one excipient (dodecyl maltoside, a non-ionic surfactant) would deactivate other excipients. EX2072 ¶162; *see Medtronic, Inc. v. Teleflex Innovations S.a.r.l.*, 69 F.4th 1341, 1349-1350 (Fed. Cir. 2023) (avoiding “hindsight bias” by considering whether “a proposed modification would interfere with a reference’s stated purpose”).

The same monograph on which Dr. Donovan relies also explains that ethanol is a “skin penetrant.” EX1016 at 13. Dr. Donovan agreed at her deposition that this

is synonymous with a penetration enhancer. EX2070, 169:21-170:4. A POSA would not have been motivated to add *any* absorption enhancer to the formulation of Gwozdz-PCT, let alone a second one. EX2072 ¶163.

b. Tocopherol

Claims 17 and 22 each recite tocopherols/tocotrienols:

1. A pharmaceutical solution for nasal administration consisting of: (a) a benzodiazepine drug; (b) one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w); (c) ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w); and (d) an alkyl glycoside. 17. The solution of claim 1, consisting of diazepam, vitamin E, ethanol, benzyl alcohol and dodecyl maltoside.	1. A pharmaceutical solution for nasal administration consisting of: (a) a benzodiazepine drug; (b) one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w); (c) ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w); and (d) an alkyl glycoside. 15. The pharmaceutical solution of claim 1, wherein the alkyl glycoside is present in pharmaceutical solution in a concentration of at least about 0.01% (w/w). 16. The pharmaceutical solution of claim 15, wherein the alkyl glycoside is present in the pharmaceutical solution in an amount of 0.01% to 1% (w/w). 22. The solution of claim 16, wherein the alkyl glycoside is dodecyl maltoside.
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A POSA would have been particularly cautious in modifying a working formulation containing tocopherols/tocotrienols, as in Gwozdz-PCT. These compounds were known to be unstable generally and sensitive to degradation from exposure to light, heat, oxygen, and water, leading to discoloration over time. *See* EX2070 at 283:18-284:13; EX2072 ¶¶82-88, 173-177 (citing EX2053-EX2059).

4. The “other pharmaceutically acceptable additives” embodiment does not establish motivation to combine

Petitioner relies on a passage in Gwozdz-PCT that an embodiment may include a long list of “additional pharmaceutically acceptable additives,” including “penetration enhancers.” Pet. at 26-27 (citing EX1009 at 10:12-16). Petitioner then

asserts that Meezan discloses “absorption enhancers” and that “[b]ased on this, a POSA was motivated to apply the teachings of Meezan related to alkyl glycosides to the pharmaceutical solutions of Gwozdz.” Pet. at 27. But as described above, just because a POSA *could* add something to Gwozdz-PCT does not mean that the POSA *would* have. There are several additional flaws with Petitioner’s approach.

a. The “penetration enhancer” language in Gwozdz-PCT was added in 2009

The reference to “penetration enhancers” does not appear in the 2008 Gwozdz-Provisional (EX1064). Rather, its first appearance is in 2009 in Gwozdz-PCT itself. *See supra* §VII; EX2072 ¶156. The “penetration enhancers” is unavailable as prior art. *See Riggs*, 131 F.4th at 1384 (“portion of the application relied on ... as prior art must be supported by the provisional application”).

b. The “other pharmaceutically acceptable additives” embodiment conflicts with other claim limitations and is not for intranasal applications

To the extent the “penetration enhancer” language is even considered (and it should not be, because it is not prior art), Petitioner also ignores the context of the “other pharmaceutically acceptable additives” embodiment of Gwozdz-PCT in which the phrase “penetration enhancers” is found.

First, Petitioner has asserted that the challenged claims should be construed to exclude all water, even trace impurities. *See supra* §§IV, IX.A.1. Yet, the “other

pharmaceutically acceptable additives” embodiment specifically includes added saline or water. EX1009, 10:3-10:14; EX2072 ¶¶157-158. The disclosure in this embodiment would, if anything, have led a POSA to develop injectable aqueous/saline compositions—not the claimed intranasal, non-aqueous compositions.

