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On behalf of **Dr. Falk Pharma GMBH**

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. FALK PHARMA GMBH,

Petitioner

v.

ELLODI PHARMACEUTICALS, L.P.,

Patent Owner

Case No. IPR2025-00054

Patent No. 11,246,828

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,246,828**

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Exhibit No.	Description
1001	U.S. Patent No. 11,246,828 to Perrett et al.
1002	U.S. Publication No. 20070111978 to Dohil et al.
1003	EP2482822B1 that was revoked by the European Patent Office
1004	The Opposition Division of the European Patent Office decision revoking EP2484822B1 with auxiliary requested claims
1005	“Guidance for Industry: Orally Disintegrating Tablets,” U.S. Food & Drug Administration, Center for Drug Evaluation and Research (CDER), 2008.
1006	Notice of Publication of FDA Guidance for Industry on Orally Disintegrating Tablets, Federal Register, Vol. 73, No. 242 at 76366, December 16, 2008.
1007	“DRAFT Guidance for Industry: Orally Disintegrating Tablets,” U.S. Food & Drug Administration, Center for Drug Evaluation and Research (CDER), 2007.
1008	International Publication No. WO2000044351 to Grother et al.
1009	Svoboda et al., “Oral formulations of budesonide: a novel treatment for inflammatory bowel disease,” Drugs of Today, 44:857-863 (2008) at 857.
1010	Tan et al., “Eosinophilic gastroenteritis treated with non-enteric-coated budesonide tablets,” European Journal of Gastroenterology & Hepatology, 13:425-427 (2001)
1011	Kolkman et al., “Evaluation of oral budesonide in the treatment of active distal ulcerative colitis,” Drugs of Today, 40:589-601 (2004)
1012	Siewert et al., “Eosinophilic gastroenteritis with severe protein-losing enteropathy: Successful treatment with budesonide,” Digestive and Liver Disease, 38:55-59 (2006)

Exhibit No.	Description
1013	Elsing et al., “Budesonide for the treatment of obstructive eosinophilic jejunitis,” Z. Gastroenterology, 45:187-189 (2007).
1014	Aceves et al., “Topical viscous budesonide suspension for treatment of eosinophilic esophagitis,” Journal of Allergy and Clinical Immunology 116:705-706 (2005)
1015	Aceves et al., “Oral Viscous Budesonide: A potential new therapy for eosinophilic esophagitis in children,” American Journal of Gastroenterology, 102:1-9 (2007)
1016	The United States Pharmacopeia, USP 32, 2009 at pages 262-263 “<701> Disintegration”
1017	Danckwerts, “Intraoral Drug Delivery: A Comparative Review,” American Journal of Drug Delivery, 1:171-186 (2003).
1018	Fu et al., “Orally fast disintegrating tablets: developments, technologies, taste-masking and clinical studies,” Critical Reviews in Therapeutic Drug Carrier Systems, 21:433-475 (2004)
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1031	Prosecution history excerpts from U.S. Application No. 12/896,005, which issued as U.S. 8,771,729
1032	RESERVED
1033	RESERVED
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1035	U.S. Patent No. 7,122,198 to Singh et al.
1036	U.S. Patent No. 7,229,641 Cherukuri et al.
1037	RESERVED
1038	RESERVED
1039	Prosecution history excerpts from U.S. Application No. 17/236,295, which issued as U.S. 11,266,598
1040	The United States Pharmacopeia Convention, Revision Bulletin, 2008, “<701> Disintegration”
1041	Conway, “Solid dosage forms,” Chapter 4.1 in Pharmaceutical Manufacturing Handbook: Production and Processes, ed. Gad, pages 235-265 (2008)
1042	“Magnesium Stearate,” Handbook of Pharmaceutical Excipients, 5th edition, eds. Rowe et al., pages 430-433 (2006)
1043	“Mannitol,” Handbook of Pharmaceutical Excipients, 5th edition, eds. Rowe et al., pages 449-453 (2006)

Exhibit No.	Description
1044	“Povidone,” Handbook of Pharmaceutical Excipients, 5th edition, eds. Rowe et al., pages 611-616 (2006)
1045	“Sucralose,” Handbook of Pharmaceutical Excipients, 5th edition, eds. Rowe et al., pages 742-743 (2006)
1046	“Polyethylene glycol,” Handbook of Pharmaceutical Excipients, 5th edition, eds. Rowe et al., pages 545-550 (2006)
1047	El-Arini et al., “Evaluation of disintegration testing of different fast dissolving tablets using the texture analyzer,” Pharmaceutical Development & Technology, 7:361-371 (2002)
1048	Prosecution history excerpts from U.S. Application No. 15/816,154, which issued as U.S. 10,632,069
1049	Prosecution history excerpts from U.S. Application No. 16/821,464, which issued as U.S. 11,246,828
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1052	U.S. Patent No. 10,632,069 to Perrett et al.

Dr. Falk Pharma GmbH (“Petitioner”) requests *inter partes* review (“IPR”) of claims 1-16 (“the challenged claims”) of U.S. Patent No. 11,246,828 (“the ’828 patent”), which is assigned to Ellodi Pharmaceuticals, L.P. (“Patent Owner” or “Ellodi”).

Dr. Falk Pharma is concurrently filing IPR petitions challenging Ellodi’s U.S. Patent Nos. 9,486,407, 10,632,069, and 11,260,061. Also, Dr. Falk Pharma recently filed a petition challenging Ellodi’s U.S. Patent No. 8,771,729 in IPR2024-01197, to which Ellodi has not yet filed a Preliminary Response and the PTAB has not yet issued an Institution Decision. All of these patents claim orally dispersing tablets (ODTs) that are obvious over the prior art and should be cancelled.

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. Ellodi has, however, acquired ownership of certain U.S. and European patents, including the '828 patent and its European equivalent, EP2482822. Ellodi sought to preclude Jorveza[®] from being used by European patients based on EP2482822. This forced Dr. Falk Pharma to initiate opposition proceedings at the European Patent Office, which resulted in the complete revocation of all of Ellodi's original and auxiliary claims. The '828 patent claims are not patentably distinct from the revoked European claims, and the USPTO should cancel all of Ellodi's claims.

The '828 patent improperly removes from the public the claimed orally dispersing tablets (ODTs) containing budesonide that disintegrate within 60 seconds. Such compositions were not inventive in the relevant 2009 time period.

ODTs were well-known by 2009. These tablets rapidly disperse in a patient's saliva in the oral cavity to release a pharmaceutically active ingredient. The released active ingredient can be topically absorbed through the mucosa of the gastrointestinal track. Such tablets are especially desirable for patients who have difficulty swallowing conventional tablets and capsules.

By 2009, there were over 40 commercially available orally dispersing tablet products marketed in the U.S. During this time period, many believed it was only a

matter of time before the majority of orally administered drugs would be formulated as an orally dispersing tablet.

The prevalence of ODTs led to the FDA issuing guidelines and recommendations to the pharmaceutical industry in 2008. The FDA guidelines recommended that ODTs should disintegrate rapidly in a patient's mouth, and also have an *in-vitro* disintegration time of approximately 30 seconds or less when tested according to the USP <701> Disintegration Test. The ordinarily skilled artisan was highly motivated to comply with the FDA's guidelines to obtain regulatory approval for an orally disintegrating formulation.

The Dohil prior art reference discloses an orally dispersing tablet containing budesonide that renders obvious the challenged claims. The Grother prior art reference emphasizes the obviousness of the challenged claims because, like Dohil, it also discloses orally dispersing tablets containing budesonide. These references present compelling evidence of obviousness. The Board should institute trial and hold that all claims from the '828 patent are unpatentable over the prior art.

II. BACKGROUND REGARDING THE '828 PATENT

The '828 patent is entitled "Orally administered corticosteroid compositions." EX1001 Title. It claims priority to a provisional application filed October 1, 2009. It issued with 16 claims, of which only claim 1 is an independent claim. The claims

are directed to orally dispersing tablets of budesonide that disintegrate within 60 seconds. For example, claim 1 recites:

1. An orally dispersing tablet comprising:
 - (i) about 0.5 mg to about 1 mg of budesonide;
 - (ii) at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity; and
 - (iii) sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof;
 - [iv] wherein upon administration a therapeutically effective amount of budesonide is deposited topically in the upper gastrointestinal tract, and
 - [v] wherein the orally dispersing tablet disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test.

EX1001 18:51-63.¹

III. LEVEL OF ORDINARY SKILL

A person of ordinary skill in the art (“POSA”) related to the ’828 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

¹ Bracketed labels [iv] and [v] are added for convenient referencing to the limitations of claim 1. The ’828 patent claims are reproduced in Appendix 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. EX1051 ¶30.

IV. STATE OF THE PRIOR ART

A. Budesonide

Budesonide is a potent, locally acting anti-inflammatory glucocorticoid that was known to treat a wide spectrum of inflammatory diseases. EX1025 1014-1015; EX1009 857. Budesonide was considered to be a desirable drug for treating inflammation of the gastrointestinal tract because it is “a locally acting corticosteroid with a high first-pass effect, which minimizes systemic side effects.” EX1010 425.

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; EX1051 ¶¶43-48.

In 2005 and 2007, Aceves et al. reported that a viscus suspension of budesonide was orally administered as a topical formulation to successfully treat eosinophilic esophagitis (EOE or EE). EX1014 706; EX1015 1, 6, 8. 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]; EX1051 ¶¶49-58.

