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Paper 10
Date: January 27, 2025

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.

IPR2024-01197
Patent 8,771,729 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and
TAWEN CHANG, *Administrative Patent Judges*.

CHANG, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

Dr. Falk Pharma v. Ellodi Pharmaceuticals
IPR2025-00054
Dr. Falk Pharma Ex. 1116

I. INTRODUCTION

Petitioner Dr. Falk Pharma GmbH ("Petitioner") filed a Petition for *inter partes* review of claims 1–40 of U.S. Patent No. 8,771,729 B2 (Ex. 1001, "the '729 patent"). Paper 2 ("Pet."). Patent Owner, Ellodi Pharmaceuticals, L.P. ("Patent Owner"), timely filed a Preliminary Response. Paper 6 ("Prelim. Resp."). The parties further submitted an authorized Reply and Sur-Reply to the Preliminary Response. Paper 7 ("Reply"); Paper 9 ("Sur-Reply"); Ex. 3002.

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has demonstrated a reasonable likelihood that at least one claim of the '729 patent is unpatentable and because we determine there is no reason to exercise our discretion to deny institution, we institute an *inter partes* review of all challenged claims on each of the Grounds raised in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition"); *see also* 37 C.F.R § 42.108(a) (2025).

A. Real Parties-in-Interest

Petitioner identifies itself as the real party-in-interest. Pet. 72. Patent Owner likewise identifies itself as the real party-in-interest. Paper 4, 1.

B. Related Proceedings

Petitioner identifies the following U.S. patents and applications related to the '729 patent: U.S. Application 61/247,642, filed on October 1, 2009; U.S. Application 14/294,660, filed on June 3, 2014, now U.S. patent number 9,486,407; U.S. Application 14/311,732, filed on June 23, 2014, now U.S. patent number 9,387,167; U.S. Application 15/205,390, filed on July 8, 2016, now U.S. patent number 9,849,084; U.S. Application 15/816,154, filed on November 17, 2017, now U.S. patent number 10,632,069; U.S. Application 16/821,464, filed on March 17, 2020, now U.S. patent number 11,246,828; U.S. Application 17/236,295, filed April 21, 2021, now U.S. patent number 11,266,598; and U.S. Application 17/569,047, filed on January 5, 2022. Pet. 72–73.

Petitioner stated in the Petition that it "is not aware of any judicial proceedings that would affect or be affected by this proceeding." Pet. 72. On November 26, 2024, Petitioner filed a Supplemental Mandatory Notice identifying the following IPR petitions as related matters:

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

- IPR2025-00056, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, regarding U.S. Patent No. 11,260,061.

Paper 8, 2.

Petitioner also identified the following proceeding as a "judicial proceeding that could affect or be affected by this proceeding":

- *Ellodi Pharmaceuticals, L.P. v. Dr. Falk Pharma GmbH*, Düsseldorf Regional Court, Case No. 4b O 43/24, Patent Litigation Chamber, Werdener Str. 1, 40227 Düsseldorf, Germany.

Paper 8, 2.

Patent Owner states that it is "not aware of any judicial or administrative matter that would affect, or be affected by, a decision in this proceeding." Paper 4, 1.

C. The '729 Patent and Relevant Background

"[C]onditions associated with inflammation of the upper portion of the gastrointestinal tract" include "eosinophilic esophagitis (EE), . . . an inflammatory condition of the esophagus." Ex. 1001, 1:21–26. The '729 patent states that "[t]here are currently no approved topically administered anti-inflammatory medications" for conditions such as EE. *Id.*

The '729 patent describes various experimental and "off-label" treatments for EE, including (1) "directing steroid medications formulated and approved for inhalation to the back of the throat such that they are not appreciably inhaled"; (2) administering a "thickened and sweetened liquid" produced by mixing sugars with "[a]queous corticosteroid preparations

intended for oral inhalation through nebulization"; and (3) "administration of corticosteroid tablets containing steroids such as prednisolone." Ex. 1001, 1:30–44. According to the '729 patent, however, these experimental and "off-label" treatments have drawbacks.

For example, the '729 patent states that patients are instructed "to rinse their mouth immediately after administration and not to swallow food or water for two hours" after "directing steroid medications formulated and approved for inhalation to the back of the throat" to treat EE, because "residual drug in the mouth and throat can lead to [candidiasis] infection, and swallowing is contraindicated because it may wash drugs away from the esophagus." Ex. 1001, 1:30–38. Furthermore, "systemic administration of corticosteroids," such as oral prednisolone, "is associated with a number of known and undesirable side-effects." *Id.* at 1:44–46.

According to the '729 patent, "[t]here is therefore a need in the art for orally administered corticosteroid formulations which provide topical (rather than systemic) treatment of inflammation of the gastrointestinal tract, particularly inflammation of the upper gastrointestinal tract, such as EE." Ex. 1001, 1:51–55.

D. Overview of Challenged Claims

Petitioner challenges claims 1–40 of the '729 patent. Claims 1 and 27, reproduced below as annotated by Petitioner with bracketed lower case Roman numerals, are the independent claims:

> 1. An orally disintegrating solid pharmaceutical composition comprising [i] less than or equal to about 20

> mg of a topically administrable corticosteroid and [ii] at least one disintegrant, [iii] wherein the solid pharmaceutical composition has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration,
>
> [iv] wherein the solid pharmaceutical composition disintegrates within 60 seconds when tested using the USP <701> Disintegration Test, and
>
> [v] wherein upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract.
>
> 27. An orally disintegrating tablet comprising [i] less than or equal to about 20 mg of a corticosteroid selected from the group consisting of fluticasone, budesonide, mometasone, and salts, solvates and esters thereof, and [ii] at least one disintegrant, [iii] wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701> Disintegration Test.

Ex. 1001, 18:21–31 (claim 1), 20:16–22 (claim 27).

Claims 2–26, 28, and 35–40 depend directly or indirectly from independent claim 1 or claim 27 and recite additional features of the composition or tablet. Ex. 1001, 18:32–20:15, 20:23–24, 20:42–57.

Claim 29 depends from claim 1 and recites "[a] method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof a pharmaceutical composition according to claim 1." Ex. 1001, 20:25–28. Claims 30–34 depend from 29 and further specify the inflammatory condition(s) treated. *Id.* at 20:29–41.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 15–16):

Ground	Claims Challenged	35 U.S.C §[1]	Reference(s)/Basis
1	1–7, 15, 20, 21, 27, 29–36	103(a)	Dohil[2]
2	1–7, 9–15, 20, 27, 28, 35, 36, 38–40	103(a)	Grother,[3] FDA Guidance[4]
3	8, 16–18	103(a)	Dohil, Venkatesh[5]
4	8, 16–26, 37	103(a)	Grother, FDA Guidance, Venkatesh

Petitioner further relies, *inter alia*, on the declaration of Dr. Alan F. Parr, Pharm.D., Ph.D. (Ex. 1030, "Parr Declaration").

