

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. FALK PHARMA GMBH,
Petitioner,

v.

ELLODI PHARMACEUTICALS, L.P.,
Patent Owner.

Case No. IPR2024-01197
Patent No. 8,771,729 B2

PATENT OWNER'S CORRECTED SURREPLY

List of Patent Owner's Exhibits

Exhibit No.	Description
2001	U.S. Patent Application Publication No. US 2009/0191275 A1 to Dohil, et al. ("Dohil 2009")
2002	U.S. Patent Application Publication No. US 2009/0169620 A1 to Venkatesh, et al. ("Venkatesh 2009")
2003	U.S. Patent Application Publication No. US 2009/0131386 A1 to Phillips ("Phillips")
2004	Prosecution History for U.S. Patent No. 10,632,069
2005	Biography of Isha Agarwal
2006	Declaration of Isha Agarwal ISO Motion for <i>Pro Hac Vice</i> Admission
2007	Declaration of Martyn Christopher Davies in Support of Patent Owner's Response
2008	<i>Curriculum Vitae</i> of Martyn Christopher Davies
2009	U.S. Patent Application Publication No. 2005/0009848 A1 ("Brantl")
2010	Clinical Trials Study, "Efficacy, Safety, and Pharmacokinetics of APT-1011 in Subjects With Eosinophilic Esophagitis (EoE)(FLUTE)," last updated Apr. 26, 2023, https://clinicaltrials.gov/study/NCT03191864?tab=results&a=11#outcome-measures
2011	Deposition of Alan F. Parr, Pharm.D., Ph.D., dated April 9, 2025
2012	"Antrum" Definition, American Medical Dictionary: A Concise and Up-to-Date Guide to Medical Terms (1998)
2013	M.E. Aulton (Ed.), <i>Pharmaceutics: The Science of Dosage Form Design</i> (2d. 2002)
2014	"Lozenge" Definition, Dennis B. Worthen (ed.), <i>Dictionary of Pharmacy</i> (2004)
2015	Paul J. Sheskey et al., <i>Handbook of Pharmaceutical Excipients</i> (8d. 2017)

Exhibit No.	Description
2016	<i>Reserved</i>
2017	<i>Reserved</i>
2018	Transcript of the August 25, 2025 deposition of Alan Parr, Pharm.D.

I. INTRODUCTION

Petitioner has failed to show that the claims of the '729 patent are unpatentable. None of Petitioner's asserted references teach or suggest an orally disintegrating tablet ("ODT") that disintegrates within 60 or 30 seconds and deposits a topical corticosteroid on the upper gastrointestinal ("GI") tract, specifically the esophagus, to treat eosinophilic esophagitis ("EoE") as required by the claims. Instead, the references disclose a lozenge that dissolves slowly over several minutes (Dohil), not an ODT that disintegrates within 60 seconds, a general platform ODT not directed to topical deposition of a drug on the esophagus or treating EoE (Grother), and a taste-masking coating that prevents the corticosteroid from being deposited in the upper GI tract (Venkatesh). Reply, 1. These references are insufficient to establish *prima facie* obviousness.

Petitioner's belated and impermissible new evidence on lozenges fails to fill the gaps in the Petition. The new references do not teach lozenges that disintegrate with 60 seconds, but rather confirm the art-recognized definition that lozenges dissolve over several minutes. Further, as admitted by Petitioner and supported by Petitioner's new evidence (EX1083), an ODT that disintegrates within 60 seconds would not produce Dohil's requisite 8-12mL of liquid necessary to provide pan-esophageal coverage and treat EoE. Reply, 10-11.

Turning to Venkatesh, Petitioner relies on U.S. Patent No. 6,139,865 (the

“’865 patent,” EX1085) to argue that Venkatesh’s taste-masking would allow drug release in the esophagus. The ’865 patent does not support Petitioner’s argument. The ’865 patent only further confirms that Venkatesh’s taste-masked coating is designed to prevent release of the drug in the mouth and ensure drug release in the stomach.

For the reasons discussed below and in PO’s Response, the Board should uphold the claims of the ’729 patent because Petitioner has not proven that the claims are obvious.