B. Orally dispersing tablets (ODTs)

Orally dispersing tablets (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.

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 dispersing tablets. EX1018 434 ; EX1017 178; EX1019 310.

The FDA defines “orally disintegrating tablets (ODTs)”² as “[a] solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue.” EX1005 1-2; EX1051 ¶¶59-64.

1. Improved patient compliance

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. EX1017 172. Difficulties with patient compliance can be significantly improved by formulating active ingredients in an orally disintegrating solid pharmaceutical composition. EX1051 ¶¶65-69.

“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.

² The '828 patent admits that “orally dispersing tablets,” “orally disintegrating tablets,” and “ODTs” are equivalent terms. EX1001 2:49-64.

Orally dispersing tablets 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; EX1051 ¶¶70-73.

2. Commercial orally dispersing tablets (ODTs)

By 2009, there were several commercially available ODT products. Exemplary products included the Zydis[®] fast-dissolving wafer, the Flashtab[®] tablet, the WOWTab[®], the Flash Dose[®] tablet, OraSolv[®], and DuraSolv[®], as shown in the following table:

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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	Migrane	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 436-439; EX1017 178-181.

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 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; EX1051 ¶¶89-97.

3. Ingredients in orally dispersing tablets (ODTs)

The ingredients used to formulate an orally dispersing tablet (ODT) include the active pharmaceutical ingredient and other ingredients that are generally referred to as “excipients.” EX1041 239.

Excipients “are categorized into groups according to their main function, although some may be multifunctional.” *Id.* 240. The main types of excipients used in tablet formulations such as ODTs include diluents, binders, lubricants, and flavor enhancers such as sweeteners. *Id.* 240 (Table 3), 259-262; EX1051 ¶74. Each of these types of excipients are discussed in the following paragraphs.

a. Diluents

A diluent is an excipient that is “added to increase the bulk of a tablet for processing and handling.” EX1041 240. “Most commercial ODTs have been developed using mannitol as the bulk excipient of choice because of its extremely low hygroscopicity, excellent compatibility, good compressibility, better sweetness, and relatively slower dissolution kinetics.” *Id.* 261.

As a bulking diluent, mannitol can desirably “impart crystallinity and hardness to the [tablet] matrix and to improve palatability.” EX1019 314. A tablet matrix formed by mannitol can have a porous structure that beneficially allows

“quick ingress of water” into the tablet, “resulting in rapid disintegration” in the oral cavity. *Id.* 311.

In addition, mannitol-based ODTs were known to beneficially provide a “so-called ‘smoothmelt action’” that provides a pleasant mouth feeling. EX1018 459; EX1043 449 (explaining that mannitol is “used as a diluent in rapidly dispersing oral dosage forms” and “imparts a cooling sensation in the mouth”). Dohil discloses the use of mannitol in its ODT formulations of budesonide. EX1002 ¶¶[0014], [0037]; EX1051 ¶¶76-79.

b. Binders

“Binders (or adhesives) are added to formulations to promote cohesiveness within powders, thereby ensuring that the tablet remains intact after compression as well as improving the flow by forming granules.” EX1041 241.

Polyvinyl pyrrolidone (PVP) is an “often” used binder for “impart[ing] adequate cohesion without retarding disintegration or dissolution” of a tablet. EX1041 241; *id.* 240 (Table 3). PVP is a desirable binder because it is “essentially nontoxic” and has “no irritant effect.” EX1044 615. Dohil discloses the use of PVP in its ODT formulations of budesonide. EX1002 ¶¶[0014], [0037].

Polyethylene glycol (PEG) is a binder having “the advantage of functioning both as a binder and as a capillary attractant.” EX1018 452. As a capillary attractant, PEG assists with water uptake into an ODT, which assists with dissolution of tablet

in the patient’s mouth. *Id.* 459 (“disintegration time can be very short as a result of fast adsorption of water by capillary force”); EX1051 ¶¶80-83.

c. Lubricants

A lubricant is an excipient that is added to reduce the friction between particles and improve the flow properties of the mixed ingredients. EX1041 241. Lubricants beneficially “reduce friction between the tablet and the die wall during compression” formulation of a tablet. *Id.*

Magnesium stearate is the most widely used lubricant in tablet formulations. EX1041 241. It is “generally regarded as being nontoxic following oral administration.” EX1042 431. Magnesium stearate is a desirable lubricant when a diluent such as mannitol is used because this combination of excipients allows tablet formulation using “conventional tableting methodologies and conventional package equipment” at a significantly decreased cost of production. EX1018 454; EX1043 452 (recommending magnesium stearate as the lubricant when mannitol is used as a diluent); EX1051 ¶¶84-85.

d. Sweeteners

A sweetener is a flavor enhancer. It was well-known that tablets designed to dissolve in the mouth, such as ODTs, should “have a pleasant taste, smoothness, and mouthfeel.” EX1041 253. The POSA was well-aware that, “[a]fter FDTs [fast disintegrating tablets] disintegrate/dissolve in the saliva, the drug in FDTs remains

in the oral cavity until it is swallowed.” EX1018 459. Thus, ODTs were known to advantageously include sweeteners to “improve patient compliance.” EX1019 314.

Sucralose was a sweetener of choice for orally administered tablets. EX1041 253 (“In order to ensure adequate sweetness and taste masking, artificial sweeteners including aspartame, saccharin, and *sucralose* are included subject to regulatory guidelines.”). Sucralose advantageously “has a sweetening power approximately 300-1000 times that of sucrose and has no aftertaste.” EX1045 742. Sucralose desirably has no known incompatibilities and no nutritional value, *id.*, and it is “generally regarded as a nontoxic and nonirritant material,” *id.* 743. Dohil discloses the use of sucralose in its ODT formulations of budesonide. EX1002 ¶¶[0014], [0037], [0046], [0047], [0053]; EX1051 ¶¶86-88.

C. Solid Orally Dispersing Tablets Of Budesonide

The formulation of budesonide as an orally dispersing tablet 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. *Supra* Section IV.A; 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, *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. Singh discloses that its rapid-melt compositions comprise a disintegrant, a non-sugar sweetener, a diluent (e.g., mannitol), a lubricant (e.g., magnesium stearate), and a binder (e.g., polyvinyl pyrrolidone). *Id.* 3:1-7, 19:60-63, 21:65, 22:5, 22:49, 22:65-67.

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, *id.* 9:64-67. Cherukuri discloses that its rapid-melt compositions comprise a disintegrant (e.g., cross-linked polyvinyl pyrrolidone), a sweetener (e.g., sucralose), a filler (e.g., mannitol), a lubricant (e.g., magnesium stearate), and a

binder (e.g., polyvinyl pyrrolidone, polyethylene glycol). *Id.* 7:25-31, 12:20-32, 14:46-49, 18:7-12, 18:32-36, 18:57-60; EX1051 ¶¶98-106.

D. 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; EX1016; EX1051 ¶¶107-110.

V. THE EPO REVOKED ELLODI’S CLAIMS

The USPTO is not the first office to adjudicate the obviousness of Ellodi’s ODT claims. In an opposition proceeding, the European Patent Office (EPO) determined that Dohil rendered obvious certain claims in EP2482822. EX1004

¶¶33-36.9; EX1003. Of particular relevance, the EPO held claim 1 of Ellodi’s Auxiliary Request 5 (AR5) was obvious over Dohil.³ A side-by-side comparison of claim 1 of the ’828 patent and EPO AR5 is shown below:

U.S. 11,246,828 Claim 1	EP2482822 (AR5) Claim 1
1. An orally dispersing tablet comprising:	1. An orally dispersing tablet comprising
(i) about 0.5 mg to about 1 mg of budesonide;	less than or equal to 20 mg of budesonide or a solvate or ester thereof,
(ii) at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity; and	at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity,
(iii) sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof;	

³ As noted in the EPO decision, Auxiliary Request 5 (AR5) was previously filed as Auxiliary Request 3(II) (AR3(II)). EX1004 ¶33. The claims appended to the EPO decision retained their prior labeling. Thus, AR5 claims are on page 27 under the heading “Claims – Auxiliary Request 3(II).” *Id.* page 27.

U.S. 11,246,828 Claim 1	EP2482822 (AR5) Claim 1
wherein upon administration a therapeutically effective amount of budesonide is deposited topically in the upper gastrointestinal tract, and	wherein the tablet is suitable for topical administration of budesonide in the upper gastrointestinal tract, and
wherein the orally dispersing tablet disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test.	wherein said tablet disintegrates within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test.

EX1001 18:50-63; EX1004 ¶33, page 27.

In holding that Dohil renders obvious claim 1 of AR5, the EPO determined that Dohil is “the closest prior art as it is also directed to oral dosage forms comprising corticosteroids for the topical treatment of the upper GI tract, e.g., of the esophagus.” EX1004 ¶36.1 (citing EX1002 ¶¶[0010]-[0013]). The EPO explained that “the dosage forms disclosed in [Dohil] [0032] represent the closest starting point to the claimed subject-matter, as the dosage form in [0032] and the claimed ODT [orally dispersing tablet] have the same release mechanism.” *Id.* ¶36.3.