Second, the broader context of Gwozdz-PCT demonstrates that the “other pharmaceutically acceptable additives” are not for nasal applications. Gwozdz-PCT provides an introduction that includes a laundry list of applications, concluding that the “most suitable route in any given case will depend on the nature and severity of the condition being treated and on the nature of the particular therapeutic agent which is being used.” EX1009, 8:32-9:18. Gwozdz-PCT then describes specific embodiments: nasal applications (*id.*, 9:20-10:2); then injections (10:3-10:16); then oral administration (10:17-11:16); parenteral administration (11:17-26); topical application (11:27-12:27); and transdermal administration (12:28-13:3). The reference to “other pharmaceutically acceptable additives” appears in the embodiment on injection application (10:3-10:16), but not in the section for “nasal applications.” *See* EX2070 at 87:15-21. EX2072 ¶159. For motivation to combine, Petitioner extracts an “other pharmaceutically acceptable additive” from an injected formulation and then, absent any reasoning or explanation, applies it to a nasal formulation. That maneuver requires impermissible hindsight.

5. Even if a POSA were to modify Gwozdz-PCT, there is no reason to modify with Meezan

Meezan does not mention “diazepam” or “benzodiazepine” or disclose their use. EX2070 (Donovan Tr.) at 148:25-149:10. Nor does Meezan mention or disclose applications of tocopherols. *Id.* 150:1-150:7. A POSA would have recognized, based on these missing limitations and others, that Meezan and Gwozdz-PCT are directed to different applications and would not have combined the references in the way Petitioner does. EX2072 ¶¶164-167. *See Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (“the prior art must be considered for all its teachings, not selectively”).

a. Meezan is directed to large macromolecules, not smaller molecules like benzodiazepines

To the extent a POSA would have considered modifying Gwozdz-PCT (for which there is no motivation to do so), the POSA would not have looked to Meezan.

Meezan does not address benzodiazepines or diazepam because Meezan concerns itself with stabilizing solutions and increasing bioavailability of peptides, proteins, nucleic acids, and other such macromolecules. EX1010 ¶¶[0064], [0070], [0092], [0146]-[0172] (Examples 1-7). These molecules are many thousands of Daltons (e.g., 30,000 Daltons), while diazepam is a typical “small molecule” with a molecular weight of only 285 Daltons. EX2072 ¶¶167-168.

While Meezan says it “anticipate[s]” using the disclosed methods with “small” molecules, that would have informed a POSA that such an application was simply a hypothesis—not a known application or actual teaching. EX1010 ¶[0130]. Indeed, every example in Meezan formulates peptides or proteins, not small molecules. EX2070 (Donovan Tr.) at 141:9-142:1, 143:14-18. And even considering the “small molecules,” for which Meezan provides no examples, they are significantly larger than the 285 Daltons of diazepam. This observation also correlates with the disclosed sizes for what Meezan considers “small molecules”: “an organic compound that has a molecular weight of less than 3 kD, or less than 1.5 kD.” EX1010 ¶[0130]. Meezan also refers to compounds that are “low molecular weight,” but Meezan defines the range very broadly to include molecules of 1,000-30,000 Daltons (“1-30 kiloDaltons”). EX1010 ¶¶[0012]-[0013]; *see* EX1010 ¶¶[0004], [0076], [0089], [0099], [00132], [0136]. This range includes peptides, proteins, and other biologics having molecular weights that are orders of magnitude larger than diazepam. EX2072 ¶169.

Petitioner attempts to narrow the gap between what Meezan teaches (proteins and other macromolecules) and what Gwozdz-PCT teaches (diazepam) by asserting:

Larger molecules inherently have a more difficult time crossing the cell membrane compared to smaller molecules.... [I]f a compound is shown to increase penetration and absorption for a large molecule, it will be expected to also increase penetration and absorption for a small molecule.

