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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.

PGR2025-00086
Patent No. 12,290,598

**PETITION FOR POST GRANT REVIEW OF
U.S. PATENT NO. 12,290,598**

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<i>AK Steel Corp. v. Sollac & Ugine</i> , 344 F.3d 1234 (Fed. Cir. 2003)	29
<i>Amgen Inc. v. Sanofi</i> , 598 U.S. 594 (2023).....	29, 35, 36
<i>Ariad Pharm., Inc. v. Eli Lilly & Co.</i> , 598 F.3d 1336 (Fed. Cir. 2010) (en banc)	24, 25
<i>Boston Sci. Scimed, Inc. v. Cordis Corp.</i> , 554 F.3d 982 (Fed. Cir. 2009)	51, 70
<i>Chiron Corp. v. Genentech, Inc.</i> , 363 F.3d 1247 (Fed. Cir. 2004)	25
<i>Dow Chem. Co. v. Nova Chems. Corp. (Can.)</i> , 803 F.3d 620 (Fed. Cir. 2015)	39
<i>Genentech, Inc. v. Novo Nordisk A/S</i> , 108 F.3d 1361 (Fed. Cir. 1997)	29, 31
<i>Inari Agriculture, Inc. v. Corteva Agriscience LLC</i> , PGR2023-00022, Paper 11 (PTAB 2023)	20, 27, 31
<i>Inguran, LLC v. Premium Genetics (UK) Ltd.</i> , PGR2015-00017, Paper 8 (PTAB 2015)	20, 41, 42, 43
<i>Juno Therapeutics, Inc. v. Kite Pharma, Inc.</i> , 10 F.4th 1330 (Fed. Cir. 2021)	25
<i>Liebel-Flarsheim Co. v. Medrad, Inc.</i> , 481 F.3d 1371 (Fed. Cir. 2007)	30

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<i>Lockwood v. Am. Airlines, Inc.</i> , 107 F.3d 1565 (Fed. Cir. 1997)	25
<i>Media Rights Techs., Inc. v. Capital One Fin. Corp.</i> , 800 F.3d 1366 (Fed. Cir. 2015)	38
<i>Nautilus, Inc. v. Biosig Instruments</i> , 572 U.S. 898 (2014).....	38
<i>Novo Nordisk Pharms., Inc. v. Bio-Technology General Corp.</i> , 424 F.3d 1347 (Fed. Cir. 2005)	43
<i>Schul Int’l Co., LLC v. Emseal Joint Systems, Ltd.</i> , PGR2018-00034, Paper 7 (PTAB 2018)	18, 20, 27
<i>Spinal Elements, Inc. v. Spectrum Spine IP Holdings, LLC</i> , PGR2021-00050, Paper 8 (PTAB 2021)	27
<i>Teva Pharms. USA, Inc. v. Sandoz, Inc.</i> , 789 F.3d 1335 (Fed. Cir. 2015)	40
<i>Tronzo v. Biomet, Inc.</i> , 156 F.3d 1154 (Fed. Cir. 1998)	41
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<i>US Endodontics, LLC v. Gold Standard Instruments, LLC</i> , PGR2015-00019, Paper 54 (PTAB 2016)	19
<i>In re Wands</i> , 858 F.2d 731 (Fed. Cir. 1988)	29, 31, 34, 37
<i>Wyeth & Cordis Corps. v. Abbott Labs.</i> , 720 F.3d 1380 (Fed. Cir. 2013)	29

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35 U.S.C. § 100	19
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35 U.S.C. § 103	9, 21
35 U.S.C. § 112	<i>passim</i>
35 U.S.C. § 321	18
37 C.F.R. § 42.8	87, 89
37 C.F.R. § 42.15	89
37 C.F.R. § 42.202	18

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 12,290,598 to Perrett et al.
1002	U.S. Publication No. 20070111978 to Dohil et al.
1003-1004	RESERVED
1005	“Guidance for Industry: Orally Disintegrating Tablets,” U.S. Food & Drug Administration, Center for Drug Evaluation and Research (CDER), 2008.
1006	RESERVED
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)
1013	Elsing et al., “Budesonide for the treatment of obstructive eosinophilic jejunitis,” <i>Z. Gastroenterology</i> , 45:187-189 (2007).

Exhibit No.	Description
1014	Aceves et al., “Topical viscous budesonide suspension for treatment of eosinophilic esophagitis,” <i>Journal of Allergy and Clinical Immunology</i> 116:705-706 (2005)
1015	Aceves et al., “Oral Viscous Budesonide: A potential new therapy for eosinophilic esophagitis in children,” <i>American Journal of Gastroenterology</i> , 102:1-9 (2007)
1016	RESERVED
1017	Danckwerts, “Intraoral Drug Delivery: A Comparative Review,” <i>American Journal of Drug Delivery</i> , 1:171-186 (2003).
1018	Fu et al., “Orally fast disintegrating tablets: developments, technologies, taste-masking and clinical studies,” <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 21:433-475 (2004)
1019	Shukla et al., “Mouth Dissolving Tablets I: An overview of formulation technology,” <i>Scientia Pharmaceutica</i> , 77:309-326 (2009) (March 6, 2009)
1020	U.S. Publication No. 20050232988 to Venkatesh et al. (“Venkatesh988”)
1021-1024	RESERVED
1025	Goodman & Gilman’s: <i>The Pharmacological Basis of Therapeutics</i> , 11th edition, eds. Brunton, Lazo, Parker, 2005
1026	Budenofalk® Brochure (2005)
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

Exhibit No.	Description
1031	Prosecution history excerpts from U.S. Application No.12/896,005
1032	RESERVED
1033	Teitelbaum et al., Eosinophilic esophagitis in children: Immunopathological analysis and response to fluticasone propionate,” Gastroenterology 122:1216-1225 (2002)
1034	Noel et al., “Clinical and immunopathologic effects of swallowed fluticasone for eosinophilic esophagitis,” Clinical Gastroenterology and Hepatology 2:568-575 (2004)
1035	U.S. Patent No. 7,122,198 to Singh et al.
1036	U.S. Patent No. 7,229,641 Cherukuri et al.
1037-1039	RESERVED
1040	USP Convention 701 Disintegration, Revision Bulletin August 1, 2008
1041	Conway, “Solid dosage forms,” Chapter 4.1 in Pharmaceutical Manufacturing Handbook: Production and Processes, ed. Gad, pages 235-265 (2008)
1042-1046	RESERVED
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)
1048-1063	RESERVED
1064	Roeder et al., “Safety and efficacy of fluticasone propionate in the topical treatment of skin diseases,” Skin Pharmacology Physiology, 18:3-11 (2004)

Exhibit No.	Description
1065	Remedios et al., “Eosinophilic esophagitis in adults: clinical, endoscopic, histologic findings, and response to treatment with fluticasone propionate,” <i>Gastrointestinal Endoscopy</i> , 63:3-12 (2006)
1066	Konikoff et al., “A randomized, double-blind, placebo-controlled trial of fluticasone propionate for pediatric eosinophilic esophagitis,” <i>Gastroenterology</i> , 131:1381-1391 (2006)
1067-1094	RESERVED
1095	Declaration of Alan F. Parr, Pharm.D., Ph.D. supporting PGR petition of U.S. 12,290,598
1096	Prosecution history excerpts from U.S. Application No. 17/569,047, which issued as U.S. 12,290,598
1097	U.S. Application No. 17/569,047 as filed on January 5, 2022 (“the ’047 Application”)
1098	U.S. Application No. 16/821,464 as filed on March 17, 2020 (“the ’464 Application”)
1099	U.S. Application No. 15/816,154 as filed on November 17, 2017 (“the ’154 Application”)
1100	U.S. Application No. 15/205,390 as filed on July 8, 2016 (“the ’390 Application”)
1101	U.S. Application No. 14/311,732 as filed on June 23, 2014 (“the ’732 Application”)
1102	U.S. Application No. 12/896,005 as filed on October 1, 2010 (“the ’005 Application”)
1103	U.S. Provisional Application No. 61/247,642 as filed on October 1, 2009 (“the ’642 Application”)
1104	The United States Pharmacopeia, USP 31, 2008 (“USP”)

Exhibit No.	Description
1105	The European Pharmacopeia, 6.0, 2008
1106	Remington: The science and practice of pharmacy, 20th edition, pages 882-884 (2000).
1107	Lee, “Pharmaceutical Preformulation,” in Pharmaceutical Manufacturing Handbook: Production and Processes, pages 881-931 (2008).
1108	Seitz et al., “Evaluation of the physical properties of compressed tablets I,” Journal of Pharmaceutical Sciences, 54:1353-1357 (1965)
1109	U.S. Patent No. 8,771,729 to Perrett et al.
1110	International Publication No. WO2002015884 to Kararli et al. (“Kararli”)
1111	International Publication No. WO2009006516 to Venkatesh et al. (“Venkatesh516”)
1112	International Publication No. WO2010127345 to Venkatesh et al. (“Venkatesh345”)
1113	International Publication No. WO2010127346 to Venkatesh et al. (“Venkatesh346”)

Dr. Falk Pharma GmbH (“Petitioner”) requests post grant review (“PGR”) of claims 1-34 (“Challenged Claims”) of U.S. Patent 12,290,598 (“the ’598 patent,” EX1001) purportedly owned by Ellodi Pharmaceuticals, L.P. (“Patent Owner”).

I. INTRODUCTION

Dr. Falk Pharma is an undisputed innovator in the fields of gastroenterology and hepatology. It has earned the respect of the medical and pharmaceutical formulation communities through its many educational outreach programs and seminars. The company’s first hepatological formulation, Hepatofalk[®], was launched in 1960 in Freiburg, Germany. By 2009, Dr. Falk Pharma had launched eight additional formulations having important gastroenterological and hepatological indications in 63 countries. The company’s newest product, Jorveza[®], is an innovative budesonide formulation that is approved for treating eosinophilic esophagitis in Europe. Dr. Falk Pharma is working with the FDA to allow U.S. patients to receive the benefits of Jorveza[®].

In contrast, Patent Owner Ellodi does not have any products on the market in Europe, the U.S., or anywhere else. What Ellodi does have is a long history of obtaining invalid patents. Ellodi acquired ownership of certain U.S. and European patents, including the patent family from which the ’598 patent issued.

Ellodi sought to preclude Jorveza[®] from being used by European patients based on three of its European patents. This forced Dr. Falk Pharma to initiate three

opposition proceedings at the European Patent Office and resulted in the revocation of Ellodi's claims.

In connection with Dr. Falk Pharma's plans to bring Jorveza[®] to U.S. patients, it filed five IPR petitions challenging Ellodi's U.S. patents:

- IPR2024-01197 challenging U.S. 8,771,729;
- IPR2025-00052 challenging U.S. 10,632,069;
- IPR2025-00054 challenging U.S. 11,246,828;
- IPR2025-00055 challenging U.S. 9,487,407; and
- IPR2025-00056 challenging U.S. 11,260,061.

The PTAB has instituted trial in all five IPR proceedings. All of these patents claim orally disintegrating tablets (ODTs) that are obvious over the prior art and should be cancelled. Petitioner has presented compelling evidence of obviousness in these IPRs. Ellodi failed to file a Patent Owner Response in IPR2025-00056, effectively conceding unpatentability in at least that case.

Since filing these IPR petitions, Dr. Falk Pharma has continued to work with the FDA to bring the benefits of Jorveza[®] to U.S. patients.

Ellodi, however, has continued its practice of seeking overly broad patents. Ellodi's newest patent, the '598 patent challenged here, claims essentially the same ODTs as its previous patents, with the exception of a new limitation that requires the claimed ODTs to have "a hardness of 4-48 N or a friability of not more than 1%."

This limitation is not only obvious over the prior art, but it also violates numerous requirements of §112 including lack of written description, enablement, and definiteness.

Ellodi's newly claimed "hardness of 4-48 N" clearly violates the written description requirement. Ellodi's application, at best, can only disclose ODTs having a hardness of 8-48 N. There is absolutely no support for ODTs having a hardness at the lower end of the claimed range of 4-7 N. For example, there is no support for ODTs having a hardness of, e.g., 4, 5, 6, or 7 N. Ellodi's claims should be cancelled for this reason alone.

Ellodi's failure to support the claimed hardness range further violates the enablement requirement. Because the application fails to disclose an ODT having a hardness of, e.g., 4-7 N, the person of ordinary skill in the art ("POSA") is likewise without guidance for making an ODT having such a hardness.

Ellodi's claimed hardness limitation is also indefinite because Ellodi fails to describe how the claimed hardness range should be measured. There are numerous prior art methods for measuring hardness that lead to significantly different values. There is no reasonable certainty as to the scope of the claimed hardness range because the '598 patent fails to inform the POSA how to measure hardness.

Ellodi's new limitation does not save its claims from obviousness. As demonstrated herein, a POSA was motivated with a reasonable expectation of

success to arrive at an ODT having a hardness and friability falling within the claimed ranges so that the tablet would have sufficient mechanical strength to withstand packaging, transportation, and handling.

This Petition presents compelling evidence of unpatentability. The PTAB should institute trial and hold that all claims from the '598 patent are unpatentable.

II. BACKGROUND REGARDING THE '598 PATENT

The '598 patent is entitled “Orally administered corticosteroid compositions.” EX1001 Title. It issued with 34 claims, of which only claim 1 is an independent claim. The claims are directed to ODTs of budesonide or fluticasone propionate that disintegrate within 60 seconds and have a specific hardness or friability. For example, claim 1 recites:

1. An orally disintegrating tablet comprising:
 - (i) about 0.5 mg to about 6 mg of a corticosteroid selected from fluticasone propionate or budesonide; and
 - (ii) at least one disintegrant,
 - [iii] wherein upon administration a therapeutically effective amount of the corticosteroid is deposited topically in the esophagus,
 - [iv] wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> Disintegration Test, and
 - [v] wherein the orally disintegrating tablet has a hardness of 4-48 N or a friability of not more than 1%.

EX1001 18:50-61.¹

A. Related Applications

The '598 patent issued from U.S. Application No. 17/569,047, filed on January 5, 2022 (“the '047 application,” EX1097). The '598 patent further claims priority to the following U.S. Application Nos.:

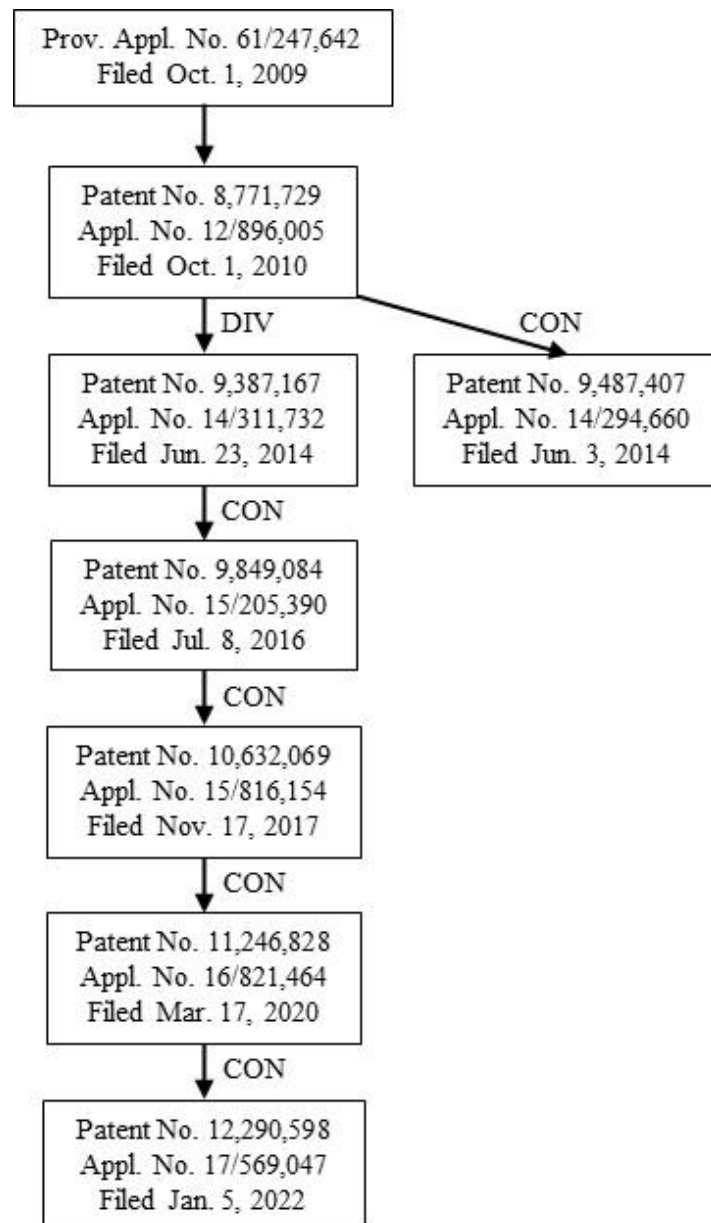
- 16/821,464 (filed March 17, 2020; EX1098);
- 15/816,154 (filed November 17, 2017; EX1099);
- 15/205,390 (filed July 8, 2016; EX1100);
- 14/311,732 (filed June 23, 2014; EX1101);
- 12/896,005 (filed October 1, 2010; EX1102); and
- 61/247,642 (filed October 1, 2009; EX1103).