The EPO determined that Dohil “clearly describes a lozenge or similar tablet, which rapidly dissolves in the mouth,” and includes “an excipient which facilitates their dispersion and dissolution.” EX1004 ¶¶26.4-26.5; EX1002 ¶[0032]. Dohil explicitly mentions solid compositions “as suitable dosage forms for the topical treatment of the upper GI tract.” EX1004 ¶36.2. Dohil discloses orally

disintegrating solid pharmaceutical compositions “comprising less than or equal to 20 mg of budesonide.” EX1004 ¶¶26.6-26.8. Dohil discloses “daily administration of 1-2 mg” of corticosteroid. EX1004 ¶26.6; EX1002 ¶¶[0015], [0032].

The EPO determined that a POSA putting Dohil’s disclosure into practice would have arrived at the claimed disintegration time of within 60 seconds as follows:

ODTs are well-known dosage forms and belong to the common technical knowledge of the skilled formulator. The skilled person is aware that their disintegration time can be modulated in order to obtain the desired therapeutic effect. Therefore, the claimed disintegration time is regarded as one of the options available to the skilled person when putting into practice the general disclosure of [0032] of [Dohil].

EX1004 ¶36.8. The EPO held that “a budesonide ODT showing a disintegration time within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test is an obvious solution to the problem” of providing a budesonide orally dispersible tablet. EX1004 ¶36.8. The EPO therefore determined that claim 1 of AR5 was obvious over Dohil.

Limitation 1(iii) from the ’828 patent provides the only substantive distinction over claim 1 of EPO AR5. However, limitation 1(iii) does ***not*** provide a ***patentable*** distinction over claim 1 of EPO AR5. Limitation 1(iii) recites “sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations

thereof” such that prior art disclosing any one of the recited ingredients renders the limitation obvious. The prior art discloses ODTs having these ingredients, which is not surprising given that limitation 1(iii) merely recites the basic, well-known ingredients that were conventionally used to formulate ODTs.

The prior art Dohil reference discloses ODT formulations of budesonide having the ingredients recited by ’828 patent limitation 1(iii). First, Dohil repeatedly discloses the use of sucralose in its ODT formulations of budesonide. EX1002 ¶¶[0014], [0037], [0046], [0047], [0053]. Second, Dohil discloses the use of mannitol and polyvinyl pyrrolidone in its ODT formulations of budesonide. EX1002 ¶¶[0014], [0037]. Third, Dohil discloses the use of magnesium stearate in its ODT formulations of budesonide. EX1002 ¶[0040]. Dohil’s disclosures render obvious limitation 1(iii).

The lack of patentability provided by limitation 1(iii) of the ’828 patent is reinforced by the Examiner’s obviousness-type double patenting rejection of ’828 patent claim 1 over claim 1 of related U.S. 10,632,069 (“the ’069 patent”). EX1049 116-117. Limitation 1(iii) of the ’828 patent is the only substantive difference between claim 1 of these two patents. *Compare* EX1001 18:50-63 *with* EX1052 18:47-56.

The Examiner of the ’828 patent found that “one of ordinary skill in the art would have found it obvious to include the components recited [in] part (iii) of the

instant claims [that eventually issued as the '828 patent] in various combinations in the ODT of the '069 Patent. Therefore, [the] instant claims and [the] claims of the '069 Patent are not patentably distinct over each other.” EX1049 117. Ellodi did not disagree, and made no effort to distinguish the claims from the '828 and '069 patents. Instead, Ellodi filed a terminal disclaimer to sidestep the rejection. *Id.* 92. Because claim 1 of the '069 patent lacks limitation 1(iii), it is substantively identical to the revoked EPO AR5 claim 1. It therefore stands un rebutted that limitation 1(iii) of the '828 patent provides no patentable distinction over '069 patent claim 1 and the revoked equivalent claim 1 of EPO AR5.

VI. RELIEF REQUESTED

Petitioner requests cancellation of claims 1-16 of the '828 patent as obvious over the asserted prior art.

A. The Asserted References Are Prior Art

The earliest claimed priority date for the '828 patent is October 1, 2009. The asserted references are all prior art to the '828 patent:

Exhibit	Reference	Date	Art Type
1002	Dohil	Published: 05/17/2007	§102(b)
1008	Grother	Published: 08/03/2000	§102(b)

Exhibit	Reference	Date	Art Type
1005	FDA Guidance	Published: 12/16/2008	§102(a) ⁴

B. Grounds of Unpatentability

IPR is requested for the following grounds of unpatentability:

Ground	Reference(s)	Basis	Challenged Claims
1	Dohil in view of the knowledge of a POSA	§103	1-16
2	Grother in view of the FDA Guidance and the knowledge of a POSA	§103	1-16

The petition is supported by the expert declaration of Dr. Alan F. Parr, Pharm.D., Ph.D. EX1051. Dr. Parr holds a Pharm.D. in pharmacy, a Ph.D. in pharmaceutical sciences, and has over three decades of experience formulating pharmaceutical compositions.

⁴ See EX1006 for 12/16/2008 publication date. Also, on 04/09/2007, the FDA published substantively identical draft guidance for the industry. *Id.*; EX1007. To the extent Ellodi attempts to swear behind the 2008 FDA Guidance, Dr. Parr has mapped the disclosures of the 2007 Draft FDA Guidance to the claims. *See, e.g.*, EX1051 ¶¶163, 289.

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 '828 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 2:49-52. This definition is equivalent to that adopted by the FDA. EX1005 2; EX1051 ¶118.

The '828 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 2:65-3:6.

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

VIII. GROUND 1: DOHIL IN VIEW OF THE KNOWLEDGE OF A POSA

Dohil discloses an orally dispersing tablet having the same ingredients claimed by the '828 patent. This section introduces Dohil, and then explains how Dohil in view of the knowledge of a POSA renders obvious claims 1-16 of the '828 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 the esophagus.” *Id.* Exemplary dosage amounts of budesonide in Dohil’s formulation include 1 mg/day. *Id.* ¶¶[0015], [0058], Table 1; EX1051 ¶114. Dohil’s formulation contains additional ingredients including sucralose, mannitol, magnesium stearate, polyvinylpyrrolidone and/or polyethylene glycol. EX1002 ¶¶[0014], [0037], [0039], [0040].

B. Claim 1

Dohil discloses orally dispersing tablets that render obvious all limitations of claim 1.

1. Preamble

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

If the preamble were limiting, Dohil discloses the recited orally dispersing tablet. For example, Dohil discloses that “[b]udesonide is provided in the form of a *lozenge which may be dissolved in the mouth*, thus reaching and coating the esophagus. The lozenge or other similar tablet, capsule, or other solid, would *dissolve rapidly in the mouth* or esophagus to produce a solution that can then coat

the esophagus.” EX1002 ¶[0032].⁵ Dohil further discloses “[b]udesonide, in the form of *a dissolving tablet*.” *Id.* ¶[0013]; *id.* ¶[0037] (disclosing “dissolving tablets”); EX1051 ¶119. A POSA would understand that Dohil’s lozenges and tablets that dissolve rapidly in the oral cavity do so without chewing. EX1051 ¶120; EX1005 1.

Dohil’s lozenges and tablets are orally dispersing tablets that dissolve rapidly in the mouth without chewing and meet the preamble. Indeed, the EPO determined that Dohil’s “dosage forms described in [0032] of [Dohil] at least overlap the ODT [orally dispersing tablet] addressed in claim 1.” EX1004 ¶26.4.

2. Limitation 1(i)

Limitation 1(i) recites “about 0.5 mg to about 1 mg of budesonide.”

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

⁵ All emphases supplied unless otherwise noted.

provided once a day.” *Id.* ¶[0031]. Dohil thus discloses a lozenge or tablet containing a daily dose of, e.g., 0.5mg and 1mg. EX1051 ¶¶121-126.

Dohil therefore discloses limitation 1(i), which was previously confirmed by the EPO as follows:

The OD [Opposition Division] is however of the opinion that the embodiment disclosed in [Dohil] [0032] can be combined with the general disclosure of [0015]. *This paragraph teaches that the compositions described in D1 [Dohil] are intended for a daily administration of 1-2 mg or 2-3 mg corticosteroids.* Thus, at most, i.e. in case of a once daily administration, the compositions of D1 comprise 3 mg corticosteroid. *As noted by O1 [Opponent 1, Dr. Falk Pharma], in case of a multiple daily administration, a lower amount of budesonide would be comprised in each tablet, thereby leading to tablets which still fall within the scope of claim 1.*

EX1004 ¶26.6.

3. Limitation 1(ii)

Limitation 1(ii) recites “at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity.”

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. Disintegrating agents were known to assist orally dispersing tablet disintegration in saliva, which facilitates the dispersal of the tablet in the oral cavity.

EX1019 310 (explaining that MDTs (Mouth Dissolving Tablets) were known that “contain agents to enhance the rate of tablet disintegration in the oral cavity and are more appropriately termed as fast-disintegrating tablets, as they may take about one minute to disintegrate completely”); EX1051 ¶¶127-131.

Dohil therefore discloses limitation 1(ii), which the EPO’s ruling confirms. EX1004 ¶26.4 (“the skilled person would understand that the tablets addressed in [0032] of [Dohil] necessarily require an excipient which facilitates their dispersion and dissolution”); *id.* ¶23.5 (“the presence of such an excipient [which facilitates the dispersal of the tablet in the oral cavity] in an ODT is self-evident for the skilled person”).

4. Limitation 1(iii)

Limitation 1(iii) recites “sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof.”

