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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. IPR2024-00056
Patent No. 11,260,061

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,260,061**

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LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 11,260,061 to Gosselin et al.
1002	U.S. Publication No. 20070111978 to Dohil et al. (“Dohil”)
1003	RESERVED
1004	RESERVED
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	RESERVED
1008	RESERVED
1009	Svoboda et al., “Oral formulations of budesonide: a novel treatment for inflammatory bowel disease,” <i>Drugs of Today</i> , 44:857-863 (2008) at 857.
1010	Tan et al., “Eosinophilic gastroenteritis treated with non-enteric-coated budesonide tablets,” <i>European Journal of Gastroenterology & Hepatology</i> , 13:425-427 (2001)
1011	Kolkman et al., “Evaluation of oral budesonide in the treatment of active distal ulcerative colitis,” <i>Drugs of Today</i> , 40:589-601 (2004)
1012	Siewert et al., “Eosinophilic gastroenteritis with severe protein-losing enteropathy: Successful treatment with budesonide,” <i>Digestive and Liver Disease</i> , 38:55-59 (2006)
1013	Elsing et al., “Budesonide for the treatment of obstructive eosinophilic jejunitis,” <i>Z. Gastroenterology</i> , 45:187-189 (2007).

Exhibit No.	Description
1014	Aceves et al., “Topical viscous budesonide suspension for treatment of eosinophilic esophagitis,” Journal of Allergy and Clinical Immunology 116:705-706 (2005)
1015	Aceves et al., “Oral Viscous Budesonide: A potential new therapy for eosinophilic esophagitis in children,” American Journal of Gastroenterology, 102:1-9 (2007)
1016	The United States Pharmacopeia, USP 32, 2009 at pages 262-263 “<701> Disintegration”
1017	Danckwerts, “Intraoral Drug Delivery: A Comparative Review,” American Journal of Drug Delivery, 1:171-186 (2003).
1018	Fu et al., “Orally fast disintegrating tablets: developments, technologies, taste-masking and clinical studies,” Critical Reviews in Therapeutic Drug Carrier Systems, 21:433-475 (2004)
1019	Shukla et al., “Mouth Dissolving Tablets I: An overview of formulation technology,” Scientia Pharmaceutica, 77:309-326 (2009) (March 6, 2009)
1020	U.S. Publication No. 20050232988 to Venkatesh et al.
1021	RESERVED
1022	RESERVED
1023	RESERVED
1024	RESERVED
1025	Goodman & Gilman’s: The Pharmacological Basis of Therapeutics, 11th edition, eds. Brunton, Lazo, Parker, 2005
1026	Budenofalk® Brochure (2005)
1027	Budenofalk® Advertisement (2007)

Exhibit No.	Description
1028	Dr. Falk Pharma Brochure (2008)
1029	<i>Curriculum Vitae</i> of Alan F. Parr, Pharm.D., Ph.D.
1030	RESERVED
1031	RESERVED
1032	RESERVED
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1034	RESERVED
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1041	Conway, “Solid dosage forms,” Chapter 4.1 in <i>Pharmaceutical Manufacturing Handbook: Production and Processes</i> , ed. Gad, pages 235-265 (2008)
1042	RESERVED
1043	RESERVED
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1047	RESERVED

Exhibit No.	Description
1048	RESERVED
1049	RESERVED
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1054	Wen, “Adsorption at solid surfaces: pharmaceutical applications,” in Encyclopedia of Pharmaceutical Technology, Third Edition, ed. Swarbrick, pages 34-45 (2007)
1055	Physical Pharmacy: Physical Chemical Principles in the Pharmaceutical Sciences, Fourth Edition, eds. Martin et al. (1993)
1056	Prosecution history excerpts from U.S. Application No. 17/211,119, which issued as U.S. Patent No. 11,260,061
1057	U.S. Publication No. 2011/0081411 to Perrett et al.
1058	U.S. Publication No. 2009/0191275 to Dohil et al. (“Dohil2009”)
1059	Redline comparison of Dohil and Dohil2009
1060	McGraw-Hill Dictionary of Scientific and Technical Terms, Sixth Edition (2003), “Adsorption”
1061	EP3041476B1
1062	The Opposition Division of the European Patent Office decision regarding EP3041476
1063	International Publication No. WO2011041509

Exhibit No.	Description
1064	Roeder et al., “Safety and efficacy of fluticasone propionate in the topical treatment of skin diseases,” Skin Pharmacology Physiology, 18:3-11 (2004)
1065	Remedios et al., “Eosinophilic esophagitis in adults: clinical, endoscopic, histologic findings, and response to treatment with fluticasone propionate,” Gastrointestinal Endoscopy, 63:3-12 (2006)
1066	Konikoff et al., “A randomized, double-blind, placebo-controlled trial of fluticasone propionate for pediatric eosinophilic esophagitis,” Gastroenterology, 131:1381-1391 (2006)
1067	Khan et al., “An approach for rapid disintegrating tablet: a review,” Int’l J. Pharm. Research and Development, 21:170-183 (2011)
1068	Prosecution history excerpts from U.S. Application No. 14/917,125, which issued as U.S. Patent No. 10,471,071
1069	“Cellulose, Silicified Microcrystalline,” Handbook of Pharmaceutical Excipients, 5th edition, eds. Rowe et al., pages 139-141 (2006)
1070	Declaration of Alan F. Parr, Pharm.D., Ph.D. regarding U.S. 11,260,061

Dr. Falk Pharma GmbH (“Petitioner”) requests *inter partes* review (“IPR”) of claims 1-30 (“the challenged claims”) of U.S. 11,260,061 (“the ’061 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. 9,468,407, 10,632,069, and 11,246,828. Also, Dr. Falk Pharma recently filed a petition challenging Ellodi’s U.S. 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 disintegrating tablets 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. 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 topically acting oral corticosteroid dosage 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 anywhere. Ellodi has, however, acquired ownership of certain U.S. patents, including

the '061 patent. The '061 patent improperly removes from the public the claimed orally disintegrating tablets (ODTs) containing a topically acting corticosteroid (such as budesonide or fluticasone propionate) with particle sizes on the micron scale that disintegrate within 60 seconds.

ODTs were well-known by 2013, the earliest priority date of the '061 patent. 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. Formulating these compositions with active ingredients having particle sizes on the micron scale was well-known because such particle sizes often improved mouthfeel, disintegration, and dissolution.

Ellodi previously disclosed and claimed ODTs containing budesonide and fluticasone with particle sizes on the micron scale in US20110081311 ("Perrett," EX1057).¹ Perrett is prior art to the '061 patent, and they share a common inventor, Gopi Venkatesh. Ellodi's '061 patent merely recycles the same subject matter it previously disclosed in Perrett. Ellodi's attempt to improperly extend its patent estate and restrict competition by retreading the same subject matter should be rejected. Indeed, Dr. Falk Pharma initiated an opposition proceeding at the European Patent

¹ Perrett issued as U.S. 8,771,729, which is the subject of IPR2024-01197.

Office (EPO) for the related European patent, EP3041476. The EPO determined that Perrett renders obvious a very similar claim to the '061 patent. The USPTO should likewise cancel Ellodi's claims.

As early as 2005, Ellodi disclosed ODTs with particle sizes on the micron scale in US20050232988 ("Venkatesh," EX1020). Perrett and the Venkatesh reference share Gopi Venkatesh as a common inventor, and Perrett incorporates-by-reference the Venkatesh reference. The Venkatesh reference reinforces that the '061 patent is nothing more than a trivial and obvious variation over Ellodi's previous disclosures.

In addition, US20090191275 ("Dohil2009," EX1058)² discloses ODTs containing corticosteroids such as budesonide and fluticasone with particle sizes on the micron scale that independently render obvious the challenged claims.

The Board should institute trial and hold that all claims from the '061 patent are unpatentable based on the compelling evidence of obviousness presented in this petition.

² Dohil2009 (EX1058) is a continuation-in-part application of the "Dohil" reference published as US20070111978 (EX1002) and relied upon in Petitioner's other IPRs challenging Ellodi's '729, '407, '069, and '828 patents. A redline comparison of Dohil and Dohil2009 is provided as EX1059.

II. BACKGROUND REGARDING THE '061 PATENT

The '061 patent claims priority to a provisional application filed September 6, 2013. It issued with 30 claims, of which only claims 1 and 19 are independent claims. The claims are directed to orally disintegrating tablets of a corticosteroid with particle sizes on the micron scale that disintegrate within 60 seconds. For example, claim 1 recites:

1. An orally disintegrating tablet comprising:
 - a. a topically acting corticosteroid or pharmaceutically acceptable salt or ester thereof, adsorbed onto a pharmaceutically acceptable carrier; and
 - b. at least one disintegrant;
- [c.i] wherein the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, is present in an amount ranging from about 0.5 mg to about 10 mg, and
- [c.ii] the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, has a mean particle size of ranging from about 100 nm to about 100 μ m; and
- [d] wherein the orally disintegrating table disintegrates within 60 seconds when tested using the USP <701> method for disintegration time.

EX1001 31:28-41.³

³ Bracketed labels are added for convenient referencing to the limitations of claims 1, 19, and 30. The '061 patent claims are reproduced in Appendix A.

III. LEVEL OF ORDINARY SKILL

A person of ordinary skill in the art (“POSA”) related to the ’061 patent would have a Ph.D., another advanced degree, or its equivalent, in areas related to pharmaceuticals, chemistry, biology, medicine, or a related discipline, and 2-3 years of experience in formulation development. Alternatively, a POSA would have a lesser degree in those fields, with at least five or more years of experience in formulation development. The POSA would also have had access to a medical doctor with a specialty in gastroenterology, and other individuals with expertise related to the above subjects. EX1070 ¶30.

IV. STATE OF THE PRIOR ART

A. Budesonide and Fluticasone Propionate for Treating Eosinophilic Esophagitis

Budesonide and fluticasone propionate are potent, locally acting anti-inflammatory glucocorticoids that were known to treat various inflammatory diseases. EX1025 1014-1015; EX1009 857; EX1064 3; EX1065 3. Budesonide and fluticasone propionate were desirable drugs for treating inflammation of the gastrointestinal tract because they were locally acting corticosteroids with a high first-pass effect, which minimized systemic side effects. EX1010 425; EX1066 1382.

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; EX1070 ¶¶45-65.

Beginning in 2005, Aceves et al. reported that formulations for the oral administration of budesonide and fluticasone propionate successfully treat eosinophilic esophagitis (EOE or EE). EX1014 706; EX1015 1, 6, 8; EX1066 1381-82.

B. Orally Disintegrating Tablets (ODTs)

1. Background and Nomenclature

Many patients were known to have difficulty swallowing tablets and gelatin capsules. Dysphagia, or difficulty in swallowing, “is common in about 35% of the general population.” EX1018 433-34; EX1019 310. Patients who have difficulty swallowing medications may have a high incidence of noncompliance with taking their medications. “Lack of patient compliance is probably the most important factor that results in suboptimal therapeutic outcome for patients.” EX1017 172. Difficulties with patient compliance can be significantly improved by formulating active ingredients in an orally disintegrating tablet (ODT). EX1070 ¶¶72-74.

ODTs were well-known by 2013. 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. EX1017 173-174; EX1018 Abstract.

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

ODTs 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; EX1070 ¶¶75-80.

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 ODTs. EX1018 434 (“The FDT is also known as fast melting, fast dispersing, rapid

dissolve, rapid melt, and/or quick disintegrating tablet.”); EX1017 178; EX1019 310.

“All FDTs approved by the [FDA] are classified as orally disintegrating tablets.” EX1018 434. The FDA defines “orally disintegrating tablets (ODTs)” as “[a] solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue.” EX1005 2; EX1070 ¶¶69-71.

2. FDA Guidance

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

The FDA Guidance teaches 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; EX1070 ¶¶90-93.

3. Commercially Available ODTs

By 2013, there were several commercially available ODT products on the market. Exemplary commercially available formulations included the Zydis[®] fast-dissolving wafer, the WOWTab[®] (With-Out-Water tablet), the Flash Dose[®] tablet, and OraSolv[®]. EX1017 178-181; EX1018 436-37. Drugs that were formulated into marketed ODTs were compiled into the following table:

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

Brand name	Active ingredient	Application	Company	Technology
Claritin [®] Reditabs [®]	Loratadine	Antihistamine	Schering Corporation	Zydis [®]
Feldene Melt [®]	Piroxicam	NSAID	Pfizer	
Maxalt [®] -MLT [®]	Rizatriptan benzoate	Migraine	Merck	
Pepcid [®] ODT	Famotidine	Anti-ulcer	Merck	
Zyprexa [®]	Olanzapine	Psychotic disorders	Eli Lilly	
Zofran [®] ODT [®]	Ondansetron	Anti-emetic	Glaxo Smith Kline	
Risperdal [®] M-Tab [™]	Risperidone	Schizophrenia	Janssen	
Zubrin [™] (pet drug)	Tepoxalin	Canine NSAID	Schering Corporation	
Zelapar [™]	Selegiline	Parkinson's disease	Elan / Amarin Corporation	
Klonopin [®] Wafers	Clonazepam	Sedation	Roche	
Children's Dimetapp [®] ND	Loratadine	Allergy	Wyeth Consumer Healthcare	
Imodium Instant Melts	Loperamide HCl	Anti-diarrheal	Janssen	
Propulsid [®] Quicksolv [®]	Cisapride monohydrate	Gastrointestinal prokinetic agent	Janssen	Quicksolv [®] OraSolv [®]
Tempra Quicklets Tempra FirsTabs	Acetaminophen	Analgesic	Bristol-Myers Squibb	
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	
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	
Hyoscyamine Sulfate ODT	Hyoscyamine sulfate	Anti-ulcer	ETHEX Corporation	OraQuick
Cibalginadue FAST	Ibuprofen	NSAID	Novartis Consumer Health	Ziplets [™]

EX1018 438-439.