EX1001 1:7-22.²

¹ Bracketed labels [iii]-[v] are added for convenient referencing to the limitations of claim 1. The '598 patent claims are reproduced in Appendix A.

² Of Petitioner's five previously filed IPR petitions, the following four petitioned patents are included in the '598 patent priority chain: (1) U.S. 8,771,729 (IPR2024-01197); (2) U.S. 10,632,069 (IPR2025-00052); (3) U.S. 11,246,828 (IPR2025-00054); and (4) U.S. 9,487,407 (IPR2025-00055). The PTAB instituted trial in all of these IPRs.

A chart showing the purported relationships between these applications is provided below:



EX1001 1:7-22.

The priority applications purport to be continuation and divisional applications. The specification of the '047 application that issued as the '598 patent

does not materially differ from the other priority applications for purposes of written description, enablement, and definiteness. Thus, for purposes of simplicity, this Petition only cites to the specification of the '047 application (EX1097).

B. Prosecution History

Ellodi filed the '047 application with 30 claims on January 5, 2022. EX1096 428-431. None of the claims contained a hardness or friability limitation.

Ellodi filed a preliminary amendment that cancelled claims 20-27 and 29-30 on July 18, 2022. *Id.* 374-379.

The Examiner issued an Office Action under pre-AIA first-to-invent provisions on March 26, 2024. *Id.* 169-178. The Examiner rejected certain claims for indefiniteness based on inconsistent usage of the terms “dispersing” and “disintegrating.” *Id.* 171-172. The Examiner issued nonstatutory double patenting rejections based on U.S. 8,771,729 and U.S. 9,486,407. *Id.* 172-176. The Examiner issued a statutory double patenting rejection based on U.S. 11,266,598. *Id.* 176-177.

Ellodi filed an Amendment and Response on July 23, 2024. *Id.* 150-167. Ellodi amended claim 1 to recite, *inter alia*, “about 0.5 mg to about 6 mg of a corticosteroid selected from fluticasone propionate or budesonide,” that the corticosteroid is deposited in the “esophagus,” and that the “*orally disintegrating*

tablet has a hardness of 4-48 N or a friability of not more than 1%.” *Id.* 151.³

Ellodi asserted that it made additional amendments to address indefiniteness as well as “conforming amendments” to dependent claims. *Id.* 156. Ellodi also added new claims 31-44. *Id.* 153-155. Ellodi asserted that “[s]upport for the claim amendments can be found throughout the application as originally filed, for example in Example 1.” *Id.* 156.⁴

Also on July 23, 2024, Ellodi filed terminal disclaimers over U.S. 8,771,729 and U.S. 9,486,407. *Id.* 157. Ellodi further asserted that amended claim 1 was not coextensive in scope with the U.S. 11,266,598 and requested withdrawal of the statutory double patenting rejection. *Id.* 157-158.

The Examiner issued a Notice of Allowance on October 22, 2024. *Id.* 73-82. The Examiner’s Reasons for Allowance stated that her literature search did not uncover prior art that teaches the amended claims. *Id.* 80.

Ellodi filed a Request for Continued Examination and an Information Disclosure Statement (IDS) on January 22, 2025. *Id.* 50-61. The IDS included material from Dr. Falk Pharma’s IPRs.

³ All emphases supplied unless otherwise noted.

⁴ As shown herein, there is no support for the claimed hardness of 4-48 N in Example 1 or anywhere else in the application.

The Examiner issued a second Notice of Allowance on March 24, 2025. *Id.* 10-18. The issue fee was paid and the '598 patent issued on May 6, 2025.

Compliance with the written description and enablement requirements were never evaluated during prosecution of the challenged claims, and there were no prior art rejections raised under §§102/103.

III. STATE OF THE PRIOR ART

A. Orally disintegrating tablets (ODTs)

1. Background and Nomenclature

Many patients were known to have difficulty swallowing tablets and gelatin capsules. Dysphagia, or difficulty in swallowing, “is common in about 35% of the general population.” EX1018 433-34; EX1019 310. Patients who have difficulty swallowing medications may have a high incidence of noncompliance with taking their medications. “Lack of patient compliance is probably the most important factor that results in suboptimal therapeutic outcome for patients.” EX1017 172. Difficulties with patient compliance can be significantly improved by formulating active ingredients in an orally disintegrating tablet (ODT). EX1095 ¶¶58-62.

ODTs were well-known by 2009. A patient’s saliva causes an ODT to disintegrate in the oral cavity, which allows the active ingredient contained in the tablet to dissolve or disperse in the saliva and become absorbed through the mucosa

of the mouth, esophagus, or other sections of the gastrointestinal track. EX1018 Abstract; EX1017 173-174.

“Solid dosage forms that can be dissolved or suspended with water in the mouth for easy swallowing are highly desirable for the pediatric and geriatric population, as well as other patients who prefer the convenience of readily administered dosage forms.” EX1018 434. Such solid dosage forms desirably disintegrate “in less than 1 minute, but it is preferred to have disintegration as soon as possible.” *Id.* 435; EX1017 178 (“Whatever mechanism is used, the drug delivery systems all disintegrate in the patient’s mouth within a minute without the need of water or chewing.”).

ODTs can advantageously promote absorption of active ingredients through the oral mucosa, pharynx, and esophagus. EX1019 310-11; EX1018 466-67. This allows transmucosal delivery through oral or esophageal mucosa that beneficially “avoid[s] long-term parenteral therapy.” EX1017 172; EX1095 ¶¶63-66.

The prior art uses several terms to refer to ODTs, such as “fast disintegrating tablets (FDTs),” EX1018 Abstract, “quick-disintegrating/dissolving tablet[s],” EX1017 178, and “mouth dissolving drug delivery systems (MDDDS),” EX1019 Abstract. Such terms were often used interchangeably in the literature to refer to orally disintegrating tablets. EX1018 434 (“The FDT is also known as fast melting,

fast dispersing, rapid dissolve, rapid melt, and/or quick disintegrating tablet.”);

EX1017 178; EX1019 310.

“All FDTs approved by the [FDA] are classified as orally disintegrating tablets.” EX1018 434. The FDA defines “orally disintegrating tablets” as “[a] solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue.” EX1005 2; EX1095 ¶¶48-53.

2. FDA Guidance

In December of 2008, the FDA published its guidance for the pharmaceutical industry regarding ODTs. EX1005. The FDA Guidance explains that ODTs are designed to disintegrate or dissolve rapidly without the need to swallow or chew for the benefit of patients with impaired swallowing. *Id.* 1.

The FDA Guidance defines ODTs as “[a] solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue.” *Id.* 2. The FDA Guidance further clarifies that ODTs are “solid oral preparations that disintegrate rapidly in the oral cavity, with an *in-vitro* disintegration time of approximately 30 seconds or less, when based on the United States Pharmacopeia (USP) disintegration test method or alternative.” *Id.* 2. The Guidance recommends “that applicants use the USP method for disintegration

testing,” *id.* 3, specifically “USP 29, <701> Disintegration, pp. 2670-2672.” *Id.* 3 n.3; EX1104 266-267; EX1007; EX1095 ¶¶54-57.

3. Commercial orally disintegrating tablets (ODTs)

By 2009, there were several commercially available ODT products on the market. Exemplary commercially available formulations included the Zydis[®] fast-dissolving wafer, the WOWTab[®] (With-Out-Water tablet), the Flash Dose[®] tablet, and OraSolv[®]. EX1017 178-181; EX1018 436-37. Drugs that were formulated into marketed ODTs were compiled into the following table:

TABLE 2. Examples of Commercially Available, Preapproval, or Submitted Orally Disintegrating Tablet Products

Brand name	Active ingredient	Application	Company	Technology
Claritin® RediTabs®	Loratadine	Antihistamine	Schering Corporation	Zydis®
Feldene Melt®	Piroxicam	NSAID	Pfizer	
Maxalt®-MLT®	Rizatriptan benzoate	Migraine	Merck	
Pepcid® ODT	Famotidine	Anti-ulcer	Merck	
Zyprexa®	Olanzapine	Psychotic disorders	Eli Lilly	
Zofran® ODT®	Ondansetron	Anti-emetic	Glaxo Smith Kline	
Risperdal® M-Tab™	Risperidone	Schizophrenia	Janssen	
Zubrin™(pet drug)	Tepoxalin	Canine NSAID	Schering Corporation	
Zelapar™	Selegiline	Parkinson's disease	Elan / Amarin Corporation	
Klonopin® Wafers	Clonazepam	Sedation	Roche	
Children's Dimetapp® ND	Loratadine	Allergy	Wyeth Consumer Healthcare	
Imodium Instant Melts	Loperamide HCl	Anti-diarrheal	Janssen	
Propulsid® Quicksolv®	Cisapride monohydrate	Gastrointestinal prokinetic agent	Janssen	Quicksolv®
Tempra Quicklets Tempra FirsTabs	Acetaminophen	Analgesic	Bristol-Myers Squibb	OraSolv®
Remeron® SolTab®	Mirtazapine	Anti-depression	Organon Inc.	
Triaminic® Softchews®	Various combinations	Pediatric cold, cough and allergy	Novartis Consumer Health	
Zomig-ZMT® and Rapimelt®	Zolmitriptan	Anti-migraine	AstraZeneca	DuraSolv®
Alavert®	Loratadine	Allergy	Wyeth Consumer Healthcare	
NuLev®	Hyoscyamine sulfate	Anti-ulcer	Schwarz Pharma	
Kemstro™	Baclofen	Anti-spastic analgesic	Schwarz Pharma	
Benadryl® Fastmelt®	Diphenhydramine citrate	Allergy, sinus pressure relief	Pfizer	WOWTAB®
Nasea OD	Ramosetron HCl	Anti-emetic	Yamanouchi	
Gaster D	Famotidine	Anti-ulcer	Yamanouchi	
Excedrin® QuickTabs	Acetaminophen	Pain reliever	Bristol-Myers Squibb	QuickTabs™
Ralivia FlashDose®	Tramadol HCl	Analgesics	Biovail	FlashDose®
Zolpidem ODT	Zolpidem tartrate	Sleep disorders	Biovail	
Fluoxetine ODT	Fluoxetine	Anti-depression	Biovail	
Nurofen® Flashtab®	Ibuprofen	NSAID	Boots Healthcare	Flashtab®
Hyoscyamine Sulfate ODT	Hyoscyamine sulfate	Anti-ulcer	ETHEX Corporation	OraQuick
Cibalginadue FAST	Ibuprofen	NSAID	Novartis Consumer Health	Ziplets™

EX1018 438-439.

By 2009, a POSA had “no doubt that the need for these [orally disintegrating pharmaceutical] systems is real, and many classes of drugs could benefit from this noninvasive type of [drug] delivery.” EX1017 183. Based on “the many benefits of FDTs [fast disintegrating tablets],” it was thought that it was “only a matter of time

until a majority of oral formulations are prepared in FDT forms.” EX1018 469; EX1095 ¶¶67-75.

B. Hardness

One test of the mechanical integrity of a tablet is the force required to cause it to break in a specific plane. This breaking force is commonly called “hardness.” EX1104 676.

There are a number of methods to quantitate tablet hardness. EX1106 883; EX1104 676-78; EX1105 2.9.8. For example, the “Monsanto” hardness tester “measures the force required to break the tablet when the force generated by a coil spring is applied diametrically to the tablet.” EX1106 883. This tester was later distributed by Stokes Div, and is therefore also known as the “Stokes” tester. *Id.* The “Strong-Cobb” hardness tester uses a manually operated air pump to increase the pressure at which a plunger is forced against a tablet placed on an anvil. *Id.* Another instrument is the “Pfizer” hardness tester, which operates on mechanistic principles of pliers. *Id.* The most common instrument used today is the “Schleuniger” apparatus, which is electrically operated. *Id.* However, there are yet other hardness testers manufactured by Key, Van Kel, Erweka, and others. *Id.* 883; EX1095 ¶¶76-77.

The hardness values measured by different testers often differ significantly from each other. EX1106 883. “The rate at which the compressive load is applied

can significantly affect results, because time-dependent processes may be involved in tablet failure.” EX1104 677. “The different methods may lead to numerically different results for a particular tablet sample, requiring that the rate of load application or displacement must be specified along with the determined breaking force.” *Id.* Even automated testers “do not produce uniform results for the same tablet due to operator variation, lack of calibration, spring fatigue, and manufacturer variation.” EX1107 928. The literature warns that tablet hardness values reported without describing the method used to measure hardness “should be seriously questioned.” EX1108 1357; EX1095 ¶¶78.

C. Friability

Another test of the mechanical integrity of tablets involves tumbling tablets in a rotating cylinder to determine their ability to resist chipping and surface abrasion. EX1104 676. The percentage weight loss after tumbling is referred to as the “friability” of the tablets. *Id.* Methods of measuring friability are described in several sources. *E.g.*, EX1104 675-76; EX1105 2.9.7; EX1095 ¶¶79-80.

D. Budesonide and Fluticasone Propionate for Treating Eosinophilic Esophagitis

Budesonide and fluticasone propionate are potent, locally acting anti-inflammatory glucocorticoids that were known to treat various inflammatory diseases. EX1025 1014-1015; EX1009 857; EX1064 3; EX1065 3. Budesonide and fluticasone propionate were desirable drugs for treating inflammation of the

gastrointestinal tract because they were locally acting corticosteroids with a high first-pass effect, which minimized systemic side effects. EX1010 425; EX1066 1382; EX1095 ¶¶81-82, ¶¶97-100.

Dr. Falk Pharma launched an orally administered capsule formulation of budesonide known as Budenofalk® in 1998. EX1026 1, 60; EX1027; EX1028 7. By 2009, nearly 1 million treatment cycles of Budenofalk® had been used by patients to treat Crohn’s disease and collagenous colitis. Budenofalk® also treated ulcerative colitis, eosinophilic gastroenteritis, and obstructive eosinophilic jejunitis. EX1011 589-590; EX1012 55; EX1013 187; EX1095 ¶¶83-86.

Beginning in 2005, Aceves et al. reported that formulations for the oral administration of budesonide and fluticasone propionate successfully treat eosinophilic esophagitis (EOE or EE). EX1014 706; EX1015 1, 6, 8; EX1066 1381-82. Clinicians from the Aceves team filed a patent application describing the topical administration of budesonide, which published as US20070111978, EX1002 (“Dohil”). Dohil discloses at least two types of formulations of budesonide:

- (1) a viscous oral suspension of budesonide, *id.* ¶¶[0021], [0030], [0046]-[0070], and
- (2) a solid oral lozenge or tablet that dissolves rapidly in the mouth or esophagus, *id.* ¶¶[0032], [0013], [0037].