Limitation 1(iii) merely recites typical excipients used by the POSA to manufacture ODTs. *Supra* Section IV.B.3.

Dohil discloses that sucralose, mannitol, magnesium stearate, polyvinylpyrrolidone, and polyethylene glycol should be included in its

formulations. EX1002 ¶¶[0014] (sucralose, mannitol, polyvinylpyrrolidone), [0037] (sucralose, mannitol, polyvinylpyrrolidone), [0039] (polyethylene glycol), [0040] (magnesium stearate). A POSA would have been motivated to include any one of these five ingredients as well as combinations of all five ingredients in Dohil's formulation with a reasonable expectation of success based on Dohil's disclosure to formulate ODTs with these ingredients. EX1051 ¶133. Although Dohil renders obvious ODTs containing all five of the recited ingredients, claim 1 is obvious if the Board finds that any one of these five ingredients would have been obvious to include in Dohil's ODTs.

Additional discussion regarding the obviousness of using each of the five ingredients recited by limitation 1(iii) in Dohil's ODT formulation is provided in the following paragraphs.

a. Sucralose

Dohil discloses the use of sucralose in its ODT formulations of budesonide. EX1002 ¶¶[0014], [0037], [0046], [0047], [0053]. Dohil discloses that “[a]ppropriate excipients may also, for example, include those that render the dissolving tablet palatable.” *Id.* ¶[0037]. The POSA was well-aware that, “[a]fter FDTs [fast disintegrating tablets] disintegrate/dissolve in the saliva, the drug in FDTs remains in the oral cavity until it is swallowed.” EX1018 459. ODTs were

therefore known to advantageously include sweeteners to improve the tablet's taste and palatability. EX1019 314.

Sucralose was a sweetener of choice for use in orally administered tablets. EX1041 253 (“In order to ensure adequate sweetness and taste masking, artificial sweeteners including aspartame, saccharin, and *sucralose* are included subject to regulatory guidelines.”). Sucralose advantageously “has a sweetening power approximately 300-1000 times that of sucrose and has no aftertaste.” EX1045 742. Sucralose desirably has no known incompatibilities and no nutritional value, *id.*, and it is “generally regarded as a nontoxic and nonirritant material,” *id.* 743.

The '828 patent mentions “sucralose” just once in the specification, and fails to ascribe any patentable contribution to the field of ODTs based on the selection of sucralose. EX1001 14:26-27.

A POSA would have been motivated to include sucralose in Dohil's formulation with a reasonable expectation of success in view of Dohil's express disclosure of sucralose and the knowledge of the POSA that sucralose was a desirable sweetener for ODTs. EX1051 ¶¶135-138.

b. Mannitol

Dohil discloses the use of mannitol in its ODT formulations of budesonide. EX1002 ¶¶[0014], [0037]. Mannitol was a desirable bulking diluent in ODTs. As a bulking diluent, mannitol was known to beneficially “impart crystallinity and

hardness to the [tablet] matrix and to improve palatability.” EX1019 314. A tablet matrix formed by mannitol often has a porous structure that beneficially allows “quick ingress of water” into the tablet, “resulting in rapid disintegration” in the oral cavity. *Id.* 311.

“Most commercial ODTs have been developed using mannitol as the bulk excipient of choice because of its extremely low hygroscopicity, excellent compatibility, good compressibility, better sweetness, and relatively slower dissolution kinetics.” EX1041 261. In addition, mannitol-based ODTs were known to beneficially provide a “so-called ‘smoothmelt action’” that provides a pleasant mouth feeling. EX1018 459; EX1043 449.

The ’828 patent admits that mannitol was “typically used in disintegrating tablet formulations.” EX1001 8:47-55.

A POSA would have been motivated to include mannitol in Dohil’s formulation with a reasonable expectation of success in view of Dohil’s express disclosure of mannitol and the knowledge of the POSA that mannitol was a desirable bulk diluent for formulating ODTs. EX1051 ¶¶139-143.

c. Magnesium Stearate

Dohil discloses the use of magnesium stearate as a lubricant in its ODT formulations of budesonide. EX1002 ¶[0040]. Magnesium stearate is the most

widely used lubricant in tablet formulations. EX1041 241. It is “generally regarded as being nontoxic following oral administration.” EX1042 431.

Magnesium stearate was a desirable lubricant when a diluent such as mannitol was used because this combination of excipients allows tablet formulation using “conventional tableting methodologies and conventional package equipment” at a significantly decreased cost of production. EX1018 454; EX1043 452 (recommending magnesium stearate as the lubricant when mannitol is used as a diluent).

The ’828 patent admits that magnesium stearate was “typically used in disintegrating tablet formulations.” EX1001 8:47-55. The ’828 patent discloses some ODT embodiments containing magnesium stearate as a lubricant (e.g., *id.* 9:52-53) and other embodiments that are substantially “free of lubricant” (*id.* 16:35-43). The ’828 patent expresses no preference to indicate a patentable difference between embodiments containing magnesium stearate and embodiments that are substantially “free of lubricant.”

A POSA would have been motivated to include magnesium stearate in Dohil’s formulation with a reasonable expectation of success in view of Dohil’s express disclosure of magnesium stearate and the knowledge of the POSA that magnesium stearate is a desirable lubricant for formulating ODTs. EX1051 ¶¶144-148.

d. Polyvinyl pyrrolidone

Dohil discloses the use of polyvinyl pyrrolidone in its ODT formulations of budesonide. EX1002 ¶¶[0014], [0037]. Polyvinyl pyrrolidone is often used as a binder/adhesive for “impart[ing] adequate cohesion without retarding disintegration or dissolution” of a tablet. EX1041 241; *id.* 240 (Table 3). Polyvinyl pyrrolidone was a desirable adhesive binder because it is “essentially nontoxic” and has “no irritant effect.” EX1044 615. A POSA would have been motivated to include polyvinyl pyrrolidone in Dohil’s formulation with a reasonable expectation of success in view of Dohil’s express disclosure of polyvinyl pyrrolidone and the knowledge of the POSA that polyvinyl pyrrolidone was a desirable binder/adhesive for use in formulating ODTs. EX1051 ¶¶149-152.

e. Polyethylene glycol

Dohil discloses the use of polyethylene glycol as a component of a coating for its ODT formulations of budesonide. EX1002 ¶[0039]. Polyethylene glycol coatings have high water permeability, which assists with the rapid dispersion of Dohil’s ODT. EX1046 546. A POSA would have been motivated to include polyethylene glycol in Dohil’s formulation with a reasonable expectation of success in view of Dohil’s express disclosure of polyethylene glycol and the knowledge of the POSA that polyethylene glycol was a desirable component of a coating for ODTs. EX1051 ¶¶153-156.

Based on the foregoing, Dohil discloses limitation 1(iii).

5. Limitation 1[iv]

Limitation 1[iv] recites “wherein upon administration a therapeutically effective amount of budesonide is deposited topically in the upper gastrointestinal tract.”

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 and 1mg. EX1051 ¶158; *supra* Section VIII.B.2. Thus, a POSA would understand that a dose of, e.g., 0.5 mg and 1 mg of corticosteroid per day is a therapeutically effective amount of budesonide. 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]; EX1051 ¶159.

Dohil therefore discloses limitation 1[iv], which the EPO proceeding confirms. EX1004 ¶36.1 (“The OD agrees with the parties in the choice of [Dohil] as the closest prior art as it is also directed to oral dosage forms comprising corticosteroids for the topical treatment of the upper GI tract, e.g. of the esophagus (*see* [0010][0013]).”); *id.* ¶26.6 (“The OD [Opposition Division] is however of the opinion that the embodiment disclosed in [Dohil] [0032] can be combined with the general disclosure of [0015]. ***This paragraph teaches that the compositions described in D1 [Dohil] are intended for a daily administration of 1-2 mg or 2-3 mg corticosteroids...*** As noted by O1 [Opponent 1, Dr. Falk Pharma], in case of a multiple daily administration, a lower amount of budesonide would be comprised in each tablet, thereby leading to tablets which still fall within the scope of claim 1.”).

6. Limitation 1[v]

Limitation 1[v] recites “wherein the orally dispersing tablet disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test.”

Dohil discloses that “[t]he lozenge or other similar tablet, capsule, or other solid, would 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 lozenges and tablets to vary “from several seconds to about a minute.” EX1018 434; EX1051 ¶162.

It would have been 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 ODTs 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 orally dissolving tablets. *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 tablet would be highly motivated to follow the FDA Guidance that such a tablet should disintegrate within

30 seconds or less when tested using the USP <701> Disintegration Test. EX1051 ¶¶163-164; *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1291-92 (Fed. Cir. 2013) (“[t]he potential for FDA approval also may properly be considered, as it was here, in determining whether one of ordinary skill would be motivated to develop a drug product”).

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 tablets that dissolve within “several seconds to about a minute” would have been a routine exercise by 2009. EX1018 434; EX1005 2; EX1020 ¶¶[0001], [0016], [0018]. 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; EX1051 ¶165.

The FDA Guidelines explain that ODTs dissolve in the patient’s saliva. EX1005 3. The USP <701> Disintegration Test called for by the FDA Guidelines “use[s] water or the specified medium as the immersion fluid.” EX1040 2. A POSA would have been motivated to perform the USP <701> Disintegration Test using simulated saliva as the immersion fluid to provide testing conditions that were as close as possible to the in vivo conditions in a patient’s mouth and more accurately

represent disintegration within the oral cavity. For example, the prior art taught that using simulated saliva was a desirable medium to use during disintegration testing because it provided conditions that are “as close as possible to the in vivo conditions” within a patient’s mouth. EX1047 367; EX1051 ¶166.