By 2013, 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; EX1070 ¶¶81-89.

C. Reduced Particle Size Improves Performance and Compliance with ODTs

The particle size of the active ingredient in an ODT impacts the composition’s dissolution performance, as well as patient compliance. A smaller particle size generated through micronization or other methods tends to improve disintegration and dissolution. EX1018 435; EX1067 172. Moreover, a smaller particle size improves mouthfeel by reducing the risk of the tablet disintegrating into fragments that a patient might feel. EX1020 ¶[0012] (“For use in an orally disintegrating tablet, the particle size of most of the taste-masked microcapsules should be less than 400 µm or less to avoid gritty mouthfeel.”); *id.* ¶[0009]; EX1070 ¶¶94-95.

D. Adsorption of Drug Particles onto the Surface of a Carrier Through Mixing Was Routine

By 2013, the adsorption of drug particles onto the solid surface of carrier and other excipients was routine and common. For example, it was well known that

“achieving content uniformity, especially for low-dose drugs” can be achieved “by adsorbing small drug particles onto the surface of large excipients,” as depicted below:

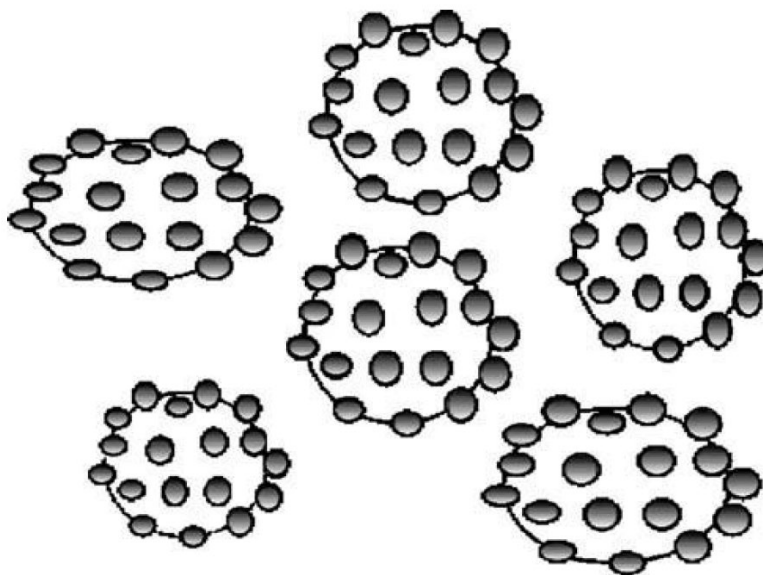


Fig. 1 Adsorption of small particles onto the surfaces of larger carrier particles.

EX1054 34, 35, Fig. 1.

Adsorption of small drug particles onto the surface of carrier excipients is generally accomplished via mixing or blending. *Id.* 35 (“[d]uring mixing... adsorption generally plays a role when the average particle size is $\leq 400\ \mu\text{m}$ ”); EX1055 382-83 (“solid-solid adsorption of a fine cohesive powder onto the surface of coarse free-flowing particles” occurs “[d]uring blending”); EX1001 10:5-8 (admitting the adsorption process “includes repeatedly mixing corticosteroid and carrier so that the blend is adsorbed onto the carrier”).

“[A]dsorbing drugs onto carrier particles... by ordered mixing can be very beneficial in several ways, such as facilitating the preparation of master batches, avoiding segregation in stable systems, promoting excellent homogeneity in mixtures, and improving content uniformity of tablets especially at low dosage.” EX1054 35; *id.* 43. Adsorption of drug particles on pharmaceutical carriers for use in ODTs beneficially provides “fast disintegration/dissolution,” as well as “increased absorption and hence higher bioavailability and reduction in dose, cost effective manufacturing process, [and] conventional packaging due to exceptional durability and wide range of doses (up to 200 mg of drug per unit).” EX1019 320; EX1070 ¶¶96-99.

E. ODTs Containing Micronized Budesonide and Fluticasone Propionate to Treat Eosinophilic Esophagitis Were Disclosed Years Before the '061 Patent

Years before the '061 patent, others, including one of the inventors listed on the face of the '061 patent (Gopi Venkatesh), disclosed ODTs containing micronized budesonide and fluticasone propionate to treat EE. For example, Perrett discloses orally disintegrating tablets of budesonide and fluticasone propionate particles with “an average particular size of less than about 4 μm ,” that disintegrate “on the order of about 60 seconds or less... or about 10 seconds or less.” EX1057 ¶¶[0015], [0039], [0045], [0060], [0085], [0086], [0089], Claim 18. Perrett teaches that using corticosteroid particles on the micron scale is important to provide a “pleasant

tasting” and “a smooth, easy-to-swallow suspension” formulation. *Id.* ¶¶[0045], [0085].

Perrett discloses and claims ODTs where “the corticosteroid is disposed over the surface of an excipient.” *Id.* Claims 19, 22, ¶[0063].

Perrett incorporates by reference another patent application filed by Venkatesh et al. published as US20050232988 (“Venkatesh,” EX1020), which emphasizes that using micronized particles in ODTs avoids grittiness and provides a “smooth creamy mouthfeel.” EX1057 ¶¶[0042], [0089]; EX1020 ¶¶[0015], [0002]; EX1070 ¶¶100-104.

V. THE EPO REVOKED ELLODI’S CLAIMS

In an opposition proceeding, the European Patent Office (EPO) determined that Perrett rendered obvious similar claims in EP3041476. EX1062 21-24; EX1061. Of particular relevance, the EPO held claim 1 of Ellodi’s Auxiliary Request 1 (AR1) was obvious over Perrett. EPO AR1 is reproduced below:

1. A pharmaceutical composition in the form of an orally disintegrating tablet comprising
 - a. particles of a topically acting corticosteroid or pharmaceutically acceptable salt, ester, or polymorph in an amount of about 5% or less by weight in the composition;
 - b. a pharmaceutically acceptable carrier; and
 - c. rapidly dispersing microgranules;

[d.] wherein the corticosteroid or pharmaceutically acceptable salt, ester, or polymorph particles are adsorbed onto the pharmaceutically acceptable carrier, and

[e.] wherein the pharmaceutically acceptable carrier is selected from the group consisting of microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, and amorphous magnesium aluminum silicate.

EX1062 5.

Claim 1 from EPO AR1 and the '069 patent are both directed to ODTs, and they both recite a corticosteroid adsorbed onto a pharmaceutically acceptable carrier.

The EPO determined that Perrett discloses adsorption of a corticosteroid onto a pharmaceutical carrier.⁴ EX1062 17-19. The EPO explained that blending fluticasone with carriers in Perrett's Example 1 "provides contact between the drug and carrier, leading implicitly to at least some adsorption." *Id.* 17-18. The EPO further explained that Perrett's "granulating" of a corticosteroid with a carrier results in drug particles being adsorbed onto the carrier. *Id.* 18. The EPO determined that a POSA "would have considered all alternative fillers and diluents proposed in [Perrett]" as carriers for corticosteroid adsorption. *Id.* 23. The EPO concluded that

⁴ Reference D3 in the EPO opposition was WO2011041509 (EX1063), which is the PCT equivalent of Perrett (EX1057).

“the subject-matter of claim 1 is obvious in view of [Perrett] alone.” *Id.* 23.⁵ The USPTO should reach the same conclusion in this proceeding.

VI. RELIEF REQUESTED

Petitioner requests cancellation of claims 1-30 of the '061 patent as obvious over the asserted prior art.

A. The Asserted References Are Prior Art

The earliest claimed priority date for the '061 patent is September 6, 2013, and the AIA thus applies to the claims of the '061 patent. The asserted references are all prior art to the '061 patent:

Exhibit	Reference	Date	Art Type
1057	Perrett	Published: 04/07/2011	§102(a)
1058	Dohil2009	Published: 07/30/2009	§102(a)

⁵ The EPO determined that claim 1 of Ellodi's Auxiliary Request 2 (AR2) was not proven obvious over Perrett. EX1062 26-28. Claim 1 of AR2, however, includes an additional limitation that requires “[wherein the pharmaceutical composition is prepared by] blending the corticosteroid or pharmaceutically acceptable salt, ester or polymorph with the pharmaceutically acceptable carrier *and passing through a de-segregating/comminuting mill at least once* before blending with other pharmaceutically acceptable excipients, and then tableting the resulting blend.” *Id.* 27. No claim in the '061 patent contains such a requirement.

Exhibit	Reference	Date	Art Type
1020	Venkatesh	Published: 10/20/2005	§102(a)
1005	FDA Guidance	Published: 12/16/2008	§102(a) ⁶

B. Grounds of Unpatentability

IPR is requested for the following grounds of unpatentability:

Ground	Reference(s)	Basis	Challenged Claims
1	Perrett	§103	1-30
2	Dohil2009 in view of the knowledge of a POSA	§103	1-2, 4-11, 17-20, 22, 29-30
3	Dohil2009 and Venkatesh in view of the knowledge of a POSA	§103	1-30

The petition is supported by the expert declaration of Dr. Alan F. Parr, Pharm.D., Ph.D. EX1070. Dr. Parr holds a Pharm.D. in pharmacy, a Ph.D. in pharmaceutical sciences, and has over three decades of experience formulating pharmaceutical compositions.

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.

⁶ See EX1006 for 12/16/2008 publication date.

A. Terms Expressly Defined in the '061 Patent

The '061 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 5:12-15. This definition is equivalent to that adopted by the FDA. EX1005 2; EX1070 ¶107.

The '061 patent defines “sugar alcohols” to refer to “hydrogenated forms of carbohydrates in which the carbonyl group (i.e., aldehyde or ketone) has been reduced to a primary or secondary hydroxyl group.” EX1001 9:29-31. The '061 confirms that “[n]on-limiting examples of suitable sugar alcohols for the rapidly dispersing granules of the pharmaceutical compositions of the present invention include e.g. arabitol, isomalt, erythritol, glycerol, lactitol, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.” *Id.* 9:32-36.

The '061 patent states that “[t]he term ‘saccharide’ is synonymous with the term ‘sugars’ includes monosaccharides such as glucose, fructose, the lactose, and ribose and disaccharides such as sucrose, lactose, maltose, trehalose, and cellobiose.” EX1001 9:36-40.

The '061 patent states that “[t]he term ‘about’, as used herein to refer to a numerical quantity, includes ‘exactly.’ For example, ‘about 30 seconds’ includes 30 seconds, exactly, as well as values close to 30 seconds (e.g., 25 seconds, 29 seconds,

31 seconds, 35 seconds, etc.). 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 5:21-27.

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

B. “Rapidly Dispersing Microgranule”

Claims 12, 16, 24, and 27 recite a “rapidly dispersing microgranule.” The specification does not define this term.

A precise definition is not necessary because the relied-upon prior art expressly discloses the same “rapidly dispersing microgranule” and ODTs comprising “rapidly dispersing microgranules.” EX1057 ¶[0042]; EX1020 ¶[0028]. Petitioner reserves its right to respond to any construction of “rapidly dispersing microgranule” proposed by Patent Owner.

C. “Adsorbed Onto A Pharmaceutically Acceptable Carrier”

Claims 1 and 30 recite a corticosteroid “adsorbed onto a pharmaceutically acceptable carrier.” Claim 19 recites fluticasone propionate “adsorbed” onto a list of specific carriers. The intrinsic record does not provide an express construction for these limitations. *See* EX1001; EX1056. The plain and ordinary meaning should apply. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005).

Adsorption is a broad term that typically involves an “adsorbent” (the material upon which adsorption occurs) and an “adsorbate” (the substance being adsorbed).