II. PETITIONER IMPROPERLY SHIFTS ITS BURDEN OF PROOF

Petitioner attempts to improperly shift its burden to prove unpatentability by requiring PO’s expert to do additional research and provide evidence of patentability. Reply, 2. “In an *inter partes* review, the burden of persuasion is on the petitioner to prove unpatentability by a preponderance of the evidence, and that burden never shifts to the patentee.” *In re Magnum Oil Tools Int’l*, 829 F.3d 1364, 1375 (Fed. Cir. 2016) (modified). In this regard, it is up to Petitioner to provide the relevant evidence of obviousness. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015) (stating that petitioner has the initial burden of production). Neither PO, nor its expert, has an obligation to perform independent literature searches to prove patentability. Further, contrary to Petitioner’s assertion, while PO’s expert testified that he has not formulated ODTs,

he has tested ODT formulations and taught college courses on ODTs. Reply, 2; EX1072, 10:16-21; EX2007, ¶¶8-19.

III. THE CLAIMS OF THE '729 PATENT ARE NOT OBVIOUS

A. Dohil Does Not Teach an ODT

Petitioner argues that Dohil's lozenge is an ODT, meaning it is considered a tablet that disintegrates within 30 seconds according to the FDA's definition. Reply, 2-3; EX1005, 2. However, Dohil does not use the term "disintegrate," it uses the term dissolve, because lozenges dissolve "slowly."¹ EX1002, [0032]; EX2013, 413; *see also* EX2014, 201 (defining a lozenge as a "solid preparation...intended to dissolve or disintegrate slowly"); EX1080, [0104]. The FDA Guidance does not support Petitioner's argument, because the FDA Guidance does not mention a lozenge.

Petitioner cites no support for its position that lozenges are ODTs and fails to address the well-understood meaning of lozenge. While Petitioner cites several synonyms for ODTs, Petitioner does not assert that lozenges are synonymous with ODTs. Pet., 6-7. Dohil does not call its lozenge or similar tablet an ODT, or

¹ While Petitioner does not say dissolve and disintegrate are the same, PO assumes Petitioner is equating the terms, even though they are not the same. EX2018, 21:19-22.

explicitly state that the lozenge or similar tablet disintegrates within 30 seconds according to the FDA Guidance. Further, Dohil's use of the phrase "dissolve rapidly" does not change the well-understood definition of a lozenge because, as Petitioner's expert admits, "dissolve" refers to drug release, not disintegration. EX1002, [0032]; EX2018, 21:19-22. Thus, Dohil also does not act as its own lexicographer to define its lozenge to mean an ODT. In fact, had Dohil intended to disclose an ODT, it could have since ODTs were well-known, but it opted to disclose a "lozenge or other similar tablet" instead. EX1002, [0032].

When read as a whole and considering the art-recognized definition of a lozenge, a POSA would understand Dohil as teaching a slow dissolving dosage form (i.e., dissolves over several minutes) that begins to release drug upon contact with saliva. EX1002, [0067], [0056]-[0070], [0032]; EX2013, 413 ("Lozenges...dissolve slowly in the mouth"); EX2014, 201 (defining a lozenge as a "solid preparation...intended to dissolve or disintegrate slowly").

1. Petitioner's New Evidence Supports PO's Position that Dohil Teaches a Slow Dissolving Lozenge

Petitioner attempts to rebut PO's arguments regarding Dohil by providing new evidence purporting to show (i) that lozenges disintegrate within 60 seconds and (ii) a lozenge that disintegrates in 60 seconds would produce a larger volume (4-5 mL/min), not the 1 mL Petitioner previously argued. Reply, 6-12. However, the new

evidence does not actually disclose a lozenge that disintegrates in 60 seconds, but one that dissolves over several minutes. Further, the volume of saliva produced by a conventional lozenge that disintegrates slowly over several minutes, matches the liquid volume Dohil teaches for dissolving its lozenge and achieving pan-esophageal coating. EX1083, 303-304; EX1002, [0032], [0067]. For example, a lozenge that dissolves over 2-3 minutes would produce 8-15 mL saliva based on Petitioner's new and belated evidence showing stimulating activities result in saliva production of 4-5 mL/min.