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[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the '729 patent has an effective filing date before March 16, 2013, the pre-AIA version of § 103 applies. Our decision, however, would be the same under either version.

[2] Dohil et al., US 2007/0111978 A1, published May 17, 2007 (Ex. 1002, "Dohil").

[3] Grother et al., WO 00/44351, published Aug. 3, 2000 (Ex. 1008, "Grother").

[4] CTR. FOR DRUG EVALUATION & RSCH. (CDER), FOOD & DRUG ADMIN., U.S. DEP'T HEALTH & HUM. SERVS., GUIDANCE FOR INDUSTRY: ORALLY DISINTEGRATING TABLETS (2008) (Ex. 1005, "FDA Guidance").

[5] Venkatesh et al., US 2005/0232988 A1, published Oct. 20, 2005 (Ex. 1020, "Venkatesh").

F. Overview of Asserted References

1. Overview of Dohil (Exhibit 1002)

Dohil teaches that "[e]osinophilic esophagitis (EE) is an emerging, and fast-growing disorder characterized by high levels of eosinophils in the esophagus, as well as basal zone hyperplasia." Ex. 1002 ¶ 3.

Dohil notes that "[l]ong term systemic steroid therapy can result in significant secondary side effects on growth and bone development, therefore topical steroid formulations are often used to treat EE and potentially other inflammatory gastrointestinal diseases and conditions involving the esophagus." Ex. 1002 ¶ 5. In particular, Dohil notes that "[s]ystemic corticosteroids and swallowed topical steroids, such as fluticasone proprionate [*sic*] . . . administered through metered-dose inhaler (MDI), have been shown to induce and maintain low esophageal eosinophil levels." *Id.* ¶ 6.

Dohil teaches, however, that "[i]t is often difficult to deliver an effective dose of corticosteroid to the targeted area of esophagus." Ex. 1002 ¶ 7. For instance, Dohil teaches that the "puff and swallow technique" used with the metered dose inhaler "is often difficult for patients . . . to perform efficiently," which "results in a less than effective dose of the topical steroid being delivered to the esophagus." *Id.* ¶ 6. Dohil teaches that there is thus "a need for novel methods for preventing and alleviating inflammatory diseases and conditions involving the esophagus," as well as "[a] liquid, long-acting topical corticosteroid preparation." *Id.* ¶ 9.

According to Dohil, one aspect of its invention relates to a pharmaceutical composition comprising a corticosteroid, such as the topical corticosteroid budesonide, and a viscosity-increasing excipient. Ex. 1002 ¶ 13. Dohil teaches that this composition may be in liquid form, but also provides corticosteroid compositions in the form of "a dissolving tablet, a dissolving wafer, a capsule, or a gel capsule," including embodiments wherein such "tablets, wafers, and capsules are formulated with at least one excipient to deliver a viscous form of the corticosteroid to the esophagus." *Id.*

2. Overview of Grother (Exhibit 1008)

Grother teaches "fast dispersing solid dosage forms that preferably dissolve in the oral cavity within sixty (60), more preferably within thirty (30), most preferably within ten (10) seconds." Ex. 1008, code (57). Grother teaches that "the use of certain modified starches at concentrations from 20 to 90% by weight . . . prepares dosage forms that are . . . stable and are able to deliver higher concentrations of an active ingredient" than the "gelatin based fast dispersing solid dosage forms" of the prior art. *Id.* Grother teaches that "the solid dosage forms according to [its] invention are obtainable by removing a solvent, such as water, from a mixture comprising an active ingredient, a modified starch and a matrix forming agent via freeze drying." *Id.*

Grother teaches that "[a]ny drug may be used as the active ingredient in the composition of [its] invention." Ex. 1008, 15:19–20. Grother teaches

that examples of suitable drugs include corticosteroids including, e.g., budesonide. *Id.* at 15:20–21, 18:15–18.

3. Overview of FDA Guidance (Exhibit 1005)

FDA Guidance notes that "the CDER Nomenclature Standards Committee developed the following definition for an [orally disintegrating tablet (ODT)] as a new dosage form in 1998: *A solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue*." Ex. 1005, 2. The Guidance emphasizes that "rapid oral disintegration in saliva with no need for chewing or drinking liquids to ingest these products," which aid patient use and compliance, are "the primary characteristics that constitute the basis for classifying a product as an ODT." *Id.*

The Guidance explains a review of "applications for products submitted to the Agency, . . . literature . . ., and . . . information from laboratories studies . . . showed that although disintegration time ranged from a few seconds to longer than a minute, a large majority of [ODT] products have in-vitro disintegration times of approximately 30 seconds or less." Ex 1005, 2. The FDA Guidance concludes that "relatively rapid disintegration is readily achievable across a variety of products" and that 30 seconds "is . . . representative of a general time period associated with drug products that have been found to have performance characteristics appropriate for a disintegrating tablet meant to be taken without chewing or liquids." *Id.* at 2–3.

Accordingly, the Guidance recommends that, "in addition to the original definition, ODTs be considered 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," where the USP method for disintegration testing is identified as "*USP 29, <701> Disintegration, pp. 2670–2672*." Ex. 1005, 2–3, 3 n.3.

4. Overview of Venkatesh (Exhibit 1020)

Venkatesh teaches that "[a]n ideal orally disintegrating tablet formulation rapidly disintegrates in the buccal cavity dispersing the contents and has a pleasant taste and smooth creamy mouthfeel (no grittiness), and complete drug release occurs in the gastrointestinal tract." Ex. 1020 ¶ 2. Venkatesh teaches that "[t]his convenience leads to better compliance with dosing regimen and as a consequence, to enhanced therapy." *Id.* Venkatesh notes, for instance, that "solid medicines, which rapidly dissolve or disintegrate in the buccal cavity, can be taken without water, so they may be easily taken by . . . aged persons, children or the 'people on the move'." *Id.* ¶ 3.