EX1055 380. Adsorption includes “[t]he surface retention of solid... molecules...

by a solid.” EX1060 41. Physical adsorption is associated with van der Waals’

forces and “is reversible, the removal of the adsorbate from the adsorbent being

known as desorption.” EX1055 380. An exemplary depiction of small drug particles

adsorbed onto the surface of larger carrier particles is depicted below:

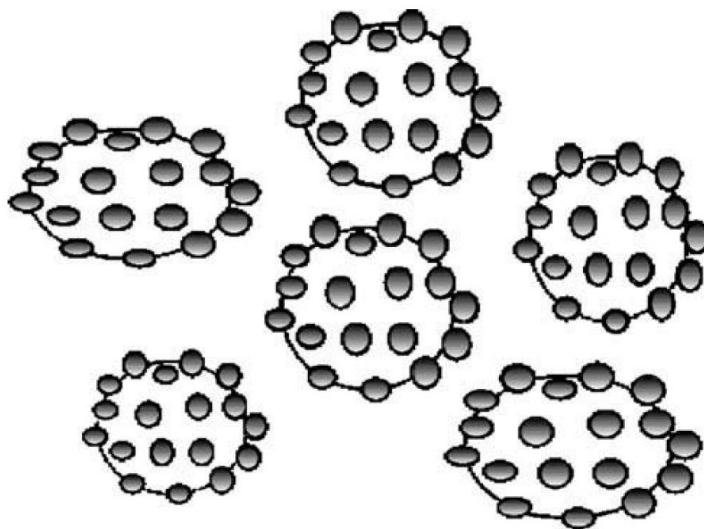


Fig. 1 Adsorption of small particles onto the surfaces of larger carrier particles.

EX1054 35 (Fig. 1); EX1070 ¶¶119-122. Accordingly, the plain and ordinary

meaning of a corticosteroid “adsorbed onto a pharmaceutically acceptable carrier”

includes “the reversible disposition of a corticosteroid particle on the surface of a

pharmaceutically acceptable carrier.”

VIII. GROUND 1: PERRETT

This section introduces Perrett, and then explains how Perrett renders obvious claims 1-30 of the '061 patent.

A. Perrett

Perrett is directed to ODTs comprising corticosteroids such as budesonide and fluticasone, which is the same subject matter claimed by the '061 patent. EX1057 ¶¶[0007], [0019], [0047], [0082]. Perrett shares a common inventor with the '061 patent (Gopi Venkatesh). Perrett discloses and renders obvious all claims of the '061 patent.

B. Claim 1

1. Preamble

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

If the preamble were limiting, Perrett discloses orally disintegrating tablets (ODTs). EX1057 ¶¶[0015], [0042], [0082]; EX1070 ¶129.

2. Limitation 1.a

Limitation 1.a recites “a topically acting corticosteroid or pharmaceutically acceptable salt or ester thereof, adsorbed onto a pharmaceutically acceptable carrier.”

Perrett discloses ODTs comprising a topically acting corticosteroid, such as budesonide and fluticasone propionate. EX1057 ¶¶[0019], [0024], [0039].

Perrett discloses preparing ODTs by “preparing corticosteroid-containing microgranules by granulating crystalline corticosteroid material having an average particle size of about 5-50 μm and one or more diluents/fillers such as lactose mannitol, microcrystalline cellulose and mixtures thereof, with a polymeric binder in a high-shear granulator or a fluid-bed coater.” EX1057 ¶¶[0089]-[0090]. Perrett’s Example 1 discloses an ODT prepared by blending fluticasone drug particles, mannitol, and crospovidone for 3-5 minutes, and then granulating using a fluid-bed apparatus. *Id.* ¶[0091]. Perrett teaches that exemplary fillers/diluents/binders include microcrystalline cellulose, and starches or modified starches, such as pregelatinized starch and maize starch (i.e., corn starch). *Id.* ¶¶[0051]-[0052]. Such fillers/diluents/binders are pharmaceutically acceptable carriers as admitted by the ’061 patent. EX1001 7:28-38.

A POSA would understand that Perrett’s granulating and blending processes in which a corticosteroid is mixed with fillers/diluents/binder carriers results in at least some of the corticosteroid being adsorbed onto a filler/diluent/binder carrier. It was known that “[d]uring mixing... adsorption generally plays a role when the average particle size is $\leq 400 \mu\text{m}$.” EX1054 35; EX1055 383 (“During blending, a fine powder of an antibiotic is adsorbed onto the surface of coarse particles of sorbitol.”). Perrett’s corticosteroids “have an average particle size of about 5-50 μm .” EX1057 ¶[0089]; *id.* ¶¶[0045], [0066]-[0067].

The '061 patent admits that mixing a corticosteroid and carrier results in adsorption onto the carrier as follows:

The corticosteroid particles are typically adsorbed onto the carrier. The process for the preparation includes repeatedly mixing corticosteroid and carrier so that the blend is adsorbed onto the carrier.

EX1001 10:5-8.

Moreover, Perrett incorporates-by-reference Venkatesh (US20050232988, EX1020), and discloses ODTs comprising the “rapidly dispersing microgranules” described in Venkatesh. EX1057 ¶¶[0042], [0089], [0013]. Venkatesh discloses formulating ODTs wherein “milled/micronized drug particles (e.g., average particle diameter less than about 50 μm , preferably less than about 25 μm) are blended with a... polymeric binder such as modified starch and hydroxypropyl methylcellulose,” and that the resulting mixture can be “milled using a size reduction mill.” EX1020 ¶[0015]. Venkatesh also discloses granulating an active pharmaceutical ingredient with “one or more pharmaceutically acceptable diluents such as mannitol, lactose and microcrystalline cellulose.” EX1020 ¶[0021]; EX1070 ¶¶131-143.

The granulating, blending, and milling disclosed by Perrett (and Venkatesh) involve repeatedly mixing the corticosteroid and carrier, which results in at least some adsorption of the corticosteroid on the surface of the carrier. EX1070 ¶¶144-145. Perrett expressly discloses and claims ODTs where “the corticosteroid is

disposed over the surface of an excipient,” which confirms that the corticosteroid is adsorbed on the surface of the excipient carrier. EX1057 Claims 19, 22, ¶[0063].

A POSA would have been motivated to adsorb Perrett’s corticosteroid onto a carrier. It was known that such adsorption “can be very beneficial in several ways, such as facilitating the preparation of master batches, avoiding segregation in stable systems, promoting excellent homogeneity in mixtures, and improving content uniformity of tablets especially at low dosage.” EX1054 35; *id.* 43. Surface adsorption of drugs on pharmaceutical carriers is advantageous for ODTs because it provides “fast disintegration/dissolution,” as well as “increased absorption and hence higher bioavailability and reduction in dose, cost effective manufacturing process, [and] conventional packaging due to exceptional durability and wide range of doses (up to 200 mg of drug per unit).” EX1019 320. A POSA would have had a reasonable expectation of success in achieving adsorption because it was known that adsorption “generally plays a role when the average particle size is $\leq 400\text{ }\mu\text{m}$,” EX1054 35, and Perrett’s disclosure that the corticosteroid particles should have a diameter of about 5-50 μm . EX1057 ¶[0089]; *id.* ¶¶[0045], [0066]-[0067]; EX1070 ¶¶146-147.

The EPO previously determined that Perrett discloses adsorption of a corticosteroid onto a pharmaceutical carrier during the opposition proceeding of Ellodi’s European equivalent patent, EP3041476 (EX1061). The EPO determined

that “adsorbed” is “rather broad and covers different degrees and mechanisms of adsorption.” EX1062 15. The EPO explained that blending fluticasone with carriers in Perrett’s Example 1 “provides contact between the drug and carrier, leading implicitly to at least some adsorption.” *Id.* 17-18. The EPO further explained that Perrett’s “granulating” of a corticosteroid with a carrier results in drug particles being adsorbed onto the carrier. *Id.* 18.

3. Limitation 1.b

Limitation 1.b recites “at least one disintegrant.”

Perrett discloses ODTs comprising a disintegrant. EX1057 ¶¶[0048], [0089]-[0090]; EX1070 ¶149.

4. Limitation 1[c.i]

Limitation 1[c.1] recites “wherein the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, is present in an amount ranging from about 0.5 mg to about 10 mg.”

Perrett discloses that its ODTs contain corticosteroid amounts ranging between 0.01 mg and 20 mg, including from about 0.5 mg to about 10 mg. EX1057 ¶¶[0040]-[0041]; EX1070 ¶151.

5. Limitation 1[c.ii]

Limitation 1[c.ii] recites “the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, has a mean particle size of ranging from about 100 nm to about 100 μm.”

Perrett discloses that its ODTs include corticosteroid particles having a particle size ranging from about 1 nm to about 300 μm. EX1057 ¶¶[0066]-[0067]; *id.* ¶[0089] (“about 5-50 μm”); EX1070 ¶153.

6. Limitation 1[d]

Limitation 1[d] recites “wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> method for disintegration time.”

Perrett discloses that its orally disintegrating corticosteroid tablets are formulated to disintegrate “within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test.” EX1057 ¶[0007]; *id.* ¶¶[0030], [0060]; EX1070 ¶¶155-156.

In sum, Perrett discloses all limitations of claim 1. A POSA would have been motivated to arrive at an ODT that renders obvious claim 1 based on Perrett at least because combining embodiments disclosed within a single prior art reference “does not require a leap of inventiveness.” *Boston Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 991 (Fed. Cir. 2009).

C. Claim 2

Claim 2 depends from claim 1 and recites “wherein the pharmaceutically acceptable carrier is selected from the group consisting of microcrystalline cellulose,... pregelatinized starch, [and] corn starch.”

Perrett discloses formulating its ODTs with microcrystalline cellulose, pregelatinized starch, and maize starch (i.e., corn starch) as fillers/diluents/binders. EX1057 ¶¶[0051]-[0052], [0070], [0072], [0089]. A POSA would readily recognize Perrett’s fillers/diluents/binders are carriers. EX1070 ¶¶158-160; EX1001 7:28-38.

D. Claim 3

Claim 3 depends from claim 2 and recites “the pharmaceutically acceptable carrier is silicified microcrystalline cellulose.”

Perrett discloses ODTs formulated with microcrystalline cellulose. EX1057 ¶¶[0051]-[0053], [0070], [0072], [0089]-[0090]. A POSA would have been motivated to use silicified microcrystalline cellulose in Perrett’s granulation and/or blending processes with an expectation of success based on the general knowledge that silicified microcrystalline cellulose “has improved compaction properties in both wet granulation and direct compression compared to conventional microcrystalline cellulose.” EX1069 139. Indeed, “[s]ilicified microcrystalline cellulose was specifically developed to address the loss of compaction that occurs with microcrystalline cellulose after wet granulation,” *id.*, and it “has greater tensile

strength and requires lower compression pressures than regular grades of microcrystalline cellulose.” *Id.* 140; 1 EX1070 ¶¶162-163.

E. Claim 4

Claim 4 depends from claim 2 and recites that the corticosteroid is “budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, or a pharmaceutically salt or ester thereof.”

Perrett discloses ODTs comprising each of the corticosteroids recited in claim 4. EX1057 ¶¶[0019], [0039], [0041], [0091]; EX1070 ¶165.

F. Claim 5

Claim 5 depends from claim 4 and recites “wherein the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, is present in an amount ranging from about 0.5 mg to about 3 mg.”

Perrett discloses that the amount of corticosteroid in its ODTs ranges from about 0.01 mg to about 20 mg, including between 0.5 mg and about 3 mg. EX1057 ¶¶[0040]-[0041]; EX1070 ¶167.

G. Claims 6 and 7

Claim 6 depends from claim 4 and recites “said topically acting corticosteroid is fluticasone or an ester thereof.”

Claim 7 depends from claim 4 and recites “said topically acting corticosteroid is fluticasone propionate.”

Perrett discloses ODTs comprising fluticasone and fluticasone propionate.

EX1057 ¶¶[0019], [0039], [0091]-[0092]; EX1070 ¶170.

H. Claims 8 and 9

Claim 8 depends from claim 1 and recites “fluticasone propionate is present in an amount of about 3 mg in the orally disintegrating tablet.”

Claim 9 depends from claim 1 and recites “fluticasone propionate is present in an amount of about 1.5 mg in the orally disintegrating tablet.”

Petitioner notes that claim 1 does not provide antecedent basis for “fluticasone propionate.” Petitioner treats claims 8 and 9 and depending from claim 7 for this proceeding.

Perrett discloses ODTs containing fluticasone propionate in amounts ranging between 0.01 mg and 20 mg, including about 1.5 mg and about 3 mg. EX1057 ¶¶[0040]-[0041]; EX1070 ¶173.

I. Claims 10 and 11

Claim 10 depends from claim 1 and recites “the corticosteroid has a mean particle size of ranging from about 100 nm to about 10 μ m.”

Claim 11 depends from claim 1 and recites “the corticosteroid has a mean particle size ranging from about 100 nm to about 4 μ m.”

Perrett discloses that its ODTs include corticosteroid particles having a particle size ranging from about 1 nm to about 300 μm , including about 100 nm, and between about 1-50 μm . EX1057 ¶¶[0066]-[0067]; EX1070 ¶176.

J. Claim 12

Claim 12 depends from claim 1 and recites “the at least one disintegrant is present in a rapidly dispersing microgranule, which comprises a sugar alcohol, or a saccharide, or a mixture thereof in addition to the at least one disintegrant.”