Pet. at 31. This argument can only make sense from a hindsight perspective. By corollary, a small molecule (e.g., diazepam in Gwozdz-PCT) does not have as much difficulty passing through the cell membrane as a large molecule. Thus, while an absorption enhancer may have been needed for the macromolecules in Meezan, a POSA would have considered an enhancer superfluous—and would not have used it—for the small molecules in Gwozdz-PCT, such as diazepam. There would have been no reason to modify the working formulation of Gwozdz-PCT with the permeation enhancer of Meezan. EX2072 ¶170; *see In re Anova Hearing Labs, Inc.*, 809 F. App'x 840, 843 (Fed. Cir. 2020) (nonprecedential) (rejecting motivation to combine where reference already included vents addressing the occlusion effect at issue and where the “Board does not explain why a person of skill in the art would conclude that [the primary reference] needed to be modified”); *Ex Parte Tsai-Ching Lu, et al.*, Appeal 2022-000521, 2022 WL 4957922, at *3 (P.T.A.B. Sept. 30, 2022) (“Adding a redundant feature does not constitute a reason to combine.”).

**b. Meezan does not teach compatibility with
tocopherol or tocopherol/alcohol carriers**

Meezan also fails to teach application to tocopherol-based solutions. Petitioner relies on Meezan ¶[0074] to state that “alkyl glycosides were shown to be successfully utilized in non-aqueous solvent systems.” Pet. at 32. This is

Petitioner's only support for using the disclosure of Meezan with a non-aqueous system. Petitioner misreads the passage. EX2072 ¶171.

First, even Dr. Donovan does not contend that Meezan discloses using alkyl glycosides with tocopherol-containing solutions like those of Gwozdz-PCT. Nowhere does “tocopherol,” “tocotrienol,” “vitamin E,” or any analog of those terms appear. EX2070 at 149:7-150:7; EX2072 ¶172.

Second, every disclosed Example in Meezan adds alkyl glycosides to aqueous solutions of peptides or proteins. None of the Examples applies alkyl glycosides to any form of nonaqueous solution (let alone diazepam or any other small molecule). The presence of water in the solutions of Meezan provides another reason to not combine Meezan with Gwozdz-PCT to arrive at the claimed invention. The claimed invention requires tocopherols, and it was known that tocopherols are susceptible to degradation in water. EX2072 ¶¶173-174; *see supra* §IX.B.3.b. In this way, Gwozdz-PCT (tocopherol solution) and Meezan (aqueous solution of alkyl glycosides) are incompatible. *See Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1358-59 (Fed. Cir. 2020) (affirming no motivation to combine where doing so would change a reference's operating principles or render it inoperable for its intended purpose).

C. **EVEN IF GWOZDZ-PCT AND MEEZAN WERE COMBINED, A POSA WOULD NOT HAVE ARRIVED AT THE CLAIMED INVENTION**

Even if a POSA would have considered Meezan, there would have been no reason to modify Gwozdz-PCT to add dodecyl maltoside. To the contrary, Meezan would have directed a POSA towards other alkyl glycosides. EX2072 ¶178.

The Petition asserts in a conclusory manner that “a POSA would routinely select dodecyl maltoside to add to Gwozdz’s solution.” Pet. at 45 (citing EX1062 ¶154). Neither Petitioner nor Dr. Donovan provides any citations to Gwozdz-PCT or Meezan—or any other evidence—to support that a POSA would “routinely select” dodecyl maltoside. Nor do they identify any *KSR* rationales or other reasoning to support this conclusory assertion. *See GCE Control Equipment Inc. v. VBOX Inc.*, IPR 2023-00326, Paper 27 at 53 (P.T.A.B. June 18, 2024) (“Under the particular facts at hand, we detect the unmistakable taint of impermissible hindsight reconstruction in Petitioner’s conclusory proposition.”).

1. **Importance of “highly branched” and longer chains**

Meezan discloses the importance of how “an ideal enhancing surfactant will stabilize the therapeutic agent.” EX1010 ¶[0003]. To achieve this goal, Meezan recommends using “highly branched” glycosides. EX1010 ¶[0149]. As a matter of basic organic chemistry, the longer the carbon chain, the more branching that can occur. EX2070, 24:15-25:12. Accordingly, Meezan discloses that tetradecyl maltoside (“TDM,” having a 14-carbon alkyl chain) has “the greatest effect,” not

dodecyl maltoside (12-carbon alkyl chain). EX1010 ¶[0149]. According to Meezan, the longer the alkyl chain, the more effective the absorption enhancer. EX1010 ¶[0157]. The “alkyl chain length, as well as the carbohydrate moiety,” has a “critical” role. EX1010 ¶[0160]. Thus, Meezan teaches to use a longer, more branched chain: TDM exceeds DDM, and “highly branched” alkyl groups have the greatest effect. EX2072 ¶¶178-180.

