

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICAL INDUSTRIES, INC.,
Petitioner,

v.

BIOFRONTERA INC.,¹
Patent Owner.

Case No. PGR2026-00021
U.S. Patent No. 12,280,146

**PATENT OWNER PRELIMINARY RESPONSE TO POST-GRANT
REVIEW PETITION**

¹ Petitioner incorrectly identifies the patent owner as Biofrontera Bioscience GmbH. However, Biofrontera Bioscience GmbH assigned all interest in U.S. Patent No. 12,280,146 to Biofrontera Inc. *See* Reel/Frame 73509/0006 recorded on Nov. 5, 2025 (available at <https://assignmentcenter.uspto.gov/search/patent>).

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PATENT OWNER'S EXHIBIT LIST

Exhibit No.	Description
2001	Declaration of Brian Larivee in support of being a provisionally recognized PTAB attorney
2002	Press Release, <i>Sun Pharma Announces Jeremy Allen as Vice President, Corporate Affairs for North America</i> (published October 22, 2025)
2003	Press Release, <i>Sun Pharma Announces the Availability of UNLOXCYTTM (cosibelimab-ipdl) for Advanced Cutaneous Squamous Cell Carcinoma (aCSCC)</i> (published January 15, 2026)
2004	Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations entry for U.S. Patent No. 12,280,146 (available at https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm) (last updated on March 19, 2026)
2005	Press Release, <i>Biofrontera Inc. Announces Patent for Propylene Glycol-Free Formula of Ameluz® (aminolevulinic acid HCl) Topical Gel, 10% Now Listed in FDA Orange Book</i> (published June 3, 2025)
2006	Press Release, <i>Biofrontera Inc. Announces Major Restructuring of Relationship With Biofrontera AG Backed By \$11 Million Investment</i> (published June 30, 2025)
2007	Press Release, <i>Biofrontera Inc. Completes Transfer of Ameluz® and RhodoLED® FDA approval and Associated Intellectual Property Portfolio</i> (published Dec. 18, 2025)
2008	Study Details for NCT03573401, Study to Evaluate the Safety and Efficacy of BF-200 ALA (Ameluz®) and BFRhodoLED® in the Treatment of Superficial Basal Cell Carcinoma (sBCC) With Photodynamic Therapy (PDT), sponsored by Biofrontera Inc.

Exhibit No.	Description
	(available at https://clinicaltrials.gov/study/NCT03573401) (last updated on January 14, 2026)
2009	Webpage of Biofrontera Clinical Trials (available at https://survey.biofrontera.com/en/clinical-trials.html) (accessed on March 19, 2026)
2010	Max Beauroyre, Clinical-Trial Costing 101: Building a Phase-By-Phase Budget Your Board Will Trust, Abacum (June 25, 2025), (available at https://www.abacum.ai/blog/clinical-trial-costing) (last visited March 19, 2026)
2011	Sertkaya, A. <i>et. al.</i> , Costs of Drug Development and Research and Development Intensity in the US, 2000-2018. JAMA Network 2024;7(6):e2415445
2012	U.S. Securities and Exchange Commission Form 10-K, Annual Report, submitted by Biofrontera Inc. on March 19, 2026
2013	Sun Pharmaceuticals Industries Ltd. Annual Report for 2024-2025

I. INTRODUCTION

Patent Owner Biofrontera, Inc. submits this Preliminary Response to the Petition for Post-Grant Review filed by Petitioner Sun Pharmaceutical Industries, Inc. (“Petitioner”) in PGR2026-00021 (“Petition”). The Petition is deficient in several critical respects, each of which shows that Petitioner has not carried its burden to show that it is more likely than not that any of claims 1-17 of U.S. Patent No. 12,280,146 (“’146 Patent” or EX1001) are unpatentable in view of Petitioner’s grounds. The Petition advances several grounds of unpatentability under both anticipation and obviousness against claims 1-17. However, all of Petitioner’s grounds rely on EX1004 (U.S. Patent No. 5,520,905 (“Uhlmann”)) as invalidating prior art for the limitations “nanoemulsion” and “wherein the formulation comprises essentially no propylene glycol” each present in the ’146 Patent’s sole independent claim. As Uhlmann fails to disclose either of these limitations, all of Petitioner’s grounds fail.

First, Petitioner’s proposed construction of “nanoemulsion” is so broad that it would cover any oil-in-water mixture. Such a construction contradicts the intrinsic record and Federal Circuit precedent for when a patentee acts as her own lexicographer. Even if the Board does not find the patentee acted as her own lexicographer, Petitioner’s impermissibly broad construction does not reflect how a person of ordinary skill in the art (“POSITA”) would understand the meaning of

“nanoemulsion” in view of the intrinsic record. The Petition fails to show that the only prior art reference it relies on for “nanoemulsion,” Uhlmann, teaches a nanoemulsion, as every challenged claim requires.

Second, the sole independent claim recites the limitation “wherein the formulation comprises essentially no propylene glycol,” and the Petition fails to show that Uhlmann teaches that limitation. None of the formulations in Uhlmann cited in the Petition are complete formulations. Instead, they include unspecified “perfume” and “preservative” components. Petitioner’s own supporting exhibits confirm that propylene glycol is used as a preservative in formulations containing the same active ingredient as Uhlmann and the ’146 Patent, 5-aminolevulinic acid (“ALA”), and Uhlmann itself suggests inclusion of propylene glycol as a solvent in its formulations. As such, Petitioner has not and cannot meet its burden to prove that Uhlmann anticipates a formulation comprising essentially no propylene glycol.

Therefore, the Board should find that Petitioner fails to demonstrate that it is more likely than not that at least one of the claims challenged in the Petition is unpatentable over the prior art in the Petition.

II. OVERVIEW OF THE ’146 PATENT

A. Summary of the Claims of the ’146 Patent

The ’146 Patent has 17 claims, with only claim 1 being independent. Independent claim 1 is reproduced below:

1. A formulation comprising:

(a) a nanoemulsion comprising:

(i) at least one aqueous component;

(ii) a carrier component comprising:

(1) at least one lipophilic component,

(2) at least one surfactant, and

(3) at least one alcohol; and

(b) 5-aminolevulinic acid and/or a derivative, a precursor, a metabolite, and/or a pharmaceutically acceptable salt thereof,

wherein the formulation comprises essentially no propylene glycol and essentially no sorbitol.