Dohil’s lozenge or tablet “dissolve[s] rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus.” *Id.* ¶[0032]; EX1095 ¶¶87-96.

E. ODTs Containing Budesonide And Fluticasone

The formulation of budesonide and/or fluticasone as an orally disintegrating solid pharmaceutical composition that would dissolve rapidly was disclosed in at least four prior art references.

First, Dohil’s disclosure of budesonide formulated into a solid oral lozenge or tablet that dissolves rapidly in the mouth or esophagus is discussed above. EX1002 ¶¶[0032], [0013], [0037].

Second, Grother discloses “fast dispersing solid dosage forms that preferably dissolve in the oral cavity within sixty (60), more preferably within thirty (30), most preferably within ten (10) seconds.” EX1008 Abstract; *id.* 13:19-22. Grother discloses a fast dispersing dosage form comprising an active ingredient, a modified starch, and a matrix forming agent. *Id.* 12:10-19, 15:19-20. Grother discloses several types of drugs suitable for its fast dispersing dosage form, *id.* 16:1-21:15, including corticosteroids, such as budesonide and fluticasone, *id.* 18:15-18.

Third, Singh discloses “fast dissolving tablets,” EX1035 1:20-23, 2:37-49, that preferably “dissolves or disperses in the mouth within one minute,” *id.* 2:29-36. Singh discloses groups of drugs that can be employed in the tablets, *id.* 3:16-19:54, including glucocorticoids such as budesonide, *id.* 16:56-17:14.

Fourth, Cherukuri discloses “a rapid-melt composition” that preferably is “a gastrointestinal therapeutic.” EX1036 1:15-20, 9:6-10. Cherukuri’s rapid-melt composition “disintegrates quickly in the mouth of the mammal,” preferably “in less than 20 seconds.” *Id.* 14:50-56. Cherukuri discloses several classes of active ingredients suitable for the rapid-melt composition, *id.* 7:51-11:52, including budesonide and fluticasone, *id.* 9:64-67; EX1095 ¶¶101-109.

IV. ELIGIBILITY FOR POST-GRANT REVIEW

The ’598 patent issued on May 6, 2025 and Petitioner has timely filed this Petition no later than nine months after the date of the grant of the patent. 35 U.S.C. §321(c); 37 C.F.R. §42.202. Petitioner certifies that the ’598 patent is available for PGR and that Petitioner is not barred or estopped from requesting PGR challenging the patent claims on the identified grounds.

The ’047 application from which the ’598 patent issued was filed after March 16, 2013, and also asserts the benefit of an application filed prior to March 16, 2013. The ’047 application is therefore a “transition application.”

A patent that issues from a transition application is eligible for PGR if the patent contains “at least one claim that was not disclosed in compliance with the written description and enablement requirements of §112(a) in the earlier application for which the benefit of an earlier filing date prior to March 16, 2013 was sought.” *See Schul Int’l Co., LLC v. Emseal Joint Systems, Ltd.*, PGR2018-00034, Paper 7 at

9 (PTAB 2018); Leahy-Smith America Invents Act (AIA) §§3(n)(1), 6(f)(2)(A), 125 Stat. 284 at 293, 311 (2011).

Ellodi disclosed for the first time—via amendment on July 23, 2024—an ODT having “a hardness of 4-48 N or a friability of not more than 1%.” EX1096 151. This claim amendment makes the ’598 patent eligible for PGR for violating two independent requirements of §112. First, there is no written description support for the claimed “hardness of 4-48 N.” Second, the specification does not enable a POSA to make an ODT having a “hardness of 4-48 N.”

As explained in detail in Ground 1 herein, the ’047 application that issued as the ’598 patent does not provide §112 written description support for the claimed hardness range of 4-48 N, and neither do any of the other priority applications. *Infra* Section VIII. The ’598 patent therefore cannot claim priority to the filing dates of the earlier filed applications, and the ’598 patent is entitled to a filing date of, at the earliest, the January 5, 2022 filing date of the ’047 application that issued as the ’598 patent. *See* 35 U.S.C. §100(i)(1)(A); *US Endodontics, LLC v. Gold Standard Instruments, LLC*, PGR2015-00019, Paper 54 at 11 (PTAB 2016) (“if claims 12-16 are shown to lack adequate §112 support in the ’311 application and all of the earlier applications to which priority is claimed, the effective filing date for those claims is the actual filing date of the ’311 application”). The ’598 patent is eligible for PGR

for at least this reason. *See* AIA §§3(n)(1); *Schul Int’l Co.*, PGR2018-00034, Paper 7 at 10-16 (finding PGR eligibility for lack of written description support).

As explained in detail in Grounds 2 and 3 herein, the specification does not enable the POSA to make an ODT having a hardness of 4-48 N. *Infra* Sections IX-X. The ’598 patent is eligible for PGR for this additional independent reason. *See* AIA §§3(n)(1); *Inguran, LLC v. Premium Genetics (UK) Ltd.*, PGR2015-00017, Paper 8 at 11 (PTAB 2015) (explaining that non-enablement is a basis for PGR eligibility); *Inari Agriculture, Inc. v. Corteva Agriscience LLC*, PGR2023-00022, Paper 11 at 52-57 (PTAB 2023) (finding PGR eligibility for non-enablement and lack of support).

**V. THERE IS A REASONABLE LIKELIHOOD THAT THE
CHALLENGED CLAIMS ARE UNPATENTABLE**

Petitioner requests cancellation of claims 1-34 of the ’598 patent as lacking written description support, lacking enablement, being indefinite, and as anticipated and obvious over the asserted prior art.

A. Grounds of Unpatentability

PGR is requested for the following grounds of unpatentability:

Ground	Reference(s)	Basis	Challenged Claims
1	Lack of Written Description	§112(a)	1-34
2	Lack of Enablement for hardness of 4-7 N	§112(a)	1-34

Ground	Reference(s)	Basis	Challenged Claims
3	Lack of Enablement for hardness of 4-48 N	§112(a)	1-34
4	Indefiniteness	§112(b)	1-34
5	Perrett (anticipation)	§102	1-34
6	Perrett (obviousness)	§103	1-34
7	Obviousness over Dohil in view of Kararli, the FDA Guidance, and the USP	§103	1-4, 9, 13-14, 18-20, 22-25, 31-32
8	Obviousness over Dohil in view of Kararli, the FDA Guidance, and the USP, and Venkatesh988	§103	5-8, 15-16
9	Obviousness over Dohil in view of Kararli, the FDA Guidance, the USP, and Venkatesh516	§103	26-28, 34
10	Obviousness over Grother in view of Kararli, the FDA Guidance, and the USP	§103	1-4, 9, 11, 13-14, 18-25, 29, 31-32
11	Obviousness over Grother in view of Kararli, the FDA Guidance, the USP, and Venkatesh988	§103	5-8, 10, 12, 15-17, 30
12	Obviousness over Grother in view of Kararli, the FDA Guidance, the USP, and Venkatesh516	§103	26-28, 33-34

This Petition is supported by the expert declaration of Dr. Alan F. Parr, Pharm.D., Ph.D. EX1095. Dr. Parr holds a Pharm.D. in pharmacy, a Ph.D. in

pharmaceutical sciences, and has over three decades of experience formulating pharmaceutical compositions. EX1029.

B. The Asserted References Are Prior Art

Despite claiming priority to a provisional application filed on October 1, 2009, the earliest effective filing date for the '598 patent is the January 5, 2022. *Supra* Section IV. The asserted references are all §102(a)(1) prior art to the '598 patent:

Exhibit	Reference	Publication Date
1109	Perrett	Issued: 07/08/2014
1002	Dohil	Published: 05/17/2007
1110	Kararli	Published: 02/28/2002
1005	FDA Guidance	Published: 12/16/2008
1104	USP	Published: 11/01/2007
1008	Grother	Published: 08/03/2000
1020	Venkatesh988	Published: 10/20/2005
1111	Venkatesh516	Published: 01/08/2009

VI. LEVEL OF ORDINARY SKILL IN THE ART

A POSA related to the '598 patent would have a Ph.D., another advanced degree, or its equivalent, in areas related to pharmaceuticals, chemistry, biology, medicine, or a related discipline, and 2-3 years of experience in formulation development. Alternatively, a POSA would have a lesser degree in those fields, with

at least five or more years of experience in formulation development. The POSA would also have had access to a medical doctor with a specialty in gastroenterology, and other individuals with expertise related to the above subjects. EX1095 ¶35.

VII. CLAIM CONSTRUCTION

All claim terms not specifically construed in this petition have been accorded their plain and ordinary meaning under a *Phillips*-type construction.

The '598 patent defines “orally disintegrating tablet”, “orally dispersing tablet”, or “ODT” to refer “to a solid dosage form of the present invention, which disintegrates rapidly in the oral cavity of a patient after administration, without chewing.” EX1001 2:54-57. This definition is equivalent to that adopted by the FDA. EX1005 2; EX1095 ¶213.

The '598 patent defines “sugar alcohols” as “hydrogenated forms of carbohydrates in which the carbonyl group (i.e., aldehyde or ketone) has been reduced to a primary or secondary hydroxyl group.” EX1001 13:36-38. The '598 patent confirms that “[n]on-limiting examples of suitable sugar alcohols for the rapidly dispersing granules of the pharmaceutical compositions of the present invention include e.g. arabitol, isomalt, erythritol, glycerol, lactitol, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.” *Id.* 13:39-43.

The '598 patent states that “[t]he term ‘saccharide’ is synonymous with the term ‘sugars’ includes monosaccharides such as glucose, fructose, the lactose, and

ribose; and disaccharides such as sucrose, lactose, maltose, trehalose, and cellobiose.” EX1001 13:43-57.

The '598 patent states that “[t]he term ‘about’, as used herein to refer to a numerical quantity, includes ‘exactly’. ... When the term ‘about’ is used in reference to a range of values, the term ‘about’ refers to both the minimum and maximum value of the range (e.g., ‘about 1-50 μm ’ means ‘about 1 μm to about 50 μm ’).” EX1001 3:3-11.

Patent Owner’s lexicography governs, and Petitioner adopts and applies each of these definitions.

VIII. GROUND 1: LACK OF WRITTEN DESCRIPTION

Claims 1-34 are unpatentable for failing to comply with the written description requirement.

A. Legal Standard

Section 112(a) requires that a patent’s written description “clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The test for sufficient written description “is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Id.* “[A]

description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.” *Id.* at 1356.

The written description requirement limits subsequent claims to the scope of an application’s disclosure, and provides a critical safeguard in preventing retroactive claiming of others’ inventions. *See Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004). This requirement is particularly important for patents issuing from continuation applications, such as the ’598 patent. *See Agilent Technologies, Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1379 (Fed. Cir. 2009).

“One shows that one is ‘in possession’ of the invention by describing the invention, with all its claim limitations.” *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (“all the limitations must appear in the specification”). “[T]he written description must lead a person of ordinary skill in the art to understand that the inventor possessed the entire scope of the claimed invention.” *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1337 (Fed. Cir. 2021).

B. Analysis

Here, the application that issued as the ’598 patent does not describe the invention with all its claimed limitations because claim limitation 1[v], which recites a “hardness of 4-48 N,” is absent from the application. Ellodi first introduced this hardness limitation by Amendment on July 23, 2024. EX1096 151. Ellodi wrongly asserted that support for this limitation is found in the application as originally filed,

including Example 1. *Id.* 156. No hardness range between 4-48 N is taught in Example 1 or anywhere else in the application. The application only teaches a hardness range from 8-48 N:

TABLE:

Tablet Parameters		
Parameter	Target	Range
Weight (mg)	100	95-105
Thickness (mm)	2.4	2.0-2.8
Hardness (N)	28	8-48
Friability	NMT 0.6%	1.0%
Weight 10 tablets (g)	1.0g	0.96-1.04

EX1097 ¶[0092] (annotated); EX1095 ¶¶112-114. There is no teaching of an ODT having a hardness less than 8 N. For example, there is no teaching of an ODT having a hardness of 7 N, 6 N, 5 N, or 4 N.

The application also does not provide any guidance how to make ODTs having a hardness less than 8 N. The lack of any disclosure of the lower end of the claimed hardness range and lack of information to guide a POSA to arrive at the low end of the claimed range does not allow a POSA to recognize that the purported inventors invented an ODT having the claimed range of hardness. EX1095 ¶115.

None of the priority applications provide any additional details that would support claim limitation 1[v]. EX1095 ¶¶116-119. The claims of the '598 patent are therefore not entitled to claim priority to the earlier filed applications.

Accordingly, the earliest effective filing date for the challenged claims is January 5, 2022 (which is the filing date of the application that issued as the '598 patent).

Under similar circumstances, the PTAB has consistently determined that failure to disclose the lower end of a claimed range is more likely than not to render claims unpatentable under §112(a). For example, in *Inari Agriculture*, the PTAB determined that an application that failed to disclose the lower end of a claimed range of sequence identity for a protein lacked written description support. *See Inari Agriculture*, PGR2023-00022, Paper 11 at 34-40. In *Spinal Elements*, the PTAB determined that an application that failed to describe the lower end of a claimed range from 50-100% lacked written description support. *See Spinal Elements, Inc. v. Spectrum Spine IP Holdings, LLC*, PGR2021-00050, Paper 8 at 11-12 (PTAB 2021). In *Schul Int'l Co.*, the PTAB determined that an application lacked written description for a claimed density range of 200-700 kg/m³ where there was no written description of such a density in the range of about 200-400 kg/m³. *See Schul Int'l Co.*, PGR2018-00034, Paper 7 at 14.

Here, the application that issued as the '598 patent fails to show that the purported inventors had possession of ODTs having a hardness below 8 N, and a POSA would not have comprehended such a hardness based on the description provided. Therefore, there is no written description support for a hardness in the

range of 4-7 N, which is covered by the claim limitation 1[v]. Accordingly, claim 1 is unpatentable under §112(a).

Each of claims 2-34 depends from claim 1. None of the dependent claims meaningfully change the claim scope for purposes of written description, at least because they do not further limit the claimed hardness range. Thus, for the same reasons that claim 1 lacks written description, claims 2-34 also lack written description and all claims are invalid under §112(a) for lack of written description support.

If Ellodi were to argue that any of its dependent claims do not encompass an ODT having a hardness of 4-48 N, then those claims would encompass an ODT having any hardness. The application that issued as the '598 patent does not describe an ODT having all possible hardness values, and such an argument would result in the dependent claims lacking written description support.

IX. GROUND 2: LACK OF ENABLEMENT FOR HARDNESS OF 4-7 N

Claims 1-34 are not enabled for at least two reasons, which are provided in Grounds 2 and 3. Ground 2 demonstrates that the specification fails to enable at least the lower end of the claimed hardness range of 4-7 N. Ground 3 demonstrates that the specification fails to enable the full scope of the claimed ODT having “a hardness of 4-48 N.”

A. Legal Standard

“[T]he more a party claims for itself the more it must enable.” *Amgen Inc. v. Sanofi*, 598 U.S. 594, 616 (2023). “If a patent claims an entire class of... compositions of matter, the patent’s specification must enable a person skilled in the art to make and use the entire class.” *Id.* at 610.

“Claims are not enabled when, at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation.” *Wyeth & Cordis Corps. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013). “[W]hen a range is claimed, there must be reasonable enablement of the scope of the range.” *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). “It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.” *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

Factors to be considered in determining undue experimentation include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

B. Analysis

Claim limitation 1[v] recites an ODT having “a hardness of 4-48 N.” However, the specification is devoid of any disclosure supporting an ODT having a hardness at the lower end of the claimed range of 4-7 N. *Supra* Section VIII.B.⁵ The application is also devoid of any guidance that would enable a POSA to arrive at an ODT having a hardness of 4-7 N. The complete lack of disclosure for the lower end of the claimed range means that Ellodi failed to enable the full scope of the claimed hardness range such that claim 1 is unpatentable for lack of enablement. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1378-80 (Fed. Cir. 2007) (holding lack of enablement where the specification failed to “describe an injector with a disposable syringe without a pressure jacket” and explaining “[t]here must be reasonable enablement of the scope of the range which, in this case, includes both injector systems with and without a pressure jacket”); EX1095 ¶¶120-122.