Perrett discloses that its ODTs comprise rapidly dispersing microgranules as described in Venkatesh. EX1057 ¶¶[0042], [0089]. Venkatesh discloses orally disintegrating tablets that comprise “rapidly dispersing microgranules prepared by granulating a sugar alcohol or a saccharide or a mixture thereof... and a disintegrant.” EX1020 Abstract, ¶¶[0014], [0018]. A POSA would have been motivated to formulate Perrett’s ODTs with rapidly dispersing microgranules according to Venkatesh’s disclosure with an expectation of success based on Perrett’s affirmative discussion of Venkatesh as well as Perrett’s incorporation-by-reference of Venkatesh’s disclosures. EX1070 ¶¶179-180.

K. Claim 13

Claim 13 depends from claim 12 and recites “the sugar alcohol or saccharide and the disintegrant are present in a ratio of sugar alcohol or saccharide to disintegrant of from 90:10 to 99:1.”

Perrett Example 1 discloses “a ratio of 95/5” of mannitol (a sugar alcohol) to crospovidone (a disintegrant). EX1057 ¶[0091]; EX1070 ¶¶182-183.

To the extent that Ellodi argues that the recited ratio of “sugar alcohol or saccharide to disintegrant” of 90:10 to 99:1 provides a patentable feature over the prior art, such an argument would run afoul of the written description requirement under 35 U.S.C. § 112. The specification discloses only the opposite ratio of *disintegrant to sugar alcohol or saccharide*, EX1001 9:65-67, which is the same ratio disclosed by Perrett, EX1057 ¶[0043].

L. Claim 14

Claim 14 depends from claim 12 and recites “the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, and low-substituted hydroxypropylcellulose.”

Perrett discloses each of the claimed disintegrants in Perrett’s rapidly dispersing microgranules. EX1057 ¶[0048]; EX1070 ¶185.

M. Claim 15

Claim 15 depends from claim 12 and recites “the sugar alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.”

Perrett discloses that the sugar alcohol or saccharide for its rapidly dispersing microgranules comprises mannitol, sorbitol, xylitol, maltitol, lactose, sucrose, maltose, and sucralose. EX1057 ¶¶[0049], [0077]; EX1070 ¶187.

N. Claim 16

Claim 16 depends from claim 12 and recites “the rapidly dispersing microgranule has a mean particle size of less than about 300 μm , and the sugar alcohol and/or saccharide has an average particle size of less than about 30 μm .”

Perrett discloses that its rapidly dispersing microgranules comprise an average particle size of less than about 300 μm and the sugar alcohol or saccharide has an average particle size of less than about 30 μm . EX1057 ¶[0042]; EX1070 ¶189.

O. Claim 17

Claim 17 depends from claim 1 and recites “the pharmaceutically acceptable carrier is present at an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.”

Perrett discloses that its ODTs comprise corticosteroid granules in amounts ranging from about 5% to about 50% by weight of the tablet, and that the granules comprise excipients, such as fillers and diluents, which a POSA would readily recognize as carriers, in amounts ranging from about 5% to about 80%. EX1057 ¶¶[0070], [0084]. These ranges include tablets with carrier excipient present at an amount of about 10% by weight of the finished tablet. EX1070 ¶¶191-193; *E.I.*

DuPont De Nemours & Co. v. Synvina C.V., 904 F.3d 996, 1006 (Fed. Cir. 2018)

(“For decades, this court and its predecessor have recognized that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.”).

P. Claim 18

Claim 18 depends from claim 1 and recites “the total weight of the tablet is in the range of from about 300 to about 900 mg.”

A POSA would have been motivated to formulate Perrett’s ODTs to have a total weight falling between about 300-900mg based on the knowledge of the POSA as represented by the FDA Guidance, which recommends that such tablets should have a weight of 500mg or less. EX1005 3; EX1070 ¶195.

Q. Claim 19

1. Preamble

The preamble recites “[a]n orally disintegrating tablet.”

If the preamble is limiting, Perrett discloses it for the reasons outlined, *supra*, in Section VIII.B.1, regarding claim 1.

2. Limitation 19.a

Limitation 19.a recites “fluticasone propionate adsorbed onto microcrystalline cellulose... pregelatinized starch, corn starch...”

Perrett renders obvious Limitation 19.a for the reasons outlined, *supra*, at Sections VIII.B.2 and VIII.G, regarding Limitation 1.a and claims 6 and 7.

3. Limitation 19.b

Limitation 19.b recites “at least one disintegrant.”

Perrett renders obvious Limitation 19.b for the reasons outlined, *supra*, at Section VIII.B.3, regarding Limitation 1.b.

4. Limitation 19[c.i]

Limitation 19[c.i] recites “the fluticasone propionate is present in an amount ranging from about 0.5 mg to about 6 mg.”

Perrett renders obvious Limitation 19[c.i] for the reasons outlined, *supra*, at Sections VIII.B.4 and VIII.H, regarding Limitation 1[c.i] and claims 8 and 9.

5. Limitation 19[c.ii]

Limitation 19[c.ii] recites that “the fluticasone propionate has a mean particle size ranging from about 100 nm to about 10 μ m.”

Perrett renders obvious Limitation 19[c.ii] for the reasons outlined, *supra*, at Sections VIII.B.5 and VIII.I, regarding Limitation 1[c.ii] and claim 10.

6. Limitation 19[d]

Limitation 19[d] recites “wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration test.”

Perrett renders obvious Limitation 19[d] for the reasons outlined, *supra*, at Section VIII.B.6, regarding Limitation 1[d].

R. Claim 20

Claim 20 depends from claim 19 and further requires “the microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, or amorphous magnesium aluminum silicate, or a combination thereof, is present in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.”

Perrett renders obvious claim 20 for the reasons outlined, *supra*, at Section VIII.O, regarding claim 17.

S. Claim 21

Claim 21 depends from claim 19 and recites “silicified microcrystalline cellulose in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.”

Perrett renders obvious claim 21 for the reasons outline, *supra*, at Sections VIII.D and VIII.O, regarding claims 3 and 17.

T. Claim 22

Claim 22 depends from claim 19 and further requires “the fluticasone propionate has a mean particle size of about 4 μm or less.”

Perrett renders obvious claim 22 for the reasons outlined, *supra*, at Section VIII.I, regarding claims 10 and 11.

U. Claim 23

Claim 23 depends from claim 21 and recites “the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, and low-substituted hydroxypropylcellulose.”

Perrett discloses that its ODTs are formulated with a disintegrant including crospovidone (crosslinked PVP), sodium starch glycolate, crosslinked sodium carboxymethyl cellulose, and low-substituted hydroxypropyl cellulose. EX1057 ¶[0048]; EX1070 ¶215.

V. Claim 24

Claim 24 depends from claim 20 and recites “the at least one disintegrant is present in a rapidly dispersing microgranule, which comprises a sugar alcohol, or a saccharide, or a mixture thereof in addition to the at least one disintegrant.”

Perrett renders obvious Claim 24 for the reasons outlined, *supra*, at Section VIII.J, regarding claim 12.

W. Claim 25

Claim 25 depends from claim 24 and recites “the sugar alcohol or saccharide and the disintegrant are present in a ratio of sugar alcohol or saccharide to disintegrant of from 90:10 to 99:1.”

Perrett renders obvious Claim 25 for the reasons outlined, *supra*, at Section VIII.K, regarding claim 13.

X. Claim 26

Claim 26 depends from claim 24 and recites “the sugar alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.”

Perrett renders obvious Claim 26 for the reasons outlined, *supra*, at Section VIII.M, regarding claim 15.

Y. Claim 27

Claim 27 depends from claim 24 and recites “the rapidly dispersing microgranule has a mean particle size of less than about 300 μm , and the sugar alcohol and/or saccharide has an average particle size of less than about 30 μm .”

Perrett renders obvious Claim 27 for the reasons outlined, *supra*, at Section VIII.N, regarding claim 16.

Z. Claim 28

Claim 28 depends from claim 19 and recites “wherein the silicified microcrystalline cellulose is present in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet, fluticasone propionate is present in an amount ranging from about 1 mg to about 3 mg, and fluticasone propionate has a mean particle size ranging from about 100 nm to about 4 μm .”

Perrett renders obvious Claim 28 for the reasons outlined, *supra*, at Sections VIII.D, VIII.H-I, VIII.O, and VIII.S-T, regarding claims 3, 8-11, 17, and 21-22.

AA. Claim 29

Claim 29 depends from claim 1 and recites “[a] method for treating eosinophilic esophagitis in an individual in need thereof, comprising administering to the individual the orally disintegrating tablet of claim 1.”

Perrett discloses that its ODTs are administered to humans to treat eosinophilic esophagitis. EX1057 ¶¶[0025], [0027]; EX1070 ¶227.

BB. Claim 30

Claim 30 depends from claim 1. The preamble recites a “method of preparing the orally disintegrating tablet of claim 1.”

Perrett renders obvious the ODTs of claim 1 for the reasons outlined, *supra*, in Section VIII.B, regarding claim 1. Perrett renders obvious the method recited by claim 30 for reasons discussed below.

1. Limitation 30(a)

Limitation 30(a) recites “micronizing the corticosteroid.”

Perrett discloses formulating its ODTs using corticosteroid on the micron scale. EX1057 ¶¶[0066]-[0067], [0089]; EX1070 ¶231.

2. Limitation 30[b.i]

Limitation 30[b.i] recites “preparing preblend 1 by blending (i) a pharmaceutically acceptable carrier, (ii) corticosteroid or pharmaceutically ester thereof, and (iii) glidant, under conditions suitable for the corticosteroid to be adsorbed onto the pharmaceutically acceptable carrier.”

Perrett discloses preparing a preblend for formulating an ODT by blending a pharmaceutically acceptable carrier and corticosteroid under conditions suitable for the corticosteroid to be adsorbed onto the pharmaceutically acceptable carrier for the reasons outlined discussed above for Limitation 1.a. *Supra* Section VIII.B.2; EX1057 ¶¶[0089]-[0090] (step (a)), ¶[0091]. Perrett discloses the use of glidants in its formulations, which were known to improve the flow properties of blends. EX1057 ¶¶[0046], [0050], [0054]; EX1020 ¶[0002]; EX1041 241; EX1070 ¶233-236. A POSA therefore would have been motivated to use a glidant in Perrett’s preblend.

3. Limitation 30[b.ii]

Limitation 30[b.ii] recites “wherein the pharmaceutically acceptable carrier is microcrystalline cellulose,... pregelatinized starch, [or] corn starch...”

Perrett discloses this limitation for the reasons outline, *supra*, in Section VIII.C, regarding claim 2.

4. Limitation 30(c)

Limitation 30(c) recites “preparing preblend 2 by blending filler, preblend 1 of step (b), disintegrant, and sweetener.”

Perrett discloses formulating its ODTs by combining preblended corticosteroid granules with filler, disintegrants and sweetener. EX1057 ¶¶[0042]-[0055], [0079]-[0092]. For example, Perrett discloses blending the preblend of corticosteroid and carrier from step (a) of ¶[0089] with “sugar alcohols and/or saccharides” fillers and a disintegrant in step (b) and a sweetener in step (c) to prepare a second preblend. *Id.* ¶[0089]. Venkatesh similarly discloses preparing blends by adding fillers, disintegrants, and sweeteners. EX1020 ¶¶[0018], [0023], [0030]; EX1070 ¶240-241.

5. Limitation 30(d)

Limitation 30(d) recites “preparing a final compressible blend, by blending a disintegrant, lubricant, filler, and preblend 2 of step (c).”

Perrett discloses formulating its orally disintegrating tablets by combining preblended corticosteroid granules with disintegrant, lubricant, and filler. EX1057 ¶¶[0042]-[0055], [0079]-[0092]. For example, Perrett discloses adding to the second preblend from step (c) of ¶[0089] an “additional disintegrant” and “microcrystalline cellulose” filler. A POSA would have been motivated to include a lubricant based on Perrett’s teachings to use a lubricant. EX1057 ¶¶[0046], [0050], [0054].

Venkatesh similarly discloses preparing blends by adding disintegrants, lubricant, and filler. EX1020 ¶¶[0002], [0018]-[0023], [0030]; EX1070 ¶¶243-244.

6. Limitation 30(e)

Limitation 30(e) recites “compressing the blend of step (d) to form a tablet.”

Perrett discloses compressing blends to form a tablet. EX1057 ¶¶[0085]-[0087], [0089]-[0090]. Venkatesh similarly discloses compressing blends to form a tablet. EX1020 Abstract, ¶¶[0002], [0024]; EX1070 ¶246. It would have been a matter of routine optimization and design choice to arrive at a process encompassed by claim 30 in view of the known benefits of ordered mixing, EX1054 35, and well-known processes for tableting ODTs.