Dependent claims 2-17 recite additional limitations to the claimed formulation.

Those additional limitations of the dependent claims are not addressed in detail in this preliminary response, but it is Patent Owner's view that the dependent claims are patentable over Petitioner's cited art at least due to the deficiencies of Uhlmann discussed herein.

B. Summary of the Disclosure of the '146 Patent

The '146 Patent discloses formulations of a hydrophilic active agent, such as an active agent containing a carboxylic acid group, which contain a nanoemulsion and which contain little or no propylene glycol. EX1001, Abstract, 1:13-16, 4:17-28, 6:17-23, 19:8-31. The disclosed compositions can be formulations for topical use. EX1001, 1:13-16. In addition, the disclosed formulations can include 5-aminolevulinic acid ("ALA") as an active agent. EX1001, 19:8-28. ALA is a

photosensitizer which is applied topically to the skin during a treatment called photodynamic therapy (“PDT”). EX1001, 2:14-22. ALA can accumulate preferentially in diseased tissues, driving synthesis of protoporphyrin IX in those tissues. *Id.* During PDT, the area is then illuminated with light at appropriate energy levels to induce a photodynamic effect in the diseased tissue. *Id.*

The ’146 Patent discloses that its formulations contain nanoemulsions. EX1001, Abstract, 1:13-16. The ’146 Patent explains that “[n]anoemulsions are a subgroup of the emulsions that contain very fine oil in water dispersions” (EX1001, 1:27-30), which are characterized by their small particle or nanovesicle size, such as less than 500 nm, less than 200 nm, or less than 100 nm. EX1001, 1:33-36, 12:65-13:6. The ’146 Patent notes that nanoemulsion “structure depends often on the manufacturing process,” and that “[t]he very small size of the oily globules is often obtained by virtue of at least one pass through a high-pressure homogenizer or a sonicator.” EX1001, 1:40-53. Further, nanoemulsions are a “fragile system and complicated to formulate to a pharmaceutical composition with a long shelf-life.... If destabilized they can become heterogeneous, milky and/or exhibit phase separation.” EX1001, 1:40-45. Despite these challenges, the ’146 Patent discloses that “[n]anoemulsions are thermodynamically more stable than conventional emulsions, making them a favorable vehicle for pharmaceutical compositions.” EX1001, 1:36-38. Nanoemulsions can also be a desirable formulation for skincare

or topical products due to their “good textural and sensual properties due to the very fine droplet or globule size.” EX1001, 45-48. The ’146 Patent discloses that the nanoemulsion structure allows an active agent containing a carboxylic acid group, such as ALA, to be at least in part bound to the surface of nanovesicles, with the remainder of the active agent dissolved in the aqueous phase. EX1001, 6:12-42.

The ’146 Patent also recognizes that, at the time of filing, polyols – such as propylene glycol – were a very popular excipient class for topical formulations due to their beneficial action as solvents, humectants, preservatives, emulsion stabilizers, and penetration enhancers. EX1001, 1:54-56, 3:61-67. Additionally, removal of propylene glycol or other polyols was traditionally considered problematic due to loss of beneficial effects with respect to emulsion stabilization and skin penetration. EX1001, 3:61-4:5, 4:17-28, 4:62-5:41. Despite this conventional wisdom, the inventors of the ’146 Patent developed and disclosed a nanoemulsion formulation omitting propylene glycol, which, surprisingly, simultaneously showed a better impurity profile and equal or even better penetration properties, in comparison to a formulation that did include propylene glycol. EX1001, 4:17-28, 5:5-41, 42:15-44:36.

C. Summary of the Prosecution History of the ’146 Patent

The ’146 Patent issued from U.S. Pat. App. No. 18/533,497 (“the ’497 Application”), filed on December 8, 2023, by Biofrontera Bioscience GmbH

(“Applicant”). EX1003, 1, 78-79. The ’146 Patent claims priority to International Patent Application No. PCT/EP2023/059291, filed on April 6, 2023. EX1003, 4, 76.

The ’497 Application was initially filed with claims 1-20. EX1003, 70-73. In response to a Restriction Requirement mailed February 12, 2024 (EX1003, 97-103), Applicant elected claim 19 “identified by the Office Action as being nanoemulsion comprising less than 1% propylene glycol and 5-aminolevulinic acid” (EX1003, 104), canceled claims 1-18, and added new claims 21-26. EX1003, 109-110.

A Non-Final Office Action mailed May 1, 2024 rejected claims 19 and 21-26 as being allegedly obvious over U.S. Pat. Pub. No. 2009/0324727 (“Roca”). EX1003, 148-151. The same Office Action also issued a rejection on the grounds of nonstatutory double patenting in view of copending application 18/533,521 (“the reference application”) in combination with Roca. EX1003, 152-155. In response, Applicant amended the claims to recite “essentially no propylene glycol” and also added new claims 27-36. EX1003, 158-162, 165-167.

A Final Office Action mailed September 6, 2024 withdrew the obviousness rejection in view of Roca and issued new obviousness rejections of claims 19, 21-25 and 27-36 in view of U.S. Pat. No. 6,559,183 (“Schmid”) and of claim 26 in view of Schmid and U.S. Pat. No. 5,152,923 (“Weder”). EX1003, 175-180. The Final Office Action also withdrew the double patenting rejection in view of Roca and

issued a new double patenting rejection in view of the reference application alone. EX1003, 183. In response, Applicant amended the claims to recite and “essentially no sorbitol,” and added new claims 37-39, with new claims 38-39 being independent. EX1003, 188-189, 195, 197-198.

A Notice of Allowance was then issued on December 24, 2024, after new independent claims 38-39 were canceled via Examiner’s Amendment, as approved by Applicant via a telephone interview. EX1003, 226-231. The Notice of Allowance stated the Reasons for Allowance as follows:

“The closest prior art, Schmid et al (USP 6,559,183), is excluded by the claimed subject matter of essentially no propylene glycol and essentially no sorbitol (See Schmid at Table 2, comprising 0.25 % sorbitol).”

EX1003, 231. The ’146 Patent issued on April 22, 2025. EX1003, 330-333. On Nov. 5, 2025, Biofrontera Bioscience GMBH assigned all interest in the ’146 Patent to Biofrontera Inc. *See* Reel/Frame 73509/0006 recorded (available at <https://assignmentcenter.uspto.gov/search/patent>).

