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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. IPR2025-00052
Patent No. 10,632,069

PETITIONER'S REPLY BRIEF

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37 C.F.R. §42.73	4, 5
72 Fed. Reg. 46716 (2007)	3
77 Fed. Reg. 48612 (2012)	4
89 Fed. Reg. 40439 (2024)	3

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Exhibit No.	Description
1001	U.S. Patent No. 10,632,069 to Perrett et al.
1002	U.S. Publication No. 20070111978 to Dohil et al.
1003	EP2482822B1 that was revoked by the European Patent Office
1004	The Opposition Division of the European Patent Office decision revoking EP2484822B1 with auxiliary requested claims
1005	“Guidance for Industry: Orally Disintegrating Tablets,” U.S. Food & Drug Administration, Center for Drug Evaluation and Research (CDER), 2008.
1006	Notice of Publication of FDA Guidance for Industry on Orally Disintegrating Tablets, Federal Register, Vol. 73, No. 242 at 76366, December 16, 2008.
1007	“DRAFT Guidance for Industry: Orally Disintegrating Tablets,” U.S. Food & Drug Administration, Center for Drug Evaluation and Research (CDER), 2007.
1008	International Publication No. WO2000044351 to Grother et al.
1009	Svoboda et al., “Oral formulations of budesonide: a novel treatment for inflammatory bowel disease,” <i>Drugs of Today</i> , 44:857-863 (2008) at 857.
1010	Tan et al., “Eosinophilic gastroenteritis treated with non-enteric-coated budesonide tablets,” <i>European Journal of Gastroenterology & Hepatology</i> , 13:425-427 (2001)
1011	Kolkman et al., “Evaluation of oral budesonide in the treatment of active distal ulcerative colitis,” <i>Drugs of Today</i> , 40:589-601 (2004)
1012	Siewert et al., “Eosinophilic gastroenteritis with severe protein-losing enteropathy: Successful treatment with budesonide,” <i>Digestive and Liver Disease</i> , 38:55-59 (2006)

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1013	Elsing et al., “Budesonide for the treatment of obstructive eosinophilic jejunitis,” Z. Gastroenterology, 45:187-189 (2007).
1014	Aceves et al., “Topical viscous budesonide suspension for treatment of eosinophilic esophagitis,” Journal of Allergy and Clinical Immunology 116:705-706 (2005)
1015	Aceves et al., “Oral Viscous Budesonide: A potential new therapy for eosinophilic esophagitis in children,” American Journal of Gastroenterology, 102:1-9 (2007)
1016	The United States Pharmacopeia, USP 32, 2009 at pages 262-263 “<701> Disintegration”
1017	Danckwerts, “Intraoral Drug Delivery: A Comparative Review,” American Journal of Drug Delivery, 1:171-186 (2003).
1018	Fu et al., “Orally fast disintegrating tablets: developments, technologies, taste-masking and clinical studies,” Critical Reviews in Therapeutic Drug Carrier Systems, 21:433-475 (2004)
1019	Shukla et al., “Mouth Dissolving Tablets I: An overview of formulation technology,” Scientia Pharmaceutica, 77:309-326 (2009) (March 6, 2009)
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1021	RESERVED
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1025	Goodman & Gilman’s: The Pharmacological Basis of Therapeutics, 11th edition, eds. Brunton, Lazo, Parker, 2005
1026	Budenofalk® Brochure (2005)

Exhibit No.	Description
1027	Budenofalk [®] Advertisement (2007)
1028	Dr. Falk Pharma Brochure (2008)
1029	<i>Curriculum Vitae</i> of Alan F. Parr, Pharm.D., Ph.D.
1030	RESERVED
1031	Prosecution history Excerpts from U.S. Application No. 12/896,005, which issued as U.S. 8,771,729
1032	RESERVED
1033	Teitlebaum et al., Eosinophilic esophagitis in children: Immunopathological analysis and response to fluticasone propionate,” <i>Gastroenterology</i> 122:1216-1225 (2002)
1034	RESERVED
1035	U.S. Patent No. 7,122,198 to Singh et al.
1036	U.S. Patent No. 7,229,641 Cherukuri et al.
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1038	RESERVED
1039	Prosecution history Excerpts from U.S. Application No. 17/236,295, which issued as U.S. 11,266,598
1040	The United States Pharmacopeia Convention, Revision Bulletin, August 1, 2008, “<701> Disintegration”
1041	Conway, “Solid dosage forms,” Chapter 4.1 in <i>Pharmaceutical Manufacturing Handbook: Production and Processes</i> , ed. Gad, pages 235-265 (2008)
1042	“Magnesium Stearate,” <i>Handbook of Pharmaceutical Excipients</i> , 5th edition, eds. Rowe et al., pages 430-433 (2006)

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1043	“Mannitol,” Handbook of Pharmaceutical Excipients, 5th edition, eds. Rowe et al., pages 449-453 (2006)
1044	“Povidone,” Handbook of Pharmaceutical Excipients, 5th edition, eds. Rowe et al., pages 611-616 (2006)
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1047	El-Arini et al., “Evaluation of disintegration testing of different fast dissolving tablets using the texture analyzer,” Pharmaceutical Development & Technology, 7:361-371 (2002)
1048	Prosecution History [Excerpts] of U.S. Application No. 15/816,154, which issued as U.S. 10,632,069
1049	Prosecution History [Excerpts] of U.S. Application No. 16/821,464 which issued as U.S. 11,246,828
1050	Declaration of Alan F. Parr, Pharm.D., Ph.D. supporting IPR petition of U.S. 10,632,069
1051-1070	RESERVED
1071	U.S. Publication No. US20110189299 to Okubo and Davies et al.
1072	2025-07-02 Deposition transcript of Dr. Martyn Davies in IPR2024-01197
1073	Schoepfer et al., “Variation in Endoscopic Activity Assessment and Endoscopy Score Validation in Adults With Eosinophilic Esophagitis,” Clinical Gastroenterology and Hepatology, 17:1477-1488 (2019).
1074	2021-04-19 Assignment of U.S. Patent Nos. 10,632,069, 9,486,407, and 8,771,729 from Adare Pharmaceuticals US, L.P. to Ellodi Pharmaceuticals, L.P. recorded at Reel 055966, Frame 0658.