Venkatesh teaches "orally disintegrating tablets and a method for their manufacture," wherein the orally disintegrating tablets are "made up of rapidly dispersing microgranules and taste-masked microcapsules." Ex. 1020 ¶ 1. Venkatesh teaches that the "rapidly dispersing microgranules [are] prepared by granulating a sugar alcohol or a saccharide or a mixture thereof having an average particle size less than about 30 microns and a

disintegrant," and the taste-masked microcapsules are "prepared by granulating a pharmaceutically acceptable formulation comprising at least one drug in a therapeutically effective amount and at least one polymeric binder . . . , wet milling the granulated mass, and microencapsulating the milled granules." *Id.*, code (57). Venkatesh teaches that "[t]he term 'drug', 'active' or 'active pharmaceutical ingredient' . . . is meant to include any therapeutic active agent indicated for oral administration." *Id.* ¶ 25.

II. ANALYSIS

A. Principles of Law

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (2012) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review). The Board may authorize an *inter partes* review if we determine that the information presented in the Petition and Patent Owner's Preliminary Response shows a reasonable likelihood that Petitioner will prevail with respect to at least one of the claims challenged in the Petition. 35 U.S.C. § 314(a).

Petitioner contends that claims 1–40 would have been obvious under § 103 in view of (1) Dohil, (2) Grother and FDA Guidance, (3) Dohil and Venkatesh, and/or (4) Grother, FDA Guidance, and Venkatesh. Pet. 15–16. A claim is unpatentable under 35 U.S.C. § 103 if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art "to combine . . . known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness over a combination of references must show that "a skilled artisan would have been motivated to combine the

teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotations omitted).

We address Petitioner's challenges with these standards in mind, and in view of the definition of the skilled artisan and the claim constructions discussed below.

B. Person of Ordinary Skill in the Art

Factual indicators of the level of ordinary skill in the art include "the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field." *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*).

Petitioner asserts that a POSA[6] for purposes of the '729 patent

> would have a Ph.D., another advanced degree, or its equivalent, in areas related to pharmaceutics, 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

[6] "POSA" refers to "person of ordinary skill in the art." Pet. 4.

> other individuals with expertise related to the above subjects.

Pet. 4–5 (citing Ex. 1030 ¶ 29).

Patent Owner has not proposed a definition of a person of ordinary skill in the art in its Preliminary Response.

On the current record, for purposes of this Decision, we apply Petitioner's proposed definition, as it appears consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the '729 Patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("the prior art itself [may] reflect[] an appropriate level" as evidence of the ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)). We note, however, that the open-ended language "at least" and "or more" expands the range of experience indefinitely with no upper bound. Therefore, we do not apply this aspect of Petitioner's formulation.

C. Claim Construction

We construe claims "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.100 (2024). Therefore, we construe the challenged claims under the framework set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). Under this framework, claim terms are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art, at the time of the

invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id.*

Petitioner states that it adopts and applies the following definitions set forth in the '729 patent (Pet. 16–18):

Claim Term(s)	**Petitioner's Construction**
"[H]aving no significant systemic glucocorticoid or mineralocorticoid activity."	"[C]orticosteroid compositions which do not provide a generalized effect in the body through absorption into the circulation, but do provide local effects through topical contact with a diseased tissue." Pet. 16 (quoting Ex. 1001, 3:11–16).
"[A]dhesive agent."	"[A]gents which promote adhesion of the corticosteroid to biological surfaces, and includes, but is not limited to bio-adhesive agents." Pet. 16 (quoting Ex. 1001, 2:66–3:2).
"[O]rally disintegrating tablet," "orally dispersing tablet," or "ODT."	"[A] solid dosage form . . ., which disintegrates rapidly in the oral cavity of a patient after administration, without chewing." Pet. 17 (quoting Ex. 1001, 2:41–44).
"[I]ntimately associated."	"[Description of] the spatial relationship between two or more components of a composition refers to components [*sic*] that are intimately mixed, such as for example in mixtures, coatings and matrices." Pet. 17 (quoting Ex. 1001, 3:6–10).
"[S]ugar alcohols."	"[H]ydrogenated forms of carbohydrates in which the carbonyl group (i.e., aldehyde or ketone) has been reduced to a primary or secondary hydroxyl group." Pet. 17 (quoting Ex. 1001, 13:10–17).
"[S]accharide"	"[S]ynonymous with the term 'sugars' includes monosaccharides such as glucose, fructose, the lactose, and ribose; and disaccharides such as sucrose, lactose, maltose, trehalose, and cellobiose." Pet. 17 (quoting Ex. 1001, 13:17–20).

Claim Term(s)	Petitioner's Construction
"[A]bout."	"[A]s used . . . to refer to a numerical quantity, includes 'exactly'. . . . When . . . used in reference to a range of values, . . . 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')." Pet. 18 (quoting Ex. 1001, 2:57–65).

Petitioner does not propose express constructions for any other claim term, stating instead that "[a]ll claim terms not specifically construed in [the Petition] have been accorded their plain and ordinary meaning under a *Phillips*-type construction." Pet. 16. Patent Owner does not address claim construction in the Preliminary Response.

Petitioner bears the burden of stating "[h]ow the challenged claim is to be construed." 37 C.F.R. § 42.104(b)(3). However, only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) ("The Board is required to construe 'only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))). Based on the preliminary record, we find it unnecessary to construe any claim term to decide whether Petitioner satisfies the "reasonable likelihood" standard for instituting trial.

Any final written decision entered in this case may include express claim constructions, or may include discussion of claim scope that differs

from that provided in our analysis below. Any final claim constructions will be based on the full trial record.

D. Ground 1: Alleged Obviousness over Dohil

Petitioner relies on Dohil, as supported by the testimony of Dr. Parr, to allege obviousness of claims 1–7, 15, 20, 21, 27, and 29–36. Pet. 18–34. Patent Owner's Preliminary Response addresses discretionary denial under 35 U.S.C. § 325(d) but does not address Petitioner's substantive allegations for any of the asserted grounds.

1. Claims 1, 2, 15, 27, 35, and 36

Petitioner maps each element of claims 1, 2, 15, 27, 35, and 36 to the disclosures in Dohil. Pet. 19–26, 29, 30–31, 33–34.

Regarding claim 1, Petitioner asserts that Dohil discloses providing budesonide in the form of a lozenge that would "***dissolve rapidly in the mouth*** or esophagus to produce a solution that can then coat the esophagus," as well as "in the form of ***a dissolving tablet***," and that both are "orally disintegrating solid pharmaceutical composition[s]" as recited in the preamble. Pet. 19 (citing Ex. 1002 ¶¶ 13, 32, 37; Ex. 1030 ¶¶ 100–102). Petitioner also relies on these disclosures, among other things, to assert that Dohil renders obvious the additional limitation of claim 15, which depends from claim 1 and further recites that the composition is "in the form of an orally disintegrating tablet." Pet. 29.