2. Examples 1-7 of Meezan would lead a POSA to TDM, not dodecyl maltoside

Meezan includes some data, presented in seven numbered Examples, analyzing certain qualities of several alkyl glycosides. EX1010 ¶¶[0146]-[0172]. The POSA would have made several observations from these disclosures.

First, every example incorporates an alkyl glycoside with a peptide or a protein, rather than a small molecule like diazepam. This choice would have made sense to a POSA in 2008-2009, as it was known that large molecules like peptides, proteins, and nucleic acids are poorly absorbed when administered by extravascular routes. EX1062 ¶106. This evidence would not have led the POSA to apply Meezan to a small molecule application, such as the diazepam solutions of Gwozdz-PCT, for which there was no need of it. EX2072 ¶¶181-182.

Second, every Example in Meezan examines characteristics of tetradecyl maltoside (TDM, 14 carbons). EX1010 ¶¶[0146]-[0172]. As discussed below,

TDM (and other alkyl glycosides) work better than dodecyl maltoside in Meezan. Among the options, Meezan's data show that dodecyl maltoside was the least effective alkyl glycoside and, in certain tests, totally ineffective. Thus, to the extent a POSA would have even looked to Meezan for an absorption enhancer for Gwozdz-PCT, the POSA would have been led to use TDM and not dodecyl maltoside. *See* EX2070 at 121:7-11 (Meezan disclosing that TDM has "the greatest effect"); EX2072 ¶¶183-187.

3. Meezan expresses no preference for dodecyl maltoside

Meezan provides a "Summary of the Invention" stating that "the present invention" includes "enhancing agents" that include "an alkyl glycoside and/or saccharide alkyl ester." EX1010 ¶[0004]. These categories of compounds are so generic as to encompass uncountable numbers of potential molecules. A POSA would not have understood Meezan to disclose that dodecyl maltoside is a preferred alkyl glycoside. EX2072 ¶188.

The vastness of "alkyl glycoside and/or saccharide alkyl ester" results from the modular nature of these types of compounds, the many options for those moieties, and the various permutations resulting from varying one or more of those moieties. The variables characterizing these categories of compounds at least include: (i) the saccharide or glycoside (e.g., which sugar); (ii) the stereochemistry of the saccharide or glycoside (e.g., D or L); (iii) the anomeric structure of the

saccharide or glycoside (α or β); (iv) substitution of heteroatoms (e.g., sulfur); (v) the alkyl chain (its size and its isomeric structure); and (vi) the linking chemistry between the moieties. EX2072 ¶¶79, 189-196.

Meezan discloses alkyl groups from 8 to 24 carbon atoms. EX1010 ¶¶[0056], [0058]; EX2072 ¶190. Regarding isomerization, the only structural isomers even mentioned are “highly branched.” EX1010 ¶[0149]; EX2072 ¶191. Meezan lists many options as potential glycosides (the sugar moiety). EX1010 ¶[0058]; EX2072 ¶192. Meezan expresses a preference for heteroatom substitution (i.e., replacing a carbon atom with a non-carbon and non-hydrogen), rather than an unsubstituted glycoside. EX1010 ¶¶[0056], [0075]; EX2072 ¶193. Meezan discloses numerous types of linkages between the alkyl group and the glycoside, and both anomeric configurations. EX1010 ¶¶[0002], [0056], [0061], [0075]; EX2072 ¶¶194-195. The only reasonably particular preference Meezan discloses is for TDM (14 carbons, not dodecyl maltoside): “An even more preferred range is from about 9 to about 16 *or about 14 carbon atoms.*” EX1010 ¶[0058] (emphasis added); *see Kuban*, 561 F.3d at 1359 (“where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness”). Petitioner’s assertion that a POSA would naturally choose one particular subgenus (dodecyl maltoside) is unsupported. EX2072 ¶199.