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1075	International Publication No. WO2003074029 to McEntee et al.
1076	International Publication No. WO2009078872 to Martin et al.
1077	U.S. Patent Publication No. 20030124184 to Mezaache et al.
1078	U.S. Patent Publication No. 20050019393 to Augsburg et al.
1079	U.S. Patent No. 7,384,921 to Tang et al.
1080	U.S. Patent Publication No. 20080132535 to Singh et al.
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1082	Than, "Individualized Drugs for Individual Needs," Review of Optometry, 146:38-43 (2009)
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1087	Narmada et al., "Formulation, evaluation and optimization of fast dissolving tablets containing amlodipine besylate by sublimation method," ARS Pharmaceutica, 50:129-144 (2009)
1088	Khan et al., "Taste masking of ondansetron hydrochloride by polymer carrier system and formulation of rapid-disintegrating tablets," AAPS PharmSciTech 8:E1-E7 (2007)
1089	CLARITIN [®] (loratadine) FDA-approved package insert
1090	ZOFRAN [®] (ondansetron) FDA-approved package insert
1091	CLARINEX [®] (desloratadine) FDA-approved package insert
1092	PEPCID [®] (famotidine) FDA-approved package insert

Exhibit No.	Description
1093-1113	RESERVED
1114	November 3, 2025 Oral Hearing Transcript Regarding IPR2025-00052, IPR2025-00054, IPR2025-00055, and IPR2025-00056
1115	U.S. Patent No. 8,771,729 to Perrett et al.
1116	Decision Granting Instituting of IPR, <i>Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.</i> , IPR2024-01197, Paper 10 (PTAB 2025)
1117	Petitioner’s Reply Brief, <i>Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.</i> , IPR2024-01197, Paper 20 (PTAB 2025)
1118	Judgment Granting Request for Adverse Judgment after Institution of Trial, <i>Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.</i> , IPR2024-01197, Paper 41 (PTAB 2025)
1119	2024-10-23 Transcript of Oral Hearing Dismissing Complaint, <i>Ellodi Pharmaceuticals, L.P. v. Dr. Falk Pharma</i> , Case No. 24-cv-01392-PTG (E.D. Va)
1120	Judgment Against Ellodi in <i>Ellodi Pharmaceuticals, L.P. v. Dr. Falk Pharma GmbH</i> , Case No. 4b O 43/24, Regional Court of Dusseldorf, Germany (Feb. 27, 2025) – Original German Language
1121	Judgment Against Ellodi in <i>Ellodi Pharmaceuticals, L.P. v. Dr. Falk Pharma GmbH</i> , Case No. 4b O 43/24, Regional Court of Dusseldorf, Germany (Feb. 27, 2025) – Certified English Language Translation
1122	U.S. Federal Trade Commission (FTC), <i>To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, Chapter 4: Competition Perspectives on Substantive Standards of Patentability</i> (2003)
1123	Comment of the U.S. Federal Trade Commission (FTC), <i>Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting</i> , PTO-P-2024-0003 (2024)

Exhibit No.	Description
1124	2025-11-19 Deposition transcript of Dr. Martyn Davies in IPR2025-00052, IPR2025-00054, and IPR2025-00055
1125	The American Heritage Dictionary of the English Language, 4th ed., 2000 - Definitions of “disintegrate” and “dissolve”
1126	Declaration of Alan F. Parr, Pharm.D., Ph.D. supporting Petitioner Reply for U.S. Patent Nos. 10,632,069, 11,246,828, and 9,486,407

I. INTRODUCTION

The '069 patent claims are obvious over the cited prior art. Dohil discloses a budesonide lozenge or tablet that dissolves rapidly in a patient's mouth. A defining characteristic of an orally dispersing tablet (ODT) is that it disintegrates rapidly in a patient's mouth. Dohil therefore teaches and suggests an ODT that renders the challenged claims obvious. The Patent Owner Response (POR) criticizes Dohil for additionally disclosing liquid formulations and argues that Dohil's lozenge must dissolve slowly. The EPO soundly rejected these same arguments from Patent Owner (PO), and they should be rejected again here. EX1004 ¶¶26.2-26.8.

Grother contains the same disclosures as the '069 patent—both teach ODTs containing corticosteroids including budesonide. PO accuses Petitioner of arbitrarily picking budesonide to use in Grother's ODT. Not so. Grother itself instructs the POSA to use budesonide in Grother's ODT.

PO's purported expert, Dr. Davies, is not a credible witness. He has no experience working with ODTs. EX1072 10:16-11:3. He didn't perform any literature searches to educate himself on the features of ODTs that he mistakenly believed were missing from the prior art. EX1072 42:15-43:14, 56:16-57:9, 134:8-135:7, 183:17-21; EX1124 10:13-11:12, 13:16-14:4, 15:20-23. Still further, PO's counsel shielded him from highly relevant evidence that directly contradicts his opinions by withholding: (1) the EPO's decision determining that Dohil renders obvious corresponding claims,

EX1072 77:22-78:9; (2) the Board’s adverse judgment against PO in IPR2024-01197, EX1124 17:13-16; and (3) prior art disclosures of rapidly dissolving lozenges, *infra* Section IV.A.1.b.

All of these issues were fully briefed in the highly related matter of IPR2024-01197, in which PO requested and received adverse judgment against patentably indistinct claims. The Board should apply patent owner estoppel to prevent PO from unfairly wasting Board and Petitioner resources by relitigating these issues again here. The challenged claims should be cancelled.

II. PATENT OWNER ESTOPPEL

When confronted with the overwhelming case of obviousness presented by Petitioner in the highly related proceeding of IPR2024-01197, PO requested and received adverse judgment by disclaiming all claims in U.S. 8,771,729 (“the ’729 patent,” EX1115). EX1118 3. PO requested adverse judgment after all briefing had been completed and just 5 days before the final oral argument was scheduled.

The ’069 patent at issue here is a continuation of the ’729 patent. PO cannot reasonably dispute that the claims of the ’069 patent are patentably indistinct from the cancelled ’729 patent claims. PO merely reworded limitation 1[ii] between the patents: in the ’729 patent the limitation reads “at least one disintegrant,” and in the ’069 patent the limitation reads “at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity.” EX1050 Appendix A at 1. Other

minor differences in claim 1 and certain dependent claims between the two patents do not create a patentable distinction. *Id.*

During prosecution, the Examiner repeatedly rejected the '069 patent application claims for obviousness-type double patenting over the '729 claims. EX1048 131, 221-222, 272-273. PO did not dispute the obviousness rejections and instead filed a terminal disclaimer over the '729 patent. *Id.* 106-109. This “terminal disclaimer is a strong clue that a patent examiner and, by concession, the applicant, thought the claims in the continuation lacked a patentable distinction over the parent.” *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1168 (Fed. Cir. 2018).

In fact, PO used terminal disclaimers in several continuation applications to obtain a thicket of duplicative patents. EX1050 Appendix A at 1. Petitioner has been forced to file multiple IPR petitions to address these duplicative claims in this proceeding and the closely related matters of IPR2024-01197, IPR2025-00054, and IPR2025-00055. The PTO has recognized the problems with terminal disclaimers filed over obvious variants in continuation applications. 72 Fed. Reg. 46716, 46719 (2007); 89 Fed. Reg. 40439 (2024). The Federal Trade Commission (FTC) has complained about “out of control” continuation practices and its negative effect on competition. EX1122 28; EX1123 2, 4.