Petitioner asserts that "[b]udesonide is a topically administrable corticosteroid" with "no significant systemic . . . activity after oral

administration," and that Dohil further discloses embodiments in which "1-2 mg or 2-3 mg of corticosteroid per day" or "budesonide at 0.5, 1, and 2 mg/day" is administered, thus disclosing limitations 1[i] and 1[iii]. Pet. 20–22 (citing, e.g., Ex. 1001, 7:6–13; Pet. Section IV.A; Ex. 1002, ¶ 15, 41, Table 1; Ex. 1030 ¶¶ 103–108, 112–116). Petitioner points to Dohil's disclosure that, "[i]f desired, ***disintegrating agents*** may be added," as disclosing limitation 1[ii]. *Id.* at 21 (citing Ex. 1002 ¶ 37).

With respect to limitation 1[iv], relating to disintegration time, Petitioner asserts that "[i]t would have been obvious to formulate Dohil's rapidly dissolving lozenge or tablet" to meet the limitation, because FDA Guidance, which Petitioner asserts represents the knowledge of the POSA, recommends that orally disintegrating tablets have a disintegration time of 30 seconds or less, when based on the USP disintegration test method recited in the claim. Pet. 23 (citing Ex. 1005, 2–3, 3 n.3).

Petitioner asserts that a POSA would have been motivated to follow the FDA Guidance because the FDA regulates the use of pharmaceutical compositions in the United States, and the FDA Guidance "provides the agency's thinking and recommendations on the topic of rapidly disintegrating oral pharmaceutical compositions." Pet. 24 (citing, e.g., Ex. 1030 ¶¶ 119–120). Petitioner further asserts a POSA would have had a reasonable expectation of success in formulating Dohil's budesonide dosage form in accordance with the FDA Guidance, based on Dohil's disclosure and a POSA's knowledge. *Id.* at 24–25 (citing, e.g., Ex. 1030 ¶ 121).

Petitioner asserts Dohil's disclosures of a "lozenge or tablet that 'dissolve[s] rapidly in the mouth'" and FDA's above-cited recommendation regarding disintegration time also render obvious the additional limitation of claim 2, which depends from claim 1 and further recites that the composition "disintegrates within 30 seconds." Pet. 26 (citing, e.g., Ex. 1002 ¶ 32).

Petitioner asserts that Dohil teaches limitation 1[v], regarding topical deposition of the corticosteroid in the upper gastrointestinal tract, because Dohil teaches that its lozenge or tablet "'dissolve[s] rapidly in the mouth or esophagus to produce a solution' of budesonide that is deposited topically in the upper gastrointestinal tract by 'coat[ing] the esophagus.'" Pet. 25 (citing Ex. 1002 ¶ 32). Petitioner asserts that these disclosures also render obvious the additional limitations of claims 35 and 36, which depend from claim 1 and claim 35, respectively, and further recite that the composition is "formulated for topical administration to the upper gastrointestinal tract" (claim 35) and "wherein the upper gastrointestinal tract is further defined as the esophagus" (claim 36). *Id.* at 33–34.

Petitioner relies on the prior art disclosures cited above with respect to claim 15 and limitations 1[i], 1[ii], and 1[iv] to assert that Dohil renders obvious independent claim 27. Pet. 30–31.

2. Claims 3–7

Claims 3–7 depend directly or indirectly from claim 1 and recite more specific or additional ingredients for the claimed composition. Petitioner points out that these ingredients are also disclosed by Dohil as suitable for use in its composition. Pet. 27 (citing, e.g., Ex. 1002 ¶¶ 13, 32 for disclosure

of "budesonide" for claim 3), 27–28 (citing, e.g., Ex. 1002 ¶¶ 13–14, 37 for disclosure of viscosity-increasing excipient ("adhesive agent") including, e.g., sodium carboxymethyl-cellulose, polyvinylpyrrolidone, and hydroxypropylmethyl-cellulose for claims 4 and 5), 28 (citing, e.g., Ex. 1002 ¶ 37 for disclosure of cross-linked polyvinylpyrrolidone ("crospovidone") as disintegrant for claim 6), 28–29 (citing, e.g., Ex. 1002 ¶¶ 14, 37 for disclosure of lactose, sucrose, and sorbitol for claim 7).

3. Claims 20 and 21

Claim 20 depends from claim 4, which claims the composition of claim 1 further comprising an adhesive agent, "wherein the adhesive agent and the corticosteroid are intimately associated." Ex. 1001, 18:40–41, 19:53–55. Claim 21 depends from claim 20 and further recites that "said corticosteroid is surrounded or encapsulated by the adhesive agent." *Id.* at 19:56–58.

Petitioner notes that the '729 patent states that the phrase "intimately associated" "describe[s] the spatial relationship between two or more components of a composition . . . that are intimately mixed, such as for example in mixtures, coatings and matrices." Pet. 17 (citing Ex. 1001, 3:6–10). Petitioner asserts that Dohil discloses the additional limitation of claim 20 because it "discloses 'combining the corticosteroid with solid excipients, ***optionally grinding a resulting mixture, and processing the mixtures of granules*** . . . to obtain tablets or dragee cores." Pet. 30 (citing, e.g., Ex. 1002 ¶ 37). Petitioner asserts that Dohil further discloses the additional limitation of claim 21 because Dohil discloses that polyvinylpyrrolidone, an

"adhesive excipient[]," is a suitable coating for dragee cores. *Id.* (citing, e.g., Ex. 1002 ¶ 39).

4. Claims 29–34

Claim 29 recites "[a] method for treating an inflammatory condition of the gastrointestinal tract comprising administering to an individual in need thereof a pharmaceutical composition according to claim 1." Ex. 1001, 20:25–28. Claims 30–34 depend from claim 29 and further specify particular inflammatory conditions. *Id.* at 20:29–41.

Petitioner points out Dohil teaches that its invention is useful for, e.g., "***alleviating the symptoms and inflammation of eosinophilic esophagitis***," the condition specifically recited in claim 31, as well as "***symptoms and inflammation associated with other diseases or conditions of the gastrointestinal tract, for example, the upper gastrointestinal tract***, where it is beneficial to target a particular target site, rather than provide systemic therapy." Pet. 32 (citing, e.g., Ex. 1002 ¶¶ 10, 11, 15).

Relying on the testimony of Dr. Parr, Petitioner asserts that "[i]t is well known that the 'upper gastrointestinal tract' includes the esophagus, glottis, epiglottis, tonsils, and oropharynx" and that, "[t]hus, a POSA would understand that Dohil's budesonide formulations that treat inflammation of the upper gastrointestinal tract include treating inflammation of the glottis, epiglottis, tonsils, and oropharynx" in addition to treating inflammation of the esophagus. Pet. 33 (citing, e.g., Ex. 1030 ¶ 163).