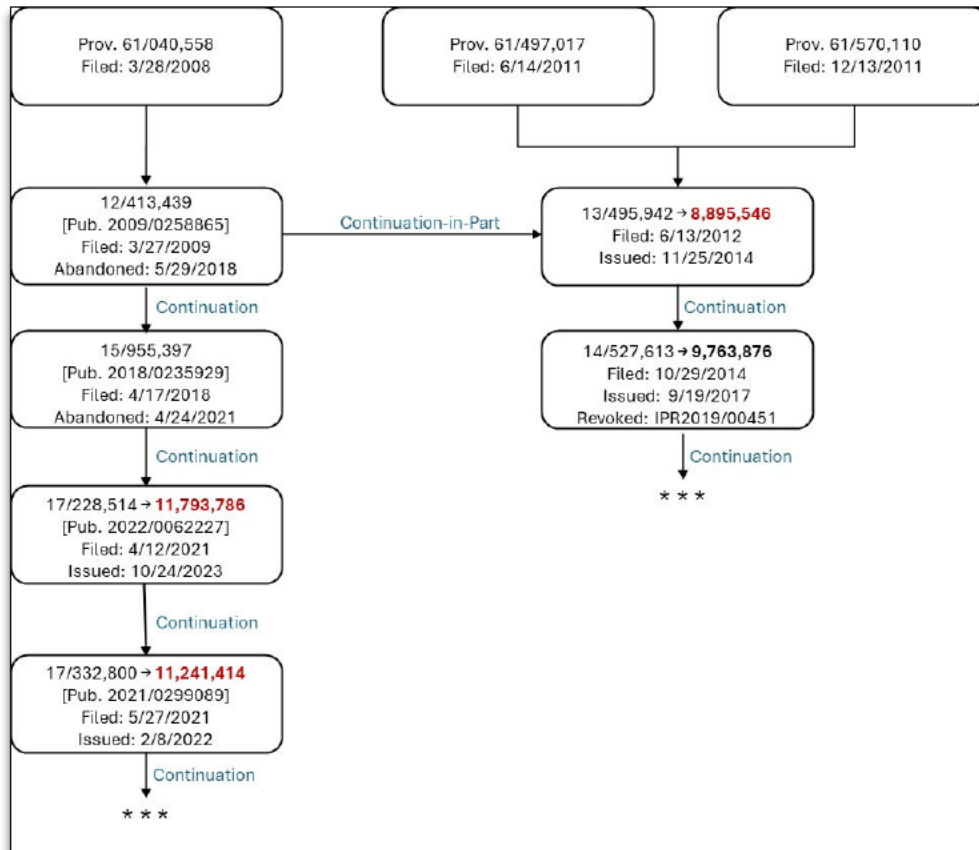
X. COLLATERAL ESTOPPEL DOES NOT APPLY

To invoke collateral estoppel Petitioner has the burden to demonstrate four elements:

(1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) the party against whom collateral estoppel is being asserted had a full and fair opportunity to litigate the issue in the first action.

Google v. Hammond Development Int’l, Inc., 54 F.4th 1377, 1381 (Fed. Cir. 2022) (“party seeking to invoke collateral estoppel must show”). Additionally, collateral estoppel “does not apply where ‘a new determination is warranted in order to take account of an intervening change in the applicable legal context or otherwise to avoid inequitable administration of the laws.’” *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 803 F.3d 620, 628 (Fed. Cir. 2015) (quoting Restatement (Second) of Judgments §28(2) (1982)).

As is undisputed, the ’546 Patent was never actually litigated. Only the ’876 Patent was litigated.



EX2068. “[S]eparate patents describe separate and distinct inventions, and it cannot be presumed that related patents rise and fall together.” *Comair Rotron, Inc. v. Nippon Densan Corp.*, 49 F.3d 1535, 1539 (Fed. Cir. 1995) (internal citations omitted) (reversing finding of collateral estoppel).

Petitioner’s attempts to shoehorn the 451 IPR into the ’546 Patent also fail because Claims 17 and 22 of the ’546 Patent include a limitation requiring dodecyl maltoside, which was not litigated in evaluating motivation to combine concerning the ’876 Patent, and the Gwozdz-PCT priority issues were not litigated and are subject to an intervening change in law.