a. Petitioner Mischaracterizes its Impermissible and Delayed Evidence Purportedly Showing Lozenges Disintegrate within 60 Seconds

The Petition does not cite to, and Petitioner's expert even admitted that he was not aware of, lozenges that disintegrate within 60 seconds. EX2011, 63:6-21. To fill in the gaps in its argument, Petitioner belatedly and impermissibly cites to several new references purportedly disclosing rapidly disintegrates lozenges, none of which actually disclose or enable a lozenge that disintegrates within 60 seconds, let alone 30 seconds.

Remarkably, Petitioner's expert testified that he did not read these references as a whole, and ignored the express and contradictory disclosures. EX2018, 11:24-42:15. Instead, Petitioner's expert simply read the word "fast" or "rapid" and went to FDA Guidance. EX2018, 11:24-12:5 (regarding EX1075); 13:25-14:20 (same);

16:21-25 (regarding EX1076); 23:5-9 (regarding EX1077); 24:25-24:4 (same); 26:9-18 (same); 27:15-22 (regarding EX1078); 28:10-29:10 (same); 33:1-19 (regarding EX1079); 34:18-36:2 (regarding EX1080); 39:13-41:2 (regarding EX1081); 41:20-42:15 (regarding EX1082). This is not surprising because, as discussed below, these references do not teach lozenges that disintegrate in 60 seconds and instead are consistent with PO's position that lozenges as known by a POSA to dissolve slowly. *In re Suong-Hyu Hyon*, 679 F.3d 1363, 1367 (Fed. Cir. 2012) ("It is impermissible within the framework of section 103 to pick and choose from any one reference only as much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." (quoting *In re Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965))).

- McEntee's examples show that the dosage forms **dissolve over 5-10 minutes**. EX1075, Examples 1, 2, 5, and 9. Further, McEntee explicitly states that "rapid release" is understood to mean that 80% of the active agent is released **within 45 minutes**. EX1075, 8:12-23.
- Martin discloses several oral dosage forms, including tablets and lozenges, which dissolve over anywhere from 20 seconds **to 120 seconds**. EX1076, ¶[0067]; *see also* EX2018, 17:19-18:2. Martin does not state that the lozenge disintegrates within 60 seconds or 30 seconds, or provide an enabling example

of such a lozenge. A POSA reading Martin, knowing the art-recognized definition of ODT and lozenge (i.e., ODTs disintegrate within 30 seconds, and lozenges dissolve “slowly”), would understand Martin as teaching a lozenge that releases a drug or dissolves in 120 seconds, whereas the other listed dosage forms, like tablets, can disintegrate faster, such as 20 to 30 seconds. EX1076, ¶[0067]; *see also* EX2013, 413; EX2014, 201.

- Mezaache describes quick dissolving tablets containing a taste-masking coating. EX1077, [0052], [0093]. Mezaache provides no examples of lozenges that dissolve within 60 seconds, and only exemplifies tablets. EX1077, [0093], [0105], [0116], [0127].
- Augsburg focuses specifically on tablets with sustained release or enteric coatings. EX1078, [0006]. While Augsburg defines a “fast-disintegrating tablet” as a tablet that disintegrates in the mouth within 60 seconds, it provides no definition or description for a lozenge. EX1078, [0061]. Augsburg only exemplifies tablets and provides no examples of lozenges that disintegrate within 60 seconds. EX1078, [0006].
- Tang only refers to a lozenge once, citing to McEntee. As discussed above, McEntee does not actually teach or enable a lozenge that disintegrates within 60 seconds. EX1079, 14:9-14.