Indeed, the PTAB previously determined that unpatentability for an application that did not support a lower end of a claimed range extends to enablement because “without the guidance that would have led the skilled artisan to envision this part of the claim scope, the artisan is likewise without the information needed to

⁵ The specification of the ’598 patent is the same as the specification of the ’047 application. *See* EX1001 1:7-18:47; EX1097 ¶¶[0001]-[0098].

make and use that part of the claim scope.” *Inari Agriculture*, PGR2023-00022, Paper 11 at 52.

Ellodi cannot rely on general knowledge in the art to fill the void in its specification. “When there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required.” *Genentech*, 108 F.3d at 1366.

Ellodi has not enabled the full scope of the claimed hardness range and claim 1 is therefore unpatentable. For the sake of completeness, Petitioner provides the following succinct analysis of the *Wands* factors to further demonstrate the glaring shortcomings in the specification’s enablement of the claimed hardness range.

1. Quantity of experimentation necessary, and Amount of guidance presented

The specification is devoid of any disclosure of an ODT having a hardness of 4-7 N. Thus, a POSA would have to make and test numerous ODT formulations to empirically determine the design parameters that would lead to the claimed ODTs having a hardness of 4-7 N. EX1095 ¶¶123-124. This amount of experimentation is undue in view of the failure of the specification to provide any discussion or guidance regarding an ODT with a hardness of 4-7 N. *See Genentech*, 108 F.3d at 1366 (failure to meet the enablement requirement “cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art”). These factors favor non-enablement.

2. Working examples

The specification does not provide a working example of an ODT having a hardness of 4-7 N. EX1095 ¶125. This factor favors non-enablement.

3. Nature of the invention

The purported invention is drawn to ODTs having a hardness between 4-48 N. As discussed above, a POSA would have to determine empirically how to arrive at the claimed ODT having a hardness of 4-7 N due to the lack of guidance in the specification. EX1095 ¶126. This factor favors non-enablement.

4. State of the prior art, Relative skill in the art, Predictability of the art

Although the level of skill in the art is high, *see supra* Section VI (defining the POSA), the lack of guidance in the '598 patent regarding an ODT having a hardness of 4-7 N does not allow the POSA to practice the full scope of the claimed ODTs. As discussed above, a POSA would have to experiment to empirically determine how to arrive at the claimed ODT having a hardness of 4-7 N because the '598 patent does not provide any guidance for arriving at the claimed ODT. This empirical process introduces unpredictability for the POSA in arriving at an ODT having a hardness of 4-7 N. EX1095 ¶127. Taken together, these factors favor non-enablement.

5. Breadth of the claims

The claims broadly cover a hardness ranging from 4-48 N. The specification, however, completely lacks any disclosure of an ODT having a hardness of 4-7 N. EX1095 ¶¶128-130. This factor favors non-enablement.

C. Conclusion

Based on the foregoing, claim 1 is unpatentable under §112(a) for lack of enablement. Each of claims 2-34 depends from claim 1. None of the dependent claims meaningfully narrow the claim scope for purposes of enablement in view of the lack of guidance provided by the specification. Thus, for the same reasons that claim 1 is not enabled, claims 2-34 also are not enabled, and all claims are invalid under §112(a) for lack of enablement.

If Ellodi were to argue that any of its dependent claims do not encompass an ODT having a hardness of 4-7 N, then those claims would encompass an ODT having any possible hardness. The specification does not describe an ODT having all possible hardness values, nor does it provide any guidance to the POSA regarding how to make an ODT having the full scope of all possible hardness values. Therefore, such an argument would result in the dependent claims being invalid under §112(a) for lack of enablement.

**X. GROUND 3: LACK OF ENABLEMENT FOR
HARDNESS OF 4-48 N**

Claim limitation 1[v] recites an ODT having “a hardness of 4-48 N.” Petitioner provides the following *Wands* factor analysis to demonstrate non-enablement of claim 1.

A. State of the prior art

The prior art demonstrates that there were numerous ways to quantify hardness, and that the different quantification methods provide significantly different hardness values. Prior art hardness testers were manufactured by Monsanto/Stokes, Strong-Cobb, Pfizer, Schleuniger, Key, Van Kel, Erweka, and others. EX1106 883. These testers used different methods to apply compressive forces to tablets. *Id.* Hardness values measured by different methods often differed significantly from each other. *Id.*; *Supra* Section III.B. For example, “[t]he rate at which the compressive load is applied can significantly affect results,” EX1104 677, and even automated testers “do not produce uniform results for the same tablet due to operator variation, lack of calibration, spring fatigue, and manufacturer variation.” EX1107 928. The literature warns that tablet hardness values reported without describing the method used to measure hardness “should be seriously questioned.” EX1108 1357; EX1095 ¶¶133-135.

Here, the specification fails to inform the POSA how hardness should be measured despite the numerous different methods of quantification known in the

prior art that provide significantly different hardness values. The specification fails to provide any guidance to the POSA as to how hardness should be determined to make ODTs having the full scope of the claimed hardness range. EX1095 ¶136. This factor favors non-enablement.

B. Quantity of experimentation necessary, and Amount of guidance presented

The specification provides one example that resulted in tablets having a hardness of 8-48 N. EX1001 17:40-18:23. The specification, however, fails to specify how the hardness values were measured for these tablets. The specification is devoid of any guidance how hardness values should be determined. This is a critical omission in view of the numerous hardness testing parameters in the prior art that were known to significantly impact the quantification of hardness. Thus, a POSA would have to experiment with numerous formulations and testing parameters to empirically arrive at ODTs having the full scope of the claimed hardness range. EX1095 ¶¶137-138. This amount of experimentation is undue in view of the failure of the specification to provide any guidance on how hardness should be determined. These factors favor non-enablement.

C. Working examples

The specification provides one example that resulted in tablets having a hardness of 8-48 N. EX1001 17:40-18:23. There is no explanation or guidance how the hardness values in the example were measured. In *Amgen*, a specification

disclosed 26 working examples (which is significantly more than the single example in the '598 patent in this proceeding), yet failed to enable the claims full scope. *See Amgen*, 598 U.S. at 612-614; EX1095 ¶139. This factor favors non-enablement.

D. Nature of the invention

The purported invention is drawn to ODTs having a hardness between 4-48 N. As discussed above, a POSA would have to determine empirically how to arrive at an ODT having the full scope of the claimed hardness range. EX1095 ¶140. This factor favors non-enablement.

E. The relative skill in the art, and Predictability of the art

Although the level of skill in the art is high, *see supra* Section VI (defining the POSA), the lack of guidance in the '598 patent regarding how to measure the claimed hardness does not allow the POSA to practice the full scope of the claimed invention. As discussed above, a POSA would have to experiment to empirically determine how to arrive at the full scope of the claimed ODT due to the lack of guidance in the specification on how hardness should be measured. This empirical process introduces unpredictability for the POSA in arriving at an ODT having the full scope of the claimed hardness. EX1095 ¶141. Taken together, these factors favor non-enablement.

F. Breadth of the claims

The claims broadly cover a hardness ranging from 4-48 N. The specification, however, provides no guidance how to measure the claimed hardness. As discussed above, different methods of measuring hardness lead to significantly different results. The application does not allow the POSA to practice the full scope of the claimed ODT for at least this reason. EX1095 ¶¶142-144.

G. Conclusion

Based on the foregoing, all *Wands* factors favor non-enablement. Claim 1 is therefore unpatentable under §112(a) for lack of enablement. Each of claims 2-34 depends from claim 1. None of the dependent claims meaningfully narrow the claim scope for purposes of enablement. Thus, for the same reasons that claim 1 is not enabled, claims 2-34 also are not enabled, and all claims are invalid under §112(a) for lack of enablement.

If Ellodi were to argue that any of its dependent claims do not encompass an ODT having a hardness of 4-48 N, then those claims would encompass an ODT having any possible hardness. The specification does not describe an ODT having all possible hardness values, nor does it provide any guidance to the POSA regarding how to make an ODT having the full scope of all possible hardness values. Therefore, such an argument would result in the dependent claims being invalid under §112(a) for lack of enablement.

XI. GROUND 4: INDEFINITENESS

Claims 1-34 are unpatentable because they are indefinite under §112(b).

A. Legal Standard

A patent “is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments*, 572 U.S. 898, 901 (2014). “[A] claim is indefinite if its language might mean several different things and no informed and confident choice is available among the contending definitions.” *Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1371 (Fed. Cir. 2015).

B. Analysis

Claim limitation 1[v] recites an ODT “having a hardness of 4-48 N.” However, there were numerous ways to quantify hardness in the prior art, and the different quantification methods provide significantly different hardness values. *Supra* Section III.B. For example, prior art hardness testers were manufactured by Monsanto/Stokes, Strong-Cobb, Pfizer, Schleuniger, Key, Van Kel, Erweka, and others. EX1106 883. These testers use different methods to apply compressive forces to tablets. *Id.* Hardness values measured by different methods often differ significantly from each other. *Id.*; *Supra* Section III.B; EX1095 ¶¶145-146.

The specification fails to provide any guidance as to how hardness should be ascertained. Thus, the POSA cannot be reasonably certain of the scope of the claimed ODT because there are multiple different ways to measure hardnesses that yield significantly different results, and it is unclear which method of measurement is intended by the claims. EX1095 ¶¶147-149. The claims are therefore indefinite under §112(b) and unpatentable.

The Federal Circuit previously held claims invalid for indefiniteness where there were four methods for measuring strain hardening and “[n]either the patent claims nor the specification [t]here discusses the four methods or provides any guidance as to which method should be used or even whether the possible universe of methods is limited to these four methods.” *See Dow Chem. Co. v. Nova Chems. Corp. (Can.)*, 803 F.3d 620, 633-34 (Fed. Cir. 2015). The Federal Circuit explained that “each of these four methods may produce different results” and the “multiple methods leading to different results [were provided] without guidance in the patent or the prosecution history as to which method should be used.” *Id.* Here, hardness can be measured by different methods that may produce significantly different results. The ’598 patent does not discuss any of the different methods for measuring hardness, and fails to provide any guidance as to which method should be used. Accordingly, claim limitation 1[v] renders the ’598 patent claims indefinite. *Id.*

As another example, the Federal Circuit held a claim invalid for indefiniteness where claims recited the term “average molecular weight,” but it was known that the “average molecular weight can be ascertained by any of three possible measures: Mp, Mn, and Mw.” *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1344-45 (Fed. Cir. 2015). The Federal Circuit explained that the claims “did not indicate which measure to use,” and “[t]he specification never defines molecular weight or even mentions Mp, Mw, or Mn.” *Id.* The court concluded that the claim was indefinite because there was no reasonable certainty as to how the average molecular weight should be measured. *Id.* Here, hardness can be measured by several possible methods that may yield significantly different results and the ’598 specification never defines how hardness should be measured. As a result, a POSA would not have reasonable certainty how the claimed hardness should be measured.

Based on the foregoing, claim 1 is indefinite. Each of claims 2-34 depends from claim 1 and therefore include the “hardness” recited by claim 1. None of the dependent claims clarify how the hardness is measured. Thus, for the same reasons that claim 1 is indefinite, claims 2-34 also are indefinite, and all claims are invalid under §112(b) for indefiniteness.

XII. GROUND 5: ANTICIPATION BY PERRETT

A. Perrett is prior art

Because the '598 patent is not entitled to claim priority prior to its effective filing date of January 5, 2022, several of the earlier filed patents and applications in the purported priority chain constitute prior art. *See Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1155-56 (Fed. Cir. 1998); *Inguran*, PGR2015-00017, Paper 8 at 17-18, 35. One such earlier patent is U.S. 8,771,729 (“Perrett,” EX1109), which issued July 8, 2014. Perrett is therefore prior art under §102(a)(1). Perrett discloses the same subject matter that was later claimed by the '598 patent. Perrett therefore anticipates claims 1-34 of the '598 patent.

B. Claim 1

Perrett’s disclosure anticipates claim 1.

1. Preamble

The preamble of claim 1 recites: “[a]n orally disintegrating tablet.”

Perrett discloses an ODT. EX1109 15:1-3, 5:16-20, 17:61-62, 19:31-33; EX1095 ¶155.

2. Limitation 1(i)

Limitation 1(i) recites “about 0.5 mg to 6 mg of a corticosteroid selected from fluticasone propionate or budesonide.”

Perrett Example 1 discloses an ODT having 4 mg of fluticasone propionate. EX1109 17:18-19, 17:46-55; *id.* 7:6-10, 7:25-49, 20:16-22; EX1095 ¶¶157-159.

3. Limitation 1(ii)

Limitation 1(ii) recites “at least one disintegrant.”

Perrett Example 1 contains crospovidone, which is a disintegrant. EX1109 17:14-15; *id.* 8:49-55, 12:66-13:1, 15:3-7, 18:58-63; EX1095 ¶¶161-162.

4. Limitation 1[iii]

Limitation 1[iii] recites “wherein upon administration a therapeutically effective amount of the corticosteroid is deposited topically in the esophagus.”

Perrett discloses topical administration to the esophagus. EX1109 3:59-62, 4:3-6, 5:11-15, 20:42-45; EX1095 ¶164.

5. Limitation 1[iv]

Limitation 1[iv] recites “wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> Disintegration Test.”

Perret discloses ODTs that disintegrate within 60 seconds via USP <701>. EX1109 17:61-62, 4:66-5:5, 10:4-11; EX1095 ¶¶166-167.

6. Limitation 1[v]

Limitation 1[v] recites “wherein the orally disintegrating tablet has a hardness of 4-48 N or a friability of not more than 1%.”

Perrett Example 1 discloses an ODT having a hardness of 8-48 N and friability of not more than 1%. EX1109 17:46-55; *id.* 8:40-48; EX1095 ¶¶169-170. Petitioner notes that “[t]he standard for enablement of a prior art reference for purposes of anticipation under section 102 differs from the enablement standard under 35 U.S.C. § 112.” *Novo Nordisk Pharms., Inc. v. Bio-Technology General Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005). Perrett’s disclosure of an ODT having a hardness of 8-48 N falls within the claimed hardness range of 4-48 N and is sufficient for anticipation.

C. Claims 2 and 3

Claim 2 depends from claim 1 and recites “comprising about 0.5 mg to about 2 mg of the corticosteroid.”

Claim 3 depends from claim 1 and recites “comprising about 3 mg of the corticosteroid.”

Perrett discloses an ODT having the claimed amounts of corticosteroid for the same reasons it anticipates limitation 1(i). *Supra* Section XII.B.2; EX1109 7:25-49, 10:16-21; EX1095 ¶173.

D. Claim 4

Claim 4 depends from claim 1 and recites “comprising a sugar alcohol and/or saccharide.”

Perrett discloses ODTs comprising a sugar alcohol and/or saccharide. EX1109 2:49-56, 8:56-62; EX1095 ¶175.

E. Claims 5-8

Claim 5 depends from claim 1 and recites “wherein the orally disintegrating tablet comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise the corticosteroid and at least one excipient, and the rapidly dispersing granules comprise the disintegrant and a sugar alcohol and/or saccharide.”

Claim 6 depends from claim 5 and recites “wherein the rapidly dispersing granules have an average particle size of less than about 300 μm , and each of the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 μm .”

Claim 7 depends from claim 5 and recites “wherein the drug particles have an average particle size of about 100-400 μm .”