This IPR and its related IPRs illustrate the inefficiencies recognized by the PTO and highlighted by the FTC. PO admits this IPR and IPR2024-01197 concern “the same

art and arguments.” POR 10 n.2. PO seeks to relitigate the same issues of unpatentability here, which is wasteful and undermines the AIA’s efficiency aims.

PO’s attempt to relitigate the same and duplicative patentability issues here should be estopped under 37 C.F.R. §42.73(d)(3). That rule prohibits “taking action inconsistent with [an] adverse judgment.” 37 C.F.R. §42.73(d)(3). “The purpose of the estoppel provision is to provide estoppel against claims that are patentably indistinct from those that were lost.” *Arthrex, Inc. v. Smith & Nephew, Inc.*, 880 F.3d 1345, 1350 (Fed. Cir. 2018). An important purpose of Rule 42.73(d)(3) is to “ensure the integrity of the trial procedures.” *Rules of Practice for PTAB Trials*, 77 Fed. Reg. 48612, 48612 (2012). Preventing a patent owner “from acting inconsistently with the outcome of an IPR proceeding ensures that the decisions in those proceedings have a practical effect.” *SoftView LLC v. Apple Inc.*, 108 F.4th 1366, 1373 (Fed. Cir. 2024).

In *SoftView*, the Federal Circuit explained that Rule 42.73(d)(3) “prohibits a patent owner from taking action inconsistent with the adverse judgment in various proceedings, **including IPR proceedings**.” *SoftView*, 108 F.4th at 1369;¹ *Rules of Practice*, 77 Fed. Reg. at 48649 (explaining Rule 42.73(d)(3) applies to judgments in IPRs). The Federal Circuit expressly empowered the Board to apply Patent Owner estoppel to issued claims, which it should do here. *SoftView*, 108 F.4th at 1375

¹ All emphases supplied unless otherwise specified.

(remanding “for further consideration of the application of the regulation to issued claims”); *see also Ex parte Nelson*, 2020 WL 8186425, at *11 (PTAB 2020) (“Making such an argument [would] contradict[] the adverse judgment in the prior [IPR] and hence [would be] taking action inconsistent with the adverse judgment” in violation of Rule 42.73(d)(3).).

In IPR2024-01197, Petitioner presented compelling obviousness arguments against the ODTs recited by the ’729 patent based on Dohil, as well as Grother in view of the FDA Guidance. Because PO previously sought and received adverse judgment on all claims of the ’729 patent, PO should be estopped under Rule 42.73(d)(3) from arguing that (1) Dohil and (2) Grother in view of the FDA Guidance do not teach or suggest an ODT as recited by the cancelled claims of the ’729 patent and the claims of the ’069 patent, which are patentably indistinct from the ’729 patent claims.

Enforcing the general provision in Rule 42.73(d)(3) by prohibiting PO from taking action inconsistent with the ’729 patent adverse judgment ensures that the judgment has a practical effect and preserves the integrity of the proceedings “by preventing actions that would undermine the outcome of [the ’729 patent proceeding].” *SoftView*, 108 F.4th at 1373. That is the only fair outcome in view of the adverse judgment requested and received by PO.

III. RELATED MATTERS

To date, all decisions in related matters have ruled against PO and in favor of Petitioner. As discussed above, the PTO recently entered adverse judgment against PO in closely related IPR2024-01197. The EPO determined that the corresponding European claims were obvious over Dohil. Petition 15-18. The Eastern District of Virginia (EDVA) and German courts have also ruled against PO (and for Petitioner).

PO filed a lawsuit in the EDVA, where it wrongly accused Petitioner of breaching a 2022 settlement agreement between the parties based on Petitioner filing the petition in IPR2024-01197. The EDVA dismissed that case because the settlement agreement has a binding forum selection clause that requires all disputes concerning the agreement to be adjudicated in Germany. EX1119 20:1-21:25.

Petitioner filed the same wrongful accusations of breaching the 2022 agreement in the German regional court of Düsseldorf. The German court determined that PO's accusations were completely unfounded, and it issued sanctions in the form of attorneys' fees against PO for "culpably breach[ing]" the agreement and "act[ing] at least negligently" by filing suit in Virginia. EX1121 20-22.

The Board should rule against PO (and for Petitioner) here as well.

IV. THE CLAIMS OF THE '069 PATENT ARE OBVIOUS

A. Dohil Renders Obvious ODTs To Treat EOE

The Petition provides compelling evidence of obviousness based on Dohil in view of the knowledge of a POSA (Ground 1).² Petition 20-39. PO raises unconvincing arguments. Petitioner succinctly Replies as follows.

1. Dohil Teaches, Suggests, And Motivates Formulating ODTs

Dohil discloses solid budesonide compositions in the form of a lozenge or tablet that “dissolve[s] rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus.” EX1002 ¶[0032]. It was desirable for a rapidly dissolving tablet to dissolve within “several seconds to about a minute.” EX1018 434. Indeed, the FDA Guidance recommends that orally dispersing tablets (ODTs) should “disintegrate[] rapidly, usually within a matter of seconds.” EX1005 2. Such rapid disintegration is a defining characteristic of an ODT, as confirmed by PO’s expert. *Id.*; EX1072 15:10-16:14. The FDA’s Guidance applies to all solid dosage forms that disintegrate or

² The use of the general knowledge of a POSA to render IPR claim limitations obvious is authorized because obviousness “*requires* an assessment of the background knowledge possessed by a [POSA].” *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337-38 (Fed. Cir. 2020) (emphasis in original) (quoting *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 401 (2007)).

dissolve rapidly, including Dohil’s rapidly dissolving lozenges. EX1005 1-2; EX1126

¶14. Dohil therefore teaches, suggests, and motivates formulating rapidly dissolving solid compositions, including ODTs. Petition 25-29; EX1050 ¶¶132-135.