5. Conclusion as to Ground 1

Based on the foregoing discussion, and having considered the arguments and evidence presented by Petitioner, including the presently unrebutted testimony of Dr. Parr, we are persuaded Petitioner has shown a reasonable likelihood of prevailing with respect to Ground 1 sufficient for purposes of institution.

E. Other Asserted Grounds of Unpatentability

Having determined that Petitioner meets the threshold showing necessary to support institution of review based on the ground that asserts obviousness over Dohil in view of the knowledge of a POSA, we decline to address whether any other ground asserted in the Petition also supports institution. *See* Pet. 15–16 (grounds chart); *see also SAS*, 138 S. Ct. at 1359–60 (requiring the Board's final written decision to address every claim the petitioner presents for review); Patent Trial and Appeal Board Consolidated Trial Practice Guide[7] ("Trial Practice Guide") (Nov. 2019) 11 ("The Board will not institute on fewer than all claims or all challenges in a petition."); *PGS Geophysical*, 891 F.3d at 1359–1360.

We emphasize our determination in this Decision is not a final determination on the construction of any claim term or the patentability of any challenged claim and, thus, leaves undecided any factual issues necessary to determine whether sufficient evidence supports Petitioner's contentions by a preponderance of the evidence in the final written decision.

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[7] Available at https://www.uspto.gov/TrialPracticeGuideConsolidated.

See TriVascular, Inc. v. Samuels, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial") (quoting 35 U.S.C. § 314(a) and comparing § 316(e)).

III. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 325(D)

The parties dispute whether the Board should exercise its discretion to deny the Petition under 35 U.S.C. § 325(d). *See generally* Pet. 68–71; Prelim. Resp. 4–50; Reply 1–5; Sur-Reply 1–5.

1. Legal Standards

Institution of *inter partes* review is discretionary. *Harmonic*, 815 F.3d at 1367 (explaining that "the PTO is permitted, but never compelled, to institute an IPR proceeding"). The Patent Office may, for example, deny institution under 35 U.S.C. § 325(d), which provides, in pertinent part, that "[i]n determining whether to institute or order a proceeding under this chapter, . . . the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office."

In evaluating whether the same or substantially the same prior art or arguments were previously presented to the Office, the Board has identified several non-exclusive factors that may be considered. *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) ("*Becton, Dickinson*"). Those factors are as follows:

> (a) the similarities and material differences between the asserted art and the prior art involved during examination;
>
> (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
>
> (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
>
> (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
>
> (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
>
> (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments.

Id.; *see also* Trial Practice Guide 62–63 (citing the *Becton, Dickinson* factors).

As more recently explained in *Advanced Bionics, LLC v. MED-EL Electromedizinishe Geräte GmbH*, IPR2019-01469, Paper 6 at 8–10 (Feb. 13, 2020) (precedential) ("*Advanced Bionics*"), the Board addresses § 325(d) applying a "two-part framework." In the first part of the framework, we ask whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office. *Advanced Bionics*, 8. Factors (a), (b), and (d) of *Becton, Dickinson* come into play under this first part of the

framework. *Id.* at 8–10. If *either* condition of the framework's first part is met, we move to part two of the framework, asking "whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of [the] challenged claims." *Id.* at 8. Factors (c), (e), and (f) of *Becton, Dickinson* fall within part two of the framework. *Id.* at 10 ("[F]actors (c), (e), and (f) relate to whether the petitioner has demonstrated material error by the Office.").

Only if the same or substantially the same art or arguments were previously presented to the Office do we then consider whether the petitioner has demonstrated error. *Advanced Bionics*, 8–10. "If the petitioner fails to show that the Office erred, the Director may exercise his discretion not to institute *inter partes* review." *Id.* at 8–9. "At bottom, this [§ 325(d)] framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown." *Id.* at 9 ("If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.").

2. Analysis

We begin our analysis with a review of the prosecution history of the '729 patent.

a) Prosecution History of the '729 Patent

The '729 patent was filed as U.S. Patent Application No. 12/896,005 ("the '005 application") on October 1, 2010, with 54 original claims.

Ex. 1001, codes (21), (22); Ex. 1031, 113–119. The '005 application claims priority to U.S. Provisional Application No. 61/247,642, filed October 1, 2009. Ex. 1001, code (60), 1:7–10.

On January 31, 2012, the Examiner issued an office action requiring Applicant to restrict the application to one of three recited inventions. Ex. 1031, 103–112. Applicant elected to prosecute the invention of claims 1–28, directed to a solid pharmaceutical composition and an orally disintegrating tablet comprising less than or equal to 20 mg of a corticosteroid. *Id.* at 97–102.

On June 6, 2012, the Examiner issued a first office action on the merits. Ex. 1031, 81–96. The Examiner examined elected claims 1–28 and rejected claims 1–22, 27, and 28 as obvious over Venkatesh '620[8] and Brantl[9] and claims 23–26 as obvious over Venkatesh '620, Brantl, and Rawas-Qalaji.[10] *Id.* at 82, 85, 94.

The Examiner found in relevant part that Venkatesh '620 teaches "a solid pharmaceutical composition in the form of an orally disintegrating tablet (ODT) comprising a therapeutically effective amount of a drug, an

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[8] Venkatesh et al., US 2009/0169620 A1, published July 2, 2009 (Ex. 2002, "Venkatesh '620"). We note that the parties refer to Exhibit 2002 as "Venkatesh 2009." We refer to Exhibit 2002 as "Venkatesh '620," i.e., the first author's last name followed by the last three digits of the publication number. The parties should follow this convention in their future papers.
[9] Brantl, US 2005/0009848 A1, published Jan. 13, 2005 ("Brantl").
[10] Rawas-Qalaji et al., US 2007/0059361 A1, published Mar. 15, 2007 ("Rawas-Qalaji").

ODT binder polymer, a sugar alcohol and/or saccharide, and a disintegrant." Ex. 1031, 85. The Examiner found that Venkatesh '620 discloses its ODT compositions "disintegrate in about 60 seconds or less, and in about 30 seconds or less on contact with saliva in the buccal cavity, as measured by using the USP <701> Disintegration Test procedures," and also identifies the corticosteroid beclomethasone as a suitable drug for use in the composition. *Id.* at 86. The Examiner acknowledged Venkatesh '620 does not expressly teach the recited amount of corticosteroid or the composition's lack of significant systemic glucocorticoid or mineralocorticoid activity, but found that Brantl filled the gaps in Venkatesh '620. *Id.* at 87.