Claim 8 depends from claim 5 and recites “wherein the drug particles have an average particle size of about 100-400 μm , the rapidly dispersing granules have an average particle size of less than about 300 μm , and each of the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 μm .”

Perrett discloses an ODT that anticipates claims 5-8. EX1109 8:1-11, 8:22-31, 11:40-52, 15:3-7, 15:14-16, 15:28-31, 15:47-54, 16:44-17:2, 17:21-27, 19:39-44, 20:4-7; EX1095 ¶¶177-179.

F. Claim 9

Claim 9 depends from claim 2 and recites “wherein the corticosteroid is budesonide.”

Perrett discloses an ODT containing budesonide. EX1109 7:6-13, 18:35-39; EX1095 ¶181.

G. Claims 10-12

Claim 10 depends from claim 5 and recites “wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.”

Claim 11 depends from claim 3 and recites “wherein the corticosteroid is fluticasone propionate.”

Claim 12 depends from claim 8 and recites “wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.”

Perrett discloses an ODT having the claimed amounts of fluticasone. EX1109 7:6-11, 7:25-49, 10:16-21, 20:23-24; EX1095 ¶¶183-184.

H. Claims 13-14

Claim 13 depends from claim 1 and recites “wherein the disintegrant is crospovidone....”

Claim 14 depends from claim 13 and recites “wherein the disintegrant is crospovidone.”

Perrett discloses an ODT containing crospovidone. EX1109 17:14-15, 8:49-55, 13:59-66; EX1095 ¶186.

I. Claims 15-16

Claim 15 depends from claim 5 and recites “wherein the sugar alcohol and/or saccharide is mannitol, sorbitol, xylitol, maltitol, arabitol, ribitol, dulcitol, iditol, isomalt, lactitol, erythritol, lactose, sucrose, maltose, or combinations thereof.”

Claim 16 depends from claim 15 and recites “wherein the sugar alcohol is mannitol.”

Perrett discloses an ODT containing the recited sugar alcohols. EX1109 17:14, 8:56-60, 13:59-66; EX1095 ¶188.

J. Claim 17

Claim 17 depends from claim 5 and recites “wherein the ratio of disintegrant to sugar alcohol, saccharide or mixture thereof in the rapidly dispersing microgranules ranges from about 90/10 to about 99/01.”

Perrett discloses the claimed ratio. EX1109 8:12-17; EX1095 ¶190.

K. Claims 18-19 and 31-32

Claim 18 depends from claim 1 and recites “the orally disintegrating tablet disintegrates within 60 seconds when tested in simulated saliva fluid using the USP <701> Disintegration Test.”

Claim 19 depends from claim 1 and recites “wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.”

Claim 31 depends from claim 20 and recites “wherein the orally disintegrating tablet disintegrates within 60 seconds when tested in simulated saliva fluid using the USP <701> Disintegration Test.”

Claim 32 depends from claim 20 and recites “wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.”

Perrett discloses an ODT that disintegrates within 30 seconds via USP <701>. EX1109 17:61-62, 4:66-5:11, 10:4-11; EX1095 ¶¶192-193.

L. Claim 20

Claim 20 recites “[a] method for treating eosinophilic esophagitis comprising administering to a patient in need thereof the orally disintegrating tablet according to claim 1.”

Perrett discloses the claimed method. EX1109 4:3-26, 4:50-57, 20:25-33; EX1095 ¶195.

M. Claims 21, 29-30, and 33

Claim 21 depends from claim 20 and recites “wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.”

Claim 29 depends from claim 14 and recites “wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.”

Claim 30 depends from claim 16 and recites “wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.”

Claim 33 depends from claim 28 and recites “wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.”

Perrett discloses an ODT having the claimed amounts of fluticasone. EX1109 7:6-11, 7:25-49, 10:16-21, 20:23-24; EX1095 ¶¶197-198.

N. Claims 22 and 34

Claim 22 depends from claim 20 and recites “wherein the orally disintegrating tablet comprises about 0.5 mg to about 2 mg of budesonide.”

Claim 34 depends from claim 28 and recites “wherein the orally disintegrating tablet comprises about 0.5 mg to about 2 mg of budesonide.”

Perrett discloses an ODT having the claimed amount of budesonide. EX1109 7:25-49, 10:16-21; EX1095 ¶200.

O. Claims 23-27

Claim 23 recites “wherein the orally disintegrating tablet has a hardness of 4-48 N.”

Claim 24 recites “wherein the orally disintegrating tablet has a friability of not more than 1%.”

Claim 25 recites “wherein the orally disintegrating has a hardness of 4-48 N and a friability of not more than 1%.”

Claim 26 recites “wherein the orally disintegrating tablet has a friability of not more than 0.6%.”

Claim 27 recites “wherein the orally disintegrating tablet has a friability of not more than 0.6%.”

Perrett anticipates claims 23-27 for the same reason it anticipates claim 1. *Supra* Section XII.B.6; EX1109 17:46-55 (disclosing tablets with a hardness of 8-48 N and a target friability of not more than 0.6%), 8:40-48 (friability of “less than about 1%” or “less than about 0.6%”); EX1095 ¶202.

P. Claim 28

Claim 28 depends from claim 27 and recites “wherein the orally disintegrating tablet has a thickness of 2-2.8 mm.”

Perrett discloses an ODT having the claimed thickness. EX1109 17:46-55; EX1095 ¶204.

XIII. GROUND 6: OBVIOUSNESS OVER PERRETT

The discussion of Perrett from Ground 5 (Section XII) is incorporated by reference here.

There is strong evidence that Perrett anticipates claims 1-34, as set forth in Ground 5 above. Should the PTAB find that Perrett does not anticipate these claims, they would have been obvious based on Perrett.

Perrett's disclosure is directed to ODTs and various embodiments thereof. Perrett instructs the POSA that "although specific embodiments of the invention have been described herein for purposes of illustration, various modifications may be made without departing from the spirit and scope of the invention" and that the "invention is not limited" by the specifically disclosed embodiments. EX1109 18:14-19. To the extent any of the referenced disclosures in Ground 5 of this Petition are considered separate embodiments, a POSA would have been motivated with a reasonable expectation of success to prepare an ODT having the claimed properties based on Perrett's disclosures of ODTs having the ingredients and properties falling within the claimed ranges, as well as Perrett's express instruction to make modifications to the specific embodiments. *Id.*; EX1095 ¶¶205-206. Combining embodiments "disclosed adjacent to each other in a prior art patent does

not require a leap of inventiveness.” *Boston Sci. Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 991 (Fed. Cir. 2009).⁶ Claims 1-34 are obvious over Perrett.

XIV. GROUND 7: DOHIL IN VIEW OF KARARLI, THE FDA GUIDANCE, AND THE USP

This section introduces Dohil and Kararli, and then explains how Dohil in view of Kararli, the FDA Guidance, and the USP render obvious claims 1-4, 9, 13-14, 18-20, 22-25 and 31-32 of the '598 patent.

A. Dohil

Dohil discloses a budesonide formulation “provided in the form of a lozenge which may be dissolved in the mouth, thus reaching and coating the esophagus.” EX1002 ¶[0032]. Dohil explains that the lozenge “or other similar tablet” will “dissolve rapidly in the mouth or esophagus to produce a solution that can then coat

⁶ Petitioner notes that the standard for reasonable expectation of success for demonstrating obviousness is different than the standard for demonstrating lack of enablement. Thus, even if the Board were to find that the specification enables the challenged claims, that would not prevent the Board from finding the claims to be obvious over the prior art. *See UCB, Inc. v. Accord Healthcare, Inc.*, 890 F.3d 1313, 1327 (Fed. Cir. 2018) (explaining that the presumption of enablement does not preclude a “finding that there was no reasonable expectation of success”).

the esophagus.” *Id.* Exemplary dosage amounts of budesonide in Dohil’s formulation include “1-2 mg or 2-3 mg.” *Id.* ¶[0015]; EX1095 ¶208.

B. Kararli

Kararli discloses rapidly disintegrating tablets for treating the upper gastrointestinal tract, including the esophagus. EX1110 Title, Abstract, 9:19-25, 15:3-15, 25:15-26:13. Kararli discloses that its tablets “disintegrate within about 30 to about 300 seconds” when tested using the USP <701> Disintegration Test. *Id.* 9:19-23 (“tablets disintegrate within about 30 to about 300 seconds after placement in a standard in vitro disintegration assay (e.g., conducted according to U.S. Pharmacopeia 24 (2000), Test No. 701) and/or disintegrate within about 5 to about 60 seconds after placement in the oral cavity of a subject”), 25:15-18.

Kararli’s tablets preferably have a hardness of about 9.8 to about 49.1 N. *Id.* 25:23-27 (“Preferably, compositions of the invention have a hardness of about 1 to about 10 kp, and more preferably of about 1 to about 5 kp.”)⁷; EX1095 ¶¶209-211.

C. Claim 1

1. Preamble

If the preamble were limiting, Dohil discloses the recited ODT. Dohil discloses that “[b]udesonide is provided in the form of a *lozenge which may be*

⁷ A hardness of 1 to 5 kp is equivalent to a hardness of 9.8 to 49.1 N. EX1095 ¶211.

dissolved in the mouth, thus reaching and coating the esophagus. The lozenge or other similar tablet, capsule, or other solid, [w]ould ***dissolve rapidly in the mouth*** or esophagus to produce a solution that can then coat the esophagus.” EX1002 ¶[0032]. Dohil further discloses “[b]udesonide, in the form of ***a dissolving tablet***.” *Id.* ¶[0013]; *id.* ¶[0037] (“dissolving tablets”). A POSA would understand that Dohil’s lozenges and tablets that dissolve rapidly in the oral cavity do so without chewing. EX1095 ¶¶213-215; EX1005 1.

2. Limitation 1(i)

Dohil discloses that “[b]udesonide is provided in the form of a lozenge which may be dissolved in the mouth.” EX1002 ¶[0032]. Dohil discloses that “[i]n certain embodiments, 1-2 mg or 2-3 mg [of] corticosteroid per day is administered to said individual.” EX1002 ¶[0015]; *id.* ¶¶[0031], [0058] (“0-1 mg/day, 1-2 mg/day, 2-3 mg/day, 3-4 mg/day, 4-5 mg/day [of]... for example, Budesonide, are administered”). Dohil’s patients were actually dosed with topically administered budesonide at 0.5, 1, and 2 mg/day. *Id.* ¶¶[0058], [0053], Table 1. “In one illustrative example, the dose is provided once a day.” *Id.* ¶[0031]. Dohil thus discloses a lozenge or tablet containing a daily dose of budesonide at, e.g., 0.5mg, 1mg, 2mg, and/or 3mg. EX1095 ¶¶217-220. Dohil therefore discloses limitation 1(i).

3. Limitation 1(ii)

Dohil discloses that “[b]udesonide is provided in the form of a lozenge” or “other similar tablet” which will “dissolve rapidly in the mouth or esophagus.” EX1002 ¶[0032]. Dohil discloses “[i]f desired, *disintegrating agents* may be added, such as the cross-linked polyvinylpyrrolidone, agar, or alginic acid or a salt thereof such as sodium alginate.” EX1002 ¶[0037]. It was known that the rapid dissolution of the lozenge or tablet would be desirably aided by at least one disintegrating agent. EX1018 446-47; EX1095 ¶¶222-223. Dohil therefore discloses limitation 1(ii).

4. Limitation 1(iii)

Dohil discloses a lozenge or tablet that “comprises a therapeutically effective amount of corticosteroid to prevent or alleviate esophageal inflammation. In certain embodiments, 1-2 mg or 2-3 mg [of] corticosteroid per day is administered to said individual.” EX1002 ¶[0015]. Dohil discloses a lozenge or tablet containing a daily dose of budesonide containing, e.g., 0.5mg, 1mg, 2mg, and/or 3mg. *Supra* Section XIV.C.2. Thus, a POSA would understand that a dose of, e.g., 0.5 mg to 3 mg of corticosteroid per day is a therapeutically effective amount of corticosteroid. EX1095 ¶225. Therefore, Dohil’s lozenge or tablet comprises a therapeutically effective amount of corticosteroid.

Upon administration of Dohil’s lozenge or tablet, it “dissolve[s] rapidly in the mouth or esophagus to produce a solution” of budesonide that is deposited topically

in the upper gastrointestinal tract by “*coat[ing] the esophagus.*” EX1002 ¶[0032].

Dohil repeatedly discloses that its formulations are designed to topically deposit a therapeutically effective amount of budesonide in the “upper gastrointestinal tract,” *id.* ¶[0010], such as “*to the esophagus,*” *id.* ¶¶[0013], [0037], [0041]; EX1095 ¶¶226-227. Dohil therefore discloses limitation 1[iii].

5. Limitation 1[iv]

Dohil discloses that “[t]he lozenge or other similar tablet, capsule, or other solid, [w]ould dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus.” EX1002 ¶[0032]. It was desirable for the disintegration time of rapidly dissolving solid compositions to vary “from several seconds to about a minute.” EX1018 434; EX1095 ¶229.

It was obvious to formulate Dohil’s rapidly dissolving lozenge or tablet to disintegrate within 60 seconds when tested using the USP <701> Disintegration Test in view of the knowledge of the POSA. The knowledge of the POSA is represented by, for example, the FDA’s Guidance for Industry on ODTs. The FDA Guidance explains that ODTs “disintegrate[] rapidly, usually within a matter of seconds.” EX1005 2. The FDA recommends that such compositions have “*an in-vitro disintegration time of approximately 30 seconds or less, when based on the United States Pharmacopeia (USP) disintegration test method* or alternative (see section IV).” *Id.* 2. The FDA Guidance “recommend[s] that applicants use the USP method

for disintegration testing,” *id.* 3, specifically “**USP 29, <701> Disintegration**” *id.* 3 n.3.

A POSA would have been motivated to follow the FDA Guidance in formulating Dohil’s rapidly dissolving lozenge or tablet containing budesonide. The FDA Guidance provides the agency’s thinking and recommendations on the topic of rapidly disintegrating oral pharmaceutical compositions. *Id.* 1. The FDA regulates the use of pharmaceutical compositions in the United States. Dohil’s formulations were intended to “be used in therapy for human patients,” EX1002 ¶[0028], and the initial testing of its formulations was conducted within the United States, *id.* ¶[0049].

A POSA seeking to formulate budesonide into an orally disintegrating pharmaceutical composition would be highly motivated to follow the FDA Guidance that such a composition should disintegrate within 30 seconds or less when tested using the USP <701> Disintegration Test. EX1095 ¶¶230-231.

A POSA would have had a reasonable expectation of success in doing so based on Dohil’s detailed description of how to formulate budesonide into a rapidly disintegrating lozenge or tablet. EX1002 ¶¶[0027]-[0041] (section entitled “Formulation”). Formulating orally disintegrating pharmaceutical compositions that dissolve within “several seconds to about a minute” would have been a routine exercise by 2009. EX1018 434; EX1005 2; EX1095 ¶232. There were many commercially available orally disintegrating systems and products available by

2009, which would have bolstered the POSA’s expectation of success. EX1017 179-181; EX1018 436-439; EX1095 ¶¶232-233.

Dohil in view of the FDA Guidance therefore renders obvious limitation 1[iv].

6. Limitation 1[v]

A POSA would have been motivated to formulate Dohil’s rapidly dissolving lozenge or tablet to have a hardness of between 4-48 N or a friability of not more than 1% with a reasonable expectation of success in view of Kararli and the USP.

Kararli is directed to ODTs. EX1110 Title, 3:14-4:18. Kararli teaches ODTs have a hardness “more preferably of about 1 to about 5 kp.” *Id.* 25:23-27. A hardness of 1-5 kp is equivalent to a hardness of 9.8-49.1 N.⁸ Kararli teaches that this hardness is important for an ODT to “have sufficient hardness for handling,” and to “withstand removal from at least a standard type of blister packaging,” and “withstand other handling such as packaging, delivery, carrying and the like.” *Id.* 25:28-26:13; *id.* 9:19-26; EX1095 ¶¶235-237.