The EPO previously determined that Dohil’s instruction to formulate budesonide in a rapidly dissolving lozenge or similar tablet renders obvious ODTs containing budesonide. EX1004 ¶¶26.3-4, 36.8. PO had a full and fair opportunity to litigate this issue at the EPO.³ PO now asks the Board to reach the opposite conclusion by (i) obfuscating Dohil’s teachings of *solid* ODT formulations of budesonide and selectively emphasizing Dohil’s *liquid* formulations, (ii) incorrectly asserting that all lozenges must dissolve slowly, (iii) mischaracterizing the amount of saliva available to dissolve ODTs, and (iv) misinterpreting Dohil’s other embodiments. Each of PO’s arguments should be rejected.

a) Dohil Teaches And Motivates ODTs

PO attempts to distract from Dohil’s rapidly dissolving lozenges and tablets by focusing on Dohil’s allegedly preferred liquid compositions. POR 2-3, 12-15, 22, 26,

³ PO argues that the EPO decision is “irrelevant.” POR 23-25. However, “notwithstanding any differences in the law,” an EPO decision is “relevant” and “probative.” *Ericsson, Inc. v. Intellectual Ventures II LLC*, IPR2014-00915, Paper 37 at 7 (PTAB 2015).

30-33. Dohil, however, is “considered for everything that it teaches, not simply [its] preferred embodiment.” *In re Applied Materials, Inc.*, 692 F.3d 1289, 1298 (Fed. Cir. 2012).

Dohil instructs the POSA to formulate budesonide as a rapidly dissolving lozenge or tablet to treat inflammation of the esophagus. EX1002 ¶[0032]. In the related IPR2024-01197, the Board recognized that Dohil teaches “corticosteroid compositions in the form of ‘a dissolving tablet, a dissolving wafer, a capsule, or a gel capsule,’ including embodiments wherein such ‘tablets, wafers, and capsules are formulated with at least one excipient to deliver a viscous form of the corticosteroid to the esophagus.’” EX1116 9 (quoting EX1002 ¶[0013]).

Dohil’s instruction to formulate budesonide as a rapidly dissolving lozenge/tablet was intuitive and compelling to a POSA in view of Dohil’s express desire to treat EOE. EX1002 ¶¶[0010], [0011], [0015]. A primary symptom of EOE is difficulty swallowing, EX1033 1218 (Table 1), as admitted by PO. EX1001 1:29-33; EX1073 1478 (admitting “dysphagia is the most frequent complaint of adult EOE patients”);⁴ EX1072 22:16-

⁴ EX1073 was co-authored and funded (*id.* 1477, 1488) by Adare Pharmaceuticals, which was the previous assignee of the ’069 patent that changed its name to Ellodi Pharmaceuticals in 2020. EX1074.

23:5; EX1126 ¶¶17-19. Rapidly dissolving tablets were especially desirable for treating patients with difficulty swallowing. EX1005 1; EX1018 434; Petition 7-15.

PO asserts there was no motivation to follow Dohil’s instruction to prepare a rapidly dissolving lozenge/tablet because Dohil did not recognize any problems with the liquid formulation from Dohil’s working examples. POR 29-31. PO ignores that rapidly dissolving solid lozenges/tablets were known to have several advantages, such as “[c]onvenience of administration and accurate dosing as compared to liquid formulations,” EX1019 311, and “good stability, accurate dosing, easy manufacturing, small packaging size, and easy handling by patients.” EX1018 434; EX1050 ¶70; EX1126 ¶20; EX1116 41.

Dohil’s liquid formulations were rudimentary and merely provided a proof-of-concept that oral formulations of budesonide successfully treat EOE. EX2011 71:16-72:2. Dohil calls for “larger placebo-controlled clinical trials [to] provide more information about dosing, efficacy and long-term safety.” EX1002 ¶[0067]. PO’s expert admitted that conducting such clinical trials with Dohil’s rudimentary liquid formulation would require a medical team to mix Pulmicort with 10 packages of Splenda twice daily for three months (i.e., 180 times) *per patient*, EX1072 93:7-95:7, 96:17-24, which would need to be repeated for hundreds to thousands of patients across several different countries, *id.* 87:14-88:19, 89:13-90:18. It was a natural next step for the POSA to follow Dohil’s instruction to formulate budesonide as a solid rapidly dissolving

lozenge/tablet because the known benefits of solid compositions such as convenient administration and good stability would facilitate Dohil’s larger clinical trial. EX2011 72:11-24; EX1126 ¶21. Any of these benefits “provide a reason for combining the elements in the manner claimed.” *KSR* 550 U.S. 398 at 420.

PO notes that Dohil’s liquid formulation was commercialized as “Eohilia” in 2024—fifteen years after the ’069 priority date. POR 32. The relevant POSA was not aware of Eohilia, and its later existence did not diminish the motivation for a POSA to have also followed Dohil’s instruction in 2009 to prepare a rapidly dissolving lozenge/tablet in view of the known advantages of such solid formulations over liquid formulations. *Applied Materials*, 692 F.3d at 1298; EX1126 ¶22. PO’s exhibit admits that ODTs were advantageous over liquid formulations for improved physical/chemical stability and providing smaller dosage forms due to the elimination of water. EX2017 344. ODTs were often easier and lower in cost to manufacture than liquid formulations. EX1050 ¶70; EX1018 434; EX1019 311.

b) Rapidly disintegrating lozenges

PO argues that Dohil ¶[0032] cannot teach or suggest a rapidly dissolving solid formulation because it uses the word “lozenge,” which PO asserts requires a slowly dissolving formulation. POR 15-16, 27-29. PO unsuccessfully raised this argument at the EPO. EX1004 ¶26.2. The EPO rejected PO’s argument and determined that Dohil ¶[0032] “clearly describes a lozenge or similar tablet, which rapidly dissolves in the

mouth” and “at least overlap[s]” with orally dispersing tablets. *Id.* ¶26.4; *id.* ¶¶26.1-26.8.

The EPO is correct. Dohil ¶[0032] clearly discloses a “rapidly” dissolving lozenge. Dohil ¶[0032] also discloses similar “tablets” that dissolve “rapidly” in the mouth. Dohil’s tablet that rapidly dissolves in the mouth fairly teaches and suggests an ODT, especially in view of the industry accepted ODT definition as “a solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue.” EX1116 37; EX1005 2; EX1126 ¶23; *supra* Section IV.A.1.

PO argues that Dohil’s rapidly “dissolving” lozenge cannot suggest an orally “disintegrating” tablet (ODT) because “disintegrating” is different than “dissolving.” POR 13, 27. The terms “dissolve” and “disintegrate” were often used interchangeably in the prior art because they occur near simultaneously with ODTs. EX1126 ¶¶24-25; EX2007 ¶47. For example, the FDA Guidance explains that ODTs “are designed to *disintegrate or dissolve* rapidly on contact with saliva.” EX1005 1; EX1018 433 (ODTs “dissolve or disintegrate in the mouth”); EX1125 523; EX1020 ¶¶[0003], [0004]; EX1001 2:56-59. The experts agree that, if a POSA were to make any distinction between the terms, a POSA would expect Dohil’s rapidly dissolving lozenge/tablet to disintegrate more rapidly than it dissolves because disintegration (the breakdown of

the lozenge/tablet into smaller particles) begins before dissolution (the process of particles becoming a solute within saliva). EX1126 ¶25; EX1124 25:17-26:19.