IX. GROUND 2: DOHIL2009 IN VIEW OF THE KNOWLEDGE OF A POSA

Dohil2009 discloses orally disintegrating tablets having the same ingredients claimed by the '061 patent. This section introduces Dohil2009, and then explains how Dohil2009 in view of the knowledge of a POSA renders obvious claims 1-2, 4-11, 17-20, 22, and 29-30 of the '061 patent.

A. Dohil2009

Dohil2009 discloses budesonide formulations in the form of lozenges or tablets that will “dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus.” EX1058 ¶[0062]. Dohil2009 teaches that other topically acting corticosteroids can be used in the formulations, including fluticasone

propionate. *Id.* ¶[0049]. Dohil2009 also teaches “grinding” the topically acting corticosteroid particles and formulating tablets with “corticosteroid microparticles hav[ing] a diameter less than 10 microns.” *Id.* ¶¶[0019], [0070]. Dohil2009 also teaches that exemplary dosage amounts of corticosteroid in its formulations range from less than 1 mg to less than 10 mg. *Id.* ¶¶[0042]-[0043]; EX1070 ¶248.

B. Claim 1

1. Preamble

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

If the preamble were limiting, Dohil2009 discloses the recited orally disintegrating tablets. For example, Dohil2009 discloses budesonide formulations in the form of tablets that “*dissolve rapidly in the mouth* or esophagus to produce a solution that can then coat the esophagus.” EX1058 ¶[0062].⁷ Dohil2009 further discloses “[b]udesonide, in the form of *a dissolving tablet*.” *Id.* ¶[0012]; *id.* ¶[0070] (disclosing “dissolving tablets”). A POSA would understand that Dohil2009’s tablets that dissolve rapidly in the mouth do so without chewing. EX1005 1; EX1070 ¶¶250-251.

⁷ All emphases supplied unless otherwise noted.

2. Limitation 1.a

Limitation 1.a recites “a topically acting corticosteroid or pharmaceutically acceptable salt or ester thereof, adsorbed onto a pharmaceutically acceptable carrier.”

Dohil2009 discloses that its oral formulations, including tablets, comprise topically acting corticosteroids, such as budesonide and fluticasone propionate. EX1058 ¶¶[0012], [0049], [0062], [0070].

Dohil2009 further teaches formulating the tablets by “combining the corticosteroids with solid excipients,” “optionally grinding the resulting mixture,” and then “processing the mixture of granules, after adding suitable auxiliaries, if desired, to obtain tablets.” *Id.* ¶[0070]. Dohil2009 teaches that exemplary solid excipients include cellulose preparations, such as maize starch (i.e., corn starch), gelatin, methyl cellulose, hydroxypropylmethyl-cellulose, sodium carboxymethylcellulose and sugars. *Id.* Such excipients are pharmaceutically acceptable carriers as described by the '061 patent. EX1001 7:28-38.

A POSA would understand that Dohil2009's process of combining the corticosteroids with solid excipients, optionally grinding the resulting mixture, and processing the resulting mixture of granules results in at least some of the corticosteroid being adsorbed onto the excipients. It was known that “[d]uring mixing... adsorption generally plays a role when the average particle size is ≤ 400

μm.” EX1054 35; EX1055 383 (“During blending, a fine powder of an antibiotic is adsorbed onto the surface of coarse particles of sorbitol.”). Dohil2009 discloses that “at least 95% of the corticosteroid microparticles have a diameter of less than 10 microns.” EX1058 ¶[0022]; *id.* ¶¶[0019], [0050]. Such microparticles advantageously improve disintegration, dissolution, and mouthfeel. *Supra* Section IV.C.

The ’061 patent admits that mixing a corticosteroid and carrier results in adsorption onto the carrier as follows:

The corticosteroid particles are typically adsorbed onto the carrier. The process for the preparation includes repeatedly mixing corticosteroid and carrier so that the blend is adsorbed onto the carrier.

EX1001 10:5-8.

Dohil2009’s combining, grinding, and processing steps involve repeatedly mixing the corticosteroid and carrier to arrive at a mixture of granules. EX1058 ¶[0070]. This process results in at least some adsorption of the corticosteroid on the surface of the carrier. EX1070 ¶¶253-260.

A POSA would have been motivated to adsorb Dohil2009’s corticosteroid onto an excipient carrier. It was known that such adsorption “can be very beneficial in several ways, such as facilitating the preparation of master batches, avoiding segregation in stable systems, promoting excellent homogeneity in mixtures, and improving content uniformity of tablets especially at low dosage.” EX1054 35; *id.*

43. Surface adsorption of drugs on pharmaceutical carriers is advantageous for ODTs because it provides “fast disintegration/dissolution,” as well as “increased absorption and hence higher bioavailability and reduction in dose, cost effective manufacturing process, [and] conventional packaging due to exceptional durability and wide range of doses (up to 200 mg of drug per unit).” EX1019 320. A POSA would have had a reasonable expectation of success in achieving adsorption because it was known that adsorption “generally plays a role when the average particle size is $\leq 400 \mu\text{m}$,” EX1054 35, and Dohil2009 discloses that the corticosteroid particles should have a diameter of less than 10 microns. EX1058 ¶¶[0022], [0019], [0050]; EX1070 ¶¶261-262.

The EPO previously determined that mixing a corticosteroid and carrier results in adsorption during the opposition proceeding of Ellodi’s European equivalent patent, EP3041476 (EX1061). The EPO determined that “adsorbed” is “rather broad and covers different degrees and mechanisms of adsorption.” EX1062 15. The EPO explained that blending a glucocorticoid with a carrier “provides contact between the drug and carrier, leading implicitly to at least some adsorption.” *Id.* 17-18; *id.* 18 (“The powder blending in [the PCT Perrett equivalent] implicitly leads to at least some adsorption of the drug on the carrier.”). The EPO further explained that “granulating the drug” with a carrier results in drug particles being adsorbed onto the carrier. *Id.* 18. The EPO rejected Ellodi’s overly restrictive

position that adsorption requires “repeated mixing *and milling* with a carrier.”

EX1062 15-16. Rather, “[t]he skilled person understands that even the mixing process of the prior art will inherently lead to at least some adhesion of the drug to the mannitol carrier.” EX1062 18.

3. Limitation 1.b

Limitation 1.b recites “at least one disintegrant.”

Dohil2009 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.” EX1058 ¶[0070]. It was known that the rapid dissolution of the tablet would be desirably aided by at least one disintegrating agent. EX1018 446-47; EX1070 ¶264.

4. Limitation 1[c.i]

Limitation 1[c.1] recites “wherein the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, is present in an amount ranging from about 0.5 mg to about 10 mg.”

Dohil2009 discloses that its ODTs comprise topically acting corticosteroids, such as budesonide and fluticasone propionate. EX1058 ¶¶[0012], [0049], [0062], [0070]. Dohil2009 further discloses that “a dissolving tablet” will contain amounts of corticosteroid ranging between, e.g., “0.1-10 mg.” *Id.* ¶[0042]; *id.* ¶[0014] (“1-2

mg or 2-3 mg”), ¶[0043]. Dohil2009’s patients were actually dosed with budesonide at 0.5, 1, and 2 mg/day. *Id.* ¶[0115], Table 1; EX1070 ¶¶266-268.

5. Limitation 1[c.ii]

Limitation 1[c.ii] recites “[wherein] the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, has a mean particle size of ranging from about 100 nm to about 100 µm.”

Dohil2009 discloses that its ODTs comprise topically acting corticosteroid particles with a mean diameter ranging from about 0.1-50 microns (i.e., 100 nm to 50 µm). EX1058 ¶[0050]; *id.* ¶[0019], [0092], [0093] (disclosing micronized budesonide). A POSA would readily understand that “mean particle size” and “mean diameter” are interchangeable terms. EX1056 161; EX1070 ¶270.

6. Limitation 1[d]

Limitation 1[d] recites “wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> method for disintegration time.”

Dohil2009 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.” EX1058 ¶[0062]. It was desirable for the disintegration time of orally disintegrating tablets to vary “from several seconds to about a minute.” EX1018 434; EX1070 ¶272.

It would have been obvious to formulate Dohil2009's orally disintegrating corticosteroid tablets to disintegrate within 60 seconds when tested using the USP <701> method for disintegration testing 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 orally disintegrating tablets. The FDA Guidance explains that orally disintegrating tablets "disintegrate[] rapidly, usually within a matter of seconds." EX1005 2. The FDA recommends that such compositions have "*an in-vitro disintegration time of approximately 30 seconds or less, when based on the United States Pharmacopeia (USP) disintegration test method* or alternative (see section IV)." *Id.* 2. The FDA Guidance "recommend[s] that applicants use the USP method for disintegration testing," *id.* 3, specifically "*USP 29, <701> Disintegration*," *id.* 3 n.3.

A POSA would have been motivated to follow the FDA Guidance in formulating Dohil2009's orally disintegrating tablets. The FDA Guidance provides the agency's thinking and recommendations on the topic ODTs. *Id.* 1. The FDA regulates the use of pharmaceutical compositions in the United States. Dohil2009's formulations were intended to "be used in therapy for human patients," EX1058 ¶[0051], and the initial testing of its formulations was conducted within the United States, *id.* ¶[0106]. A POSA seeking to formulate ODTs 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> method for disintegration testing. EX1070 ¶¶273-275; *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 Dohil2009’s detailed description of how to formulate topically acting corticosteroids into rapidly disintegrating tablets. EX1058 ¶¶[0051]-[0094] (section entitled “Formulation”). Formulating ODTs that dissolve within “several seconds to about a minute” would have been a routine exercise by 2013. EX1018 434; EX1005 2. There were many commercially available ODT products available by 2013, which would have bolstered the POSA’s expectation of success. EX1017 179-181; EX1018 436-439; EX1070 ¶¶276-277.

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 pharmaceutically acceptable carrier is selected from the group consisting of microcrystalline cellulose... [and] corn starch.”

Dohil2009 discloses formulating its ODTs by “combining the corticosteroids with solid excipients” and then “processing the mixture of granules, after adding

suitable auxiliaries, if desired, to obtain tablets.” EX1058 ¶[0070]. Dohil2009 teaches that exemplary solid excipients include cellulose preparations, such as maize starch (i.e., corn starch). *Id.*; EX1070 ¶¶279-281.

D. Claim 4

Claim 4 depends from claim 2 and recites that the corticosteroid is “budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, or a pharmaceutically salt or ester thereof.”

Dohil2009 discloses ODTs comprising the claimed corticosteroids. EX1058 ¶¶[0049], [0062], [0012]; EX1070 ¶283.

E. Claim 5

Claim 5 depends from claim 4 and recites “wherein the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, is present in an amount ranging from about 0.5 mg to about 3 mg.”

Dohil2009 discloses ODTs containing corticosteroid amounts ranging between 0.01 mg and 20 mg, including between “about 0.5 mg to about 2 mg.” EX1058 ¶[0042]; *id.* ¶¶[0014], [0043]; EX1070 ¶285.

F. Claims 6-9

Claim 6 depends from claim 4 and recites “said topically acting corticosteroid is fluticasone or an ester thereof.”

Claim 7 depends from claim 4 and recites “said topically acting corticosteroid is fluticasone propionate.”

Claim 8 depends from claim 1 and recites “fluticasone propionate is present in an amount of about 3 mg in the orally disintegrating tablet.”

Claim 9 depends from claim 1 and recites “fluticasone propionate is present in an amount of about 1.5 mg in the orally disintegrating tablet.”

Petitioner notes that claim 1 does not provide antecedent basis for “fluticasone propionate.” Petitioner treats claims 8 and 9 as depending from claim 7 for this proceeding.

Dohil2009 discloses ODTs comprising fluticasone and fluticasone propionate. EX1058 ¶[0049]. Dohil2009 discloses ODTs containing corticosteroid amounts of about 1.5 mg and about 3mg. EX1058 ¶[0042]; *id.* ¶¶[0014], [0043]; EX1070 ¶290.

G. Claims 10 and 11

Claim 10 depends from claim 1 and recites “the corticosteroid has a mean particle size of ranging from about 100 nm to about 10 μ m.”

Claim 11 depends from claim 1 and recites “the corticosteroid has a mean particle size ranging from about 100 nm to about 4 μ m.”

Dohil2009 discloses ODTs comprising topically acting corticosteroid particles with a mean diameter ranging from about 0.1-50 microns (i.e., 100 nm to

50 μm), including diameters less than 10 μm . EX1058 ¶[0050]; *id.* ¶¶[0019], [0092], [0093] (disclosing micronized budesonide); EX1070 ¶293. Dohil2009's ranges overlap with the claimed ranges, which is *prima facie* obvious.

H. Claims 17 and 18

Claim 17 depends from claim 1 and recites “the pharmaceutically acceptable carrier is present at an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.”

Claim 18 depends from claim 1 and recites “the total weight of the tablet is in the range of from about 300 to about 900 mg.”