III. CLAIM CONSTRUCTION OF “NANOEMULSION”

The claims should be construed “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b); *see also*

Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). A patentee may act as her own lexicographer when she “clearly set[s] forth a definition of the disputed claim term” and “clearly express[es] an intent to redefine the term.” *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (internal quotations omitted). Here, the Patent Owner acted as its own lexicographer by clearly setting forth a definition for “nanoemulsion,” among other terms. Petitioner ignores the full scope of the definition and instead proposes adopting only a single feature that is so broad it would render both the “nano” and “emulsion” of “nanoemulsion” meaningless. A comparison of the parties proposed constructions is below:

<u>Term</u>	<u>Patent Owner’s Construction</u>	<u>Petitioner’s Construction</u>
“nanoemulsion” All challenged claims (1-17)	“a dispersion of oil in water characterized by a mean particle or nanovesicle size of less than 500 nm and a narrow nanovesicle size distribution”	“a dispersion of oil in water”

**A. Patent Owner Acted As Its Own Lexicographer Where the
Definition Is Contained In a Paragraph – Not Six Words**

Between columns 12 and 14 of the specification, the inventors include a series of paragraphs beginning with the phrase “*As used herein*”² and a term in quotation marks followed by definitions. EX1001, 12:55-14:15. The Federal Circuit has repeatedly acknowledged that the phrase “as used herein” is an “unambiguous[]” indicator that the patentee is acting as her own lexicographer “by stating that the term has a particular meaning within the patent.” *Abbott Lab’ys v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1210 (Fed. Cir. 2007); *Parkervision, Inc. v. Vidal*, 88 F.4th 969, 976 (Fed. Cir. 2023); *Google LLC v. Nobots LLC*, No. 2024-1432, 2025 WL 3240056, at *1 (Fed. Cir. Nov. 20, 2025) (finding “as used herein” indicative of lexicography and stating “[T]he patent places each phrase in quotation marks to confirm that lexicography is afoot.”).

For context, the specification’s definition section is included below:

² Emphasis always added, unless otherwise specified.

12	13
glycerin, diglycerin, polyglycerin, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol, pentylene glycol, hexylene glycol, 1,3-propanediol, 1,5-pentanediol, octane-1,2-diol, polyethyleneglycols, particularly 5 having from 2 to 50 ethylene oxide groups, and monosac- “Aging” as used herein, refers to alteration, disintegration and/or degradation of the formulation, affecting chemical and physical stability during storage, in particular under 40 stressed conditions. Such physical or chemical changes due to storage may include, but are not limited to Ostwald ripening, flocculation, coalescence and/or breaking, which may lead to a change in vesicle size or polydispersity index. “Aging” as used herein, may include the formation of 45 impurities after storage, for example for 6 months at 25° C. or 40° C. Typical impurities of formulations comprising 5-aminolevulinic acid as active agent are 2-hydroxypropyl-δ-aminolevulinate and an impurity characterized by $m/z=246$. 50 The inventors have found that the formulations of the present invention are surprisingly stable and resistant to aging. In particular, the formulations of the present invention comprise fewer impurities than prior art formulations, even after storage, for example for 6 months at 25° C. or 40° C. 55 As used herein, “stressed conditions” for storage are temperatures significantly exceeding room temperature (e.g., 40° C.). As used herein, a “nanovesicle emulsion” or a “nanoemulsion” is a dispersion of oil in water (oil-in-water dispersion, oil-in-water emulsion, O/W emulsion). The nanoemulsion can be monophasic, transparent and/or slightly opalescent. The nanoemulsions of the present invention can be colloidal systems, which include dispersed nanovesicles comprising a lipid core surrounded by at least one surfactant 60 or emulsifier monolayers. The nanoemulsions and the formulations comprising the nanoemulsions of the present invention are characterized by a mean particle or nanove-	sicle size of less than 500 nm less, than 200 nm, or less than 100 nm. The nanoemulsions and the formulations comprising the nanoemulsions of the present invention has a narrow (homogeneous) nanovesicle size distribution, for example a 5 nanovesicle size distribution characterized by a polydispersity index of less than or equal to 0.4. As used herein, “nanovesicle”, “nano vesicle”, “lipid vesicles”, “oil droplets”, “droplets” and “oil globules” are interchangeable and refer to small oil droplets in an oil in water emulsion. A lipid vesicle of an average size (see 10 above, e.g., below 500, 200, 100 nm) that is compiled of a monolayer of a surfactant and a lipid core. In the present invention, the nanovesicles can have a size of less than or equal to 500 nm, or less than or equal to 300 nm, preferably 15 in the range of 5 nm to 200 nm, more preferably in the range of 5 nm to 100 nm. As used herein, the term “nanoparticle” or “nano particle”, is distinguished form “nanovesicles”, and refers to solid particles, which are not described in this invention. The 20 formulation of the present invention may be a formulation which is essentially free of nanoparticles. “Essentially free of nanoparticles” means, that the formulation comprises less than or equal to 2% by weight, or less than or equal to 1% by weight of, or does not comprise nanoparticles. Nanopar- 25 ticles are mainly inorganic, solid lipids or polymeric solid particles may have a size of below 100 nm, below 200 nm, or below 500. The size can be determined by the methods as described herein. For example, the formulation may be 30 essentially free of nanoparticles with a diameter of less than 100 nm, as determined by dynamic light scattering. As used herein, “topical use” of the formulation of the invention describes an application to a particular place on or in the body, in particular the human body. This includes, but 35 is not limited to administration of the formulation to body surfaces such as the skin or mucous membranes. The topical use can be epicutaneous, meaning that the formulation is directly administered to the skin. In particular the topical use is a pharmaceutical use.

As can be seen, each paragraph constitutes a definition. Nothing in the Federal Circuit’s case law requires that the definition be limited to a single sentence as Petitioner seems to suggest, only that a definition be clearly set forth. In fact, in the context of lexicography, the Federal Circuit has affirmed the use of a patentee’s multi-sentence definition. *See, e.g., Parkervision*, 88 F.4th at 976 (“Sentence 3 uses the phrase ‘as used herein’ to indicate that the descriptions in sentences 4 and 5 that follow are applicable to the ’551 patent as a whole rather than to a specific

embodiment.”). As discussed below, *Parkervision* is instructive for reading the definition set forth by the patentee here.