- Singh discloses a “quick-dissolving lozenge or tablet.” EX1080, [0043], cl. 11. Singh defines “dissolve” as occurring with 15, 6, or 5 minutes. EX1080, [0028]. Singh describes a lozenge that dissolves at a “rapid rate” as dissolving in 2-3 minutes and “quick-dissolving” tablets as dissolving in 5 minutes. EX1080, [0104]-[0105]. Notably, Petitioner cites to claim 11 for support, but omits claim 12 that claims dissolution in 6 minutes or less. Reply, 8; EX1080, cl. 12.
- Barman does not disclose any examples of a lozenge, only fast dissolving tablets. EX1081, [0035]. Barman also discloses that its “fast disintegrating tablets” have a disintegration time of 5 minutes, which directly contradicts Petitioner’s reliance on FDA Guidance. EX1081, [0036].
- Than mentions a “quick-dissolving lozenge,” but provides no disintegration rate. EX1082, 2.

Based on the above, a POSA reading these references would understand the disclosure to be consistent with the art-recognized definition, and PO’s position, that lozenges dissolve slowly and are not ODTs that disintegrate within 60 seconds.

Ignoring what the references actually disclose, and based solely on the use of the term “fast,” Petitioner’s expert relied on FDA Guidance to argue that these lozenges in EX1075-1082 disintegrate within 30 seconds. EX2018, 11:24-12:5 (regarding EX1075); 13:25-14:20 (same); 16:21-25 (regarding EX1076); 23:5-9 (regarding EX1077); 24:25-24:4 (same); 26:9-18 (same); 27:15-22 (regarding

EX1078); 28:10-29:10 (same); 33:1-19 (regarding EX1079); 34:18-36:2 (regarding EX1080); 39:13-41:2 (regarding EX1081); 41:20-42:15 (regarding EX1082). None of these references cite the FDA Guidance and, moreover, the FDA Guidance is directed to ODTs, not lozenges, which the art teaches are different – i.e., a lozenge is not an ODT. Further, the FDA Guidance does not teach the use of ODTs to topically deposit any drug on the esophagus, or treatment of any disease. *See* POR, 18. Thus, these references do not rectify the deficiency in the Petition that lozenges are not ODTs and do not rapidly disintegrate as defined in the FDA Guidance for ODTs. On the contrary, the newly cited references supports PO's position that a lozenge dissolves slowly over several minutes, as it is defined in the art.

b. The Claimed ODT Would Not Achieve Dohil's Intended Purpose of Producing 8-12mL of Liquid to Provide Pan-Esophageal Coating

Petitioner argues that placing a lozenge in the mouth increases saliva production to 4-5mL/min, and that it would provide “the viscous solution disclosed in Dohil that coats the esophagus.” Reply, 11 (citing EX1083, 303-304). As an initial matter, Petitioner's new evidence and argument is late and should not be considered. Petitioner's argument is also incorrect. A lozenge that dissolves slowly, such as over at least 2-3 minutes, would produce 8-15mL saliva, the same amount of liquid Dohil requires for pan-esophageal coverage to effectively treat EoE. EX1002, [0067]. This is further supported by Dohil, which specifically teaches using a lozenge to produce

8-12mL liquid for pan-esophageal coating (“its volume (8-12 ml) provides pan-esophageal mucosal coverage...” and “the lozenge may be ground or otherwise dissolved...reaching a total volume presented in the embodiments herein,” i.e. 8-12mL). EX1002, [0032], [0067]. In contrast, the claimed ODT disintegrates within 30 or 60 seconds, and at this disintegration rate, would produce at most 2 or 5mL liquid, which is 2-6 times less than Dohil’s 8-12mL required for pan-esophageal coating and efficacy. EX1083, 303-304. Thus, Petitioner’s new evidence supports PO’s argument that Dohil teaches a lozenge that dissolves over several minutes, not within 60 seconds.

Because an ODT that disintegrates in 30 seconds or 60 seconds would not achieve Dohil’s intended purpose and principal of operation of administering 8-12mL of liquid to the esophagus to provide pan-esophageal coverage, a POSA would not have considered Dohil to teach an ODT, and would have had no motivation or reasonable expectation of success to treat EoE with the claimed ODT. Petitioner attempts to circumvent this, citing PO’s expert, to manufacture a reasonable expectation of success by implying that a POSA would have known – as of the ’729 patent’s filing – that 1-2mL of saliva is a sufficient amount to deposit a topical corticosteroid to the esophagus. Reply, 11. Petitioner, however, misconstrues the testimony. PO’s expert actually testified that the ’729 patent is the first disclosure of a topical corticosteroid being deposited onto the upper GI tract using an ODT that

dissolves in 60 or 30 seconds. EX1072, 25:15-27:5. This was not, as Petitioner suggests, known before the '729 patent, but information that was derived from the '729 patent itself. Such a result is surprising and unexpected.