To the extent that Ellodi argues that the “simulated saliva” recited by limitation 1[iv] provides a patentable feature over the prior art, such an argument should be soundly rejected. 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 (“However, at three locations in the Specification, ‘simulated saliva’ is mistakenly referred to as the testing medium. This is corrected herein by amendment.”). In view of Ellodi’s admission that “simulated saliva” constitutes an obvious error in its specification, any argument by Ellodi that the “simulated saliva” recited by limitation 1[iv] provides a patentable distinction over the prior art would run afoul of the written description requirement under 35 U.S.C. § 112.

Based on the foregoing, Dohil in view of the knowledge of a POSA renders obvious limitation 1[iv], which the EPO’s ruling confirms as follows:

[A] budesonide ODT [orally dispersing tablet] showing a disintegration time within 60 seconds in simulated saliva fluid when tested using the USP <701> Disintegration Test is an obvious solution to the problem.

... ODTs are well-known dosage forms and belong to the common technical knowledge of the skilled formulator. The skilled person is aware that their disintegration time can be modulated in order to obtain the desired therapeutic effect. Therefore, the claimed disintegration time is regarded as one of the options available to the skilled person when putting into practice the general disclosure of [0032] of [Dohil].

EX1004 ¶36.8.

Dohil in view of the knowledge of a POSA therefore renders obvious claim 1.

C. Claim 2

Claim 2 depends from claim 1 and recites “wherein the at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity is at least one disintegrant.”

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; EX1051 ¶170.

Dohil therefore renders obvious claim 2, which is supported by the EPO’s ruling. EX1004 ¶26.4 (“the skilled person would understand that the tablets

addressed in [0032] of [Dohil] necessarily require an excipient which facilitates their dispersion and dissolution”).

D. Claim 3

Claim 3 depends from claim 1 and recites “comprising sucralose.”

As discussed above for limitation 1(iii), a POSA would have been motivated to include sucralose in Dohil’s formulation with a reasonable expectation of success in view of Dohil’s express disclosure of sucralose and the knowledge of the POSA that sucralose was a desirable sweetener for ODTs. *Supra* Section VIII.B.4.a; EX1051 ¶173. Dohil therefore renders claim 3 obvious.

E. Claim 4

Claim 4 depends from claim 1 and recites “comprising sucralose and mannitol.”

As discussed above for limitation 1(iii), Dohil discloses using sucralose and mannitol in the formulation of its ODT. *Supra* Sections VIII.B.4.a-b. A POSA would have been motivated to include mannitol and sucralose in Dohil’s ODT formulation with a reasonable expectation of success in view of Dohil’s express disclosure of mannitol and sucralose, as well as and the knowledge of the POSA that mannitol was the bulk excipient of choice for ODTs and that sucralose was a desirable sweetener to improve the taste and palatability of ODTs. *Supra* Sections VIII.B.4.a-b; EX1051 ¶¶175-180. Dohil therefore renders obvious claim 4.

F. Claim 5

Claim 5 depends from claim 1 and recites “comprising sucralose, mannitol, and magnesium stearate.”

As discussed above for claim 4, a POSA would have been motivated to include sucralose and mannitol in Dohil’s formulation with a reasonable expectation of success. *Supra* Section VIII.E.

Magnesium stearate was a desirable lubricant when mannitol is used as the bulk diluent because this combination of excipients allows tablet formulation using “conventional tableting methodologies and conventional package equipment” at a significantly decreased cost of production. EX1018 454; EX1043 452 (recommending magnesium stearate as the lubricant when mannitol is used as a diluent).

A POSA would have been motivated to include mannitol, sucralose, and magnesium stearate in Dohil’s ODT formulation with a reasonable expectation of success in view of Dohil’s express disclosure of mannitol, sucralose, and magnesium stearate. *Supra* Section VIII.B.4.a-c. This motivation was reinforced by the knowledge of the POSA that mannitol was the bulk diluent of choice for ODTs, that sucralose was a desirable sweetener to improve the taste and palatability of ODTs, and that magnesium stearate was a desirable lubricant when mannitol was used as

the bulk diluent. *Supra* Sections VIII.B.4.a-c; EX1051 ¶¶181-185. Dohil therefore renders obvious claim 5.

G. Claim 6

Claim 6 depends from claim 1 and recites “comprising sucralose, mannitol, magnesium stearate, and polyvinyl pyrrolidone.”

As discussed above for claim 5, a POSA would have been motivated to include sucralose, mannitol, and magnesium stearate in Dohil’s formulation with a reasonable expectation of success. *Supra* Section VIII.F.

A POSA would have been motivated to include at least one binder/adhesive agent in Dohil’s ODT formulation “to promote cohesiveness within powders, thereby ensuring that the tablet remains intact after compression as well as improving the flow by forming granules.” EX1041 241. Tablets typically contain at least one binder/adhesive agent for these purposes. *Id.* Polyvinyl pyrrolidone was a desirable binder/adhesive for “impart[ing] adequate cohesion without retarding disintegration or dissolution” of a tablet. *Id.*; *id.* 240 (Table 3). In addition, polyvinyl pyrrolidone was “essentially nontoxic” and has “no irritant effect.” EX1044 615.

A POSA would have been motivated to include mannitol, sucralose, magnesium stearate, and polyvinyl pyrrolidone in Dohil’s ODT formulation with a reasonable expectation of success in view of Dohil’s express disclosure of mannitol,

sucralose, magnesium stearate, and polyvinyl pyrrolidone. *Supra* Section VIII.B.4.a-d. This motivation was reinforced by the knowledge of the POSA that mannitol was the bulk diluent of choice for ODTs, that sucralose was a desirable sweetener to improve the taste and palatability of ODTs, that magnesium stearate was a desirable lubricant when mannitol was used as the bulk diluent, and that polyvinyl pyrrolidone was a desirable binder/adhesive for forming tablets. *Supra* Sections VIII.B.4.a-d; EX1051 ¶¶186-192. Dohil therefore renders obvious claim 6.

H. Claim 7

Claim 7 depends from claim 1 and recites “comprising sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, and polyethylene glycol.”

As discussed above for claim 6, a POSA would have been motivated to include sucralose, mannitol, magnesium stearate, and polyvinyl pyrrolidone in Dohil’s formulation with a reasonable expectation of success. *Supra* Section VIII.G.

Polyethylene glycol was a water soluble polymer that provided tablet coatings with high water permeability to assist with rapid dissolution of a tablet, EX1046 546, while also aiding in keeping an ODT intact during handling. EX1018 445.

A POSA would have been motivated to include mannitol, sucralose, magnesium stearate, polyvinyl pyrrolidone, and polyethylene glycol in Dohil’s ODT formulation with a reasonable expectation of success in view of Dohil’s express

disclosure of mannitol, sucralose, magnesium stearate, polyvinyl pyrrolidone, and polyethylene glycol. *Supra* Section VIII.B.4.a-e. This motivation was reinforced by the knowledge of the POSA that mannitol was the bulk diluent of choice for ODTs, that sucralose was a desirable sweetener to improve the taste and palatability of ODTs, that magnesium stearate was a desirable lubricant when mannitol was used as the bulk diluent, that polyvinyl pyrrolidone was a desirable binder/adhesive for forming tablets, and that polyethylene glycol is a desirable component of a coating for tablets. *Supra* Sections VIII.B.4.a-e; EX1051 ¶¶193-200.

A similar combination of excipients was known to be commercially available as the “Flashtab” ODT, which contained acetaminophen and caffeine as the active ingredients, as well as the following excipients: mannitol, sucralose, magnesium stearate, polyvinyl pyrrolidone (“povidone”), and propylene glycol. EX1041 260, Table 10.

Dohil renders obvious claim 7 for at least these reasons.

I. Claim 8

Claim 8 depends from claim 1 and recites “comprising sucralose and magnesium stearate.”

Claim 8 is obvious over Dohil for the reasons discussed above regarding claim 5. *Supra* Sections VIII.F, VIII.B.4.a-c; EX1051 ¶¶201-207.

J. Claim 9

Claim 9 depends from claim 1 recites “comprising sucralose and polyvinyl pyrrolidone.”

Claim 9 is obvious over Dohil for the reasons discussed above regarding limitation 1(iii) and claim 6. *Supra* Sections VIII.B.4.a, VIII.B.4.d, VIII.G.

A POSA would have been motivated to include polyvinyl pyrrolidone and sucralose in Dohil’s ODT formulation with a reasonable expectation of success in view of Dohil’s express disclosure of polyvinyl pyrrolidone and sucralose, as well as and the knowledge of the POSA that polyvinyl pyrrolidone was a desirable binder/adhesive agent for formulating ODTs and that sucralose was a desirable sweetener to improve the taste and palatability of ODTs. *Supra* Sections VIII.B.4.a, VIII.B.4.d; EX1051 ¶¶208-215. Dohil therefore renders obvious claim 9.

K. Claim 10

Claim 10 depends from claim 1 and recites “comprising sucralose and polyethylene glycol.”

Claim 10 is obvious over Dohil for the reasons discussed above regarding limitation 1(iii) and claim 7. *Supra* Sections VIII.B.4.a, VIII.B.4.e, VIII.H.