PO incorrectly interprets Dohil's lozenge as only providing "an initial rapid release of drug and then dissolv[ing] slowly." POR 15-16, 27-28. The plain reading of Dohil ¶[0032] is that "[t]he lozenge" (i.e., the entire lozenge) would dissolve rapidly in the mouth. EX1126 ¶26. Dohil ¶[0032] contrasts its "rapidly" dissolving lozenge with other formulations "designed for slow release." *Id.* PO's interpretation incorrectly combines these two distinct formulations into one slow release formulation. PO implies that this interpretation is required because rapidly dissolving lozenges were unknown in the prior art. POR 2, 15-16. PO is wrong. Dohil's rapidly dissolving lozenge disclosure is reinforced by numerous other examples in the prior art:

- McEntee teaches "[f]ast melt formulations are typically in the form of tablets or lozenges that dissolve or disperse in a patient's mouth within a minute" and "improve patient compliance." EX1075 3:20-28.
- Martin teaches "orally disintegrating tablets, wafers, pellets, or lozenges of the present invention release their analgesic content" including within "about 20 seconds to about 60 seconds," EX1076 ¶[0067], and "[g]enerally, a sublingual tablet, wafer, pellet, or lozenge should dissolve or disintegrate quickly," *id.* ¶[0060].

- Mezaache teaches “lozenges, which, when ingested, quickly dissolve in the mouth,” EX1077 ¶¶[0002], [0003], “generally in less than 30 seconds,” *id.* ¶[0040].
- Augsburg teaches “tablets or lozenges which have rapid disintegration rates,” EX1078 ¶[0043], including “a rapidly disintegrating lozenge,” *id.* ¶[0143], between 0-60 seconds, *id.* ¶[0061].
- Tang teaches “a tablet or lozenge” that dissolves within a minute. EX1079 14:9-14.
- Singh teaches a “quick-dissolving lozenge or tablet.” EX1080 Claim 11, ¶[0057].
- Barman teaches a “fast dissolving lozenge.” EX1081 Claims 31, 33, ¶[0044].
- Than teaches a “quick-dissolving lozenge.” EX1082 2; EX1126 ¶¶27-39.

PO was aware that rapidly dissolving lozenges were disclosed in the prior art, EX1117 7-8, but failed to address them in its POR. Even worse, PO failed to inform its expert about these numerous prior art examples such that his opinions were based on an uncorrected belief that rapidly dissolving lozenges did not exist in the prior art. EX1124 40:16-41:16; EX2007 ¶91. PO’s position and reliance on its uninformed expert is devoid of credibility.

Between 1994-2004, rapidly dissolving lozenges dissolved within 60 seconds or less. EX1077 ¶[0040]; EX1075 3:20-28; EX1078 ¶¶[0043], [0061]; EX1079 14:9-14. Between 2006-2007, rapidly dissolving lozenges were disclosed that dissolved

within a few minutes. EX1081 ¶[0036]; EX1080 ¶¶[0104]-[0105]. In 2007, a rapidly dissolving lozenge was disclosed that dissolved within about 5-120 seconds. EX1076 ¶[0067]. In December of 2008, the FDA Guidance standardized the disintegration rate for rapidly dissolving dosage forms at 30 seconds or less as tested via USP <701>. EX1005 2-3. Thus, by the 2009 priority date of the '069 patent, a POSA reading Dohil's disclosure of a rapidly dissolving lozenge/tablet would have viewed the disintegration time for the lozenge/tablet as desirably being 30 seconds or less. EX1126 ¶¶40-41.

Dohil's use of the word "lozenge" to describe its rapidly dissolving composition is appropriate because lozenges are typically used to formulate topical drugs that "have very few systemic adverse effects" and "treat[] local mouth diseases and sore throats." EX1017 181; EX1126 ¶42. A primary symptom of EOE is difficulty swallowing due to inflammation of the throat/esophagus. *Supra* Section IV.A.1.a. Budesonide was known to topically treat inflammation of the esophagus. Petition 5-6. Dohil's description of a rapidly dissolving "lozenge" appropriately signals to the POSA that the formulation will rapidly dissolve to release budesonide to topically treat a patient's inflamed throat/esophagus.

PO rehashes its unsuccessful argument from the EPO that Dohil's rapidly dissolving lozenge/tablet cannot include a disintegrant. POR 28-29; EX1004 ¶26.2. In rejecting this argument, the EPO explained that Dohil's ¶[0032] rapidly dissolving

tablets “necessarily require an excipient which facilitates their dispersion and dissolution.” EX1004 ¶26.4. Dohil discloses disintegrants for use in its formulations. EX1002 ¶[0037]. It was known that the rapid disintegration of a lozenge or tablet is desirably aided by at least one disintegrating agent. EX1018 446-47; EX1050 ¶¶124-126; EX1076 ¶[0064]; EX1077 ¶[0010]; EX1078 ¶¶[0083]-[0084], [0079], [0085]; EX1080 ¶¶[0061], [0083]; EX1126 ¶43.

c) Patients produce sufficient saliva to coat the esophagus

PO asserts that Dohil requires a large volume (8-12 mL) of a viscous liquid to coat the esophagus. PO argues that a patient’s saliva is of insufficient volume (1-2 mL) and viscosity to coat the esophagus with a rapidly dissolving lozenge or tablet. POR 14-16, 28, 33-34, 38. There are multiple problems with PO’s argument.

First, PO’s argument goes against Dohil’s express disclosure. Dohil teaches that its rapidly dissolving lozenge/tablet does “dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus.” EX1002 ¶[0032]. Dohil explains that its tablets “are formulated with at least one excipient to deliver a viscous form of the corticosteroid to the esophagus.” *Id.* ¶[0013]. Such an excipient “increase[s] the resulting liquid viscosity of the dissolved tablet, enabling it to reach the esophagus, for example, to coat the esophagus.” *Id.* ¶[0037]; *id.* ¶[0043]; EX1124 29:25-31:6, 33:6-34:25, 109:2-110:5. Based on Dohil’s teachings, a POSA reasonably expected that the

patient's saliva would successfully mix with the rapidly dissolving lozenge/tablet to produce a solution of sufficient volume and viscosity to coat the esophagus. EX1126 ¶¶46-47.