Moreover, the phrase “as used herein” is not the only way that patentee clearly communicated a definition for “nanoemulsion.” In the definitional paragraph for “nanoemulsion,” the patentee also uses the phrase “the present invention” to limit nanoemulsions based on the mean particle/nanovesicle size as well as the nanovesicle size distribution. The Federal Circuit has held “[w]hen a patent thus describes the features of the ‘present invention’ as a whole, this description limits the scope of the invention.” *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1308 (Fed. Cir. 2007); *Honeywell Int’l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318-19 (Fed. Cir. 2006); *Lemoine v. Mossberg Corp.*, No. 2020-2140, 2021 WL 4199934, at *3 (Fed. Cir. Sept. 15, 2021) (citing *Honeywell* and affirming district court’s construction). Because the patentee has used the phrase “the present invention” within an unambiguously definitional paragraph, it is evident that a proper construction of “nanoemulsion” must be limited based on nanovesicle size and size distribution as set out in the specification of the ’146 Patent.

Petitioner and its expert make no effort to address the full paragraph containing the definition for nanoemulsions. Petitioner’s only claim construction is limited to a conclusory, two sentence paragraph. Petition, 9-10. Petitioner and its expert ignore the additional required features contained in the paragraph defining

“nanoemulsions,” and ignore the patentee’s use of “in the present invention” in the definitional paragraph. Petitioner’s scant, conclusory analysis shows only that it read the first sentence in the paragraph and stopped reading the rest of the definition. *See* Petition, 10 (citing EX1001, 12:58-60); EX1002, ¶¶ 76-77.

The ’146 Patent’s full “nanoemulsion” definitional paragraph is provided below:

As used herein, a “nanovesicle emulsion” or a “nanoemulsion” is a dispersion of oil in water (oil-in-water dispersion, oil-in-water emulsion, O/W emulsion). The nanoemulsion can be monophasic, transparent and/or slightly opalescent. The nanoemulsions of the present invention can be colloidal systems, which include dispersed nanovesicles comprising a lipid core surrounded by at least one surfactant or emulsifier monolayers. The nanoemulsions and the formulations comprising the nanoemulsions of the present invention are characterized by a mean particle or nanovesicle size of less than 500 nm, less than 200 nm, or less than 100 nm. The nanoemulsions and the formulations comprising the nanoemulsions of the present invention has a narrow (homogeneous) nanovesicle size distribution, for example a nanovesicle size distribution characterized by a polydispersity index of less than or equal to 0.4.

EX1001, 12:58-13:6.

The “nanoemulsion” definitional paragraph discloses the meaning of the term through both permissive and required features. Patent Owner’s construction adopts

all of the required features while Petitioner's construction adopts only a single required featured.

Both parties agree that the first sentence discloses a requirement of the claimed nanoemulsion, namely that a “‘nanoemulsion’ *is* a dispersion of oil in water.” The second and third sentences use permissive language to describe possible features of a nanoemulsion, and thus not part of the definition:

The nanoemulsion *can be* monophasic, transparent and/or slightly opalescent. The nanoemulsions of the present invention *can be* colloidal systems, which include dispersed nanovesicles comprising a lipid core surrounded by at least one surfactant or emulsifier monolayers.

EX1001, 12:60-65.

The final two sentences again provide required limitations on “nanoemulsion” by disclosing the “nanoemulsions of the present invention” has certain mean nanovesicle size and distribution requirements:

The nanoemulsions and the formulations comprising the *nanoemulsions of the present invention are characterized* by a mean particle or nanovesicle size of less than 500 nm, less than 200 nm, or less than 100 nm. The nanoemulsions and the formulations comprising the *nanoemulsions of the present invention has* a narrow (homogeneous) nanovesicle size distribution, for example a

nanovesicle size distribution characterized by a polydispersity index of less than or equal to 0.4.

EX1001, 12:65-13:6. Just as in *Parkervision*, the definition is provided in multiple sentences, but the patentee's lexicography makes clear the definition is applicable to the patent as a whole. *Parkervision*, 88 F.4th at 976. Thus, the proper construction of "nanoemulsion" in accordance with the required features of the nanoemulsion of the present invention, is "a dispersion of oil in water characterized by a mean particle or nanovesicle size of less than 500 nm and a narrow nanovesicle size distribution."

B. Intrinsic Evidence Demonstrates that Petitioner's Construction Is Faulty Because It Reads the "Nano" Out of "Nanoemulsion"

Petitioner's construction of "nanoemulsion" being any "dispersion of oil in water" is so unreasonably broad that it also covers conventional emulsions and microemulsions despite the '146 Patent distinguishing a nanoemulsion from these other emulsions. *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (noting that the Board may not "construe claims during IPR so broadly that its constructions are *unreasonable* under general claim construction principles") (emphasis in original), *overruled in another respect, Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (*en banc*).

Even under the more permissive "broadest reasonable interpretation" standard, the Federal Circuit has cautioned against reading claims so broadly that they cover more than intended by the specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255,

1260 (Fed. Cir. 2010) (overturning Board construction that was “unreasonably broad” and which did not “reasonably reflect the plain language and disclosure” of the specification). This is even more true under the *Phillips* standard now used in IPRs. *Phillips*, 415 F.3d at 1315; *PPC Broadband, Inc. v. Corning Optical Commc’ns RF, LLC*, 815 F.3d 747, 756 (Fed. Cir. 2016) (construction was “straight-forward” under *Phillips* where “[Patent Owner’s] construction is the only construction of the term consistent with the use of the same term throughout the specification”).

Here, the ’146 Patent regularly and repeatedly distinguishes between emulsions, microemulsions, and nanoemulsions. For instance, just before introducing the definition of “nanovesicle emulsion” or “nanoemulsion,” the ’146 Patent states,

The *small size of the nanovesicles* and their *high homogeneity* confers on them advantageous properties *which distinguish them from conventional emulsions....*

EX1001, 12:28-30. In the Background section, the ’146 Patent explains that, consistent with the “nano” language, the size of the vesicles is part of what distinguishes a nanoemulsion from other emulsions. EX1001, 1:24-28 (“Emulsions or micro emulsions can be oil in water, water in oil or middle phased dispersions, often dispersed with surfactants as emulsifiers. *Nanoemulsions are a subgroup of the emulsions that contain very fine oil in water dispersions.*”). Throughout the

specification, the patentee emphasizes the size of the nanovesicles. *See* EX1001, 13:12-16 (“In the present invention, the nanovesicles can have a size of less than or equal to 500 nm, or ... more preferably in the range of 5 nm to 100 nm.”), 13:57-61, 27:60-65.