A. PETITIONER FAILS TO SHOW THAT COLLATERAL ESTOPPEL APPLIES TO OBVIOUSNESS OVER GWOZDZ-PCT WITH MEEZAN

Collateral estoppel does not apply to whether there existed a motivation to combine or whether each limitation of Claims 17 and 22 of the '546 Patent was disclosed in the prior art. *See* Pet. at 8-10. As part of obviousness, a motivation to combine inquiry must focus on whether a POSA would have been motivated to arrive at the specific invention claimed. *See Virtek Vision*, 97 F.4th at 886-887; *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.*”) (cleaned up) (emphasis added). Likewise, whether the prior art discloses or teaches a claim necessarily depends on the specific claims at issue, and obviousness must be assessed on a claim-by-claim basis. *See MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1377-78 (Fed. Cir. 2018) (remanding where Board applied collateral estoppel to independent claims but failed to separately analyze dependent claims).

First, the '876 and '546 Patents are directed to different statutory classes. *See* 35 U.S.C. §101. The '876 Patent claims recite “[a] method of treating a patient,” whereas the '546 Patent claims recite “[a] pharmaceutical solution.”

Second, as detailed above (*supra* §II.A), Patent Owner filed a statutory disclaimer that disclaimed Claims 1-16 and 18-21 of the '546 Patent to streamline this proceeding. Whereas the previous independent claims recited an “alkyl glycoside,” now the only remaining claims—Claims 17 and 22—are limited to “dodecyl maltoside,” which is a subset of the much larger alkyl glycoside genus.

1. A pharmaceutical solution for nasal administration consisting of:

- (a) a benzodiazepine drug;
- (b) one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w);
- (c) ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w); and
- (d) an alkyl glycoside.

17. The solution of claim 1, consisting of diazepam, vitamin E, ethanol, benzyl alcohol and dodecyl maltoside.

1. A pharmaceutical solution for nasal administration consisting of:

- (a) a benzodiazepine drug;
- (b) one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w);
- (c) ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w); and
- (d) an alkyl glycoside.

15. The pharmaceutical solution of claim 1, wherein the alkyl glycoside is present in pharmaceutical solution in a concentration of at least about 0.01% (w/w).

16. The pharmaceutical solution of claim 15, wherein the alkyl glycoside is present in the pharmaceutical solution in an amount of 0.01% to 1% (w/w).

22. The solution of claim 16, wherein the alkyl glycoside is dodecyl maltoside.

Whether a POSA would have combined Gwozdz-PCT and Meezan to reach the '546 Patent's invention in Claims 17 and 22, requiring dodecyl maltoside, is a fundamentally different question from whether the POSA would have done so for the '876 Patent's claims requiring an alkyl glycoside.

While the sub-genus dodecyl maltoside comprises hundreds of species, the broader category of alkyl glycosides to which it belongs encompasses *countless* species of structurally distinct molecules varying in characteristics such as chain length (i.e., how many carbons), isomeric configuration (e.g., linear versus branched, as well as the degree of branching), stereochemistry, and linkage chemistry.

EX2072 ¶¶80, 189. These structural differences are not academic; they alter functional and biologic properties. EX2070 (Donovan Tr.) at 22:10-23:22, 25:13-25:24.

This distinction matters because Claims 17 and 22 of the '546 Patent expressly require “dodecyl maltoside,” whereas the Board in the 451 IPR only addressed claims reciting “alkyl glycoside.” Petitioner here asserts “a POSA would routinely select dodecyl maltoside to add to Gwozdz’s solution.” Pet. at 45 (citing EX1062 ¶154). Yet neither Petitioner nor Dr. Donovan cites Gwozdz-PCT, Meezan, or any other evidence to support this conclusory assertion, nor do they offer any *KSR* rationale or other reasoning sufficient to meet Petitioner’s burden. Moreover, as explained above, Meezan emphasizes TDM (14 carbons, not dodecyl maltoside): “An even more preferred range is from about 9 to about 16 *or about 14 carbon atoms.*” EX1010 ¶[0058] (emphasis added). “[A] difference in the claims that would alter a POSITA’s motivation to combine prior art references would be material to the invalidity analysis.” *See TQ Delta, LLC v. 2Wire, Inc.*, 2021 WL 2671296, at *6 (D. Del. June 29, 2021).