Second, PO mischaracterizes Dr. Parr's deposition testimony to infer that a patient would "only produce about 1-2 mL of liquid" with Dohil's lozenge/tablet. POR 33. Dr. Parr actually testified that a patient tends to *swallow* 1-2 mL of liquid at a time. EX2011 50:17-24. It was known that 1-2 mL of saliva triggers a swallowing reflex. EX2005 304. PO failed to ask Dr. Parr how much saliva a patient produces *when a lozenge or tablet is placed in the mouth*. It was known that placing a substance in the oral cavity (such as a lozenge/tablet) causes a patient's saliva production to increase to about 4-5 mL/min or more. *Id.* 303-304. This 4-5 mL/min of saliva trickles slowly down the esophagus as it is swallowed approximately 1-2 mL at a time. *Id.* 304; EX2011 50:17-51:3, 52:6-8. This volume of saliva is sufficient to dissolve Dohil's lozenge/tablet and produce the viscous solution disclosed by Dohil that coats the esophagus. EX1002 ¶¶[0032], [0013], [0037], [0043]; EX1126 ¶¶48-51. PO's expert admitted Dohil discloses that **5 mL** of a viscous liquid is sufficient to coat the esophagus. EX1124 64:5-65:24; EX1002 ¶[0031] ("the dosage may be provided in, for example 5-50 ml"); EX1126 ¶¶44-45. PO's expert also admitted that the viscous solution of budesonide formed from the rapidly dissolving lozenge/tablet coats the esophagus so that it adheres to the esophageal tissue for "sufficiently long such that you

have the topical treatment of the EOE by budesonide.” EX1124 28:16-29:1. PO’s expert further admitted that 1-2 mL of saliva is, in fact, sufficient to deposit a corticosteroid topically in the upper gastrointestinal tract. EX1072 25:15-27:5.

PO incorrectly argues that a POSA would not have followed Dohil’s instruction to prepare a rapidly dissolving lozenge/tablet because it would “change the principle operation” of Dohil’s liquid formulation and render the lozenge/tablet “unsatisfactory for its intended purpose.” POR 32-33. Dohil explains that its rapidly dissolving lozenge/tablet operates by dissolving “rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus.” EX1002 ¶[0032]; *id.* ¶¶[0013], [0037], [0043]. Dohil’s rapidly dissolving lozenge/tablet therefore has the same principle of operation as its liquid formulations, which is to provide a solution of budesonide that coats the esophagus. Dohil’s prior art embodiments operate on the same principles and support a finding of obviousness. *See In re Umbarger*, 407 F.2d 425, 430-31 (CCPA 1969); EX1126 ¶52.

Dohil’s solid lozenge/tablet was expected to operate for Dohil’s intended purpose of coating the esophagus. The excipients in Dohil’s rapidly dissolving lozenge/tablet mix with the patient’s saliva to produce a viscous solution containing budesonide that coats the esophagus. EX1002 ¶¶[0032], [0013], [0037], [0043]; EX1072 17:19-22; EX1126 ¶53. The EPO explained that Dohil’s rapidly dissolving lozenges/tablets provide an “indirect way of forming a budesonide-containing liquid

in situ in the mouth, which is able to coat the esophagus,” EX1004 ¶36.3, because these formulations contain excipients “which are meant to increase the viscosity of the liquid resulting from the dissolution of the tablet,” *id.* ¶26.7.

It was obvious for a POSA to follow Dohil’s instruction to prepare rapidly dissolving lozenges/tablets to improve budesonide formulations for patients suffering from inflammation of the esophagus. *See KSR*, 550 U.S. at 417 (“if a technique has been used to improve one [composition], and a [POSA] would recognize that it would improve similar [compositions] in the same way, using the technique is obvious”).

d) PO misinterprets Dohil’s alternative embodiments

Dohil discloses a rapidly dissolving lozenge/tablet that is dissolved *in a patient’s mouth*, and it also discloses a second (alternative) embodiment where the lozenge is “ground or otherwise dissolved” *in a liquid prior to administration* for the minority of patients that “may have difficulty with a dissolving lozenge.” EX1002 ¶[0032]. These are clearly two alternative embodiments of administration because they are separated by the word “*Or.*” *Id.*

PO argues that Dohil’s second embodiment of administering Dohil’s rapidly dissolving lozenge/tablet cannot suggest an ODT because an ODT is not permitted to be ground/dissolved before administration. POR 28. This is nonsense. Dohil’s second embodiment of administering a lozenge by grinding/dissolving prior to

administration is appropriate for the subpopulation of patients that experience difficulty with a dissolving lozenge (likely due to dexterity, reflex, or other symptomatic issues). EX1002 ¶¶[0032]; EX1126 ¶¶54-56. A POSA would have also recognized that many other patients would benefit from following the first embodiment of administering a rapidly dissolving lozenge/tablet to a patient's mouth because the prior art recognizes that rapidly dissolving lozenges/tablets desirably provide convenient oral administration to improve compliance for many patients. Petition 7-10. This teaches and suggests an ODT, *supra* Section IV.A.1.a, and is more than sufficient for obviousness because any need or problem can “provide a reason for combining the elements in the manner claimed.” *KSR*, 550 U.S. at 420.

2. Dohil teaches inclusion of sucralose

PO incorrectly asserts, without any support by its expert, that Dohil does not disclose sucralose in its rapidly dissolving lozenge/tablet. POR 34. Dohil discloses sucralose in its rapidly dissolving lozenge/tablet formulation at EX1002 ¶¶[0014], [0037], and further motivates the use of sucralose as a sweetener to “render the dissolving tablet palatable.” *Id.* ¶[0037]; Petition 33-34; EX1050 ¶¶159-163.

3. There was a reasonable expectation of success

PO wrongly asserts that Petitioner and its expert were unable to identify any prior art ODT containing a topically active drug deposited in the upper gastrointestinal tract. POR 35. Petitioner and its expert identified Dohil, Grother,

Singh, and Cherukuri, which disclose ODTs containing budesonide. Petition 5-6, 13-14.

Budesonide was known to be topically active. *Id.* 5. ODTs rapidly dissolve in the mouth (which is part of the upper gastrointestinal tract), thereby depositing the drug in the upper gastrointestinal tract. *Id.* 6-7. Petitioner also provided a review article that teaches ODTs were designed to “release the drug to the oral mucosa,” EX1017 178, and that many prior art studies had shown topical therapy with corticosteroids to treat inflammatory mucosal diseases, *id.* 176. Other prior art teaches that ODTs are beneficial “when local action in the mouth is desirable such as local anesthetic for toothaches, oral ulcers, cold sores, or teething.” EX1087 129; EX1088 E1; EX1126 ¶¶7-9.