In response, Applicant contended that Venkatesh '620 discloses a "laundry list" of corticosteroids but "does not particularly highlight that drugs should be used relative to whether they have . . . significant systemic activity." Ex. 1031, 72. Applicant contended that Brantl is not directed to ODTs and, furthermore, is "primarily directed to oral compositions comprising an antiviral for treatment of inflammatory bowel disease" that only "<u>optionally</u> further comprise a corticosteroid." *Id.* at 72–73.

In addition, Applicant amended its claims to include the limitation, "wherein upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract"[11] and added dependent claims 55–60.[12]

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[11] Applicant added this limitation to both independent claims 1 and 27. Ex. 1031, 61, 65. However, as issued, claim 27 does not include this limitation. Ex. 1001, 20:16–22.
[12] Claims 55–56 corresponds to claims 35–40 of the '729 patent.

Ex. 1031, 61, 65, 69. Applicant contended that neither Venkatesh '620 nor Brantl, which teaches releasing the corticosteroid in the intestine, suggests this limitation. *Id.* at 72–73. Applicant further contended that, in light of Brantl's teaching to target drug release in the intestine, a skilled artisan would not have been motivated to combine Brantl with Venkatesh '620, which teaches compositions designed for rapid disintegration. *Id.* at 74.

The Examiner then issued a second, final rejection. Ex. 1031, 39–56. The Examiner found that, in light of the limitation in the amended claims that "corticosteroid is deposited topically in the upper gastrointestinal tract," Applicant's arguments regarding the rejections based on Venkatesh '620 and Brantl were persuasive. *Id.* at 41. The Examiner accordingly withdrew those rejections. *Id.* at 42. However, the Examiner issued new rejections of claims 1–7, 15, 27, 28, 55, 56, and 58–60 as obvious over Phillips,[13] claims 8–22 and 57 as obvious over Phillips and Venkatesh '620, and claims 23–26 as obvious over Phillips, Venkatesh '620, and Rawas-Qalaji. *Id.* at 42, 47, 53.

The Examiner found in relevant part that Phillips teaches (1) pharmaceutical compositions for treating inflammation of the gastrointestinal tract; (2) the composition comprises a corticosteroid such as fluticasone propionate; (3) the amount of corticosteroid is from about 100 μg to about 20 mg; and (4) the composition is "formulated into solid dosage

[13] Phillips, US 2009/0131386 A1, published May 21, 2009 (Ex. 2003, "Phillips").

forms and administered locally." Ex. 1031, 43. The Examiner also found Phillips teaches formulating the solid dosage forms, e.g., tablets, "such that the dosage forms substantially dissolve or disintegrate in the mouth and/or esophagus, prior to reaching the stomach." *Id.*

The Examiner acknowledged Phillips does not provide an example or embodiment of a solid dosage form containing the recited amounts of a corticosteroid, but found that it would have been obvious to combine Phillips's teachings to arrive at such a composition. Ex. 1031, 43–44. The Examiner also noted that the limitations of "no significant systemic . . . activity" and "corticosteroid [being] deposited topically in the upper gastrointestinal tract" would have been obvious over Phillips's disclosures of local administration of its solid dosage form, which further contains an excipient that increases interaction with a surface of the gastrointestinal tract such as the esophagus. *Id.* at 44–45. Finally, the Examiner noted that "[t]he limitation of the time period for disintegration is a property associated with the solid dosage form" and shifted the burden to Applicant to show that the prior art does not possess or render obvious this property. *Id.* at 45.

In the rejection of dependent claims 8–22 and 57 over Phillips and Venkatesh '620, the Examiner relied on both Phillips and Venkatesh '620 to render obvious the limitation of an orally disintegrating tablet (ODT) in claim 15, the limitation in claim 16 regarding the ODT comprising drug particles and rapidly dispersing granules, and the limitation in claim 57 regarding the ODT comprising a sugar alcohol, a disintegrant, and microcrystalline cellulose. Ex. 1031, 50, 52. The Examiner further relied on

Venkatesh '620 for the disclosure of the limitation in claim 8 that the composition is "substantially free of lubricant," the limitations in claims 9–11 and 12–14 relating to, respectively, antifungal and antiviral agents, the limitation in claim 20 relating to an "intimately associated" adhesive agent and corticosteroid, and the limitations in claims 17–19, 21, and 22 relating to particle size and specific arrangement of the components in the solid pharmaceutical composition. *Id.* at 49–52.

After a telephone interview with the Examiner, Applicant filed an amendment and response to the Final Action, amending claim 1 to recite "[a]n orally disintegrating solid pharmaceutical composition" in place of "[a] solid pharmaceutical composition" in the preamble and "topically administrable corticosteroid" in place of "corticosteroid," and further amending both independent claims 1 and 27 to require "at least one disintegrant" in the composition or tablet. Ex. 1031, 23–38.

Applicant contended in its response that Phillips "is directed primarily to liquid dosage forms" and "does not teach or suggest a[n] orally disintegrating solid pharmaceutical composition that can disintegrate within sixty seconds." Ex. 1031, 31. Applicant contended that "a dosage form can substantially dissolve or disintegrate in the mouth or esophagus in more than sixty seconds" and that, because Phillips "does not disclose any particular solid composition with any particular combination of components[,] . . . there is no basis to assume that a composition according to *Phillips* would inherently disintegrate within sixty seconds." *Id.* at 31–32.

Applicant contended that "[d]issolution within sixty seconds is an important feature of the invention," because "prolonged contact of corticosteroids to the mouth or throat can lead to an oral yeast infection." Ex. 1031, 32. Applicant contended Phillips "provides no reason to have a rapid disintegration time, particularly one of about 60 seconds as recited" in the claims, because Phillips fails to recognize using a liquid composition instead of a disintegrating solid composition comprising a corticosteroid promotes the undesirable effect of oral yeast infection. *Id.* at 31.