A POSA would have been motivated to include polyethylene glycol and sucralose in Dohil’s ODT formulation with a reasonable expectation of success in view of Dohil’s express disclosure of polyethylene glycol and sucralose, as well as

the knowledge of the POSA that polyethylene glycol was desirable for coating ODTs and that sucralose was a desirable sweetener to improve the taste and palatability of ODTs. *Supra* Sections VIII.B.4.a, VIII.B.4.e; EX1051 ¶¶216-222. Dohil therefore renders obvious claim 10.

L. Claims 11-13

Claim 11 depends from claim 1 and recites “comprising two or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.”

Claim 12 depends from claim 1 and recites “comprising three or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.”

Claim 13 depends from claim 1 and recites “comprising four or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.”

Claim 11 is obvious for at least the reasons discussed above regarding claims 4-10. *Supra* Sections VIII.E-K. Claim 12 is obvious for at least the reasons discussed above regarding claims 5-7. *Supra* Sections VIII.F-H. Claim 13 is obvious for at least the reasons discussed above regarding claims 6-7. *Supra* Sections VIII.G-H; EX1051 ¶¶223-227.

Dohil therefore renders obvious claims 11-13.

M. Claim 14

Dependent claim 14 recites “[a] method for treating eosinophilic esophagitis comprising administering to an individual in need thereof an orally dispersing tablet according to claim 1.”

Dohil discloses using its formulations to treat eosinophilic esophagitis as follows:

The methods of the present invention are useful, for example, for preventing and *alleviating the symptoms and inflammation of eosinophilic esophagitis....*

EX1002 ¶[0010]; *id.* ¶¶[0011], [0015], [0023]; EX1051 ¶¶228-230. Dohil renders obvious claim 14.

N. Claims 15 and 16

Claim 15 depends from claim 1 and requires “about 0.5 mg of budesonide.”

Claim 16 depends from claim 1 and requires “about 1 mg of budesonide.”

Claims 15 and 16 are obvious over Dohil for the same reasons discussed above for limitation 1(i). *Supra* Section VIII.B.2; EX1051 ¶¶231-234.

IX. GROUND 2: GROTHER IN VIEW OF THE FDA GUIDANCE

Grother discloses an orally dispersing tablet formulation having the same ingredients claimed by the ’828 patent. A POSA would have been motivated to follow the FDA Guidance in formulating Grother’s orally dispersing tablet formulation to disintegrate within 60 seconds using the USP <701> Disintegration

Test with a reasonable expectation of success. This section introduces Grother, and then explains how Grother in view of the FDA Guidance renders obvious claims 1-16 of the '828 patent.

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, *id.* 18:15-18; EX1051 ¶236.

B. Claim 1

Grother in view of the FDA Guidance discloses orally dispersing formulations that render obvious all limitations of claim 1.

1. Preamble

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

If the preamble were limiting, Grother discloses the recited orally dispersing tablet. 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 (describing “the resulting tablet”). 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; EX1051 ¶¶240-242. A POSA would understand that Grother’s fast dispersing solid dosage forms that dissolve rapidly within the oral cavity do so without chewing. EX1005 1; EX1051 ¶243. Grother discloses the preamble.

2. Limitation 1(i)

Limitation 1(i) recites “about 0.5 mg to about 1 mg of budesonide.”

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 specific examples of 10 mg and 12.5 mg of active ingredient per dosage form. *Id.* 29, Table I.

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 budesonide, *id.* 18:15-18. A POSA would have been motivated to select budesonide 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 was a well-known corticosteroid with desirable anti-inflammatory activity. *Supra* Section IV.A; EX1051 ¶¶246-248.

It was generally known that a therapeutically effective dosage of budesonide desirably ranged from, e.g., 0.5-1mg. 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); EX1051 ¶249. 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

[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 and 1 mg/day. *Id.* ¶¶[0058], [0053], Table 1.

Based on Grother’s instruction that its compositions should normally have 1-20% by weight active ingredient and the general knowledge in the art that topically administrable formulations of budesonide contain, e.g., 0.5-1mg of budesonide, a POSA would have been motivated to formulate budesonide in Grother’s compositions at, e.g., 0.5-1 mg, with a reasonable expectation of success. EX1051 ¶¶250-251. Grother therefore renders obvious an ODT comprising about 0.5 mg to about 1 mg of budesonide.

3. Limitation 1(ii)

Limitation 1(ii) recites “at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity.”

The ’828 patent admits that “pharmaceutically acceptable ingredients” include disintegrants, EX1001 2:57-64, and that disintegrants include starch, pregelatinized starch, and carboxymethyl starch. EX1001 9:46-51.

Grother’s fast dispersing dosage form rapidly disperses within seconds of being placed in a patient’s oral cavity. EX1008 Abstract, 13:19-22. 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.” *Id.* 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. Thus, Grother’s modified starch facilitates the rapid dispersion of the fast dispersing dosage form in the oral cavity. EX1051 ¶¶253-257.

Therefore, 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 pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity” required by limitation 1(ii).

4. Limitation 1(iii)

Limitation 1(iii) recites “sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof.”

Claim 1 is obvious if the Board finds that any one of the five recited ingredients would have been obvious to include in Grother’s formulations. A POSA would have been motivated to include any one of these five ingredients as well as combinations of all five ingredients in Grother’s formulations with a reasonable expectation of success.

a. Sucralose

Grother discloses the use of sweeteners in its formulations. EX1008 15:7-8 (“sweeteners or taste-masking agents may also be incorporated into the composition”). Sucralose was a sweetener of choice for use in orally administered tablets. EX1041 253. Sucralose advantageously “has a sweetening power approximately 300-1000 times that of sucrose and has no aftertaste.” EX1045 742. Sucralose desirably has no known incompatibilities and no nutritional value, *id.*, and it is “generally regarded as a nontoxic and nonirritant material,” *id.* 743.

A POSA would have been motivated to include sucralose in Grother’s formulations with a reasonable expectation of success in view of Grother’s disclosure of sweeteners being incorporated into Grother’s formulations and the knowledge of the POSA that sucralose was a desirable sweetener for such formulations. EX1051 ¶¶260-263.

b. Mannitol

Grother discloses that “[m]atrix forming agents suitable for use in the present invention include sugars such as mannitol...” EX1008 14:16-21. Grother discloses that “[t]he preferred matrix forming agent is mannitol.” *Id.* 13:12.

Mannitol was a desirable bulking diluent in ODTs. *Supra* Section IV.B.3.a. The ’828 patent admits that mannitol was “typically used in disintegrating tablet formulations.” EX1001 8:47-55.

A POSA would have been motivated to include mannitol in Grother's formulation with a reasonable expectation of success in view of Grother's express disclosure of mannitol as its preferred matrix forming agent and the knowledge of the POSA that mannitol was a desirable bulk diluent for such formulations. EX1051 ¶¶264-268.

c. Magnesium Stearate

Grother discloses that the “most commercially popular form” of its formulation is made in dies having “preformed depressions” to produce a tablet “that dissolves rapidly on contact with saliva.” EX1008 32:12-17. Magnesium stearate was a desirable lubricant when mannitol is used as the bulking diluent because this combination of excipients allows tablet formulation using “conventional tableting methodologies and conventional package equipment” at a significantly decreased cost of production. EX1018 454; EX1043 452. A lubricant such as magnesium stearate is added to beneficially “reduce friction between the tablet and the die wall during compression” formulation of a tablet. EX1041 241.

The '828 patent admits that magnesium stearate was “typically used in disintegrating tablet formulations.” EX1001 8:47-55.

A POSA would have been motivated to include magnesium stearate in Grother's formulation with a reasonable expectation of success in view of Grother's disclosure that mannitol is its preferred matrix forming agent and the knowledge of

the POSA that magnesium stearate is a desirable lubricant for formulations using mannitol as the bulk matrix forming agent. EX1051 ¶¶269-274.

d. **Polyvinyl pyrrolidone and polyethylene glycol**

Grother discloses that “[t]he fast dispersing dosage form according to the invention may also contain, in addition to the active ingredient and modified starch, *other matrix forming agents* and secondary components.” EX1008 14:7-9. “One or more matrix forming agents may be incorporated into the solution or suspensions prior to solidification.” *Id.* 14:22-23.

Grother’s matrix forming agent includes polyvinylpyrrolidone. *Id.* 14:9-15. Polyvinyl pyrrolidone was often used as a binder/adhesive for “impart[ing] adequate cohesion without retarding disintegration or dissolution” of a tablet. EX1041 241; *id.* 240 (Table 3). A POSA would have been motivated to include polyvinyl pyrrolidone in Grother’s formulation with a reasonable expectation of success in view of Grother’s express disclosure of polyvinyl pyrrolidone and the knowledge of the POSA that polyvinyl pyrrolidone was a desirable binder/adhesive for use in such formulations. EX1051 ¶¶276-279.

Grother’s formulations desirably “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. Polyethylene glycol is a binder having “the advantage of functioning both as a binder and as a capillary attractant.” EX1018

452. As a capillary attractant, polyethylene glycol assists with water uptake into a dispersing tablet, which assists with dissolution of tablet in the patient’s mouth. *Id.* 459 (“disintegration time can be very short as a result of fast adsorption of water by capillary force”). A POSA would have been motivated to include polyethylene glycol in Grother’s formulation with a reasonable expectation of success in view of Grother’s disclosure that its formulations should rapidly dissolve within a patient’s mouth and the knowledge of the POSA that polyethylene glycol was a desirable binder that advantageously acts as a capillary attractant to assist with dissolution in the patient’s mouth. EX1051 ¶¶280-282.