PO asserts that there was no reasonable expectation of success in arriving at the claims. POR 35-36. The claims are merely directed to ODTs. Formulating such tablets was within the level of ordinary skill in the art. For example, Dohil teaches the POSA to formulate orally dissolving tablets of budesonide. Petition 24-27. So do Grother, Singh, and Cherukuri. *Id.* 13-14, 40-43. There were at least 30 commercial orally dispersing products guiding the POSA to successfully arrive at the claimed formulations. *Id.* 8-10. The FDA Guidance confirms that “relatively rapid disintegration is readily achievable across a variety of products.” EX1116 10; EX1005 2.

The '069 specification admits that ODTs are prepared via a “conventional granulator,” a “conventional oven,” and a “conventional rotary tablet press.” EX1001 16:57-17:2; EX1126 ¶74. The specification does not provide any special contribution to the field regarding the formulation of ODTs. There was a reasonable expectation of success, and the claims are obvious because “the claimed invention adds nothing beyond the teachings of [the prior art].” *Merck & Co. Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1374 (Fed. Cir. 2005).

4. Dohil Teaches And Suggests The Claimed Dosages With An Expectation Of Success

PO asserts that a POSA cannot extrapolate dosage amounts from Dohil’s successful treatment of EOE using *liquid* formulations from Examples 1-3 because there are supposedly different considerations in formulating *solid* compositions. POR 36-37.

PO ignores that Dohil teaches appropriate dosages for budesonide that apply to its solid formulations, which provides a reasonable expectation of success. EX1002 ¶¶[0015], [0031]; Petition 22-29. As discussed above, Dohil’s rapidly dissolving lozenge/tablet and liquid formulations share the mechanistic principle of providing a solution of budesonide that coats the esophagus. EX1126 ¶¶58-59. PO’s exhibit admits that an ODT dosage is “generally bioequivalent” to the same liquid dose. EX2017 345.

The POSA's expectation of success is bolstered by numerous FDA-approved examples of solid ODT formulations that have the same drug dosage amount as the corresponding liquid formulation, including:

- CLARITIN[®] (loratadine) ODT and liquid syrup are dosed at 10 mg, EX1089 2;
- ZOFTRAN[®] (ondansetron) ODT and oral solution are both dosed at either 4 or 8 mg, EX1090 5:125-128;
- CLARINEX[®] (desloratadine) ODT and liquid syrup are dosed at 5 mg, EX1091 19; and
- PEPCID[®] (famotidine) ODT and oral suspension are dosed at 40 mg, EX1092 1-2; EX1126 ¶60.

5. Dohil Teaches And Suggests The Claimed Methods Of Treatment

For claims 15-17, PO repeats its previous assertion that Dohil does not teach or suggest the claimed ODT. POR 37. PO is incorrect. *Supra* Section IV.A.1.

PO also repeats its previous assertion that Dohil does not provide an expectation of success in achieving the volume/viscosity required to cover the esophagus. POR 37-38. PO is, again, incorrect. *Supra* Section IV.A.1.c; EX1126 ¶¶61-62.

B. A POSA Would Have Been Motivated Based On Grother In View Of The FDA Guidance

The Petition provides compelling evidence of obviousness based on Grother in view of the FDA Guidance (Ground 2). Petition 39-60. Petitioner provides the following Reply to the POR.

1. Grother And The FDA Guidance Teach, Suggest, And Motivate Formulating ODTs With Budesonide

Grother teaches an ODT formulation, EX1008 12:10-19, in which any drug may be used, including budesonide. *Id.* 15:19-20, 18:15-18; Petition 40-43. Grother’s instruction to use budesonide in its ODT formulation teaches, suggests, and motivates its use in Grother’s ODT.

PO accuses Petitioner of “arbitrarily pick[ing] budesonide” from “disparate embodiments” and “misstat[ing] the law.” POR 41-43. It is PO, however, that misapplies the law. Petitioner has not arbitrarily picked budesonide from disparate embodiments within Grother. Grother itself undeniably instructs that budesonide should be predictably used in its ODT formulation. EX1008 15:19-20, 18:15-18. The Board found that Grother “teaches that examples of suitable drugs include corticosteroids including, e.g., budesonide.” EX1116 9-10. PO makes no allegation that Grother teaches away from its instruction to use this drug. The motivation to use this drug comes directly from Grother, which is appropriate because “[t]he

motivation to combine [can come] from the prior art reference itself.” *Acoustic Tech., Inc. v. Itron Networked Sols.*, 949 F.3d 1366, 1375 (Fed. Cir. 2020).

PO’s expert seeks to diminish Grother’s instruction to use budesonide because it is included in a “long list” of other drugs that may also be used with Grother’s “platform” ODT formulation. EX2007 ¶¶127-130; POR 41-44. Yet, when confronted with his own “platform” formulation, he inconsistently testified that *all* classes of drugs included in his long lists are suitable for his formulation. EX1072 178:7-179:1, 180:18-181:3; EX1071 Abstract, ¶¶[0043]-[0044]. Regardless of his inconsistent positions, Grother is “relevant for all [it] contain[s]” and must be considered for “its power to suggest solutions” to the POSA. *In re Young*, 927 F.2d 588, 591 (Fed. Cir. 1991). Grother’s instruction to use budesonide is more than sufficient for obviousness.

Grother’s instruction to use budesonide in its ODT formulation is reinforced by at least three other prior art references that also teach the use of budesonide in ODTs—Dohil, Cherukuri, and Singh. Petition 13-14 (citing EX1002, EX1035, EX1036); EX1126 ¶¶64-66.

PO asserts that Grother does not suggest using a “topical/non-systemic drug” because Grother did not expressly state that budesonide is a topically acting drug. POR 38-44. A POSA knew that budesonide was a potent topically acting drug that successfully treats inflammation of the gastrointestinal tract, including EOE.

Petition 5-6. This background knowledge must be considered in reading the prior art. *See Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013). Grother appropriately refrained from providing such “information readily understood by practitioners, lest every patent be required to be written as a comprehensive tutorial and treatise for the generalist, instead of a concise statement for persons in the field.” *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1119 (Fed. Cir. 2002); EX1126 ¶¶67.

PO asserts that there was no motivation or reasonable expectation of success in using Grother’s ODT to treat inflammation of the esophagus such as EOE because Grother doesn’t state that its ODT topically deposits a drug in the upper gastrointestinal tract. POR 38-40. Such an express statement is not required because Grother teaches that its ODT rapidly releases the drug in a patient’s oral cavity, which was known to deposit the drug in the upper gastrointestinal tract and further deposit the drug topically on the esophagus when the patient swallows. Petition 44-45; EX1008 3:18-22, 1:10-11, 32:10; *supra* Section IV.A.3. The FDA Guidance confirms that ODTs are designed and expected to deposit drugs in the upper gastrointestinal tract. EX1005 1; EX1126 ¶¶68-69.

a) **Grother And The FDA Guidance Teach And Suggest The Claimed Dosages With An Expectation Of Success**

PO asserts that a POSA would not have been motivated to arrive at the claimed dosage amounts with a reasonable expectation of success because there are

supposedly different considerations in formulating solid ODTs to deposit a topical drug in the upper gastrointestinal tract than formulating liquid compositions, enterically coated tablets, and rectal foam. POR 44-45. This assertion is unavailing for several reasons.