With respect to the rejection over the combination of Phillips and Venkatesh '620, Applicant contended that Venkatesh '620 does not cure the deficiencies of Phillips, because Venkatesh '620 "does not teach or suggest topical delivery of drugs," and, like Phillips, "fails to recognize the importance of minimizing exposure of the oral cavity to corticosteroids in order to prevent oral yeast infections." Ex. 1031, 33. Applicant contended that, "[a]ccordingly, the artisan would not combine the teachings of [Phillips and Venkatesh '620] to provide a solid formulation that deposits a corticosteroid topically in the upper gastrointestinal tract while minimizing the possibility of an oral yeast infection by disintegrating within 60 seconds." *Id.*

The Examiner subsequently rejoined previously withdrawn claims 29–34, directed to the process of using the claimed compositions, and

allowed claims 1–34 and 55–60. Ex. 1031, 19–20. As the reasons for allowance, the Examiner stated:

> Applicants amended claims 1 and 27 to recite the limitations of "orally disintegrating" and "at least one disintegrant". In light of the amendments, Applicants' arguments . . . regarding the importance of the disintegration within 60 seconds and how this minimizes the chance of an oral yeast infection were persuasive. Phillips . . . does not teach or suggest an orally disintegrating solid pharmaceutical composition (or an orally disintegrating tablet) *that disintegrates within 60 seconds.* Although Phillips teaches solid dosage forms, this reference is silent with respect to any disintegration time. Venkatesh . . . and Rawas-Qalaji . . . do not teach or suggest the limitation of the disintegration time or the topical delivery of drugs.

Id. at 19.

b) § 325(d) Framework: Part One

We turn next to the first part of the *Advanced Bionics* framework, which examines whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office.

Petitioner's unpatentability challenges rely on four prior art references: Dohil, Grother, FDA Guidance, and Venkatesh. Pet. 15–16. Patent Owner argues that the disclosures of all of the prior art references asserted in the Petition are "substantially the same and cumulative of the art and arguments previously considered by the Office." Prelim. Resp. 7, 33. Patent Owner contends that Dohil is substantially similar to Phillips and

identical to Dohil '275,[14] which was before the Examiner during prosecution of a related patent application. *Id.* at 7. Patent Owner asserts that Grother, FDA Guidance, and Venkatesh are all substantially similar to Venkatesh '620.[15] *Id.* at 33; *see also id.* at 7.

For purposes of this Decision, we need not address in detail whether the references asserted in the Petition are substantially the same as the art previously presented to the Patent Office. As discussed below, even if the asserted references are substantially the same, we are persuaded Petitioner has demonstrated, under the second part of the *Advanced Bionics* framework, that the Office erred in a manner material to the patentability at least with respect to the claims challenged as obvious over Dohil.

c) § 325(d) Framework: Part Two

In part two of the framework, we consider "whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of [the] challenged claims," taking into consideration *Becton, Dickinson* factors (c), (e), and (f). *Advanced Bionics*, 8.

As to *Becton, Dickinson* factor (e), "whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art," Petitioner asserts among other things that the Examiner did not have the

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[14] Dohil et al., US 2009/0191275 A1, published July 30, 2009 (Ex. 2001, "Dohil '275").
[15] The parties also do not dispute that Venkatesh is cited in the Specification of the '729 patent. Pet. 69 (citing Ex. 1001, 8:1–6, 16:35–36); Prelim. Resp. 30.

benefit of (1) "the specific teachings of the FDA Guidance that are representative of the POSA's knowledge that orally disintegrating compositions should have an *in-vitro* disintegration time of approximately 30 seconds or less based on the USP <701> Disintegration Test," which "directly addresses the limitation the Examiner asserted was missing from the prior art during examination," or (2) "Dr. Parr's accompanying expert declaration explaining the POSA's understanding of the references." Pet. 70–71 (citing, e.g., Ex. 1005, 3); *see also* Reply 5.[16]

Patent Owner contends that "Petitioner merely states that the FDA Guidance pointing to the USP <701> Disintegration Test was overlooked, but offers no explanation as to how this led to a material error." Prelim. Resp. 49. Patent Owner similarly argues that Petitioner's expert declaration does not constitute "new evidence that warrants reconsideration of the same prior art," because "the declaration just repeats arguments in the Petition and the expert fails to support his testimony with objective evidence." *Id.* at 31, 49. We evaluate these opposing arguments in light of *Becton, Dickinson* factors (c) and (f).

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[16] Because we find the Petition sufficiently articulated Petitioner's position that the Examiner materially erred because they did not have the benefit of the FDA Guidance during prosecution, we are not persuaded by Patent Owner's contention that "Petitioner failed to meet its burden of showing material error and is foreclosed from raising new arguments concerning error in a reply." Prelim. Resp. 32, 50.

We turn first to *Becton, Dickinson* factor (c), "the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection." Although none of the art in Petitioner's asserted grounds was applied in a rejection during the prosecution of the '729 patent, we acknowledge that Phillips and Venkatesh '620 – which Patent Owner alleges are substantially the same as Dohil and Venkatesh – both formed the basis for rejections during the prosecution of the '729 patent.[17] Ex. 1031, 85 (rejection over Venkatesh '620 and Brantl), 94 (rejection over Venkatesh '620, Brantl, and Rawas-Qalaji), 42 (rejection over Phillips), 47 (rejection over Phillips and Venkatesh '620), 53 (rejection over Phillips, Venkatesh '620, and Rawas-Qalaji).

However, relevant to both factors (c) and (e), "the extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments," we agree with Petitioner that the Examiner materially erred because the Examiner did not have the benefit of the teachings of the FDA Guidance, which Petitioner relies on in Grounds 1 (Dohil) and 3 (Dohil and Venkatesh) as representative of the knowledge of a POSA with regard to orally disintegrating tablets. *See, e.g.*, Pet. 23.

In particular, the Examiner stated in the reason for allowance that, in light of Applicant's claim amendment to recite the limitations of "orally

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[17] We also acknowledge Patent Owner's contention that Dohil is "identical" to Dohil '275, and that Dohil '275 formed the basis of rejections during the prosecution of an application related to the '729 patent. Prelim. Resp. 7, 19–20 (citing, e.g., Ex. 2004, 54).

disintegrating" and "at least one disintegrant," Applicant's arguments regarding "the importance of the disintegration within 60 seconds and how this minimizes the chance of an oral yeast infection were persuasive." Ex. 1031, 19. The Examiner noted that, "[a]lthough Phillips teaches solid dosage forms, [it] is silent with respect to any disintegration time." *Id.* More specifically, the Examiner emphasized that Phillips "does not teach or suggest an orally disintegrating solid pharmaceutical composition (or an orally disintegrating tablet) *that disintegrates within 60 seconds*." *Id.*

The FDA Guidance, however, provides a definition of an orally disintegrating tablet (ODT) as "*[a] solid dosage form containing medicinal substances which disintegrates rapidly,* ***usually within a matter of seconds****, when placed upon the tongue*." Ex. 1005, 2 (emphasis added).[18] The FDA Guidance further recommends that, "[b]ased on the original product rationale and Agency experience," and "in addition to the original definition," "ODTs be considered 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 USP <701> Disintegration Test cited in the claims (or equivalent alternative). *Id.* at 2–3

[18] Unlike Phillips, which is "silent with respect to any disintegration time," Ex. 1031, 19, Dohil teaches that embodiments where the solid dosage form "wo[u]ld dissolve *rapidly* in the mouth or esophagus to produce a solution that can then coat the esophagus." Ex. 1002 ¶ 32 (emphasis added). Thus, we find the FDA Guidance, and its discussion of "disintegrating rapidly," to warrant reconsideration of Dohil to an even greater extent than Phillips.