Grother in view of the knowledge of a POSA renders obvious limitation 1(iii).

5. Limitation 1[iv]

Limitation 1[iv] recites “wherein upon administration a therapeutically effective amount of budesonide is deposited topically in the upper gastrointestinal tract.”

As discussed above, a POSA would have been motivated to formulate budesonide in Grother’s compositions at, e.g., 0.5 mg and 1 mg, which constitutes a therapeutically effective amount of budesonide. *Supra* Section IX.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 in the form of a fast dispersing dosage form would release budesonide rapidly in the oral cavity, which will topically deposit budesonide in the oral cavity of the upper gastrointestinal tract. EX1051 ¶¶283-286. Grother therefore discloses limitation 1(iv).

6. Limitation 1[v]

Limitation 1[v] recites “wherein the orally dispersing tablet disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test.”

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 would have been obvious to formulate budesonide 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 Guidance for Industry on ODTs. The FDA Guidance recommended that orally dispersing 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. The FDA Guidance provides the agency’s recommendations on the topic of orally dispersing 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 30 seconds or less when tested using the USP <701> Disintegration Test. EX1051 ¶¶288-290; *Allergan*, 726 F.3d at 1291-92.

A POSA would have 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 dispersing pharmaceutical compositions that dissolve within “several seconds to about a minute” would have been a routine exercise by 2009. EX1018 434; EX1005 2. The

numerous commercially available orally dispersing systems and products available by 2009 would have bolstered the POSA's expectation of success. EX1017 179-181; EX1018 436-439; EX1051 ¶¶291-292. The EPO determined that orally dispersing tablets were "well-known dosage forms and belong to the common technical knowledge of the skilled formulator" such that "[t]he skilled person is aware that their disintegration time can be modulated in order to obtain the desired therapeutic effect." EX1004 ¶36.8.

Grother in view of the FDA Guidance therefore renders obvious an orally dispersing tablet that disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test. Based on the foregoing, Grother in view of the FDA Guidance renders obvious claim 1.

C. Claim 2

Claim 2 depends from claim 1 and recites "wherein the at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity is at least one disintegrant."

The '828 patent admits that disintegrants include starch, pregelatinized starch, and carboxymethyl starch. EX1001 9:46-51 ("suitable disintegrants include.... 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 and renders obvious the “at least one disintegrant” required by claim 2. EX1051 ¶¶294-297.

D. Claim 3

Claim 3 depends from claim 1 and recites “comprising sucralose.”

As discussed above for limitation 1(iii), a POSA would have been motivated to include sucralose in Grother’s formulation with a reasonable expectation of success in view of Grother’s disclosure of sweeteners being incorporated into Grother’s formulations and the knowledge of the POSA that sucralose was a desirable sweetener for such formulations. *Supra* Section IX.B.4.a; EX1051 ¶¶298-300. Grother in view of the FDA Guidance renders claim 3 obvious.

E. Claim 4

Claim 4 depends from claim 1 and recites “comprising sucralose and mannitol.”

As discussed above for limitation 1(iii), Grother discloses that mannitol is its preferred matrix forming agent. *Supra* Section IX.B.4.b.

A POSA would have been motivated to include mannitol and sucralose in Grother's formulation with a reasonable expectation of success in view of Grother's express disclosure of mannitol as its preferred matrix forming agent and Grother's disclosure of incorporating sweeteners into the formulation, as well as and the knowledge of the POSA that mannitol was the bulk excipient of choice for ODT formulations and that sucralose was a sweetener of choice to improve the taste and palatability of such formulations. *Supra* Sections IX.B.4.a-b; EX1051 ¶¶301-306. Grother in view of the FDA Guidelines renders obvious claim 4.

F. Claim 5

Claim 5 depends from claim 1 and recites “comprising sucralose, mannitol, and magnesium stearate.”

As discussed above for claim 4, a POSA would have been motivated to include mannitol and sucralose in Grother's formulation with a reasonable expectation of success. *Supra* Section IX.E.

Magnesium stearate was a desirable lubricant when mannitol is used as the bulk diluent. *Supra* Section IX.B.4.c.

A POSA would have been motivated to include mannitol, sucralose, and magnesium stearate in Grother's formulation with a reasonable expectation of

success in view of Grother’s disclosure that mannitol is its preferred matrix forming agent, the knowledge of the POSA that magnesium stearate is a desirable lubricant for formulations using mannitol as the bulk matrix forming agent, and Grother’s disclosure of incorporating sweeteners into the formulation, as well as the knowledge of the POSA that sucralose was a sweetener of choice to improve the taste and palatability of such formulations. *Supra* Sections IX.B.4.a-c; EX1051 ¶¶307-311. Grother in view of the FDA Guidelines renders obvious claim 5.

G. Claim 6

Claim 6 depends from claim 1 and recites “comprising sucralose, mannitol, magnesium stearate, and polyvinyl pyrrolidone.”

As discussed above for claim 5, a POSA would have been motivated to include mannitol, sucralose, and magnesium stearate in Grother’s formulation with a reasonable expectation of success. *Supra* Section IX.F.

Grother’s matrix forming agents include polyvinylpyrrolidone. EX1008 14:9-15. Polyvinyl pyrrolidone was “often” used as a binder/adhesive for “impart[ing] adequate cohesion without retarding disintegration or dissolution” of a tablet. EX1041 241; *id.* 240 (Table 3); *supra* Section IX.B.4.d.

A POSA would have been motivated to include mannitol, magnesium stearate, sucralose, and polyvinyl pyrrolidone in Grother’s formulation with a reasonable expectation of success in view of Grother’s disclosure that mannitol is its

preferred matrix forming agent, the knowledge of the POSA that magnesium stearate is a desirable lubricant for formulations using mannitol as the bulk matrix forming agent, Grother's disclosure of incorporating sweeteners into the formulation as well as the knowledge of the POSA that sucralose was a sweetener of choice to improve the taste and palatability of such formulations, and Grother's disclosure that its matrix forming agents include polyvinyl pyrrolidone as well as the knowledge of the POSA that polyvinyl pyrrolidone was a desirable binder/adhesive for forming tablets. *Supra* Sections IX.B.4.a-d; EX1051 ¶¶312-318. Grother in view of the FDA Guidelines renders obvious claim 6.

H. Claim 7

Claim 7 depends from claim 1 and recites “comprising sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, and polyethylene glycol.”

As discussed above for claim 6, a POSA would have been motivated to include sucralose, mannitol, magnesium stearate, and polyvinyl pyrrolidone in Grother's formulation with a reasonable expectation of success. *Supra* Section IX.G.

A POSA would have been motivated to additionally include polyethylene glycol in Grother's formulation with a reasonable expectation of success in view of Grother's disclosure that its formulations should rapidly dissolve within a patient's mouth and the knowledge of the POSA that polyethylene glycol was a desirable

binder that advantageously acts as a capillary attractant to assist with dissolution in the patient's mouth. *Supra* Section IX.B.4.d; EX1051 ¶¶319-324. Grother in view of the FDA Guidelines renders obvious claim 7.

I. Claim 8

Claim 8 depends from claim 1 and recites “comprising sucralose and magnesium stearate.”

Claim 8 is obvious over Grother and the FDA Guidance for reasons discussed above regarding claim 5. *Supra* Section IX.F; EX1051 ¶¶325-327. Grother in view of the FDA Guidelines renders obvious claim 8.

J. Claims 9

Claim 9 depends from claim 1 recites “comprising sucralose and polyvinyl pyrrolidone.”

A POSA would have been motivated to include polyvinyl pyrrolidone and sucralose in Grother's formulation with a reasonable expectation of success in view of Grother's disclosure that its matrix forming agents include polyvinyl pyrrolidone as well as the knowledge of the POSA that polyvinyl pyrrolidone was a desirable binder/adhesive for forming tablets, and Grother's disclosure of incorporating sweeteners into the formulation as well as the knowledge of the POSA that sucralose was a sweetener of choice to improve the taste and palatability of such formulations.

Supra Sections IX.B.4.a, IX.B.4.d; EX1051 ¶¶328-335. Grother in view of the FDA Guidelines renders obvious claim 9.

K. Claim 10

Claim 10 depends from claim 1 and recites “comprising sucralose and polyethylene glycol.”

A POSA would have been motivated to include polyethylene glycol and sucralose in Grother’s formulation with a reasonable expectation of success in view of Grother’s disclosure that its formulations should rapidly dissolve within a patient’s mouth as well as the knowledge of the POSA that polyethylene glycol was a desirable binder that advantageously acts as a capillary attractant to assist with dissolution in the patient’s mouth, and Grother’s disclosure of incorporating sweeteners into the formulation as well as the knowledge of the POSA that sucralose was a sweetener of choice to improve the taste and palatability of such formulations. *Supra* Sections IX.B.4.a, IX.B.4.d; EX1051 ¶¶336-341. Grother in view of the FDA Guidelines renders obvious claim 10.

L. Claims 11-13

Claim 11 depends from claim 1 and recites “comprising two or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.”

Claim 12 depends from claim 1 and recites “comprising three or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.”