The ’146 Patent also emphasizes the narrow size distribution of nanovesicles. *See* EX1001, 1:33-36, 14:35-45 (discussing methods for assessing nanovesicle size distribution, 28:12-26 (tying size distribution measured by polydispersity index to the disclosed embodiments), 31:52-55. The Patent Owner also provides “Example 4: Determination of Vesicle Size and Polydispersity Index by Dynamic Light Scattering” to explain to a POSITA one way to measure for vesicle size and size distribution using dynamic light scattering. *Id.* at 41:45-67. Thus, a POSITA would understand from the specification’s repeated disclosure that the size of the nanovesicles and size distribution were critical aspects of a nanoemulsion – not just that it is an oil-in-water emulsion.

The ’146 Patent also explains that formation of a nanoemulsion is process dependent and, in many cases, can require a specialized manufacturing process. EX1001, 1:40-53. The ’146 Patent states that nanoemulsion “structure depends often o[n] the manufacturing process,” and “[t]he very small size of the oily globules is often obtained by virtue of at least one pass through a high-pressure homogenizer or a sonicator.” EX1001, 1:40-53.

The '146 Patent explains that the differences between nanoemulsions and other emulsions are functionally important. For instance, “Nanoemulsions are thermodynamically *more stable than conventional emulsions....*” *Id.*, 1:36-39). Throughout the specification, the inventors explain that stability was a fundamentally important aspect of their invention. *See* EX1001, Abstract (“The present invention relates to oil in water nanoemulsions which are essentially free of propylene glycol. The nanovesicle formulations are particularly stable in regard to shelf life at different storage temperatures.”), 2:23-24 (“Known formulations of ALA for topical use on the skin, are instable in aqueous solutions.”), 12:50-52 (“The inventors have found that the formulations of the present invention are surprisingly stable and resistant to aging.”).

Likewise, a POSITA would understand the '146 Patent's teaching that “nanoemulsions ... can carry active agents more efficiently” to be a contrast with conventional emulsions. Thus, from the specification alone, a POSITA would understand that a “nanoemulsion” possessed different structural characteristics than a regular emulsion or a microemulsion and that those structural characteristics conferred specific functional advantages that were important to the purpose of the invention. Even without clear lexicography, a POSITA would understand that there were differences between any “dispersion of oil in water” and the “nanoemulsion”

of the invention. A construction that reads “nano” out of “nanoemulsion” would thus contradict the intrinsic record and should not be adopted.

Just as it failed to address the full paragraph setting forth the definition of “nanoemulsion,” Petitioner and its expert do not address any of the intrinsic evidence present in the specification that confirms a POSITA would have understood a nanoemulsion to be narrower than just “a dispersion of oil in water.” *See* Petition, 9-10; EX1002, 77-78; *see also Straight Path IP Grp., Inc. v. Sipnet EU S.R.O.*, 806 F.3d 1356, 1361 (Fed. Cir. 2015) (reversing construction inconsistent with the plain meaning of the claim language and stating “the proper construction of any claim language must, among other things, stay true to the claim language, and . . . the court’s focus remains on understanding how a person of ordinary skill in the art would understand the claim terms.”) (cleaned up); *In re Abbott Diabetes Care Inc.*, 696 F.3d 1142, 1151 (Fed. Cir. 2012) (even under broadest reasonable construction standard, finding construction was erroneous when it was inconsistent with the specification). The Petition’s failure to address the specification’s intrinsic evidence further underscores its erroneous construction of “nanoemulsion.”

C. Petitioner’s Own Exhibits Provide Extrinsic Evidence that Its Construction Is Wrong

Patent Owner’s extrinsic evidence of record underscores the differences between an emulsion and a nanoemulsion. In its section titled “Technology

Background,” the Petition cites to EX1011 and EX1020, which further underscore that nanoemulsions are different than emulsions or microemulsions. Consistent with the ’146 Patent’s definition of “nanoemulsion,” Petitioner’s EX1011 confirms that “[t]he globule size is [a] very essential aspect to differentiate emulsion, micro emulsion and nano emulsion” and that “[s]tability issues like creaming, flocculation, coalescence, and sedimentation are rarely observed in nano-emulsion.” EX1011, 7. Likewise, EX1020 confirms that nanoemulsions differ both from coarse emulsions and even microemulsions, both in droplet size and in functional characteristics:

Nanoemulsions are oil-in-water (O/W), water-in-oil (W/O) dispersion of two immiscible liquids stabilized using an appropriate surfactant. ... Small droplet size gives them a clear or hazy appearance which differs from milky white color associated with coarse emulsion it ***should not be confused with microemulsion.***

EX1020, 2. Collectively, the intrinsic and extrinsic evidence of record confirms that Patent Owner’s proposed construction is correct, and that Petitioner’s construction ignores the differences between nanoemulsions and other emulsions.

IV. PROPOSED GROUNDS OF REJECTION ARE NOT LIKELY TO SUCCEED

Petitioner’s proposed grounds of rejection are unlikely to succeed because its purported anticipatory reference for independent claim 1, Uhlmann, fails to disclose

multiple recited elements.³ Specifically, Petitioner asserts Ground IA, alleging that claim 1 is anticipated by Example 5 of Uhlmann, and Ground IIA, alleging that claim 1 is anticipated by Example 3 of Uhlmann. Petition, 3. Petitioner does not raise any obviousness argument with respect to claim 1.