Dohil2009 discloses that its tablets comprise various amounts of the topically acting corticosteroid, and that the amount of excipients used can affect the quantity of corticosteroid required. EX1058 ¶¶[0033], [0055]. The '061 patent fails to ascribe any patentable contribution to the field of ODTs based on the selection of a carrier at 10% w/w of the tablet. Modifying Dohil2009's formulations to result in ODTs with a carrier present at an amount of about 10% w/w based on the total weight of the tablet, and/or a tablet in the range of from about 300 to about 900 mg would have been a matter of routine experimentation and optimization. Formulating ODTs that included these characteristics would have been obvious to a POSA based on Dohil2009 in view of the knowledge of a POSA. EX1005 3; EX1070 ¶¶296-297.

I. Claim 19

1. Preamble

The preamble recites “[a]n orally disintegrating tablet.”

If the preamble is limiting, Dohil2009 renders it obvious. *Supra* Section IX.B.1.

2. Limitation 19.a

Limitation 19.a recites “fluticasone propionate adsorbed onto... corn starch.”

Dohil2009 renders obvious Limitation 19.a for the reasons outlined, *supra*, at Sections IX.B.2 and IX.F, regarding Limitations 1.a and claims 6 and 7.

3. Limitation 19.b

Limitation 19.b recites “at least one disintegrant.”

Dohil2009 renders obvious Limitation 19.b for the reasons outlined, *supra*, at Section IX.B.3, regarding Limitation 1.b.

4. Limitation 19[c.i]

Limitation 19[c.i] recites “the fluticasone propionate is present in an amount ranging from about 0.5 mg to about 6 mg.”

Dohil2009 renders obvious Limitation 19[c.i] for the reasons outlined, *supra*, at Sections IX.B.4 and IX.E-F, regarding Limitation 1[c.i] and claims 5 and 6-9.

5. Limitation 19[c.ii]

Limitation 19[c.ii] recites that “the fluticasone propionate has a mean particle size ranging from about 100 nm to about 10 μ m.”

Dohil2009 renders obvious Limitation 19[c.ii] for the reasons outlined, *supra*, at Section IX.B.5, regarding Limitation 1[c.ii].

6. Limitation 19[d]

Limitation 19[d] recites “wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.”

Dohil2009 in view of the knowledge of a POSA renders obvious Limitation 19[d] for the reasons outlined, *supra*, at Section IX.B.6, regarding Limitation 1[d].

J. Claim 20

Claim 20 depends from claim 19 and further requires “the microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, or amorphous magnesium aluminum silicate, or a combination thereof, is present in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.”

Claim 20 would have been obvious over Dohil2009 in view of the knowledge of a POSA for the reasons outlined, *supra*, at Section IX.H, regarding claim 17.

K. Claim 22

Claim 22 depends from claim 19 and further requires “wherein fluticasone propionate has a mean particle size of about 4 μm or less.”

Claim 22 would have been obvious over Dohil2009 in view of the knowledge of a POSA for the reasons outlined, *supra*, at Section IX.G, regarding claims 10-11.

L. Claim 29

Claim 29 depends from claim 1 and recites “[a] method for treating eosinophilic esophagitis in an individual in need thereof, comprising administering to the individual the orally disintegrating tablet of claim 1.”

Dohil2009 discloses that its ODTs should be administered to humans to treat eosinophilic esophagitis. EX1058 ¶¶[0009], [0019], [0037]; EX1070 ¶315.

M. Claim 30

Claim 30 depends from claim 1. The preamble recites a “method of preparing the orally disintegrating tablet of claim 1.” Dohil2009 renders obvious the recited method for reasons discussed below.

1. Limitation 30(a)

Limitation 30(a) recites “micronizing the corticosteroid.”

Dohil2009 discloses formulating ODTs with “corticosteroid microparticles hav[ing] a diameter of less than 10 microns.” EX1058 ¶¶[0019], [0022], [0050]; EX1070 ¶319.

2. Limitation 30[b.i]

Limitation 30[b.i] recites “preparing preblend 1 by blending (i) a pharmaceutically acceptable carrier, (ii) corticosteroid or pharmaceutically ester thereof, and (iii) glidant, under conditions suitable for the corticosteroid to be adsorbed onto the pharmaceutically acceptable carrier.”

Dohil2009 discloses preparing a preblend for formulating an ODT by blending a corticosteroid with solid excipients to produce granules under conditions where the corticosteroid is adsorbed onto the pharmaceutically acceptable carrier for the reasons outlined, *supra*, in Section IX.B.2, regarding Limitation 1.a. A POSA would have been motivated to include a glidant in Dohil2009's preblend to improve the flow properties of the blend. EX1041 241; EX1070 ¶¶321-322. Indeed, Dohil2009 discloses excipients known to function as glidants in its formulations. EX1058 ¶¶[0013], [0071]-[0072], [0091].

3. Limitation 30[b.ii]

Limitation 30[b.ii] recites “wherein the pharmaceutically acceptable carrier is microcrystalline cellulose... [or] corn starch.”

Dohil2009 discloses this Limitation for the reasons outline, *supra*, in Section IX.C, regarding claim 2.

4. Limitation 30(c)

Limitation 30(c) recites “preparing preblend 2 by blending filler, preblend 1 of step (b), disintegrant, and sweetener.”

Dohil2009 discloses “adding suitable auxiliaries” to the preblended granules. EX1058 ¶[0070]. Dohil2009 discloses that suitable auxiliaries include “fillers such as sugars [and] cellulose preparations,” “disintegrating agents,” and “sweeteners.” EX1058 ¶¶[0070], [0075], [0080]. Dohil2009's instruction to add these auxiliaries

to the preblended granules renders obvious the “preblend 2” recited by Limitation 30(c). EX1070 ¶¶326-328.

5. Limitation 30(d)

Limitation 30(d) recites “preparing a final compressible blend, by blending a disintegrant, lubricant, filler, and preblend 2 of step (c).”

As discussed for Limitation 30(c), Dohil2009 discloses “adding suitable auxiliaries” that include a disintegrant, lubricant, and filler before processing the resulting blend into a tablet. EX1058 ¶¶[0070], [0075], [0080]. It would have been a matter of routine experimentation and optimization to a POSA to follow Dohil2009’s instruction to add suitable auxiliaries to its mixture of granules to arrive at a blend that renders obvious Limitation 30(d). EX1070 ¶330.

6. Limitation 30(e)

Limitation 30(e) recites “compressing the blend of step (d) to form a tablet.”

Dohil2009 discloses “processing” a mixture or blend “to obtain tablets.” EX1058 ¶[0070]. A POSA would readily recognize that tablets are advantageously and routinely formed by compressing a blend, and thus Dohil2009’s disclosure of “processing” a mixture or blend “to obtain tablets” comprises compressing the blend to form a tablet. EX1041 238-239, 261; EX1070 ¶332.

**X. GROUND 3: DOHIL2009 AND VENKATESH IN VIEW OF THE
KNOWLEDGE OF A POSA**

This section describes Venkatesh, and then explains how Dohil2009 and Venkatesh in view of the knowledge of a POSA renders obvious claims 1-30 of the '061 patent.

A. Venkatesh

Gopi Venkatesh is listed as a co-inventor on the '061 patent and on Venkatesh (EX1020).

Venkatesh discloses “orally disintegrating tablets made up of rapidly dispersing microgranules.” EX1020 ¶[0001]. Venkatesh’s ODTs rapidly disintegrate in the buccal cavity within “preferably less than 60 seconds.” *Id.* ¶[0016]. Venkatesh’s ODTs can be formulated using “any therapeutic active agent indicated for oral administration.” *Id.* ¶[0025].

B. Claim 1

Dohil2009 in view of the knowledge of a POSA renders obvious claim 1. As outlined below, to the extent Patent Owner asserts that Dohil2009 fails to disclose any claim 1 limitations, Venkatesh certainly does. Venkatesh reinforces that a POSA would have been motivated to arrive at an ODT encompassed by claim 1 with a reasonable expectation of success.

1. Preamble

If the preamble is limiting, Dohil2009 renders it obvious for the reasons outlined, *supra*, at Section IX.B.1. Moreover, Venkatesh discloses “a tablet that rapidly disintegrates in the oral cavity.” EX1020 Abstract, ¶[0001]; EX1070 ¶340.

2. Limitation 1.a

Dohil2009 renders Limitation 1.a obvious for the reasons outlined, *supra*, at Section IX.B.2.

Moreover, Venkatesh discloses formulating ODTs where “milled/micronized drug particles (e.g., average particle diameter less than about 50 μm , preferably less than about 25 μm) are blended with a... polymeric binder such as modified starch and hydroxypropyl methylcellulose,” and that the resulting mixture can be “milled using a size reduction mill.” EX1020 ¶[0015]. Venkatesh further discloses granulating an active pharmaceutical ingredient with “one or more pharmaceutically acceptable diluents such as mannitol, lactose and microcrystalline cellulose.” EX1020 ¶[0021].

The blending/grinding/milling disclosed by Dohil2009 and Venkatesh renders obvious adsorbing corticosteroid drug particles on the surface of a carrier in an ODT. *Supra* Section IX.B.2; EX1070 ¶¶342-345.

3. Limitation 1.b

Dohil2009 renders Limitation 1.b obvious for the reasons outlined, *supra*, at Section IX.B.3. Moreover, Venkatesh discloses ODTs comprising a “disintegrant.” EX1020 Abstract, ¶[0014]; EX1070 ¶¶347-348.

4. Limitation 1[c.i]

Dohil2009 renders Limitation 1[c.i] obvious for the reasons outlined, *supra*, at Section IX.B.4. Moreover, Venkatesh discloses ODTs that weigh 1 gram and comprise an active ingredient in “an amount of about 0.01 to 30% by weight,” which is between about 0.1 mg and 300 mg. EX1020 ¶¶[0025], [0037]; EX1070 ¶¶350-352.

5. Limitation 1[c.ii]

Dohil2009 renders Limitation 1[c.ii] obvious for the reasons outlined, *supra*, at Section IX.B.5. Moreover, Venkatesh discloses ODTs comprising an active ingredient with a “particle size less than about 50 microns,” EX1020 ¶[0025], to provide a smooth creamy mouthfeel without grittiness. *Id.* ¶[0009]; EX1070 ¶¶354-355.

6. Limitation 1[d]

Dohil2009 renders Limitation 1[d] obvious for the reasons outlined, *supra*, at Section IX.B.6. Moreover, Venkatesh discloses ODTs that “rapidly disintegrate

(e.g., less than 120 seconds, preferably less than 60 seconds) in the buccal cavity.”

EX1020 ¶[0016]; EX1070 ¶¶357-358.

7. Combining Dohil2009 and Venkatesh

Dohil2009 and Venkatesh disclose ODTs and methods of making such tablets. As discussed above, they both disclose the same or similar formulation ingredients to arrive at ODTs. A POSA would have been motivated to modify Dohil2009’s ODTs in view of Venkatesh’s disclosures because such modifications would have been expected to lead to an ODT with improved “smooth creamy mouthfeel” having “no grittiness.” EX1020 ¶¶[0002], [0012] [0018]. The POSA had a reasonable expectation of success based on the disclosures within Venkatesh and its teaching that such ODT formulations “don’t require a special pharmaceutical production technique and can be simply and easily produced by a normal equipment.” EX1020 ¶[0018]; EX1070 ¶359.

C. Claim 2

Dohil2009 in view of the knowledge of a POSA renders claim 2 obvious for the reasons outlined, *supra*, at Section IX.C. To the extent Patent Owner asserts that Dohil2009 fails to disclose this claim, Venkatesh discloses that formulating ODTs with microcrystalline cellulose beneficially imparts resilient characteristics to the tablet. EX1020 ¶[0021]; EX1070 ¶¶361-362.

D. Claim 3

Claim 3 depends from claim 2 and recites “the pharmaceutically acceptable carrier is silicified microcrystalline cellulose.”

As discussed for claim 2, a POSA would have been motivated to use microcrystalline cellulose in Dohil2009’s ODTs based on Venkatesh’s disclosure that microcrystalline cellulose imparts resilient characteristics to the resulting tablet. EX1020 ¶[0021]. A POSA would have been motivated to further improve the tablet by modifying the microcrystalline cellulose to be silicified microcrystalline cellulose with an expectation of success based on the general knowledge that silicified microcrystalline cellulose “has improved compaction properties in both wet granulation and direct compression compared to conventional microcrystalline cellulose.” EX1069 139. Indeed, “[s]ilicified microcrystalline cellulose was specifically developed to address the loss of compaction that occurs with microcrystalline cellulose after wet granulation,” *id.*, and it “has greater tensile strength and requires lower compression pressures than regular grades of microcrystalline cellulose.” *Id.* 140; EX1070 ¶¶364-365.

E. Claim 4

Dohil2009 in view of the knowledge of a POSA renders claim 4 obvious for the reasons outlined, *supra*, at Section IX.D. Venkatesh reinforces that the inclusion of any particular corticosteroid in an ODT was obvious because such tablets can be

formulated with “any therapeutic active agent indicated for oral administration.”

EX1020 ¶[0025]; EX1070 ¶¶367-368.