2. No Motivation to Modify Dohil's Lozenge

Petitioner argues that Dohil's lozenge or similar tablet is an ODT, and that ODTs are designed for patients with difficulty swallowing. Pet., 2, 7-8; Reply, 4-5; *see also* EX1018, 434. However, Dohil states that for patients who may have difficulty with the "dissolving lozenge, the lozenge can be ground up or otherwise dissolved...reaching a total volume presented in the embodiments herein." i.e., 8-12mL. EX1002, [0032]. Petitioner asserts, without support, that this disclosure in Dohil should be ignored because it relates to patients with dexterity, reflex or other symptoms making use of a lozenge difficult. Reply, 12-14. If, as Petitioner contends, a lozenge is an ODT, then these same patients, for the same reasons, could not use an ODT and thus there would be no motivation to modify Dohil's lozenge. Nonetheless, this disclosure confirms Dohil's lozenge *is not* an ODT that would rapidly disintegrate because if it were, the lozenge would not need to be "ground up" or dissolved in 8-12 ml of a liquid which is then swallowed to treat EoE. EX1002, [0032], [0067].

3. Dohil's Disclosures Focus on a Liquid Formulation

Contrary to Petitioner's assertion, Dohil's liquid formulation is not a

distraction, but rather the invention of Dohil, and the only formulation exemplified and tested. Reply, 4. As Petitioner points out, Dohil's examples and embodiments show "proof-of-concept"² of an oral liquid formulation that successfully treats EoE. Reply, 5. Because Dohil's liquid formulation was efficacious, the "natural next step," would be to make a commercially viable *liquid* formulation, not switching to an entirely different disintegrating tablet as proposed by Petitioner. Reply, 6. As PO's expert explained in his deposition there were many commercially acceptable liquid formulations on the market, and a POSA would have been able to take Dohil's "proof of concept" formulation and make a commercially viable liquid formulation for Dohil's larger clinical study. EX1072, 99:2-101:25, 104:24-106:25. In fact, that is exactly what happened. Dohil's "proof of concept" formulation was developed as "Eohilia," a liquid budesonide composition for treating EoE sold by Takeda Pharmaceuticals, Inc. Dohil was issued as U.S. Patent No. 8,324,192 which is listed in the Orange Book for Eohilia. PO was the first to develop an ODT for EoE, which

² The only proof-of-concept provided in Dohil must be the efficacy of an 8-12mL liquid formulation. As explained in the '729 patent and Dohil, corticosteroids were already known treatments for EoE. EX1001, 1:30-35; EX1002, [0006]; *see also* EX1014 (showing budesonide has previously been used to treat EoE); EX1015 (same).

is being investigated in Phase 3 clinical trials. As Petitioner acknowledged, Dohil's liquid formulation worked, and thus there would be no motivation to convert Dohil's liquid formulation to an ODT that disintegrates within 60 seconds or less. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349-50 (Fed. Cir. 2000) (affirming non-obviousness where "there was no apparent disadvantage" to the prior art mechanism); *Apple Inc. v. Luxembourg S.A.*, IPR2017-02041, slip op. at 24-25 (PTAB Mar. 8, 2018) (Paper 10) (denying institution where Petitioner failed to address whether existing methods already attained the stated goal).

4. Preparing an ODT Based on Dohil is Impermissible Hindsight

Petitioner incorrectly argues that a POSA would have combined Dohil with the general knowledge of a POSA alone³ or in further view of Venkatesh to arrive at the claimed invention because "rapidly dissolving solid formulations were known to have several advantages," including stability, dosing, and manufacturing. Reply, 5. Petitioner's argument fails for several reasons.