Collateral estoppel fails because it applies only to issues “actually litigated,” not issues that merely “*could have been raised* in the prior litigation.” *Purdue Pharma L.P. v. Iancu*, 767 F. App’x 918, 922-23 (Fed. Cir. 2019) (cleaned up) (original emphasis). Petitioner has not demonstrated that, in the 451 IPR, the parties

actually litigated motivation to combine or whether each limitation was disclosed in the prior art for Claims 17 and 22 of the '546 Patent, whose scope is limited to the narrower subgenus “dodecyl maltoside,” as opposed to the broader “alkyl glycoside” genus.

The claim in the 451 IPR that the Board found “illustrative of the challenged claims” does not contain “dodecyl maltoside” and is reproduced below:

1. A method of treating a patient with a disorder which is treatable with a benzodiazepine drug, comprising:

administering to one or more nasal mucosal membranes of a patient a pharmaceutical solution for nasal administration consisting of

a benzodiazepine drug,

one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w);

ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w); and

an alkyl glycoside.

EX1040 at 4-5 (emphasis added) (quoting '876 Patent claim 1). In the 451 IPR, “dodecyl maltoside” appeared only in certain dependent claims, and the parties never litigated motivation to combine or whether the prior art taught each limitation as related to dodecyl maltoside. In fact, the patent owner did not address that limitation at all before the Board in the '451 IPR, focusing its arguments exclusively on the alkyl glycoside genus. See EX2076 at 23-40 (discussing alkyl glycoside genus but

not dodecyl maltoside subgenus). Rather, the only discussion of the dodecyl maltoside limitation by the patent owner was a single mention where it was “relegated to a footnote” concerning written description. IPR2025-00465, Paper 13 at 23-24 (P.T.A.B. Sept. 16, 2025); IPR2025-00466, Paper 13 at 25-26 (P.T.A.B. Sept. 16, 2025). Failure to contest an issue, or even stipulating to an issue, does not comprise litigating that issue for collateral estoppel purposes. *See Purdue Pharma*, 767 F. App’x. at 922 (““An issue is not actually litigated ... if it is a stipulation between the parties.... [or] a judgment entered by confession, consent, or default....””) (citing Restatement (Second) of Judgments § 27, cmt. e.).

In short, Petitioner cannot establish that these issues were actually litigated (Factor 2), and collateral estoppel fails. The 451 IPR petitioner itself recognized that the Board did not squarely address the “dodecyl maltoside” piece, arguing to the Federal Circuit that “Neurelis’ argument regarding the dodecyl maltoside limitation appearing in claims 27-28 and 30-33 was never advanced below. In fact, ...separate arguments were not presented for any of the dependent claims (i.e., 2-36).” EX2028, 44. Petitioner’s collateral estoppel argument should be rejected for what it is: an attempt to evade its burden to prove invalidity of each challenged claim on a claim-by-claim basis—a showing it cannot make as to Claims 17 and 22 of the ’546 Patent. *See MaxLinear*, 880 F.3d at 1377-78.

B. PETITIONER FAILS TO SHOW THAT COLLATERAL ESTOPPEL APPLIES TO THE PRIORITY DATE OF GWOZDZ-PCT

Collateral estoppel does not apply to Gwozdz-PCT's prior art status in this case. "Patent Owner's apparent concession that Gwozdz [PCT] was prior art during the 451 IPR does not equate to the issue being actually litigated." Paper 13 at 15. Indeed, the final written decision in the 451 IPR noted: "Patent Owner does not contest that Gwozdz [PCT] is entitled to this filing date" of Gwozdz-Provisional. EX1040, 14. Failure to contest an issue, or even stipulating to an issue, does not comprise litigating that issue for collateral estoppel purposes. *See Purdue Pharma*, 767 F. App'x. at 922.