Kararli’s teaching is reinforced by the knowledge of the POSA, which is represented by, for example, the United States Pharmacopeia (“USP”). USP standards have been recognized as an authority in the pharmaceutical field for over 200 years “because they are authoritative and science-based and are established by

⁸ 1 kilopond (kp) is equivalent to 9.8N; EX1095 ¶237.

a transparent and credible process.” EX1104 viii. USP is “recognized by law and custom in many countries throughout the world,” including the U.S. *Id.* USP teaches that hardness is an important indicator of mechanical strength for tablets to “be able to withstand the rigors of handling and transportation experienced in the manufacturing plant, in the drug distribution system, and in the field at the hands of the end users (patients/consumers).” *Id.* 676. USP also teaches that friability is another important indicator of mechanical strength for tablets and recommends a friability “of not more than 1.0% is considered acceptable for most products.” *Id.*; EX1095 ¶238.

A POSA would have been motivated to follow Kararli and USP’s recommendations in formulating Dohil’s rapidly dissolving lozenge/tablet to have a hardness of 9.8-49.1 N and a friability of not more than 1% to provide a lozenge/tablet of sufficient mechanical strength to handle packaging, transportation, and handling. A POSA had a reasonable expectation of success in formulating Dohil’s rapidly dissolving lozenge/tablet to have a hardness falling within the range of 4-48 N or a friability falling within the range of 0-1% given the disclosures of Kararli, the USP, and several of Patent Owner’s own prior art publications that disclose ODTs having hardness and friability within the claimed ranges. *See* EX1111 22:7-26 (Example 1 ODTs with hardness of “8-48 N” and friability of “NMT [not more than] 1.0%”); EX1112 38 (Table 3 disclosing ODTs with hardness

of 6.8 and 6.92-6.95 N, and friability of 0.24-0.31%), 48 (Table 12 disclosing ODTs hardnesses between 41.3 and 46.0 N, and friability between 0.20-0.51%); EX1113 38 (Table 3), 48 (Table 12); EX1095 ¶¶239-241.

Dohil in view of Kararli, the FDA Guidance, and the USP therefore render obvious claim 1.

D. Claims 2-3

Claims 2 and 3 are obvious for the same reasons discussed above for limitation 1(i). *Supra* Section XIV.C.2; EX1095 ¶244.

E. Claim 4

Dohil discloses the use of mannitol in its ODT formulations. EX1002 ¶¶[0014], [0037]. Mannitol was the bulk excipient of choice for ODTs. EX1041 261; EX1095 ¶¶246-248. The '598 patent admits that mannitol is a sugar alcohol that was “typically used in disintegrating tablet formulations.” EX1001 8:52-60, 9:10-11. Claim 4 is therefore obvious.

F. Claim 9

Claim 9 is obvious for the same reasons discussed above for Claim 1. *Supra* Section XIV.C; EX1095 ¶250.

G. Claims 13-14

The '598 patent admits that crospovidone is “cross-linked PVP [polyvinylpyrrolidone].” EX1001 9:3-7, 13:8; *id.* 12:13 (“polyvinylpyrrolidone (PVP)”), 12:31-32.

Dohil teaches that, “[i]f desired, disintegrating agents may be added, such as the *cross-linked polyvinylpyrrolidone*, agar, or alginic acid or a salt thereof such as sodium alginate.” EX1002 ¶¶0037; EX1095 ¶¶252-253. Claims 13-14 are therefore obvious.

H. Claims 18-19

A POSA would have been motivated to formulate Dohil’s rapidly dissolving lozenge or tablet to disintegrate within 30 seconds when tested using the USP <701> Disintegration Test with a reasonable expectation of success. *Supra* Section XIV.C.5. The FDA recommended that such compositions have “an in-vitro disintegration time of approximately 30 seconds or less,” EX1005 2, using the USP <701> test. *Id.* 3 n.3; EX1095 ¶255.

If Ellodi argues that the “simulated saliva” recited by claims 18-19 provides a patentable feature over the prior art, such an argument should be rejected. EX1005 3; EX1040 2; EX1047 367; EX1095 ¶¶256-257. During prosecution of a parent patent, U.S. 8,771,729, Ellodi admitted that the phrase “in simulated saliva” was “[a]n obvious error in the Specification,” which it corrected by amending the

specification and claims to remove any and all reference to “simulated saliva.”

EX1031 70; *id.* 71.

Claims 18-19 are therefore obvious.

I. Claim 20

Dohil discloses using its formulations to treat eosinophilic esophagitis. EX1002 ¶[0010]; *id.* ¶¶[0011], [0023]; EX1095 ¶259. Claim 20 is therefore obvious.

J. Claim 22

Claim 22 is obvious for the same reasons discussed above for Claims 1 and 20. *Supra* Sections XIV.C, XIV.I; EX1095 ¶261.

K. Claims 23-25

Claims 23-25 are obvious for the same reasons discussed above for claim limitation 1[v]. *Supra* Section XIV.C.6; EX1095 ¶263.

L. Claims 31-32

Claims 31-32 are obvious for the same reasons discussed above for Claims 1 and 18-20. *Supra* Sections XIV.C, XIV.H-I; EX1095 ¶265.

XV. GROUND 8: DOHIL IN VIEW OF KARARLI, THE FDA GUIDANCE, THE USP, AND VENKATESH988

This section introduces Venkatesh988, and then explains how Dohil in view of Kararli, the FDA Guidance, the USP, and Venkatesh988 render obvious dependent claims 5-8 and 15-16 of the '598 patent.

A. Venkatesh

Dr. Gopi Venkatesh is listed as a co-inventor on the '598 patent and US2005/0232988 (EX1020, Venkatesh988).

Venkatesh988 discloses “orally disintegrating tablets and a method for their manufacture.” EX1020 ¶[0001]. Venkatesh’s ODTs can be formulated using “any therapeutic active agent indicated for oral administration.” *Id.* ¶[0025]; EX1095 ¶¶267-268.

B. Claim 5

Claim 5 depends from claim 1 and recites “wherein the orally disintegrating tablet comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise the corticosteroid and at least one excipient, and the rapidly dispersing granules comprise the disintegrant and a sugar alcohol and/or saccharide.”

Venkatesh988 discloses “an orally disintegrating tablet made up of rapidly dispersing microgranules and taste-masked microcapsules” of drug particles. EX1020 ¶[0001]; *id.* ¶¶[0018], [0025] (microcapsule drug particles). The drug particles are granulated with diluent excipients. *Id.* ¶[0021]. Venkatesh988 discloses that “this invention relates to pharmaceutical compositions comprising rapidly dispersing microgranules of a disintegrant and sugar alcohol or a saccharide.” *Id.* ¶[0014]; *id.* ¶¶[0018], ¶[0028] (“sugar alcohol” and “saccharide”).

Venkatesh988 therefore discloses ODTs comprising drug particles comprising excipients and rapidly dispersing microgranules comprising a disintegrant, a sugar alcohol and/or saccharide.

The POSA would have been motivated for the budesonide in Dohil’s tablet to comprise drug particles with an excipient and the disintegrant to be rapidly dispersing granules that include a sugar alcohol and/or saccharide based on Venkatesh988. Venkatesh988 teaches that formulating ODTs to have drug particles and rapidly-dispersing microgranules comprising sugar alcohol and/or saccharide in combination with the disintegrant beneficially “avoid[ed] gritty mouthfeel,” EX1020 ¶[0012], to assist with providing a “smooth creamy mouthfeel (no grittiness),” *id.* ¶[0002]; EX1095 ¶¶270-273.

The POSA had a reasonable expectation of success based on Venkatesh988. Venkatesh988 teaches that its formulations “don’t require a special pharmaceutical production technique and can be simply and easily produced by a normal equipment.” EX1020 ¶[0018]; EX1095 ¶¶274-275.

Dohil in view of Kararli, the FDA Guidance, the USP, and Venkatesh988 therefore render obvious claim 5.

C. Claims 6-8

Claim 6 depends from claim 5 and recites “wherein the rapidly dispersing granules have an average particle size of less than about 300 μm , and each of the

disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 μm .”

Claim 7 depends from claim 5 and recites “wherein the drug particles have an average particle size of about 100-400 μm .”

Claim 8 depends from claim 5 and recites “wherein the drug particles have an average particle size of about 100-400 μm , the rapidly dispersing granules have an average particle size of less than about 300 μm , and each of the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 μm .”

Venkatesh988 discloses drug particles that advantageously have “an average particle size of 200 μm and can be effectively taste masked by coacervation by phase separation to produce taste-masked particles with optimum size distribution” and provide “a smooth creamy mouthfeel.” EX1020 ¶[0015].

Venkatesh988 discloses that the rapidly dispersing granules “typically” have an “average particle size of not more than 300 μm .” EX1020 ¶[0020]. A small particle size assists with mouthfeel. *Id.* ¶¶[0019], [0009], [0025].

Venkatesh988 discloses “rapidly dispersing microgranules of a disintegrant and sugar alcohol or a saccharide whose average particle size is not more than 30 μm ,” which is advantageous in “effectively taste-mask[ing] by coacervation.” EX1020 ¶[0014]; *id.* ¶[0018] (“preferably not more than 20 μm ”), ¶[0028].

A POSA would have been motivated to formulate budesonide in an ODT based on Dohil, and also having drug particles with a particle size less than 400 μm , rapidly dispersing granules with a particle size less than 300 μm , and a disintegrant and sugar alcohol and/or saccharide with a particle size less than 30 μm based on Venkatesh988 to avoid a gritty texture and improve mouthfeel with an expectation of success. EX1095 ¶¶277-281.

Claims 6-8 are therefore obvious.

D. Claims 15-16

Claim 15 depends from claim 5 and recites “wherein the sugar alcohol and/or saccharide is mannitol, sorbitol, xylitol, maltitol, arabitol, ribitol, dulcitol, iditol, isomalt, lactitol, erythritol, lactose, sucrose, maltose, or combinations thereof.”

Claim 16 depends from claim 15 and recites “wherein the sugar alcohol is mannitol.”

Dohil discloses budesonide ODTs formulated with mannitol and sorbitol as sugar alcohol excipients. EX1002 ¶¶[0014], [0037]. Mannitol was the bulk excipient of choice for ODTs. EX1041 261; EX1095 ¶¶283-285.

Venkatesh988 discloses that “[t]he dispersible microgranules comprise a sugar alcohol such as mannitol.” EX1020 ¶¶[0032], [0047]. Venkatesh988 further discloses that “[t]he sugar alcohol may be selected from the group consisting of mannitol, sorbitol, xylitol, maltitol and the like....” *Id.* ¶[0028].

Claims 15-16 are therefore obvious.

XVI. GROUND 9: DOHIL IN VIEW OF KARARLI, THE FDA GUIDANCE, THE USP, AND VENKATESH516

This section introduces Venkatesh516, and then explains how Dohil in view of Kararli, the FDA Guidance, the USP, and Venkatesh516 render obvious dependent claims 26-28 and 34 of the '598 patent.

A. Venkatesh516

Venkatesh516 discloses “pleasant tasting, orally dissolving or disintegrating tablet (ODT) compositions comprising lamotrigine.” EX1111 1:8-10. Venkatesh516’s ODTs have a friability target of “<0.6%.” *Id.* 22:1-2, 22:21, 23:27; EX1095 ¶287.

B. Claims 26-27

Claim 26 depends from claim 1 and recites “wherein the orally disintegrating tablet has a friability of not more than 0.6%.”

Claim 27 depends from claim 25 and recites “wherein the orally disintegrating tablet has a friability of not more than 0.6%.”

It was obvious to formulate Dohil’s rapidly dissolving lozenge/tablet to have a friability of less than 1%. *Supra* Section XIV.C.6. A POSA would have been motivated to formulate Dohil’s lozenge/tablet to have a friability of not more than 0.6% with a reasonable expectation of success in view of Venkatesh516.

Venkatesh516 discloses ODTs having a “target” friability of “<0.6%.” EX1111 22:1-2, 22:21 (“NMT [not more than]” 0.6%), 23:27. Venkatesh516 further discloses that such a friability is sufficiently low for the ODT “to be suitable for packaging in HDPE bottles and push-through film backed or peel-off paper backed blister packs using conventional equipment for storage, transportation and commercial distribution.” *Id.* 16:23-27; *id.* 19:10-11, 19:25-26; EX1095 ¶¶289-292.

Dohil in view of Kararli, the FDA Guidance, the USP, and Venkatesh516 render obvious claims 26-27.

C. Claim 28

Claim 28 depends from claim 27 and recites “wherein the orally disintegrating tablet has a thickness of 2-2.8 mm.”

Venkatesh516 discloses ODTs having a “target” thickness of 2.40 mm. EX1111 22:19. A POSA would have been motivated to follow Venkatesh516’s instruction with a reasonable expectation of success to target a thickness of 2.40 mm when formulating Dohil’s rapidly dissolving lozenge/tablet to provide an appropriately thick tablet to impart sufficient mechanical strength while also providing appropriate mouthfeel to the patient. EX1095 ¶¶294-295.

Claim 28 is therefore obvious.

D. Claim 34

Claim 34 depends from claim 28 and recites “wherein the orally disintegrating tablet comprises about 0.5 mg to about 2 mg of budesonide.”

Claim 34 is obvious for the same reasons discussed above for claims 1, 25, and 27-28. *Supra* Sections XIV.C, XIV.K, XVI.B-C; EX1095 ¶297.

XVII. GROUND 10: GROTHER IN VIEW OF KARARLI, THE FDA GUIDANCE, AND THE USP

This section introduces Grother and explains how Grother in view of Kararli, the FDA Guidance, and the USP render obvious claims 1-4, 9, 11, 13-14, 18-25, 29 and 31-32.

A. Grother

Grother discloses “fast dispersing solid dosage forms that preferably dissolve in the oral cavity within sixty (60), more preferably within thirty (30), most preferably within ten (10) seconds.” EX1008 Abstract. Grother’s fast dispersing dosage form comprises an active ingredient, a modified starch, and a matrix forming agent as follows:

There is disclosed a fast dispersing solid dosage form designed to release an active ingredient rapidly in the oral cavity characterized in that said dosage form is essentially free of mammalian gelatin and comprises:

at least one active ingredient;

at least one modified starch at a concentration of from 20 to 90% by weight of said solid dosage form; and
at least one matrix forming agent;
wherein said solid dosage form is obtainable by removing a solvent from a mixture comprising said active ingredient, said modified starch and said matrix forming agent.

EX1008 12:10-19. Grother discloses that “[a]ny drug may be used as the active ingredient in the composition of the present invention,” *id.* 15:19-20, including budesonide and fluticasone, *id.* 18:15-18; EX1095 ¶299.

B. Claim 1

Grother in view of Kararli, the FDA Guidance, and the USP disclose ODTs that render obvious all limitations of claim 1.

1. Preamble

If the preamble were limiting, Grother discloses the recited ODT. For example, Grother discloses “a fast dispersing solid dosage form designed to release an active ingredient rapidly in the oral cavity.” EX1008 12:10-19; *id.* 1:10-11, 3:18-20, 32:10. Grother’s process for making the fast dispersing solid dosage form results in a tablet. *Id.* 32:10-17. Grother discloses “fast dispersing solid dosage forms that preferably dissolve in the oral cavity within sixty (60), more preferably within thirty (30), most preferably within ten (10) seconds.” *Id.* Abstract; *id.* 13:19-22. A POSA would understand that Grother’s fast dispersing solid dosage form that dissolves

rapidly within the oral cavity does so without chewing. EX1005 1; EX1095 ¶¶302-305.

2. Limitation 1(i)

Grother discloses that “the active ingredient is generally present in an amount from 0.2 to 95%, normally 1 to 20%, by weight of the composition of the dried dosage form.” EX1008 21:16-18. Grother discloses that 60 mg is generally the “upper value” per dosage form. *Id.* 26:22-27:1.