Anticipation is a high bar to clear, which requires that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987); *see also TF3 Ltd. v. Tre Milano, LLC*, 894 F.3d 1366, 1374 (Fed. Cir. 2018). But even that “does not tell the whole story. Because the hallmark of anticipation is prior invention, the prior art reference...must not only disclose all elements of the claim...but must also disclose those elements ‘arranged as in the claim.’” *Net MoneyIn, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). Accordingly, anticipation must be established “without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the

³ Claims 2-17 all depend from claim 1. Therefore, Petitioner’s arguments as to anticipation of these claims fail for the same reasons as discussed with respect to claim 1. Further, in its obviousness grounds as to certain dependent claims (Grounds IB, IC, IIB, and IIC), Petitioner fails to account for the missing elements discussed herein. Petition, 33 n. 3, 39, 61 n. 5, 67-73. Accordingly, Petitioner has also failed to carry its burden as to the dependent claims, for at least these reasons.

teachings of the cited reference,” *Endo Pharms. Inc. v. Actavis Labs. UT, Inc.*, 2015 WL 12910639 at *14 (E.D. Tex. 2015) (quoting *Application of Arkley*, 59 C.C.P.A. 804, 807 (C.C.P.A. 1972) (emphasis in original)), because “anticipation is not proven by multiple, distinct teachings that the artisan might somehow combine....” *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1069, 1071-72 (Fed. Cir. 2017) (internal quotations omitted). Any difference between the prior art and the claims is properly the province of obviousness under Section 103, not anticipation under Section 102. *Enplas Display Device Corp. v. Seoul Semiconductor Co., Ltd.*, 909 F.3d 398, 405 (Fed Cir. 2018); *Application of Arkley*, 59 C.C.P.A. at 807.

A. Uhlmann Is Not Anticipatory Because It Fails to Disclose a Nanoemulsion Under Either Party’s Proposed Construction

The Petition fails because all grounds rely on the premise that Uhlmann anticipates the nanoemulsion of independent claim 1, when Uhlmann is devoid of such teaching. Uhlmann makes no mention of nanoemulsions. At most, Uhlmann discusses emulsions in general without demonstrating those emulsions are nanoemulsions. Perhaps even more problematic is that Uhlmann does not even disclose that Examples 3 and 5 are even emulsions (let alone nanoemulsions), which are the only two examples of Uhlmann relied on in the Petition.

Petitioner “bear[s] the burden of proving the challenged claims are unpatentable under the correct construction.” *Bayer Pharma Aktiengesellschaft v.*

Mylan Pharms. Inc., 152 F.4th 1400, 1406 (Fed. Cir. 2025); *Fanduel, Inc. v. Interactive Games LLC*, 966 F.3d 1334, 1341 (Fed. Cir. 2020) (“the burden of proving invalidity in an IPR remains on the petitioner throughout the proceeding”) (citing 35 U.S.C. § 316(e)). Petitioner has failed to meet that burden here.

**i. Uhlmann Fails Under Any Reasonable Construction
Consistent With the Specification of the '146 Patent**

To begin with, Petitioner has hung the entirety of its analysis in the Petition on its faulty construction of “nanoemulsion,” which reads “nano” out of “nanoemulsion” and ignores the specification of the '146 Patent. Petition, 17, 44. In presenting its arguments, Petitioner demonstrates the absurd breadth of its construction. For instance, Petitioner contends that Uhlmann anticipates the claimed nanoemulsion because it discloses an “O/W” (oil-in-water) cream or milk. *Id.* Even assuming this skin cream was an emulsion, there is no disclosure that it is a nanoemulsion.

As explained previously, the proper construction of “nanoemulsion” is “a dispersion of oil in water characterized by a mean particle or nanovesicle size of less than 500 nm and a narrow nanovesicle size distribution.” *See supra* Section III. Uhlmann makes no mention of nanovesicles, vesicle size, or particle size. In fact, there is no discussion of vesicles anywhere in Uhlmann. There is no teaching anywhere in Uhlmann that shows it discloses a nanoemulsion “characterized by a

mean particle or nanovesicle size of less than 500 nm, less than 200 nm, or less than 100 nm.” EX1001, 12:65-13:2. Likewise, Uhlmann presents no teaching or mention of nanovesicle size distribution. As such, there is no teaching in Uhlmann that shows it discloses a “a narrow (homogeneous) nanovesicle size distribution.” EX1001, 13:2-6.

Even if the Board does not adopt Patent Owner’s proposed construction, the proper construction of nanoemulsion cannot encompass a conventional emulsion in view of the specification of the ’146 Patent distinguishing nanoemulsions from conventional emulsions. *See supra* Section III; EX1001, 12:28-36 (distinguishing nanoemulsions from “conventional emulsions”). Yet, a “conventional emulsion” is precisely what the Petition argues anticipates the claimed nanoemulsion. Petition, 17, 44 (alleging that Uhlmann discloses “an emulsion”). Petitioner never tries to explain why Uhlmann discloses anything other than a conventional emulsion.

Petitioner’s expert merely repeats the conclusory refrain from the Petition that a nanoemulsion is “a dispersion of oil in water” without further explanation as to why this disclosure would be a nanoemulsion to a POSITA. Thus, his opinion that Uhlmann discloses a nanoemulsion is entitled to no weight. EX1002, ¶¶ 87-88, 178-179; *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (PTAB Aug. 24, 2022) (precedential) (“[T]he cited declaration testimony is conclusory and

unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight.”) (collecting cases).

In short, there is no evidence that Uhlmann discloses a “nanoemulsion” under Patent Owner’s proposed construction or any reasonable construction consistent with the specification of the ’146 Patent.⁴

**ii. Petitioner Has Failed to Carry Its Burden to Show
Uhlmann is Anticipatory Even Under Its Own Proposed
Construction**

Petitioner has not established that either Example 3 or Example 5 of Uhlmann are emulsions or even “dispersions of oil in water.” *See* Petition, 17-18; 44-45. Examples 3 and 5 simply state that the examples are “milk O/W” and “cream O/W,” respectively. EX1004, 8:55, 9:20. Nowhere in the specification does Uhlmann state that these specific examples are emulsions or dispersions of oil in water.