Claim 13 depends from claim 1 and recites “comprising four or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.”

Claim 11 is obvious for at least the reasons discussed above regarding claims 4-10. *Supra* Sections IX.E-K. Claim 12 is obvious for at least the reasons discussed above regarding claims 5-7. *Supra* Sections IX.F-H. Claim 13 is obvious for at least the reasons discussed above regarding claims 6-7. *Supra* Sections IX.G-H; EX1051 ¶¶342-346.

M. Claim 14

Claim 14 depends from claim 1 and recites “[a] method for treating eosinophilic esophagitis comprising administering to an individual in need thereof an orally dispersing tablet according to claim 1.”

Grother teaches formulating its fast dispersing solid dosage form with “budesonide,” which was a known “corticosteroid.” EX1008 18:15. Budesonide was known to be a potent, locally acting anti-inflammatory corticosteroid that was desirable for treating eosinophilic esophagitis. *Supra* Section IV.A; EX1014 706; EX1015 1, 6, 8; EX1002 ¶¶[0010], [0011], [0015]; EX1051 ¶¶348-353.

A POSA would have been motivated to formulate Grother’s fast dispersing solid oral dosage forms with budesonide to treat eosinophilic esophagitis with a reasonable expectation of success. Grother in view of the FDA Guidance renders obvious claim 14.

N. Claims 15 and 16

Claim 15 depends from claim 1 and recites “comprising about 0.5 mg of budesonide.”

Claim 16 depends from claim 1 and recites “comprising about 1 mg of budesonide.”

Claims 15 and 16 are obvious over Grother and the FDA Guidance for the same reasons as limitation 1(i). *Supra* Section IX.B.2; EX1051 ¶¶354-362.

X. 325(D) DOES NOT APPLY

This petition warrants institution and should not be subject to discretionary denial under the Board’s precedential test articulated in *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB 2020).

First, this Petition is based on three prior art references: Dohil, Grother, and the FDA Guidance. Grother and the FDA Guidance were not made of record during prosecution of the ’828 patent. Thus, there is no colorable 325(d) challenge for

Ground 2 based on Grother in view of the FDA Guidance. The Board should therefore institute trial based on at least Ground 2.

Second, during prosecution of the parent '069 patent the Examiner rejected the pending claims as obvious over a Dohil equivalent. EX1048 123-130, 215-221. The Examiner found that the Dohil equivalent disclosed all limitations of the pending claims from the '069 patent. *Id.* 123-130. At the time of the Examiner's rejections, the pending claims did not contain a limitation reciting "the orally dispersing tablet disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test." *Id.* 182-183.

In response to the Examiner's obviousness rejection, Patent Owner amended the then-pending claims of the parent '069 patent to add a disintegration testing requirement that is identical to limitation 1[v] of the present '828 patent. *Id.* 103. Patent Owner argued nonobviousness based on the newly added disintegration testing limitation. *Id.* 105-106. The Examiner issued a Notice of Allowance for the parent '069 patent finding the claims allowable based on disintegration testing limitation. *Id.* 55-56.

The Dohil equivalent also was discussed during prosecution of the present '828 patent in an interview. EX1049 99; EX1039 30. The same Examiner examined both the present '828 patent and the parent '069 patent. The Examiner did not issue a rejection based on Dohil for the present '828 patent. Patent Owner nevertheless

asserted nonobviousness of the present '828 patent claims over Dohil and the other prior art raised by the Examiner based on the disintegration testing limitation. EX1049 90-91, 98-99.

The Examiner's allowance of the parent '069 patent and present '828 patent constitutes an error material to the patentability of the challenged claims. *Advanced Bionics*, Paper 6 at 8-9. The Examiner did not have the benefit of the FDA Guidance during prosecution of either patent. The Examiner therefore overlooked the specific teachings of the FDA Guidance that are representative of the POSA's knowledge that orally disintegrating compositions should have a disintegration time of approximately 30 seconds or less based on the USP <701> Disintegration Test. EX1005 3. This knowledge directly addresses the limitation that the Patent Owner asserted was missing from the POSA's knowledge during examination of the patents. EX1049 90-91, 98-99; EX1048 55-56, 105-106.

Furthermore, the Examiner did not have the benefit of this Petition mapping the prior art references to Patent Owner's claims and Dr. Parr's accompanying expert declaration explaining the POSA's understanding of the prior art. Dr. Falk Pharma has presented a sufficient showing that the Examiner overlooked relevant disclosures representative of the knowledge of a POSA that invalidate the claims such that the Office erred in a manner material to patentability. Ground 1 presents compelling challenges to patentability that warrant institution.

The Board should institute trial based on Grounds 1 and 2.

XI. NO SECONDARY CONSIDERATIONS

There is no evidence of secondary considerations of nonobviousness. Should Ellodi make allegations regarding secondary considerations, Petitioner will respond.

XII. MANDATORY NOTICES, STANDING, AND PAYMENT

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.

- *Ellodi Pharmaceuticals, LP v. Dr. Falk Pharma GmbH*, Case No. 24-cv-1392 (E.D. Va);
- *Ellodi Pharmaceuticals, LP v. Dr. Falk Pharma GmbH*, Düsseldorf Regional Court, Case No. 4b O 43/24, Patent Litigation Chamber, Werdener Str. 1, 40227 Düsseldorf, Germany.

Petitioner is aware of the following U.S. patents and patent applications related to the '828 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;
- 17/236,295 filed April 21, 2021, now U.S. patent number 11,266,598;
- and
- 17/569,047 filed on January 5, 2022.

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) Phillip J. Minnick (Reg. No. 81,223) 2esf@knobbe.com 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.

XIII. PAYMENT OF FEES

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

XIV. REQUIREMENTS FOR REVIEW

Petitioner certifies that the '828 patent is available for IPR and that it is not barred or estopped from requesting this IPR.

XV. CONCLUSION

Claims 1-16 of the '828 patent are unpatentable and should be canceled.

IPR Petition – Patent No. 11,246,828
Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.

Dated: October 24, 2024 Respectfully submitted,

By: /Nathanael Luman/

Nathanael Luman (Reg. No. 63,160)
KNOBBE MARTENS OLSON & BEAR, LLP

Attorney for Petitioner Dr. Falk Pharma GmbH

APPENDIX A

Listing of Challenged Claims from U.S. Patent No. 11,246,828	
Claim 1	
Preamble	An orally dispersing tablet comprising:
(i)	about 0.5 mg to about 1 mg of budesonide;
(ii)	at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity; and
(iii)	sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof;
[iv]	wherein upon administration a therapeutically effective amount of budesonide is deposited topically in the upper gastrointestinal tract, and
[v]	wherein the orally dispersing tablet disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test.
Claim 2	
--	The orally dispersing tablet of claim 1, wherein the at least one pharmaceutically acceptable ingredient which facilitates the dispersal of the tablet in the oral cavity is at least one disintegrant.
Claim 3	
--	The orally dispersing tablet of claim 1, comprising sucralose.
Claim 4	
--	The orally dispersing tablet of claim 1, comprising sucralose and mannitol.

Listing of Challenged Claims from U.S. Patent No. 11,246,828	
Claim 5	
--	The orally dispersing tablet of claim 1, comprising sucralose, mannitol, and magnesium stearate.
Claim 6	
--	The orally dispersing tablet of claim 1, comprising sucralose, mannitol, magnesium stearate, and polyvinyl pyrrolidone.
Claim 7	
--	The orally dispersing tablet of claim 1, comprising sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, and polyethylene glycol.
Claim 8	
--	The orally dispersing tablet of claim 1, comprising sucralose and magnesium stearate.
Claim 9	
--	The orally dispersing tablet of claim 1, comprising sucralose and polyvinyl pyrrolidone.
Claim 10	
--	The orally dispersing tablet of claim 1, comprising sucralose and polyethylene glycol.
Claim 11	
--	The orally dispersing tablet of claim 1, comprising two or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.

Listing of Challenged Claims from U.S. Patent No. 11,246,828	
Claim 12	
--	The orally dispersing tablet of claim 1, comprising three or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.
Claim 13	
--	The orally dispersing tablet of claim 1, comprising four or more of sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone or polyethylene glycol.
Claim 14	
--	A method for treating eosinophilic esophagitis comprising administering to an individual in need thereof an orally dispersing tablet according to claim 1.
Claim 15	
--	The orally dispersing tablet of claim 1, comprising about 0.5 mg of budesonide.
Claim 16	
--	The orally dispersing tablet of claim 1, comprising about 1 mg of budesonide.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,246,828 contains 13,300 words according to the word-processing program used to prepare this paper. The foregoing word count complies with the 14,000 word type-volume limit specified by 37 C.F.R. § 42.24(a)(1).

Dated: October 24, 2024 By: /Nathanael Luman/
Nathanael Luman (Reg. No. 63,160)
KNOBBE MARTENS OLSON & BEAR, LLP

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 11,246,828, PETITIONER’S POWER OF ATTORNEY, AND EXHIBITS 1001-1020, 1025-1036, and 1038-1039 were served by FedEx on the Patent Owner at the correspondence address of record for the subject patent as follows:

58249 - COOLEY LLP
ATTN: IP Docketing Department
1299 Pennsylvania Avenue, NW Suite 700
Washington, DC 20004
UNITED STATES

Dated: October 24, 2024 By: /Nathanael Luman/
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