The 451 IPR panel found Gwozdz-PCT was entitled to the benefit of Gwozdz-Provisional, but only because the PCT claims were identical to the provisional claims. EX1040 at 13-14. The Board relied on then-controlling Federal Circuit precedent, which allowed a reference patent to trace priority to its provisional application if the provisional merely provided written-description support for the reference patent's claims. *Id.* at 14 (citing *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1381 (Fed. Cir. 2015)).

Last year, however, the Federal Circuit tightened the requirements for a prior art reference to trace priority to a provisional. Specifically, the court specified that—in addition to claim support—a "provisional application *must also* provide written

description support for the specific portions of the patent specification identified and relied on in the prior art rejection.” *Riggs*, 131 F.4th at 1384 (emphasis added). Thus, under *Riggs*, a reference constitutes prior art only for what “it teaches as of its earliest accorded filing date.” *Id.* at 1385.

Here, Petitioner relies on Gwozdz-PCT’s use of “penetration enhancer” to establish a motivation to combine. But that term appears nowhere in Gwozdz-Provisional. *See supra* §IX.B. Thus, under *Riggs*, Petitioner cannot rely on the “penetration enhancer” disclosure of Gwozdz-PCT and cannot establish priority to the provisional. The 451 IPR decision was based on different set of facts and law, and collateral estoppel does not apply. *Dow Chem.*, 803 F.3d at 629-30; *see Bingaman v. Dep’t of Treasury*, 127 F.3d 1431, 1437-38 (Fed. Cir. 1997) (finding collateral estoppel inapplicable where later agency decisions adopted “significantly narrower” interpretation of statutory standard than did administrative judge in prior case).

XI. CONCLUSION

For the reasons above, the Board should conclude that Petitioner has failed to meet its burden of providing that Gwozdz-PCT is prior art, that Gwozdz-PCT is available to be used as an obviousness reference, and that the combination of Gwozdz-PCT and Meezan renders obvious claims 17 and 22 of the ’546 Patent.

Date: January 5, 2026

Respectfully submitted,

/Michael Sitzman/

Michael Sitzman

(Reg. No. 42,150)

MCDERMOTT WILL & SCHULTE LLP

415 Mission St Suite 5600

San Francisco, CA 94105-2616

Tel: +1 628 2183917

msitzman@mwe.com

Lead Counsel for Patent Owner

CERTIFICATION OF WORD COUNT

The undersigned hereby certifies that the portions of the above-captioned PATENT OWNER'S RESPONSE specified in 37 C.F.R. § 42.24 have 10,558 words, in compliance with the 14,000 word limit set forth in 37 C.F.R. § 42.24. This word count was prepared using Microsoft Word 365 V.2503.

Dated: January 5, 2026

/Michael Sitzman/

Michael Sitzman (Reg. No. 42,150)

MCDERMOTT WILL & SCHULTE LLP

415 Mission St Suite 5600

San Francisco, CA 94105-2616

Tel: +1 628 2183917

msitzman@mwe.com

Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing PATENT OWNER'S RESPONSE and supporting EXHIBITS 2034-2072 and 2075-2076 were served on counsel of record for the Petitioner by filing this document through PTAB P-TACTS and by sending the same via electronic mail to the following addresses:

James P. Murphy
Reg. No. 55,474
Polsinelli PC
1000 Louisiana Street
Suite 6400
Houston, Texas 77002
Tel: (713) 374-1600
jpmurphy@polsinelli.com

Corey Casey
Reg. No. 66,950
Polsinelli PC
900 West 48th Place
Suite 900
Kansas City, Missouri 64112
Tel: (816) 572-4439
ccasey@polsinelli.com

Mark Deming
Reg. No. 69,263
Polsinelli PC
150 N. Riverside Plaza Suite 300
Chicago, IL 60606
mdeming@polsinelli.com

Chad A. Landon
Provisionally Recognized Pro Hac Vice
Polsinelli PC
1401 I St. NW Suite 800 Washington,
DC 20005
clandmon@polsinelli.com

Dated: January 5, 2026

/Michael Sitzman/
Michael Sitzman (Reg. No. 42,150)
MCDERMOTT WILL & SCHULTE LLP
415 Mission St Suite 5600
San Francisco, CA 94105-2616
Tel: +1 628 2183917
msitzman@mwe.com

Lead Counsel for Patent Owner