To overcome this discrepancy, Petitioner cites to Uhlmann at 6:39-48, which discusses hydrodispersions. *See* Petition, 18, 45. Uhlmann’s discussion of hydrodispersions clarifies that *hydrodispersions are not emulsions*, let alone nanoemulsions. EX1004, 6:42-44 (“Unlike O/W emulsions which are characterised

⁴ The Petition does not argue that a “nanoemulsion” is inherent in Uhlmann. Nor does Petitioner provide any evidence to show that Uhlmann inherently discloses a “nanoemulsion.”

by a similar phase arrangement, hydrodispersions are predominantly free of emulsifiers.”); *see also* 6:44-48 (distinguishing between emulsions and hydrodispersions).⁵

At best, the Petition shows that some examples provided in the specification *could be* O/W emulsions or *could be* O/W hydrodispersions, but there is no disclosure that Example 3 or 5 actually is an O/W emulsion (as opposed to some other formulation). Instead, the Petition applies general disclosures about O/W emulsions and hydrodispersions to argue that Examples 3 and 5 are emulsions, but only does so by asking a POSITA to piece together separate passages and assumptions contrary to the Federal Circuit’s requirements for establishing anticipation. *See Microsoft*, 878 F.3d at 1071-72 (“anticipation is not proven by multiple, distinct teachings that the artisan might somehow combine...”) (internal quotations omitted); *Net MoneyIn*, 545 F.3d at 1370 (collecting cases and stating

⁵ Uhlmann’s clear distinction between “emulsions” and “hydrodispersions” is further extrinsic evidence of the weakness of its claim construction positions. It is readily apparent that Petitioner’s broad construction reads “nano” out of “nanoemulsion.” But by relying on a hydrodispersion as prior art, Petitioner confirms that it is seeking a construction that reads “emulsion” out of “nanoemulsion,” too.

“The test is thus more accurately understood to mean ‘arranged or combined in the same way as in the claim.’”).

By asking the Board to connect the dots between disparate areas of the specification, Petitioner’s arguments are better understood to be directed towards an obviousness challenge, rather than anticipation. However, Petitioner did not allege obviousness as a grounds of rejection for claim 1, the sole independent claim, and has not provided any evidence on why a POSITA would combine the disclosure about O/W emulsions with the specific Examples 3 and 5 in Uhlmann. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (Board cannot “adopt arguments on behalf of petitioners that could have been, but were not, raised by the petitioner during an IPR.”).

Thus, even under its own faulty construction, Petitioner has not carried its burden to show that Examples 3 and 5 are nanoemulsions.

**B. Uhlmann Is Not Anticipatory Because It Fails to Disclose
“Wherein the Formulation Comprises Essentially No Propylene
Glycol”**

Independent claim 1 of the ’146 Patent recites that “the formulation comprises essentially no propylene glycol.”⁶ EX1001, cl. 1. Petitioner takes the position that

⁶ Claims 2-17 of the ’146 Patent also require this limitation by virtue of their dependence from claim 1.

“essentially no” means that “the formulation is either free of compound X or comprises less than 0.1% (w/w)...based on the total weight of the formulation.” Petition, 29 n. 2. Regardless of this characterization, Petitioner has failed to satisfy its burden to show this limitation is disclosed under either of its grounds – Ground IA (anticipation by Example 5 of Uhlmann) or Ground IIA (anticipation by Example 3 of Uhlmann).

Both Example 5 and Example 3 of Uhlmann are silent as to propylene glycol. EX1004, Exs. 5, 3. However, while “a reference need not state a feature’s absence in order to disclose a negative limitation,”⁷ the law also requires something more than complete silence for an anticipatory disclosure. *In re Strongbridge Dublin Ltd.*, 2025 WL 751116 at *4 (Fed. Cir. Mar. 10, 2025) (For anticipation, “[t]here must be **something more** to suggest that the silence is significant, or other reasons that establish by a preponderance of the evidence that it is likely that one or more of the patients in Sansone were **not** taking famotidine....”); *IBM Corp. v. Iancu*, 759 Fed. Appx. 1002, 1011 (Fed. Cir. 2019) (“[E]ven if the Board were correct that Mellmer is ‘silent’ about the content of the accessCard, that characterization would not alone support a finding that there was *no* user authentication action...” for purposes of anticipation.) (emphasis in original); *Amneal Pharmaceuticals LLC v. Almirall, LLC*,

⁷ *AC Techs. S.A. v. Amazon.com, Inc.*, 912 F.3d 1358, 1367 (Fed. Cir. 2019)

IPR2019-00207, Paper 58, 41 (PTAB May 29, 2020), (“*It is not Garrett’s mere silence* as to the presence of adapalene, *but its disclosure of complete* dapstone *formulations* to treat acne in its absence that suggests that adapalene is not included....”).

Petitioner relies on *Almirall, LLC v. Amneal Pharmaceuticals LLC*, 28 F.4th 265 (Fed. Cir. 2022) (affirming the Board’s holding in *Amneal*, IPR2019-00207)) for the principle that the necessary “something more” can be disclosure of a complete formulation lacking the excluded ingredient. Petition, 29-30, 57-58. Petitioner, echoed by its expert, alleges that each of Uhlmann’s Example 5 and Example 3 “details a *complete formulation*...which excludes the possibility of an additional unnamed ingredient.” Petition, 29-30, 57-58; *see also* EX1002, ¶¶ 121, 213. The problem for Petitioner is that neither example in Uhlmann is actually a complete formulation. Both Examples 5 and 3 include classes of unspecified ingredients, in unspecified amounts (“q.s.”), under the headings “preservative” and “perfume.”

		<u>Example 3</u>	
		Sun Milk O/W	Percentage by weight
<u>Example 5</u>			
Day-car skin cream O/W	Percentage by weight		
PEG-5 Glycerylstearate	2.00	Octylmethoxycinnamate	5.0
Glycerylstearate	3.00	Butylmethoxydibenzoylmethane	1.0
Cyclomethicone	3.00	Cetearylalcohol + PEG-40 castor oil +	2.5
Caprylic/capric triglyceride	3.00	Sodiumcetearylsulphate	
Cetylalcohol	3.00	Glyceryllanolate	1.0
Octylmethoxycinnamate	2.50	Laurylmethicon copolyol	0.5
δ-aminolevulinic acid	5.00	Mineral oil (DAB 9)	5.0
Ethanol	1.00	Caprylic/capric triglyceride	5.0
Hyaluronic acid	0.05	Acrylamide/sodiumacrylate copolymer	0.3
Tocopherylacetate	0.50	Cyclomethicone	2.0
Glycerine	4.00	TiO ₂	1.0
Perfume, preservatives	q.s.	δ-aminolevulinic acid	1.0
Water, fully demineralised	make up to 100.00	Glycerine	3.0
		EDTA solution (14%)	0.5
		Ethanol	5.0
		Perfume, preservative	q.s.
		Water, fully demineralised	make up to 100.0

EX1004, Exs. 5, 3. Rather than “exclud[ing] the possibility of an additional unnamed ingredient,” as Petitioner alleges, these formulations actually expressly *include* additional unnamed ingredients because Uhlmann is totally silent as to what ingredients the “perfume” and “preservatives” of Examples 5 and 3 are comprised of. Accordingly, these incomplete formulations cannot anticipate the claims.