First, neither Dohil nor any other prior art reference discusses problems with

³ Pursuant to Director Stewart's July 31, 2025 Memorandum enforcing 37 C.F.R. § 42.104(B)(4), Petitioner improperly uses the "general knowledge" of a POSA to supply missing claim limitations. *See, e.g., Pet.*, 23-26, 36-37, 41, 50-51.

Dohil's liquid, and a POSA would not have recognized Dohil's liquid to have issues with stability, dosing, manufacturing, or the like, necessitating a change in type of dosage form to an ODT. *In re Schweickert*, 676 F. App'x 988, 994–96 (Fed. Cir. 2017) (finding no motivation to pursue a modification where the “record describes no problem in [the prior art] that would be resolved by the [proposed modification].”) As explained in PO's Response, neither Dohil, nor Petitioner or its expert, identify any issues with Dohil's liquid formulation warranting any change. POR, 29.

Second, if stability, dosing, or manufacturing, were a problem, Petitioner fails to explain why Dohil's disclosed lozenge would not have solved those issues. *Ex parte Salerno*, Appeal 2011-004947, Application 12/359,805, 2013 WL 5603478, at *2 (P.T.A.B. Sept. 23, 2013) (reversing rejection because “reason proffered by the Examiner to modify the teachings ... is already performed by” the prior art reference, and is the “result of hindsight analysis”). Thus, if stability, dosing or manufacturing a liquid formulation were an issue—they were not—Dohil discloses a solution that does not require a POSA to create a new, and undisclosed, ODT formulation.

B. Venkatesh's Taste-Masking Preclude the Drug from being Deposited on the Esophagus

Venkatesh is directed to coating bitter drugs with a taste-masking layer to prevent drug release in the mouth. EX1020, [0009], [0018], [0022], [0027], and

Examples 2-6 showing 12% or less drug release in 5 minutes. While taste-masking is disclosed in the '729 patent, PO's expert also testified that taste-masking and the disclosure in the '729 patent incorporating Venkatesh is not claimed because taste-masking prevents the corticosteroid from being topically deposited on the upper GI tract. EX1072, 132:22-135:7; POR, 33; *see Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) ("We do not read limitations from the specification into claims; we do not redefine words.").

Petitioner, in its Reply, is relying on the '865 patent to rebut PO's argument that Venkatesh cannot be combined with Dohil to arrive at the claimed ODT. Reply, 14-17; EX1085. Petitioner is trying to remedy deficiencies in its Petition, which Petitioner cannot do. Further, Petitioner's argument that the '865 patent is particularly important for the invention claimed in the '729 patent because it is cited in the '729 patent is simply wrong. Reply, 16. The '865 patent is directed to taste-masking, like Venkatesh, which is an unclaimed embodiment. EX1001, 14:19-46.

Petitioner also misconstrues the '865 patent's discussion of the impact of the taste-masking layer on the drug release profile. Reply, 15-16. As explained in the '865 patent, the purpose of a taste-masking layer is to prevent "immediate release of the microencapsulated drug in the mouth" for at least 1 minute but not interfere with drug release in the gut where adsorption occurs, such that the taste-masked formulation is bioequivalent to a non-taste-masked formulation. EX1085, 7:29-31,

9:15-30 (“An ideal taste-masking microcapsule would allow no dissolution of the drug at all in one minute.”). This allows for taste-masked ODTs to be substituted for conventional immediate release tablets. None of Petitioner’s citations to the ’865 patent indicate that the drug is released in the esophagus. Reply, 15-16. In fact, the ’865 states the opposite. Specifically, the ’865 patent discloses: “The process parameters, microcapsule components, and relative quantities of components described hereinabove will generally provide a ‘targeted’ release profile, i.e., *wherein drug release does not generally occur in the mouth*, but does occur very shortly thereafter, and is virtually complete *within a matter of minutes*...Also, the ability to provide at least about 75% or even greater dissolution at dissolution times of about *30 minutes*, or even more preferably at dissolution times of *about 15 minutes*, is even more preferred.” EX1085, 8:37-9:14. This confirms the ’865 patent releases the drug in the stomach, not the mouth or esophagus.