F. Claim 5

Dohil2009 in view of the knowledge of a POSA renders claim 5 obvious for the reasons outlined, *supra*, at Section IX.E. To the extent Patent Owner asserts that Dohil2009 fails to disclose this claim, Venkatesh discloses ODTs that weigh 1 gram and comprise an active ingredient in “an amount of about 0.01 to 30% by weight,” which is between about 0.1 mg and 300 mg. EX1020 ¶¶[0025], [0037]; EX1070 ¶¶370-371.

G. Claims 6-9

Dohil2009 and Venkatesh render claims 6-9 obvious for the reasons outlined, *supra*, at Section IX.F.

Venkatesh reinforces that the inclusion of any particular corticosteroid in an ODT was obvious because such tablets can be formulated with “any therapeutic active agent indicated for oral administration.” EX1020 ¶[0025]. Venkatesh further reinforces the obviousness of the amounts recited by claims 8-9 by disclosing ODTs that weigh 1 gram and comprise an active ingredient in “an amount of about 0.01 to 30% by weight,” which is between about 0.1 mg and 300 mg. EX1020 ¶¶[0025], [0037]; EX1070 ¶¶376-377.

H. Claims 10 and 11

Dohil2009 in view of the knowledge of a POSA renders claims 10-11 obvious for the reasons outlined, *supra*, at Section IX.G. Venkatesh reinforces the obviousness of claims 10-11 by disclosing ODTs comprising an active ingredient with a “particle size less than about 50 microns.” EX1020 ¶¶[0025]; EX1070 ¶¶380-381.

I. Claim 12

Claim 12 depends from claim 1 and further recites “at least one disintegrant is present in a rapidly dispersing microgranule, which comprises a sugar alcohol, or a saccharide, or a mixture thereof in addition to the at least one disintegrant.”

Venkatesh discloses ODTs comprising “rapidly dispersing microgranules prepared by granulating a sugar alcohol or a saccharide or a mixture thereof... and a disintegrant.” EX1020 Abstract, ¶¶[0014], [0018].

A POSA would have been motivated to formulate Dohil2009’s ODTs with the rapidly dispersing microgranules disclosed in Venkatesh because the rapidly dispersing microgranules (1) facilitate rapid disintegration of the tablet, (2) facilitate formulating active ingredients into taste-masked formulations, and (3) facilitate good mouthfeel. *See* EX1020 ¶¶[0002], [0009], [0015], [0018]. A POSA would reasonably expect to successfully make this combination because Venkatesh provides detailed disclosures regarding the manufacture of its formulations. Indeed,

Venkatesh teaches that is formulations “don’t require a special pharmaceutical production technique and can be simply and easily produced by a normal equipment.” EX1020 ¶[0018]; EX1070 ¶¶383-384.

J. Claim 13

Claim 13 depends from claim 12 and further requires “the sugar alcohol or saccharide and the disintegrant are present in a ratio of sugar alcohol or saccharide to disintegrant of from 90:10 to 99:1.”

Venkatesh Example 1 discloses “6.65 kg of mannitol” (a sugar alcohol) and “350 g of crosslinked povidone” (a disintegrant), which is a ratio of 95:5. EX1020 ¶[0032]; EX1070 ¶387.

To the extent that Ellodi argues that the recited ratio of “sugar alcohol or saccharide to disintegrant” of 90:10 to 99:1 provides a patentable feature over the prior art, such an argument would run afoul of the written description requirement under 35 U.S.C. § 112. The specification discloses only the opposite ratio of *disintegrant to sugar alcohol or saccharide*. EX1001 9:65-67.

K. Claim 14

Claim 14 depends from claim 12 and further requires “the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, and low-substituted hydroxylpropylcellulose.”

The '061 patent admits that crospovidone is “cross-linked PVP [polyvinylpyrrolidone].” EX1001 9:22-24, 11:22-23.

Dohil2009 teaches “[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.” EX1058 ¶[0070].

Venkatesh discloses “a disintegrant is selected from the group consisting of crospovidone (crosslinked PVP), sodium starch glycolate, crosslinked sodium carboxymethyl cellulose... and low substituted hydroxypropyl cellulose.” EX1020 ¶[0029]; EX1070 ¶¶390-391.

L. Claim 15

Claim 15 depends from claim 12 and further requires “the sugar alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.”

Dohil2009 discloses budesonide ODTs formulated with mannitol and sorbitol as sugar alcohol excipients. EX1058 ¶¶[0013], [0070]. Mannitol was the bulk excipient of choice for ODTs. EX1041 261.

Venkatesh also discloses that “the sugar alcohol may be selected from the group consisting of mannitol, sorbitol, xylitol, maltitol and the like while the saccharide may be selected from the group consisting of lactose, sucrose, maltose or as a mixture of two or more.” EX1020 ¶[0028]; EX1070 ¶¶393-394.

M. Claim 16

Claim 16 depends from claim 12 and further requires that “the rapidly dispersing microgranule has a mean particle size of less than about 300 μm , and the sugar alcohol and/or saccharide has an average particle size of less than about 30 μm .”

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

Venkatesh discloses “rapidly dispersing microgranules of a disintegrant and sugar alcohol or a saccharide whose average particle size is not more than 30 μm ,” which is advantageous in “effectively taste-mask[ing] by coacervation.” EX1020 ¶[0014]; *id.* ¶[0018] (“preferably not more than 20 μm ”), ¶[0028]; EX1070 ¶¶396-397.

N. Claims 17 and 18

Dohil2009 in view of the knowledge of a POSA renders claims 17 and 18 obvious for the reasons outlined, *supra*, at Section IX.H.

In addition, Venkatesh discloses finished tablets that weigh 1 gram. EX1020 ¶¶[0037], [0045]. A POSA would have been motivated to formulate Dohil2009’s ODTs to be between 300-900mg. EX1005 3; EX1070 ¶401; *E.I. DuPont*, 904 F.3d

at 1006 (“it is not inventive to discover the optimum or workable ranges by routine experimentation”).

O. Claim 19

1. Preamble

If the preamble is limiting, Dohil2009 and Venkatesh render it obvious for the reasons outlined, *supra*, at Sections IX.B.1 and X.B.1.

2. Limitation 19.a

Dohil2009 and Venkatesh render obvious Limitation 19.a for the reasons outlined, *supra*, at Sections IX.B.2, IX.F, X.B.2, and X.G.

3. Limitation 19.b

Dohil2009 and Venkatesh render obvious Limitation 19.b for the reasons outlined, *supra*, at Sections IX.B.3 and X.B.3.

4. Limitation 19[c.i]

Dohil2009 and Venkatesh render obvious Limitation 19[c.i] for the reasons outlined, *supra*, at Sections IX.B.4 and X.B.4.

5. Limitation 19[c.ii]

Dohil2009 and Venkatesh render obvious Limitation 19[c.ii] for the reasons outlined, *supra*, at Sections IX.B.5 and X.B.5.

6. Limitation 19[d]

Dohil2009 and Venkatesh in view of the knowledge of a POSA renders obvious Limitation 19[d] for the reasons outlined, *supra*, at Sections IX.B.6 and X.B.6.

P. Claim 20

Dohil2009 and Venkatesh in view of the knowledge of a POSA render obvious Claim 20 for the reasons outlined, *supra*, at Sections IX.H and X.N, regarding claim 17.

Q. Claim 21

Claim 21 depends from claim 19 and further requires “silicified microcrystalline cellulose in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.”

Dohil2009 in view of Venkatesh renders obvious claim 21 for the same reasons outlined, *supra*, at Sections X.D and X.N, regarding claims 3 and 17.

R. Claim 22

Dohil2009 and Venkatesh in view of the knowledge of a POSA render obvious Claim 22 for the reasons outlined, *supra*, at Sections IX.G and X.H, regarding claims 10-11.

S. Claim 23

Claim 23 depends from claim 21 and further requires that “the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, and low-substituted hydroxypropylcellulose.”

The '061 patent admits that crospovidone is “cross-linked PVP [polyvinylpyrrolidone].” EX1001 9:22-24, 11:22-23.

Dohil2009 discloses “[i]f desired, *disintegrating agents* may be added, such as the cross-linked polyvinylpyrrolidone.” EX1058 ¶¶0070]; EX1070 ¶¶422-423.

T. Claim 24

Claim 24 depends from claim 20 and further requires that “the at least one disintegrant is present in a rapidly dispersing microgranule, which comprises a sugar alcohol, or a saccharide, or a mixture thereof in addition to the at least one disintegrant.”

Dohil2009 and Venkatesh in view of the knowledge of a POSA render obvious Claim 24 for the reasons outlined, *supra*, at Section X.I, regarding claim 12.

U. Claim 25

Claim 25 depends from claim 24 and further requires that “the sugar alcohol or saccharide and the disintegrant are present in a ratio of sugar alcohol or saccharide to disintegrant of from 90:10 to 99:1.”

Dohil2009 and Venkatesh in view of the knowledge of a POSA render obvious Claim 25 for the reasons outlined, *supra*, at Section X.J, regarding claim 13.

V. Claim 26

Claim 26 depends from claim 24 and further requires that “the sugar alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.”

Dohil2009 and Venkatesh in view of the knowledge of a POSA render obvious Claim 26 for the reasons outlined, *supra*, at Section X.L, regarding claim 15.

W. Claim 27

Claim 27 depends from claim 24 and further requires that “the rapidly dispersing microgranule has a mean particle size of less than about 300 μm , and the sugar alcohol and/or saccharide has an average particle size of less than about 30 μm .”

Dohil2009 and Venkatesh in view of the knowledge of a POSA render obvious Claim 27 for the reasons outlined, *supra*, at Section X.M, regarding claim 16.

X. Claim 28

Claim 28 depends from claim 19 and further requires that “the silicified microcrystalline cellulose is present in an amount of about 10% w/w based on the

total weight of the orally disintegrating tablet, fluticasone propionate is present in an amount ranging from about 1 mg to about 3 mg, and fluticasone propionate has a mean particle size ranging from about 100 nm to about 4 μm .”

Dohil2009 in view of Venkatesh renders obvious claim 28 for reasons outlined, *supra*, at Sections X.D, X.G-H, X.N, and X.Q-R, regarding claims 3, 8-11, 17, and 21-22.

Y. Claim 29

Dohil2009 in view of the knowledge of a POSA renders obvious claim 29 for the reasons outlined, *supra*, at Section IX.L regarding claim 29. Venkatesh is consistent with Dohil2009’s disclosures by teaching that ODTs comprise “any therapeutic active agent.” EX1020 ¶[0025]; EX1070 ¶436.

Z. Claim 30

Claim 30 depends from claim 1 and recites a “method of preparing the orally disintegrating tablet of claim 1.” Dohil2009 and Venkatesh in view of the knowledge of a POSA renders obvious claim 1 for the reasons outlined, *supra*, in Sections IX.B and X.B. As outlined below, to the extent Patent Owner asserts that Dohil2009 fails to disclose limitations in claim 30, Venkatesh does, and a POSA would have been motivated to formulate Dohil2009’s ODTs according to the formulation steps outlined in Venkatesh with a reasonable expectation of success.

1. Limitation 30(a)

Dohil2009 in view of the knowledge of a POSA renders obvious Limitation 30(a) for the reasons outlined, *supra*, in Section IX.M.1. Moreover, Venkatesh discloses formulating orally disintegrating tablets by micronizing or milling the active ingredient particles to reduce particle size to the micron scale. EX1020 ¶¶[0015], [0021]; EX1070 ¶¶440-441.

2. Limitation 30[b.i]

Dohil2009 in view of the knowledge of a POSA renders obvious Limitation 30[b.i] for the reasons outlined, *supra*, in Section IX.M.2. Moreover, Venkatesh discloses preparing a preblend for formulating an ODT by blending an active ingredient under conditions suitable for the active ingredient to be adsorbed onto the pharmaceutically acceptable carrier for the reasons outlined, *supra*, in Section VIII.B.2. EX1070 ¶¶443-445.

3. Limitation 30[b.ii]

Dohil2009 in view of the knowledge of a POSA renders obvious Limitation 30[b.ii] for the reasons outlined, *supra*, in Section IX.M.3. Moreover, Venkatesh discloses this limitation for the reasons outline, *supra*, in Section X.C, regarding claim 2.

4. Limitation 30(c)

Dohil2009 in view of the knowledge of a POSA renders obvious Limitation 30(c) for the reasons outlined, *supra*, in Section IX.M.4. Moreover, Venkatesh discloses mixing and granulating the active ingredient with fillers, disintegrants, and sweeteners to prepare blends. EX1020 ¶¶[0018], [0023], [0030]; EX1070 ¶¶450-451.

5. Limitation 30(d)

Dohil2009 in view of the knowledge of a POSA renders obvious Limitation 30(d) for the reasons outlined, *supra*, in Section IX.M.5. Moreover, Venkatesh discloses mixing and granulating the active ingredient with fillers, disintegrants, and lubricants to prepare blends for tableting. EX1020 ¶¶[0002], [0018], [0023], [0030]; EX1070 ¶¶453-454.