(emphasis added). We agree with Petitioner that this additional evidence warrants reconsideration of Dohil (which Patent Owner argues is similar to Phillips) and arguments related thereto, because it "directly addresses the limitation the Examiner asserted was missing from [Phillips] during examination," i.e., the claimed disintegration time. Pet. 71.

Patent Owner argues that the FDA Guidance "simply states that orally disintegrating tablets should disintegrate within 60 seconds as measured using the USP <701> Disintegration Test." Prelim. Resp. 48 (citing Ex. 1005). Patent Owner asserts that both that test itself and Venkatesh '620, which teaches tablets that disintegrate within 60 seconds as measured using the test, were considered by the Examiner. *Id.*; *see also id.* at 49–50. Patent Owner emphasizes that the Examiner did not overlook the teaching of the disintegration time in the prior art, because the Examiner initially rejected the claims over (1) Venkatesh '620 in view of Brantl and (2) Phillips in view of Venkatesh '620, before Applicant overcame these rejections. *Id.* at 46–47; Sur-Reply 4.

We acknowledge that the Examiner initially rejected the claims over prior art combinations having Venkatesh '620 as a primary reference, and further rejected some of the dependent claims over Phillips in combination with Venkatesh '620. Ex. 1031, 47, 53, 85. However, the Examiner did not reject the independent claims over the combination of Phillips and Venkatesh '620, relying instead on Phillips for disclosure of the limitation

regarding disintegration time. Ex. 1031, 45.[19] Furthermore, despite acknowledging that Venkatesh '620 teaches an ODT composition that "disintegrate[s] . . . in about 30 seconds or less on contact with saliva in the buccal cavity, as measured using the USP <701> Disintegration Test," elsewhere during the prosecution history, including in the rejection of the dependent claims over Phillips and Venkatesh '620, *see, e.g.*, Ex. 1031, 47, 48–49, the Examiner stated in the Reasons for Allowance that Venkatesh '620 and Rawas-Qalaji "do not teach or suggest the limitation of the disintegration time or the topical delivery of drugs." *Id.* at 19.

Moreover, we are persuaded that even if the Examiner had determined the independent claims to be patentable over Phillips and Venkatesh '620, the FDA Guidance and the Parr Declaration provide additional evidence and facts that warrant reconsideration of Dohil (which Patent Owner argues is similar to Phillips) and arguments related thereto. As Petitioner notes, albeit

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[19] In its arguments with respect to the first step of the *Advanced Bionics* framework, Patent Owner argues the Petition does not present different combinations merely because the Petition relies on Venkatesh as a secondary reference whereas Venkatesh '620 was relied on as a primary reference during prosecution. Sur-Reply 3. Patent Owner contends "Petitioner cites no authority establishing that this alleged distinction is material" and further asserts that, "[f]or Ground 3, Petitioner relies on substantially the same combination – Dohil in combination with Venkatesh – as the Examiner – Phillips in combination with Venkatesh ['620]." *Id.* at 3–4. However, "the extent to which the asserted art was evaluated during examination" is a factor to be considered during the second step of the *Advanced Bionics* framework.

in the context of the first rather than the second step of *Advanced Bionics*, FDA Guidance "provides agency recommendations on the desirable disintegration time and testing parameters for orally disintegrating compositions," "evidences the widespread general knowledge of the POSA," and "provides a strong motivation to formulate orally disintegrating compositions according to its authoritative guidance that is not equivalent to the less-known Venkatesh 2009 reference." Reply 2.

Petitioner's assertions are supported by Petitioner's declarant Dr. Parr, who notes that "[t]he FDA regulates the use of pharmaceutical compositions in the United States," that "Dohil's formulations were intended to 'be used in therapy for human patients,'" and that "the initial testing of its formulations was conducted within the United States." Ex. 1030 ¶ 120. Accordingly, based on the current record, we are persuaded by Dr. Parr's testimony that "[a] person of ordinary skill in the art seeking to formulate budesonide into an orally disintegrating pharmaceutical composition would [have been] highly motivated to follow the FDA Guidance" regarding disintegration time. *Id.*

We acknowledge this motivation may differ from that advanced by Applicant during prosecution – i.e., to minimize the chance of an oral yeast infection. *See, e.g.*, Ex. 1031, 19. However, "neither the particular motivation nor the avowed purpose of the patentee controls" in determining obviousness. *KSR*, 550 U.S. at 419. Instead, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed."

Id. at 20. In this regard, we note that the FDA Guidance further teaches that orally disintegrating tablets were developed to be "more convenient to use and to address potential issues of patient compliance for certain product indications and patient populations," and that its recommended disintegration time is "[b]ased on the original product rationale and Agency experience." Ex. 1005, 1–2. This provides yet other reasons – convenience and patient compliance – for a skilled artisan to adopt the claimed disintegration time for Dohil's compositions that was not considered by the Examiner.

For reasons discussed above, we are also not persuaded by Patent Owner's argument that "Petitioner cites no legal authority establishing a more 'widespread' reference[, e.g., the FDA Guidance,] cannot, per se, be non-cumulative to another allegedly 'lesser known' reference [e.g., Venkatesh '620]." Sur-Reply 2–3. Although both Venkatesh '620 and the FDA Guidance describe similar disintegration times for ODT compositions using the same test, the description in Venkatesh '620 is specific to its own invention, whereas the FDA Guidance provides an industry recommendation for ODT dosage forms in general.

Considering *Becton, Dickinson* factors (c), (e), and (f) together, we conclude that, to the extent Dohil is cumulative of Phillips, Petitioner has made a sufficient showing of error in the Office's prior consideration of Phillips so as to "demonstrate[] that the Office erred in a manner material to the patentability of the challenged claims." *See Advanced Bionics*, 8. Accordingly, because at least two of the four asserted grounds present

additional evidence not previously presented to the Office warranting reconsideration, we decline to exercise our discretion to deny institution based on § 325(d).

IV. CONCLUSION

For the reasons provided above, we decline to exercise our discretion under § 325(d), and we institute *inter partes* review based on all the Grounds presented in the Petition.

V. ORDER

In consideration of the foregoing, it is ORDERED that the Petition is granted, and trial is instituted.

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which will commence on the entry date of this decision.

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