Petitioner’s argument that a taste-masking layer would release a sufficient amount of drug in the esophagus is unsupported and illogical. Reply, 15-17. In order for Petitioner’s position to be correct, the taste-masking layer must provide a burst release of drug within 1-2 seconds following 1 minute of no drug release. EX1085, 7:29-31, 9:15-30 (“An ideal taste-masking microcapsule would allow no dissolution of the drug at all in one minute.”). However, the data in the ’865 patent’s examples also do not show drug release occurring within 1-2 seconds after 1 minute of no drug

release. EX1085, 12:43-14:45. Petitioner's fails to explain how a taste-masked drug that does not release any drug for 60 seconds, would suddenly release all drug instantaneously such that a therapeutically effective amount of the drug is deposited on the esophagus. Reply, 17.

This understanding of "immediate release" as complete drug release in the gut is evidenced by Venkatesh's Examples 2-6 showing 12% or less drug release in 5 minutes. EX1020, [0035]-[0054]. Thus, a POSA would understand "immediate release" in the context of the '865 patent to refer to complete release of the drug in the gut within 15 minutes, such that the drug is bioequivalent to a non-taste-masked form.

Petitioner's expert argued that the '865 patent's discussion of the mechanism for drug release – pores in the taste-masking coating that allow for drug release (EX1085, 9:31-45) – indicates that a drug could be deposited on the esophagus after administration. EX2018, 66:2-12; Reply, 15-16. This is incorrect for the reasons explained above and is not a POSA's understanding of immediate release as used in the '865 patent. This discussion in the '865 patent is purely theoretical – the paragraph begins with "not limited by any theory" and provides two theories. Specifically, the '865 patent states that "it is believed" that drug release occurs through either 1) pores in the taste-masking coating or 2) breakage of the coating. EX1085, 9:30-55. The latter theory, breakage of the taste-masking coating, does not

fit Petitioner's argument that drug leaks through pores in the taste-masking layer immediately upon contact with saliva. Notably, the '865 patent also describes the taste-masking layer as an "impervious coating," teaching that the drug cannot diffuse through the polymer coating. EX1085, 1:65, cl. 7.

It is also non-sensical and inconsistent for Petitioner to argue that the claims encompass taste-masking (Reply 14-15) while also arguing that the mouth is part of the upper GI tract and ODTs achieve systemic absorption in the mouth, so a POSA would be motivated to use an ODT (Reply, 1). If the mouth is part of the upper GI tract, then a POSA formulating a topically acting drug for topical delivery to the upper GI tract would not combine Dohil or Grother with Venkatesh's taste-masking technology because it is designed to *prevent* drug release and absorption in the mouth.

Petitioner has failed to show how the '865 patent demonstrates that Venkatesh's taste-masking layer would allow the topical corticosteroid to be deposited in the esophagus. Thus, Petitioner has not provided any motivation to combine Venkatesh with Dohil or Grother and gives no reason for a POSA to have developed the claimed ODT with taste-masking technology for the treatment of EoE.

C. Grother Does Not Teach Using a Topical Corticosteroid for Topical Therapy in its Platform Technology

Petitioner's argument regarding Grother is based solely on the fact that Grother lists budesonide and fluticasone in its laundry list of drugs. Reply, 21-23. Petitioner argues that Grother's disclosure shows that budesonide and fluticasone would predictably work with Grother's ODT but offers no reason as to *why* a POSA would look to Grother and make an ODT with a topical corticosteroid when Grother also lists hundreds of other drugs. Reply, 22. This is the epitome of hindsight. The Federal Circuit has made clear that the pertinence of the reference to the inventor's problem "must be recognizable with the foresight of a person of ordinary skill, not with hindsight of the inventor's successful achievement." *Airbus S.A.S. v. Firepass Corp.*, 941 F.3d 1374, 1382 (Fed. Cir. 2019) (quoting *Sci. Plastic Prods., Inc. v. Biotage AB*, 766 F.3d 1355, 1359 (Fed. Cir. 2014)). The pertinence of Grother is not recognizable to the problem of treating EoE. As PO's Response explains, Grother does not mention treating EoE, or any disease, or differentiate between topical and systemically acting drugs. POR, 41-42.