6. Limitation 30(e)

Dohil2009 in view of the knowledge of a POSA renders obvious Limitation 30(e) for the reasons outlined, *supra*, in Section IX.M.6. Moreover, Venkatesh discloses compressing blends to form a tablet. EX1020 Abstract, ¶[0002]; EX1070 ¶¶456-457.

XI. 325(D) SHOULD NOT BE APPLIED

This petition should not be subject to discretionary denial under the Board's two step test. *See Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB 2020) (precedential).

Under Step 1, the Board analyzes whether (a) the same or substantially the same art previously was presented to the USPTO or (b) the same or substantially the same arguments previously were presented to the USPTO. *Id.* at 9 (referencing *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18) (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph).

Perrett, Dohil2009, and Venkatesh were submitted to the USPTO during prosecution of the '061 patent. EX1001 1, 2. Venkatesh is cited in the '061 patent specification. *Id.* 10:29-33.

During prosecution, the Examiner did not apply Perrett, Dohil2009, or Venkatesh as a primary reference to reject the claims. Instead, the claims were rejected over US20060051414 to Ramalho as a primary reference. EX1056 159-164. Ellodi focused its arguments on Ramalho purportedly lacking two claim elements. First, Ellodi argued that Ramalho failed to disclose a topically acting corticosteroid. *Id.* 111-12, 118-19. Second, Ellodi argued that Ramalho failed to disclose micronized drug particles, and therefore failed to disclose a drug adsorbed

onto a carrier. *Id.* 111. The Examiner withdrew the obviousness rejections in view of Ellodi’s arguments. EX1056 46.

Because Perrett and Dohil2009 are used as primary references in this Petition, the arguments presented herein differ substantially from those presented during examination of the ’061 patent.

During prosecution of the parent patent (U.S. 10,471,071), Perrett was applied as a primary anticipation and obviousness reference. EX1068 85-91. Ellodi asserted that Perrett failed to disclose a corticosteroid adsorbed onto a carrier. *Id.* 73-76, 79. The Examiner withdrew the rejection in view of Ellodi’s arguments. *Id.* 57.

The arguments presented herein differ substantially from those presented during examination of the ’071 patent because Dohil2009 was not used as a primary reference during prosecution of that patent.

Even accepting that Perrett, Dohil2009, and Venkatesh were “previously presented,” under *Advanced Bionics* Step 1, the Office “erred in a manner material to the patentability of the challenged claims” under Step 2. *Advanced Bionics*, Paper 6 at 8-9. There can be no reasonable dispute that Perrett and Dohil2009 each disclose ODTs comprising topically acting corticosteroids, such as fluticasone and budesonide. EX1057 ¶¶[0039], [0091]; EX1058 ¶[0049]; *supra* Sections VIII.B.2, IX.B.2. Also, there can be no reasonable dispute that Perrett and Dohil2009 each

disclose ODTs with drug particles on the micron scale. EX1057 ¶¶[0045], [0066], [0085]; EX1058 ¶¶[0019], [0070]; *supra* Sections VIII.B.5, IX.B.5.

With respect to adsorption, Perrett and Dohil2009 each disclose blending processes in which a micronized corticosteroid is mixed with carriers that results in adsorption onto the carrier. *Supra* Sections VIII.B.2, IX.B.2. Indeed, Perrett expressly discloses and claims ODTs where “the corticosteroid is disposed over the surface of an excipient,” which confirms that the corticosteroid is adsorbed on the surface of the excipient carrier. EX1057 Claims 19, 22, ¶[0063].

Perrett and Dohil2009 each disclose the claim elements that Ellodi argued were critical to distinguishing the claims from the prior art during examination, which misled the Examiner. The Office therefore erred in a manner material to the patentability of the challenged claims by not applying Perrett and Dohil2009 as a primary reference, as this Petition does, and by overlooking the key portions of these references that clearly disclose the purportedly distinguishing claim elements.

Importantly, the '061 and '071 patents were allowed before the EPO rendered its decision holding Ellodi's similar claim as being obvious over Perrett. EX1062 23. Thus, the Examiner did not have the benefit of the EPO's decision. The EPO determined that Perrett discloses all of the claim limitations, including topically acting corticosteroids and the adsorption of such corticosteroids onto a pharmaceutical carrier. *Id.* 17-19.

The Examiner also did not have the benefit of this Petition mapping the references to Ellodi's claims, and it did not have Dr. Parr's accompanying expert declaration explaining the POSA's understanding of the references. Here, Petitioner presents a sufficient showing that the Examiner overlooked disclosures that invalidate the claims such that the Office erred in a manner material to patentability. This Petition presents compelling challenges to patentability that warrant institution.

XII. NO SECONDARY CONSIDERATIONS

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

XIII. 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 '061 patent:

- 61/874,450 filed on September 6, 2013;
- 14/917,125 filed on March 7, 2016, now U.S. Patent No. 10,471,071;
- 16/578,568 filed September 23, 2019, now U.S. patent number 11,166,961; and
- 17/559,068 filed on December 22, 2021.

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) Jared C. Bunker (Reg. No. 58,474) 2esf@knobbe.com 2jcb@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.

XIV. 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 thirty claims is requested.

XV. REQUIREMENTS FOR REVIEW

Petitioner certifies that the '061 patent is available for IPR and that it is not barred or estopped from requesting this IPR.

XVI. CONCLUSION

Claims 1-30 of the '061 patent are unpatentable and should be canceled.

IPR Petition – Patent No. 11,260,061
Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.

Dated: October 24, 2024 Respectfully submitted,

By: /Nathanael Luman/

Nathanael Luman (Reg. No. 63,160)
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APPENDIX A

Listing of Challenged Claims from U.S. Patent No. 11,260,061	
Claim 1	
Preamble	An orally disintegrating tablet comprising:
a.	a topically acting corticosteroid or pharmaceutically acceptable salt or ester thereof, adsorbed onto a pharmaceutically acceptable carrier; and
b.	at least one disintegrant,
[c.i]	wherein the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, is present in an amount ranging from about 0.5 mg to about 10 mg, and
[c.ii]	the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, has a mean particle size of ranging from about 100 nm to about 100 μ m; and
[d]	wherein the orally disintegrating table disintegrates within 60 seconds when tested using the USP <701> method for disintegration time.
Claim 2	
--	The orally disintegrating tablet of claim 1, wherein the pharmaceutically acceptable carrier is selected from the group consisting of microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, and amorphous magnesium aluminum silicate.
Claim 3	
--	The orally disintegrating tablet of claim 2, wherein the pharmaceutically acceptable carrier is silicified microcrystalline cellulose.

Listing of Challenged Claims from U.S. Patent No. 11,260,061	
Claim 4	
--	The orally disintegrating tablet of claim 2, wherein said topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, is budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, or a pharmaceutically salt or ester thereof.
Claim 5	
--	The orally disintegrating tablet of claim 4, wherein the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, is present in an amount ranging from about 0.5 mg to about 3 mg.
Claim 6	
--	The orally disintegrating tablet of claim 4, wherein said topically acting corticosteroid is fluticasone or an ester thereof.
Claim 7	
--	The orally disintegrating tablet of claim 4, wherein said topically acting corticosteroid is fluticasone propionate.
Claim 8	
--	The orally disintegrating tablet of claim 1, wherein fluticasone propionate is present in an amount of about 3 mg in the orally disintegrating tablet.
Claim 9	
--	The orally disintegrating tablet of claim 1, wherein fluticasone propionate is present in an amount of about 1.5 mg in the orally disintegrating tablet.

Listing of Challenged Claims from U.S. Patent No. 11,260,061	
Claim 10	
--	The orally disintegrating tablet of claim 1, wherein the corticosteroid has a mean particle size of ranging from about 100 nm to about 10 μ m.
Claim 11	
--	The orally disintegrating tablet of claim 1, wherein the corticosteroid has a mean particle size ranging from about 100 nm to about 4 μ m.
Claim 12	
--	The orally disintegrating tablet of claim 1, wherein the at least one disintegrant is present in a rapidly dispersing microgranule, which comprises a sugar alcohol, or a saccharide, or a mixture thereof in addition to the at least one disintegrant.
Claim 13	
--	The orally disintegrating tablet of claim 12, wherein the sugar alcohol or saccharide and the disintegrant are present in a ratio of sugar alcohol or saccharide to disintegrant of from 90:10 to 99:1.
Claim 14	
--	The orally disintegrating tablet of claim 12, wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, and low-substituted hydroxylpropylcellulose.
Claim 15	
--	The orally disintegrating tablet of claim 12, wherein the sugar alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.

Listing of Challenged Claims from U.S. Patent No. 11,260,061	
Claim 16	
--	The orally disintegrating tablet of claim 12, wherein the rapidly dispersing microgranule has a mean particle size of less than about 300 μm , and the sugar alcohol and/or saccharide has an average particle size of less than about 30 μm .
Claim 17	
--	The orally disintegrating tablet of claim 1, wherein the pharmaceutically acceptable carrier is present at an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.
Claim 18	
--	The orally disintegrating tablet of claim 1, wherein the total weight of the tablet is in the range of from about 300 to about 900 mg.
Claim 19	
Preamble	An orally disintegrating tablet comprising:
a.	fluticasone propionate adsorbed onto microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, amorphous magnesium aluminum silicate, or combinations thereof; and
b.	at least one disintegrant, wherein:
[c.i]	the fluticasone propionate is present in an amount ranging from about 0.5 mg to about 6 mg, and
[c.ii]	the fluticasone propionate has a mean particle size ranging from about 100 nm to about 10 μm ; and
[d]	wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701> Disintegration Test.

Listing of Challenged Claims from U.S. Patent No. 11,260,061	
Claim 20	
--	The orally disintegrating tablet of claim 19, wherein the microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, or amorphous magnesium aluminum silicate, or a combination thereof, is present in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.
Claim 21	
--	The orally disintegrating tablet of claim 19, comprising silicified microcrystalline cellulose in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet.
Claim 22	
--	The orally disintegrating tablet of claim 19, wherein fluticasone propionate has a mean particle size of about 4 μm or less.
Claim 23	
--	The orally disintegrating tablet of claim 21, wherein the disintegrant is selected from the group consisting of crospovidone, sodium starch glycolate, crosslinked carboxymethyl cellulose, and low-substituted hydroxylpropylcellulose.
Claim 24	
--	The orally disintegrating tablet of claim 20, wherein the at least one disintegrant is present in a rapidly dispersing microgranule, which comprises a sugar alcohol, or a saccharide, or a mixture thereof in addition to the at least one disintegrant.
Claim 25	
--	The orally disintegrating tablet of claim 24, wherein the sugar alcohol or saccharide and the disintegrant are present in a ratio

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	of sugar alcohol or saccharide to disintegrant of from 90:10 to 99:1.
Claim 26	
--	The orally disintegrating tablet of claim 24, wherein the sugar alcohol or saccharide is selected from the group consisting of sucralose, lactose, sucrose, maltose, mannitol, sorbitol, xylitol, maltitol, and mixtures thereof.
Claim 27	
--	The orally disintegrating tablet of claim 24, wherein the rapidly dispersing microgranule has a mean particle size of less than about 300 μm , and the sugar alcohol and/or saccharide has an average particle size of less than about 30 μm .
Claim 28	
--	The orally disintegrating tablet of claim 19, wherein the silicified microcrystalline cellulose is present in an amount of about 10% w/w based on the total weight of the orally disintegrating tablet, fluticasone propionate is present in an amount ranging from about 1 mg to about 3 mg, and fluticasone propionate has a mean particle size ranging from about 100 nm to about 4 μm .
Claim 29	
--	A method for treating eosinophilic esophagitis in an individual in need thereof, comprising administering to the individual the orally disintegrating tablet of claim 1.
Claim 30	
Preamble	A method of preparing the orally disintegrating tablet of claim 1, comprising the steps of:
(a)	micronizing the corticosteroid;

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[b.i]	preparing preblend 1 by blending (i) a pharmaceutically acceptable carrier, (ii) corticosteroid or pharmaceutically ester thereof, and (iii) glidant, under conditions suitable for the corticosteroid to be adsorbed onto the pharmaceutically acceptable carrier,
[b.ii]	wherein the pharmaceutically acceptable carrier is microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, and amorphous magnesium aluminum silicate;
(c)	preparing preblend 2 by blending filler, preblend 1 of step (b), disintegrant, and sweetener;
(d)	preparing a final compressible blend, by blending a disintegrant, lubricant, filler, and preblend 2 of step (c);
(e)	compressing the blend of step (d) to form a tablet.

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. 11,260,061 contains 13,853 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/
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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. 11,260,061, PETITIONER’S POWER OF ATTORNEY, AND EXHIBITS 1001-1002, 1005-1006, 1009-1020, 1025-1029, 1041, and 1054-1070 were served by FedEx on the Patent Owner at the correspondence address of record for the subject patent as follows:

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