First, PO's expert admits that "there is no dispute that budesonide, fluticasone, or other topical corticosteroids could be used to treat inflammation of the upper gastrointestinal tract." EX2007 ¶¶65; *id.* ¶¶77. Second, PO and its expert fail to articulate how any supposedly different consideration in formulating solid ODTs to deposit a topical drug in the upper gastrointestinal tract versus other types of formulations would be material to the dosage amount of drug used in Grother's ODT. Third (and contrary to PO's assertions otherwise, POR 45), the Petition and Dr. Parr explain that a POSA was motivated to formulate Grother's ODTs with budesonide at, e.g., 0.5, 1, and 3 mg, with a reasonable expectation of success based on Grother's instruction that its compositions should normally have 1-20% by weight active ingredient and the general knowledge in the art that topically administrable formulations of budesonide typically contain, e.g., 0.5, 1, and 3 mg of budesonide. Petition 41-43; EX1050 ¶¶203-205; EX1126 ¶¶75-78. Fourth, the POSA's expectation of success is bolstered by numerous FDA-approved examples of solid ODT formulations having the same drug dosage as the corresponding liquid formulation. *Supra* Section IV.A.4. Fifth, the '069 patent fails to distinguish

between different dosage amounts across different formulations. EX1001 7:32-8:7; EX1126 ¶¶79-80. Sixth, PO’s expert admits that Grother’s ODT formulation “works with any class of drugs.” EX2007 ¶130.

**b) Grother And The FDA Guidance Teach And Suggest
The Claimed Methods of Treatment**

For claims 15-17, PO repeats its previous assertion that Grother and the FDA Guidance do not provide a motivation or reasonable expectation of success in using Grother’s ODT to treat inflammation of the upper gastrointestinal tract. POR 45-46. PO is incorrect. *Supra* Section IV.B.1.

V. NO SECONDARY CONSIDERATIONS

PO asserts secondary considerations of unexpected results and copying. POR 46-54. PO fails to establish any unexpected results or copying, and fails to overcome the strong *prima facie* case of obviousness.

A. No Unexpected Results

1. No Nexus

PO fails to show the required nexus between the purported unexpected results and the challenged claims. *Novartis AG v. Torrent Pharm. Ltd.*, 853 F.3d 1316, 1330-31 (Fed. Circ. 2017). PO asserts that the EX2006 study showed that an effervescent tablet of budesonide was surprisingly efficacious and reduced candidiasis compared to liquid formulations of budesonide. POR 46-48. There is no nexus because PO fails to show that the study tablet meets all the limitations of

the challenged claims, and PO's expert admitted he did not make that showing. EX1124 88:17-89:3, 96:10-99:19. Indeed, he was not asked to do so. *Id.* 58:12-20.

For example, PO fails to show that the study tablet “disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test,” as required by limitation 1[iv] in the challenged claims. EX1124 88:17-89:3, 96:10-97:12; EX1126 ¶¶99. EX2006 is silent regarding USP <701>. PO also fails to show that the study tablet includes any of the excipients required by '069 claims 3-8. EX1124 97:13-99:19; EX1126 ¶¶100.

PO also fails to show the purported unexpected results are commensurate with the full scope of the challenged claims. *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 965 (Fed. Cir. 2014). The study tablet comprised 1 or 2 mg budesonide, while the challenged claims encompass tablets between 0.5-5 mg budesonide. EX2006 1; EX1126 ¶¶101, 108-112.

2. No Comparison To The Closest Prior Art

PO fails to show unexpected results “compared with the closest prior art.” *Kao Corp. v. Unilever U.S. Inc.*, 441 F.3d 963, 970 (Fed. Cir. 2006); *Novartis*, 853 F.3d at 1331. PO's expert was not even aware of this requirement. EX1124 50:19-52:14, 53:16-55:5. PO asserts that the study tablet showed unexpected results compared to *liquid* formulations of budesonide. POR 46-48. The EPO determined that liquid formulations were not the closest prior art, and instead determined that

Dohil’s ¶[0032] **solid** lozenge/tablet was the closest prior art. EX1004 ¶¶36.2-3. Dr. Parr agrees with the EPO. EX1126 ¶¶102-105; EX1124 59:11-14, 59:23-60:16.

3. No Unexpected Stability

PO asserts that an ODT formulated with budesonide and sucralose was unexpectedly stable compared to a budesonide ODT formulated with aspartame. POR 48-49. PO fails to demonstrate unexpected results because it fails to show that a budesonide ODT formulated with aspartame is the closest prior art. *Kao Corp.*, 441 F.3d at 970; EX1126 ¶113.

B. No Copying

1. No Access Or Replication

PO asserts that Petitioner’s Jorveza® tablet copied the challenged claims. POR 49-54. “Not every competing product that arguably falls within the scope of a patent is evidence of copying.” *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004). “Rather, copying requires the replication of a specific product.” *Id.* PO fails to show that Petitioner had access to, or changed its product based on, the challenged patent or PO’s products that are covered by any challenged claims. POR 49-54. Indeed, PO has no products to copy.

2. The Lee Report Lacks Credibility

PO relies on a report by Dr. Lee to assert that Jorveza® disintegrates within 60 seconds using the USP <701> test required by the claims. POR 51; EX2029. Dr.

Lee's testing apparatus, however, does not conform with USP <701>. The wire mesh at the bottom of each tube appears to be too large and there is a break in the mesh. EX1126 ¶114. These deviations from USP <701> impact the fluid dynamics within the apparatus, which is likely to have adversely impacted the measured disintegration time. *Id.* ¶¶115-116. Moreover, Dr. Lee's results are at odds with the official disintegration time reported in the Jorveza® label of 2-20 minutes. EX2030 26. The Lee Report provides no explanation for these significant discrepancies, and lacks credibility.

VI. CONCLUSION

The challenged claims should be cancelled.

Dated: December 10, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this PETITIONER’S REPLY BRIEF contains 6,591 words according to the word-processing program used to prepare this paper. The foregoing word count complies with the 6,600-word type-volume limit authorized by the Board in Paper 23 of this proceeding.

Dated: December 10, 2025

By: /Nathanael R. Luman/
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this **PETITIONER’S REPLY BRIEF AND EXHIBIT NOS. 1033, 1071-1082, 1087-1092, AND 1115-1126** were served by email on the Patent Owner at the following email addresses:

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