Grother discloses that “[a]ny drug may be used as the active ingredient in the composition of the present invention,” EX1008 15:19-20, including corticosteroids, such as fluticasone and budesonide, *id.* 18:15-18. A POSA would have been motivated to select budesonide or fluticasone as an active ingredient in Grother’s fast dispersing solid dosage form based on Grother’s express disclosure to do so. *Boston Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 991 (Fed. Cir. 2009) (“Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness”). In addition, budesonide and fluticasone were well-known corticosteroids with desirable anti-inflammatory activity. *Supra* Section III.D-E; EX1095 ¶¶307-308.

It was known that dosages of budesonide desirably ranged from, e.g., 0.5-3mg. For example, Aceves 2005 successfully treated two patients suffering from eosinophilic esophagitis with 0.5 mg dosages of budesonide. EX1014 705-706

(describing budesonide dosage of twice daily “500 µg,” which is 0.5 mg); EX1095 ¶309. Aceves 2007 dosed seventeen patients with 1 mg of daily budesonide. EX1015 5; *id.* 4 (Table 1). Aceves 2007 reported that “[m]ost of our patients responded to 1 mg daily” of budesonide. *Id.* 7.

Dohil discloses that “[i]n some embodiments of the invention, 0-1 mg/day, 1-2 mg/day, 2-3 mg/day [of]... for example, Budesonide, are administered to a patient.” EX1002 ¶[0058]; *id.* ¶[0031]. Dohil’s patients were actually dosed with topically administered budesonide at 0.5, 1, and 2 mg/day. *Id.* ¶¶[0058], [0053], Table 1. “In one illustrative example, the dose is provided once a day.” *Id.* ¶[0031].

Based on Grother’s instruction that its compositions should normally have 1-20% by weight active ingredient a POSA would have been motivated to formulate budesonide in Grother’s compositions at, e.g., 0.5, 1, and 3 mg, with a reasonable expectation of success. EX1095 ¶¶310-311.

It was known that dosages of fluticasone for topical administration desirably ranged from, e.g., 0.044-0.44 mg (EX1033 1217) and 0.44-1.32 mg (EX1034 573 & Table 1); EX1095 ¶¶312-316. Based on Grother’s instruction that its compositions should normally have 1-20% by weight active ingredient a POSA would have been motivated to formulate fluticasone in Grother’s compositions at, e.g., 1.32 mg, with a reasonable expectation of success.

Grother therefore renders obvious an ODT that comprises 0.5 mg to 6 mg of budesonide or fluticasone.

3. Limitation 1(ii)

The '598 patent admits that disintegrants include starch, pregelatinized starch, and carboxymethyl starch. EX1001 9:49-54 (“suitable disintegrants include e.g.... starch, pregelatinized starch, and carboxymethyl starch”).

Grother’s fast dispersing dosage form comprises “at least one modified starch at a concentration of from 20 to 90% by weight of said solid dosage form.” EX1008 12:10-19. Grother’s modified starch includes pregelatinized starches and oxidized starches containing carboxyl groups, *id.* 5:10-6:5, which beneficially “may be used as the primary structure forming agent in FDDF’s [fast dispersing dosage forms] to form physically robust products while maintaining the desired rapid dispersion characteristics of the products,” *id.* 4:2-4. The at least one modified starch, such as the pregelatinized starch and oxidized starch containing carboxyl groups, in Grother’s formulation meets the “at least one disintegrant” required by limitation 1(ii). EX1095 ¶¶318-319. Grother therefore discloses at least one disintegrant.

4. Limitation 1(iii)

As discussed above, a POSA would have been motivated to formulate budesonide or fluticasone in Grother’s compositions at dosage amounts that

constitute a therapeutically effective amount of budesonide or fluticasone. *Supra* Section XVII.B.2.

Grother discloses “a pharmaceutical composition for oral administration in the form of a fast dispersing dosage form ***designed to release an active ingredient rapidly in the oral cavity.***” EX1008 3:18-20; *id.* 1:10-11 (“This invention relates to a pharmaceutical composition for oral administration in the form of a fast dispersing dosage form.”), 13:19-22, 32:10. A POSA would understand that oral administration of budesonide or fluticasone in the form of a fast dispersing dosage form would release the drug rapidly in the oral cavity, where it is then swallowed and topically deposited in the esophagus. EX1095 ¶¶321-322. Grother therefore discloses limitation 1[iii].

5. Limitation 1[iv]

Grother discloses “fast dispersing solid dosage forms that preferably dissolve in the oral cavity within sixty (60), more preferably within thirty (30), most preferably within ten (10) seconds.” EX1008 Abstract; *id.* 13:19-22 (“the term ‘fast dispersing dosage form (FDDF)’ refers to compositions which disintegrate/disperse within 1 to 60 seconds, preferably 1 to 30 seconds, more preferably 1 to 10 seconds and particularly 2 to 8 seconds, of being placed in the oral cavity.”).

It was obvious to formulate budesonide or fluticasone in Grother’s fast dispersing solid dosage form to disintegrate within 60 seconds when tested using the

USP <701> Disintegration Test in view of the FDA’s Guidance for Industry on ODTs. The FDA Guidance recommended that orally disintegrating formulations should have “an *in-vitro* disintegration time of approximately 30 seconds or less, when based on the United States Pharmacopeia (USP) disintegration test method or alternative (see section IV).” EX1005 2. The FDA Guidance “recommend[s] that applicants use the USP method for disintegration testing,” *id.* 3, specifically “USP 29, <701> Disintegration,” *id.* 3 n.3.

A POSA would have been motivated to follow the FDA Guidance in formulating Grother’s fast dispersing solid dosage form containing budesonide or fluticasone. The FDA Guidance provides the agency’s recommendations on the topic of orally disintegrating pharmaceutical compositions. *Id.* 1. The FDA regulates the use of pharmaceutical compositions in the United States. Grother’s formulations were intended to “enhance patient compliance.” EX1008 32:5-7. A POSA seeking to formulate budesonide into an orally disintegrating pharmaceutical composition would be highly motivated to follow the FDA Guidance that such a composition should disintegrate within 60 seconds when tested using the USP <701> Disintegration Test. EX1095 ¶¶324-326.

A POSA had a reasonable expectation of success based on Grother’s description of how to formulate active ingredients into a fast dispersing solid dosage form. *See, e.g.,* EX1008 13:18-15:20. Formulating orally disintegrating

pharmaceutical compositions that dissolve within “several seconds to about a minute” was a routine exercise by 2009. EX1018 434; EX1005 2. The numerous commercially available orally disintegrating systems and products available by 2009 bolstered the POSA’s expectation of success. EX1017 179-181; EX1018 436-439; EX1095 ¶¶327-328.

Grother in view of the FDA Guidance therefore renders obvious limitation 1[iv].

6. Limitation 1[v]

A POSA would have been motivated to formulate Grother’s fast dispersing solid dosage form containing budesonide or fluticasone to have a hardness of between 4-48 N or a friability of not more than 1% with a reasonable expectation of success in view of Kararli and the USP.

Kararli is directed to ODTs. EX1110 Title, 3:14-4:18. Kararli teaches ODTs have a hardness “more preferably of about 1 to about 5 kp.” *Id.* 25:23-27. A hardness of 1-5 kp is equivalent to a hardness of 9.8-49.1 N.⁹ Kararli teaches that this hardness is important for an ODT to “have sufficient hardness for handling,” and to “withstand removal from at least a standard type of blister packaging,” and

⁹ 1 kilopond (kp) is equivalent to 9.8N; EX1095 ¶332.

“withstand other handling such as packaging, delivery, carrying and the like.” *Id.* 25:28-26:13; *id.* 9:19-26; EX1095 ¶¶330-332.

Kararli’s teaching is reinforced by the knowledge of the POSA, which is represented by, for example, the United States Pharmacopeia (“USP”). USP standards have been recognized as an authority in the pharmaceutical field for over 200 years “because they are authoritative and science-based and are established by a transparent and credible process.” EX1104 viii. USP is “recognized by law and custom in many countries throughout the world,” including the U.S. *Id.* USP teaches that hardness is an important indicator of mechanical strength for tablets to “be able to withstand the rigors of handling and transportation experienced in the manufacturing plant, in the drug distribution system, and in the field at the hands of the end users (patients/consumers).” *Id.* 676. USP also teaches that friability is another important indicator of mechanical strength for tablets and recommends a friability “of not more than 1.0% is considered acceptable for most products.” *Id.*; EX1095 ¶333.

A POSA would have been motivated to follow Kararli and USP’s recommendations in formulating Grother’s fast dispersing dosage form to have a hardness of 9.8-49.1 N and a friability of not more than 1% to provide a formulation of sufficient mechanical strength to handle packaging, transportation, and handling. A POSA had a reasonable expectation of success in formulating Grother’s fast

dispersing dosage form to have a hardness falling within the range of 4-48 N or a friability falling within the range of 0-1% given the disclosures of Kararli, the USP, and several of Patent Owner’s own prior art publications that disclose ODTs having hardness and friability within the claimed ranges. *See* EX1111 22:7-26 (Example 1 ODTs with hardness of “8-48 N” and friability of “NMT [not more than] 1.0%”); EX1112 38 (Table 3 disclosing ODTs with hardness of 6.8 and 6.92-6.95 N, and friability of 0.24-0.31%), 48 (Table 12 disclosing ODTs hardnesses between 41.3 and 46.0 N, and friability between 0.20-0.51%); EX1113 38 (Table 3), 48 (Table 12); EX1095 ¶¶334-336.

Grother in view of Kararli, the FDA Guidance, and the USP therefore render obvious claim 1.

C. Claims 2-3

Claims 2 and 3 are obvious for the same reasons discussed above for limitation 1(i). *Supra* Section XVII.B.2; EX1095 ¶338.

D. Claim 4

Grother discloses mannitol as its preferred matrix forming excipient. EX1008 13:12. Mannitol was the bulk excipient of choice for ODTs. EX1041 261; EX1095 ¶340. The ’598 patent admits that mannitol is a sugar alcohol that was “typically used in disintegrating tablet formulations.” EX1001 8:52-60, 9:10-11. Claim 4 is therefore obvious.

E. Claim 9

Claim 9 is obvious for the same reasons discussed above for Claim 1. *Supra* Section XVII.B; EX1095 ¶342.

F. Claim 11

Claim 11 is obvious for the same reasons discussed above for Claim 1. *Supra* Section XVII.B; EX1095 ¶344.

G. Claims 13-14

Grother's fast dispersing dosage form comprises "at least one modified starch." EX1008 12:10-19. Grother's modified starch includes oxidized starches containing carboxyl groups and crosslinked starches, *id.* 5:10-6:5, which beneficially "may be used as the primary structure forming agent in FDDF's [fast dispersing dosage forms] to form physically robust products while maintaining the desired rapid dispersion characteristics of the products," *id.* 4:2-4. Sodium starch glycolate is a commercially available disintegrant made by carboxymethylation and crosslinking. A POSA understood that sodium starch glycolate was included in Grother's disclosure of modified starches. EX1095 ¶¶346-347.

Kararli discloses that its ODTs may contain one or more additional pharmaceutically acceptable excipients including disintegrants. EX1110 22:5-9. Kararli discloses that the disintegrant may be sodium starch glycolate or crospovidone. EX1110 24:11-17 ("Pharmaceutically acceptable disintegrants that

can optionally be present... include starches, sodium starch glycolate,... celluloses, e.g., purified cellulose, methylcellulose, sodium carboxymethylcellulose, carboxymethylcellulose,... *crospovidone*... and mixtures thereof.”); EX1095 ¶¶348-349.

Claims 13-14 are therefore obvious.

H. Claims 18-19

A POSA would have been motivated to formulate Grother’s fast dispersing solid dosage form to disintegrate within 30 seconds when tested using the USP <701> Disintegration Test with a reasonable expectation of success. *Supra* Section XVII.B.5. The FDA recommended that such compositions have “an in-vitro disintegration time of approximately 30 seconds or less,” EX1005 2, using the USP <701> test. *Id.* 3 n.3.

If Ellodi argues that the “simulated saliva” recited by claims 18-19 provides a patentable feature over the prior art, such an argument should be rejected. *Supra* Section XIV.H; EX1095 ¶¶351-354.

Claims 18-19 are therefore obvious.

I. Claim 20

Grother teaches formulating its fast dispersing solid dosage form with budesonide or fluticasone, which were known corticosteroids. EX1008 18:15-18. *Supra* Section XVII.B.2. Budesonide and fluticasone were known to be potent,

locally acting anti-inflammatory glucocorticoids that were desirable for treating inflammation of the gastrointestinal tract. *Supra* Section III.D-E. In particular, budesonide and fluticasone were known to successfully treat several inflammatory conditions of the gastrointestinal tract, including eosinophilic esophagitis. EX1014 706 (treating eosinophilic esophagitis); EX1015 1, 6, 8 (treating eosinophilic esophagitis); EX1002 ¶¶[0010], [0011], [0015] (treating inflammation of the esophagus, including eosinophilic esophagitis); *Supra* Section III.D; EX1095 ¶356. A POSA would have been motivated to formulate Grohter's fast dispersing solid oral dosage form with budesonide or fluticasone to treat eosinophilic esophagitis with a reasonable expectation of success.

Claim 20 is therefore obvious.

J. Claims 21 and 29

Claims 21 and 29 are obvious for the same reasons discussed above for Claims 1, 13-14 and 20. *Supra* Sections XVII.B, XVII.G, XVII.I; EX1095 ¶358.

K. Claim 22

Claim 22 is obvious for the same reasons discussed above for Claims 1 and 20. *Supra* Sections XVII.B, XVII.I; EX1095 ¶360.

L. Claims 23-25

Claims 23-25 are obvious for the same reasons discussed above for claim limitation 1[v]. *Supra* Section XVII.B.6; EX1095 ¶362.

M. Claims 31-32

Claims 31-32 are obvious for the same reasons discussed above for Claims 1 and 18-20. *Supra* Sections XVII.B, XVII.H-I; EX1095 ¶364.

XVIII. GROUND 11: GROTHER IN VIEW OF KARARLI, THE FDA GUIDANCE, THE USP, AND VENKATESH988

This section explains how Grother in view of Kararli, the FDA guidance, the USP, and Venkatesh988 render obvious dependent claims 5-8, 10, 12, 15-17 and 30 of the '598 patent.

A. Claim 5

Venkatesh988 discloses “an orally disintegrating tablet made up of rapidly dispersing microgranules and taste-masked microcapsules” of drug particles. EX1020 ¶[0001]; *id.* ¶¶[0018], [0025] (microcapsule drug particles). The drug particles are granulated with diluent excipients. *Id.* ¶[0021]. Venkatesh988 discloses that “this invention relates to pharmaceutical compositions comprising rapidly dispersing microgranules of a disintegrant and sugar alcohol or a saccharide.” *Id.* ¶[0014]; *id.* ¶¶[0018], ¶[0028] (“sugar alcohol” and “saccharide”). Venkatesh988 therefore discloses ODTs comprising drug particles comprising excipients and rapidly dispersing microgranules comprising a disintegrant, a sugar alcohol and/or saccharide.

The POSA would have been motivated for the budesonide or fluticasone in Grother’s fast dispersing solid dosage form to comprise drug particles with an

excipient and the disintegrant to be rapidly dispersing granules that include a sugar alcohol and/or saccharide based on Venkatesh988. Venkatesh988 teaches that formulating ODTs to have drug particles and rapidly-dispersing microgranules comprising sugar alcohol and/or saccharide in combination with the disintegrant beneficially “avoid[ed] gritty mouthfeel,” EX1020 ¶[0012], to assist with providing a “smooth creamy mouthfeel (no grittiness),” *id.* ¶[0002]; EX1095 ¶¶367-368.