As Petitioner points out, budesonide formulations at the time Grother was filed were enterically coated (e.g., Budenofalk). Pet., 5. Enteric coatings are designed to prevent the drug from being released until after the drug passes into the lower GI/intestines. POR, 6 n.2. Thus, if a POSA were starting with Grother, a POSA

would most likely have enterically coated budesonide, which would not produce the claimed invention.

Petitioner attempts to discredit PO's argument by pointing to a patent publication by PO's expert. Reply, 22 (citing EX1071). This argument is unavailing. EX1071 was introduced improperly for the first time during PO's expert's deposition. In particular, Petitioner points to EX1071, which is PO's expert's patent on a platform drug delivery system, for a list of drugs that work for the disclosed platform drug delivery system. All of the drugs listed in EX1071 share a physical property being charged at a particular pH, which is why they all work for the specific delivery platform. EX1071, [0041]. A POSA reading the patent would understand this physical property, know why those classes of drugs were chosen, and understand that there would be a reasonable expectation of success in using those drugs in the platform technology.

The same is not true for Grother. A POSA reading Grother would understand that Grother is a platform ODT technology that could work for a number of drugs listed, but would have no teaching or guidance from Grother or the prior art to formulate an ODT containing a topical corticosteroid, or have any expectation of success that that ODT would treat EoE.

D. Neither Dohil's nor Grother's Dosages Can be Easily Transferred to an ODT Comprising a Topical Corticosteroid

Petitioner argues that a POSA would have an expectation of success in extrapolating dosage amounts from liquid formulations disclosed in Dohil to solid formulations (Reply, 19-20) and from the general disclosure of an ODT in Grother (Reply, 26-27). A POSA would have no reasonable expectation of success in applying either Grother's or Dohil's dosages to the ODTs claimed in the '729 patent. POR, 38, 50-52. There are many considerations that go into modifying the mode of administration and determining the proper dosage.

In changing Dohil's formulation from 8-12mL of liquid to an ODT, a POSA would consider the amount of drug deposited, distribution, and contact time in the upper GI tract. As explained above, an ODT produces less than Dohil's 8-12mL that provides pan-esophageal coverage. There is no teaching in Dohil or Grother regarding how to determine the dose of a topical drug in an ODT based on a liquid. Petitioner cites to several solid formulations that have the same dosage as their liquid counterparts. Reply, 19. It is particularly telling that none of these are topical drugs, let alone topical corticosteroids, but rather systemically acting drugs. EX2018, 43:6-16 (regarding EX1089); 46:15-19 (regarding EX1090); 49:14-19 (regarding EX1091); 54:19-23 (regarding EX1092). Because these drugs are systemic, the same dose would be needed to achieve the same clinical effects.

A POSA would understand Grother's ODT platform relates to dosing generally, and not specific to topically acting drugs. Because Grother discloses a wide range of drugs, it does not teach or enable a POSA any particular dose for an ODT containing a topical corticosteroid that is deposited on the upper GI tract. Additionally, systemic drugs have different dosing considerations which do not apply to topical corticosteroids. Thus, a POSA would have no motivation, or reasonable expectation of successfully modifying Grother's ODT platform, selecting a corticosteroid, or obtaining the correct dose necessary for topical administration in the esophagus.

IV. CONCLUSION

For the foregoing reasons, the Challenged Claims are patentable.

Date: September 10, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), I certify that this surreply complies with the type-volume limits of 37 C.F.R. § 42.24(c)(1) because it contains 4,805 words, according to the word-processing system used to prepare this petition, excluding the parts of this preliminary response that are exempted by 37 C.F.R. § 42.24(c) (including the table of contents, a table of authorities, an exhibits list, a listing of facts, a certificate of service or this certificate of word count, or appendix of exhibits).

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**CERTIFICATION OF SERVICE
UNDER 37 C.F.R. §§ 42.6(e), 42.105(a)**

I, Sanya Sukduang, hereby certify that on September 10, 2025, the foregoing Patent Owner's Corrected Surreply pursuant to 37 C.F.R. § 42.8 were served electronically via email on the following counsel of record for Petitioner as follows:

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