This is especially true, given that evidence in the record shows that “preservatives” include propylene glycol. For instance, in the Background section describing the state of the art at the time of filing, the ’146 Patent states that “[p]ropylene glycol is known to have advantageous properties, such as...*preservative* effects....” EX1001, 1:57-64. Additionally, U.S. Pat. Pub. No. 2015/0238457 – published before the priority date of the ’146 Patent and cited by Petitioner and its expert as providing background information as to the technology – discloses propylene glycol as a preservative specifically for use with an ALA

active ingredient. EX1019, [0008] (“...5-ALA in Intrasil Gel...Intrasil Gel is a hydrogel comprising...*propylene glycol* (20%) *as a* humectant and *preservative*.”). In fact, even Uhlmann itself discloses using “propylene glycol” as a solvent “[w]here the cosmetic or dermatological preparation is a solution or lotion.” EX1004, 5:53-63.

Further, Petitioner admits both that the Example 5 and 3 formulations are incomplete and that it is possible for them to include preservative amounts exceeding 0.1% (w/w). In its arguments regarding claim 5 of the ’146 Patent, Petitioner reaches to a secondary reference – Palazzolo – to purportedly supply typical amounts of the “perfume” and “preservative,” which are missing from Examples 5 and 3. Petition, 32-33 (acknowledging the formulations include an unknown “amount of ‘perfume, preservative’ which is marked as ‘q.s.’... ‘q.s.’ means a ‘sufficient quantity’ of the ingredient specified by the supplier of that ingredient. And amounts of ‘perfume’ and ‘preservative’ in such formulations range from 0.01-5.0% (w/w) and 0.01-2% (w/w), respectively.”) (internal citations omitted); *see also* EX1002, ¶¶ 167-173, 262-268. In short, in arguing obviousness of claim 5 (Grounds IC and IIC), Petitioner concedes that Uhlmann’s Examples 5 and 3 can include up to 2% of preservatives, of which propylene glycol is a known example and is disclosed in Uhlmann as compatible with its formulation. Accordingly, Petitioner has failed to “establish[] that a skilled artisan would understand [the] negative limitation to necessarily be

present” in Examples 5 or 3. *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1020 (Fed. Cir. 2022).

Even, *arguendo*, taking the view most favorable for Petitioner at this stage, it is at best ambiguous whether or not propylene glycol is included in Examples 5 and 3 of Uhlmann, and the Federal Circuit has explained that ambiguity is not enough for anticipation – “[i]f, as appears, the Board meant that it simply could not tell one way or the other...Silence in that sense would not by itself suffice for the Petitioner to meet its burden to prove, by a preponderance of the evidence, that there was no user authentication action....” *IBM*, 759 Fed. Appx. at 1011 (emphasis removed); *see also Wasica Finance GmbH v. Continental Auto. Sys., Inc.*, 853 F. 3d 1272, 1284 (Fed. Cir. 2017) (“[A]mbiguous references do not, as a matter of law, anticipate a claim.”). Similarly, the incomplete and ambiguous Examples 5 and 3 that Petitioner has offered here do not suffice to meet its burden for institution.

None of Petitioner’s legal citations change this conclusion. Initially, each of the cases Petitioner cites deal with disclosure of a negative limitation in the context of obviousness rather than in the context of anticipation. Petition, 30, 58 (citing *United Services Auto. Ass’n v. PNC Bank N.A.*, No. 2023-2244, 2025 WL 706080, at *3 (Fed. Cir. Mar. 5, 2025); *Almirall, LLC*, 28 F.4th 265; *Amneal Pharmaceuticals LLC v. Almirall, LLC*, IPR2019-00207, Paper 58, 41.).

Even assuming the principles set out in these cases are applicable under the much stricter standard for anticipation, they do not support the conclusion Petitioner is seeking here. In *Almirall*, the Federal Circuit affirmed the Board’s finding in *Amneal* that the primary reference’s disclosure of a complete formulation lacking adapalene, was sufficient to render obvious a claim reciting a negative limitation excluding adapalene. *Almirall*, 28 F.4th at 271; *Amneal*, IPR2019-00207, Paper 58, 41-42. However, in *Almirall*, the formulations disclosed in the primary reference (WO 2009/061298 (“Garrett”)) were true complete formulations, without unspecified classes and amounts of ingredients as there are in Uhlmann. *Compare* Garrett, 23:21-24 with EX1004, Exs. 5, 3. Further, in *United Services Auto. Ass’n*, the Federal Circuit found that obviousness of the recited negative limitation was “not founded solely on [the primary reference’s] silence” but also on “internal context within the reference.” 2025 WL 706080 at *3. In *United Services Auto. Ass’n*, internal context confirmed the absence of the excluded method step. *Id.* Here, far from confirming exclusion, additional context within Uhlmann actually *encourages* inclusion of propylene glycol. EX1004, 5:53-63 (“Where the cosmetic or dermatological preparation is a solution or lotion, solvents which may be used are...propylene glycol.”). Petitioner’s own citations and documents thus confirm that Uhlmann’s incomplete formulations, which are open to inclusion of propylene

glycol as a preservative or solvent, are insufficient to support Petitioner's burden for institution.

V. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that the Board decline to institute a PGR proceeding based on the Petition.

Dated: April 27, 2026

Respectfully submitted,

/James P. Murphy/

James P. Murphy

Reg. No. 55,474

Polsinelli PC

1000 Louisiana Street

Suite 6400

Houston, Texas 77002

Brian Larivee

pro hac vice

Polsinelli PC

One International Place

100 Oliver St.

Suite 3900

Boston, Massachusetts 02110

Kendall Gurule

Reg. No. 77,605

Polsinelli PC

1401 I St NW Suite 800

Washington, DC 20005

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on April 27, 2026, complete copies of the foregoing document, including all supporting exhibits, are being served via email on the following counsel of record for Petitioner:

Yung-Hoon Ha

yha@desmaraisllp.com

Bridget P. Belcher

bbelcher@desmaraisllp.com

SunPharmaPGRService@desmaraisllp.com

/Ericka McNeil/
Ericka McNeil

Polsinelli PC
1000 Louisiana Street
Suite 6400
Houston, Texas 77002