The POSA had a reasonable expectation of success based on Venkatesh988. Venkatesh988 teaches that its formulations “don’t require a special pharmaceutical production technique and can be simply and easily produced by a normal equipment.” EX1020 ¶[0018]; EX1095 ¶¶369-370.

Grother in view of Kararli, the FDA guidance, the USP, and Venkatesh988 render obvious claim 5.

B. Claims 6-8

Venkatesh988 discloses drug particles that advantageously have “an average particle size of 200 μm and can be effectively taste masked by coacervation by phase separation to produce taste-masked particles with optimum size distribution” and provide “a smooth creamy mouthfeel.” EX1020 ¶[0015].

Venkatesh988 discloses that the rapidly dispersing granules “typically” have an “average particle size of not more than 300 μm .” EX1020 ¶[0020]. A small particle size assists with mouthfeel. *Id.* ¶¶[0019], [0009], [0025].

Venkatesh988 discloses “rapidly dispersing microgranules of a disintegrant and sugar alcohol or a saccharide whose average particle size is not more than 30 μm ,” which is advantageous in “effectively taste-mask[ing] by coacervation.” EX1020 ¶[0014]; *id.* ¶[0018] (“preferably not more than 20 μm ”), ¶[0028].

A POSA would have been motivated to formulate budesonide or fluticasone in an ODT based on Grother, and also having drug particles with a particle size less than 400 μm , rapidly dispersing granules with a particle size less than 300 μm , and a disintegrant and sugar alcohol and/or saccharide with a particle size less than 30 μm based on Venkatesh988 to avoid a gritty texture and improve mouthfeel with an expectation of success. EX1095 ¶¶372-376.

Claims 6-8 are therefore obvious.

C. Claims 10, 12, and 30

Claims 10, 12, and 30 are obvious over Grother in view of Kararli, the FDA Guidance, the USP, and Venkatesh988 for the same reasons discussed herein for Claims 1, 5, 8, and 15-16. *Supra* Sections XVII.B, XVIII.A-B, XVIII.D; EX1095 ¶378.

D. Claims 15-16

Grother discloses mannitol as its preferred matrix forming excipient. EX1008 13:12. Mannitol was the bulk excipient of choice for ODTs. EX1041 261.

Venkatesh988 discloses that “[t]he dispersible microgranules comprise a sugar alcohol such as mannitol.” EX1020 ¶¶[0032], [0047]. Venkatesh988 further discloses that “[t]he sugar alcohol may be selected from the group consisting of mannitol, sorbitol, xylitol, maltitol and the like....” *Id.* ¶[0028]; EX1095 ¶¶380-382.

Claims 15-16 are therefore obvious.

E. Claim 17

Claim 17 depends from claim 5 and recites “wherein the ratio of disintegrant to sugar alcohol, saccharide or mixture thereof in the rapidly dispersing microgranules ranges from about 90/10 to about 99/01.”

Grother discloses that its fast dispersing solid dosage form comprises at least one modified starch at a concentration of from 20 to 90% by weight, and preferably 50 to 90% by weight. EX1008 12:14-15, 13:3-4. Grother’s modified starch is a disintegrant. *Supra* Section XVII.B.3.

Grother discloses mannitol as its preferred matrix forming excipient. EX1008 13:12. Mannitol was the bulk excipient of choice for ODTs. EX1041 261; EX1095 ¶¶384-385. The ’598 patent admits that mannitol is a sugar alcohol. EX1001 8:52-60, 9:10-11.

In the embodiment where Grother’s fast dispersing solid dosage form has a modified starch at a concentration of 90% by weight, the matrix forming agent is necessarily present in an amount less than 10% by weight. When this embodiment

has mannitol selected as the preferred matrix forming agent, it has a ratio of modified starch (a disintegrant) to mannitol (a sugar alcohol) falling within the claimed range of from about 90/10 to about 99/01; EX1095 ¶¶386-387.

Grother in view of Kararli, the FDA guidance, the USP, and Venkatesh988 render obvious claim 17.

XIX. GROUND 12: GROTHER IN VIEW OF KARARLI, THE FDA GUIDANCE, THE USP, AND VENKATESH516

This section explains how Grother in view of Kararli, the FDA Guidance, the USP, and Venkatesh516 render obvious dependent claims 26-28 and 33-34 of the '598 patent.

A. Claims 26-27

It was obvious to formulate Grother's fast dispersing solid dosage form to have a friability of less than 1%. *Supra* Section XVII.B.6. A POSA would have been motivated to formulate Grother's fast dispersing solid dosage form to have a friability of not more than 0.6% with a reasonable expectation of success in view of Venkatesh516.

Venkatesh516 discloses ODTs having a "target" friability of "<0.6%." EX1111 22:1-2, 22:21 ("NMT [not more than]" 0.6%), 23:27. Venkatesh516 further discloses that such a friability is sufficiently low for the ODT "to be suitable for packaging in HDPE bottles and push-through film backed or peel-off paper backed

blister packs using conventional equipment for storage, transportation and commercial distribution.” *Id.* 16:23-27; *id.* 19:10-11, 19:25-26; EX1095 ¶¶390-393.

Grother in view of Kararli, the FDA Guidance, the USP, and Venkatesh516 render obvious claims 26-27.

B. Claim 28

Venkatesh516 discloses ODTs having a “target” thickness of 2.40 mm. EX1111 22:19. A POSA would have been motivated to follow Venkatesh516’s instruction with a reasonable expectation of success to target a thickness of 2.40 mm when formulating Grother’s fast dispersing solid dosage form to provide an appropriately thick tablet to impart sufficient mechanical strength while also providing appropriate mouthfeel to the patient. EX1095 ¶¶395-396.

Claim 28 is therefore obvious.

C. Claim 33

Claim 33 is obvious for the same reasons discussed above for Claims 1, 25, and 27-28. *Supra* Sections XVII.B, XVII.L, XIX.A-B; EX1095 ¶398.

D. Claim 34

Claim 34 is obvious for the same reasons discussed above for claims 1, 25, and 27-28. *Supra* Sections XVII.B, XVII.L, XIX.A-B; EX1095 ¶400.

XX. NO SECONDARY CONSIDERATIONS

Should Ellodi make allegations regarding secondary considerations in this proceeding, Petitioner will respond.

XXI. BIFURCATED PROCESS FOR DISCRETIONARY BRIEFING

Should Ellodi make allegations regarding discretionary issues, Petitioner will respond. See <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process> at Sections I.C, III.A (last accessed August 13, 2025).

XXII. MANDATORY NOTICES

Pursuant to 37 C.F.R. §42.8(a)(1), the mandatory notices identified in 37 C.F.R. §42.8(b) are provided below as part of this Petition.

A. Real Party-In-Interest (37 C.F.R. §42.8(b)(1))

Dr. Falk Pharma GmbH is the real party in interest. Petitioner is aware of no other entities that have a financial interest in, or could be substantially affected by the outcome of, this proceeding.

B. Related Matters (37 C.F.R. §42.8(b)(2))

Petitioner is aware of the following judicial proceedings that could affect or be affected by this proceeding:

- IPR2024-01197, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, regarding U.S. Patent No. 8,771,729;

- IPR2025-00052, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, regarding U.S. Patent No. 10,632,069;
- IPR2205-00054, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, regarding U.S. Patent No. 11,246,828;
- IPR2025-00055, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, regarding U.S. Patent No. 9,486,407; and
- IPR2025-00056, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, regarding U.S. Patent No. 11,260,061.

Petitioner is aware of the following U.S. patents and patent applications related to the '598 patent:

- 61/247,642 filed on October 1, 2009;
- 12/896,005 filed on October 1, 2010, now U.S. patent number 8,771,729;
- 14/294,660 filed on June 3, 2014, now U.S. patent number 9,486,407;
- 14/311,732 filed on June 23, 2014, now U.S. patent number 9,387,167;
- 15/205,390 filed on July 8, 2016, now U.S. patent number 9,849,084;
- 15/816,154 filed on November 17, 2017, now U.S. patent number 10,632,069;
- 16/821,464 filed on March 17, 2020, now U.S. patent number 11,246,828;

- 17/236,295 filed April 21, 2021, now U.S. patent number 11,266,598;
and
- 19/170,231 filed on April 4, 2025.

C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3))

Petitioner provides the following designation of counsel, all of whom are included in Customer No. 20,995 identified in Petitioner’s Power of Attorney.

Lead Counsel	Back-up Counsel
Nathanael Luman (Reg. No. 63,160) 2nrl@knobbe.com Knobbe, Martens, Olson, & Bear, LLP <u>Postal and Hand-Delivery Address:</u> 3579 Valley Centre Drive, Suite 300 San Diego, CA 92130 Telephone: 858-707-4000 Facsimile: 858-707-4001	Eric S. Furman (Reg. No. 45,664) 2esf@knobbe.com Phillip J. Minnick (Reg. No. 81,223) 2pjm@knobbe.com Knobbe, Martens, Olson, & Bear, LLP <u>Postal and Hand-Delivery Address:</u> 3579 Valley Centre Drive, Suite 300 San Diego, CA 92130 Telephone: 858-707-4000 Facsimile: 858-707-4001

D. Service Information (37 C.F.R. §42.8(b)(4))

Please direct all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to BoxFalkPharma@knobbe.com.

XXIII. PAYMENT OF FEES

The Office may charge the §42.15(b) fee and any additional fees that may be due to Deposit Account No. 11-1410. Review of thirty-four claims is requested.

XXIV. CONCLUSION

Claims 1-34 of the '598 patent are unpatentable and should be canceled.

Respectfully submitted,

KNOBBE MARTENS OLSON & BEAR, LLP

Dated: September 19, 2025 By: /Nathanael R. Luman/

Nathanael R. Luman (Reg. No.63,160)

Eric S. Furman (Reg. No. 45,664)

Phillip J. Minnick (Reg. No. 81,223)

Counsel for Petitioner

Dr. Falk Pharma GmbH

APPENDIX A

Listing of Challenged Claims from U.S. Patent No. 12,290,598	
Claim 1	
Preamble	An orally disintegrating tablet comprising:
(i)	about 0.5 mg to about 6 mg of a corticosteroid selected from fluticasone propionate or budesonide; and
(ii)	at least one disintegrant;
[iii]	wherein upon administration a therapeutically effective amount of the corticosteroid is deposited topically in the esophagus,
[iv]	wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> Disintegration Test, and
[v]	wherein the orally disintegrating tablet has a hardness of 4-48 N or a friability of not more than 1%.
Claim 2	
--	The orally disintegrating tablet of claim 1, comprising about 0.5 mg to about 2 mg of the corticosteroid.
Claim 3	
--	The orally disintegrating tablet of claim 1, comprising about 3 mg of the corticosteroid.
Claim 4	
--	The orally disintegrating tablet of claim 1, comprising a sugar alcohol and/or saccharide.

Listing of Challenged Claims from U.S. Patent No. 12,290,598	
Claim 5	
--	The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet comprises drug particles and rapidly dispersing granules, wherein the drug particles comprise the corticosteroid and at least one excipient, and the rapidly dispersing granules comprise the disintegrant and a sugar alcohol and/or saccharide.
Claim 6	
--	The orally disintegrating tablet of claim 5, wherein the rapidly dispersing granules have an average particle size of less than about 300 μm , and each of the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 μm .
Claim 7	
--	The orally disintegrating tablet of claim 5, wherein the drug particles have an average particle size of about 100-400 μm .
Claim 8	
--	The orally disintegrating tablet of claim 5, wherein the drug particles have an average particle size of about 100-400 μm , the rapidly dispersing granules have an average particle size of less than about 300 μm , and each of the disintegrant and sugar alcohol and/or saccharide have an average particle size of about 1-30 μm .
Claim 9	
--	The orally disintegrating tablet of claim 2, wherein the corticosteroid is budesonide.
Claim 10	
--	The orally disintegrating tablet of claim 5, wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.

Listing of Challenged Claims from U.S. Patent No. 12,290,598	
Claim 11	
--	The orally disintegrating tablet of claim 3, wherein the corticosteroid is fluticasone propionate.
Claim 12	
--	The orally disintegrating tablet of claim 8, wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.
Claim 13	
--	The orally disintegrating tablet of claim 1, wherein the disintegrant is crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, low-substituted hydroxylpropylcellulose, mannitol, xylitol, sorbitol, maltol, maltitol, lactose, sucrose, maltose, or combinations thereof.
Claim 14	
--	The orally disintegrating tablet of claim 13, wherein the disintegrant is crospovidone.
Claim 15	
--	The orally disintegrating tablet of claim 5, wherein the sugar alcohol and/or saccharide is mannitol, sorbitol, xylitol, maltitol, arabitol, ribitol, dulcitol, iditol, isomalt, lactitol, erythritol, lactose, sucrose, maltose, or combinations thereof.
Claim 16	
--	The orally disintegrating tablet of claim 15, wherein the sugar alcohol is mannitol.
Claim 17	
--	The orally disintegrating tablet of claim 5, wherein the ratio of disintegrant to sugar alcohol, saccharide or mixture thereof in the

Listing of Challenged Claims from U.S. Patent No. 12,290,598	
	rapidly dispersing microgranules ranges from about 90/10 to about 99/01.
Claim 18	
--	The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet disintegrates within 60 seconds when tested in simulated saliva fluid using the USP <701> Disintegration Test.
Claim 19	
--	The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.
Claim 20	
--	A method for treating eosinophilic esophagitis comprising administering to a patient in need thereof the orally disintegrating tablet according to claim 1.
Claim 21	
--	The method of claim 20, wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.
Claim 22	
--	The method of claim 20, wherein the orally disintegrating tablet comprises about 0.5 mg to about 2 mg of budesonide.
Claim 23	
--	The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet has a hardness of 4-48 N.
Claim 24	
--	The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet has a friability of not more than 1%.

Listing of Challenged Claims from U.S. Patent No. 12,290,598	
Claim 25	
--	The orally disintegrating tablet of claim 1, wherein the orally disintegrating has a hardness of 4-48 N and a friability of not more than 1%.
Claim 26	
--	The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet has a friability of not more than 0.6%.
Claim 27	
--	The orally disintegrating tablet of claim 25, wherein the orally disintegrating tablet has a friability of not more than 0.6%.
Claim 28	
--	The orally disintegrating tablet of claim 27, wherein the orally disintegrating tablet has a thickness of 2-2.8 mm.
Claim 29	
--	The orally disintegrating tablet of claim 14, wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.
Claim 30	
--	The orally disintegrating tablet of claim 16, wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.
Claim 31	
--	The method of claim 20, wherein the orally disintegrating tablet disintegrates within 60 seconds when tested in simulated saliva fluid using the USP <701> Disintegration Test.

Listing of Challenged Claims from U.S. Patent No. 12,290,598	
Claim 32	
--	The method of claim 20, wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.
Claim 33	
--	The orally disintegrating tablet of claim 28, wherein the orally disintegrating tablet comprises about 3 mg of fluticasone propionate.
Claim 34	
--	The orally disintegrating tablet of claim 28, wherein the orally disintegrating tablet comprises about 0.5 mg to about 2 mg of budesonide.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that this **PETITION FOR POST-GRANT REVIEW OF U.S. PATENT NO. 12,290,598** exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a) contains 16,600 words according to the word-processing program used to prepare this paper. The foregoing word count complies with the 18,700 word type-volume limit specified by 37 C.F.R. §42.24(a)(1).

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 19, 2025 By: /Nathanael R. Luman/

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Counsel for Petitioner

Dr. Falk Pharma GmbH

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this **PETITION FOR POST GRANT REVIEW OF U.S. PATENT NO. 12,290,598, PETITIONER’S POWER OF ATTORNEY, AND EXHIBITS 1001-1002, 1005, 1007-1015, 1017-1020, 1025-1029, 1031, 1033-1036, 1040-1041, 1047, 1064-1066, AND 1095-1113** were served by FedEx overnight delivery on the Patent Owner at the correspondence address of record for the subject patent as follows:

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