

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.

IPR2025-00056
Patent 11,260,061 B2

Before JOHN G. NEW, ZHENYU YANG, and RYAN H. FLAX,
Administrative Patent Judges.

FLAX, *Administrative Patent Judge.*

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

I. INTRODUCTION

Ellodi Pharmaceuticals, L.P. (“Patent Owner”) is the owner of U.S. Patent 11,260,061 B2 (Ex. 1001, “the ’061 patent”). Paper 3, 1 (Patent Owner Mandatory Notices). On October 24, 2024, Dr. Falk Pharma GMBH (“Petitioner”) filed a Petition for *inter partes* review challenging the patentability of claims 1–30 of the ’061 patent (all claims). Paper 1, 1 (“Pet.”). On March 12, 2025, Patent Owner filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”). On April 9, 2025, we authorized Petitioner to file a Reply (directed to discretionary denial under § 325(d) and claim construction issues) and Patent Owner to file a Sur-reply, which were each filed in this proceeding. Paper 8 (“Preliminary Reply” or “Prelim. Reply”); Paper 9 (“Preliminary Sur-reply” or “Prelim. Sur-reply”).

Under 37 C.F.R. § 42.4(a), we have authority to determine whether to institute trial in an *inter partes* review. We may institute an *inter partes* review if the information presented in the petition filed under 35 U.S.C. § 311, and any preliminary response filed under § 313, shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314.

After reviewing the parties’ submissions in view of the existing record, we conclude that Petitioner demonstrates a reasonable likelihood it would prevail in showing that at least one challenged claim of the ’061 patent is unpatentable under the presented grounds. *See* Pet. Moreover, we decline to exercise discretion to deny institution. Therefore, we grant institution of *inter partes* review. Our reasoning is discussed below.

A. REAL PARTIES-IN-INTEREST

Petitioner states, “Dr. Falk Pharma GmbH is the real party in interest.”
Pet. 77. Patent Owner states, “Ellodi Pharmaceuticals, L.P. is the real party-in-interest.” Paper 3, 1.

B. RELATED MATTERS

Petitioner lists the following as related matters: (1) *Ellodi Pharmaceuticals, LP v. Dr. Falk Pharma GmbH*, Case No. 24-cv-1392 (E.D. Va); (2) *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; (3) IPR2024-01197, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, regarding U.S. Patent 8,771,729; (4) IPR2025-00052, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, regarding U.S. Patent 10,632,069; (5) IPR2025-00054, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, regarding U.S. Patent 11,246,828; (6) IPR2025-00055, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, regarding U.S. Patent 9,486,407; (7) U.S. Application 61/874,450, filed on September 6, 2013; (8) U.S. Application 14/917,125, filed on March 7, 2016, now U.S. Patent 10,471,071; (9) U.S. Application 16/578,568, filed September 23, 2019, now U.S. Patent 11,166,961; and (10) U.S. Application 17/559,068, filed on December 22, 2021. Pet. 77–78; Paper 6, 1 (Pet. Updated Mandatory Notices).

Patent Owner, in contrast with the list above, states it “is not aware of any judicial or administrative matter that would affect, or be affected by, a decision in this proceeding.” Paper 3, 1.

C. THE '061 PATENT AND RELEVANT BACKGROUND

The '061 patent, titled “CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS,” issued on March 1, 2022, from U.S. Application 17/211,119, which was filed on March 24, 2021. Ex. 1001, codes (10), (21), (22), (45). The '061 patent indicates priority to a series of other patent applications, including an earliest-filed provisional application 61/874,450, which was filed on September 6, 2013.¹ *Id.* at code (60).

The '061 patent indicates its invention relates to:

orally administered compositions of topically acting corticosteroids for the treatment of inflammation of the gastrointestinal tracts such as eosinophilic esophagitis [(EOE)]. The present invention also provides a method for treating conditions associated with inflammation of the gastrointestinal tract in an individual. The method comprises administering to an individual in need thereof a pharmaceutical composition of the present invention as orally disintegrating tablets comprising a topically active corticosteroid adsorbed onto a pharmaceutically acceptable carrier such as silicified microcrystalline cellulose.

Ex. 1001, Abstract; *see also id.* at 1:27–45.

The Specification states that systemic treatments with corticosteroids, like prednisone, were effective to treat such conditions, but that there were potential adverse effects of such treatments. *Id.* at 1:45–53. The use of inhaler-administered steroids was one way of directly treating the throat, but problematic issues were presented with such a therapy. *Id.* at 1:54–64. Oral solutions were also tested as a direct therapy. *Id.* at 2:5–29. The invention

¹ Petitioner acknowledges this earliest asserted priority date and does not contest that the '061 patent's claims are entitled thereto. Pet. 4.

is described as an orally disintegrating tablet (ODT), which provides a solution to, as yet, insufficient direct therapies to deliver corticosteroids to the throat to treat inflammatory conditions like EOE using micronized drug particles. *Id.* at 2:30–4:34.

The '061 patent describes an ODT that may include, for example, one of a variety of corticosteroids in the form of crystals that are 100 μ m or smaller (or possibly in amorphous form) in a dose of about 0.5–18 mg (or less than 5% by weight of the composition), one or more excipients to facilitate disintegration of the ODT, a sugar alcohol or a saccharide (also an excipient), a pharmaceutically acceptable carrier suitable for adsorption of the drug and with which the drug is mixed to form a blend during production (the blend may also include other components), a bio-adhesive agent, an adhesive agent, fillers, diluents, binders, an anti-fungal agent, and an anti-viral agent (or various combinations of the aforementioned components). *See id.* at 5:53–12:56.

The '061 patent describes the corticosteroid may be blended with the pharmaceutically acceptable carrier, which is “suitable for adsorption of the drug.” *Id.* at 7:28–32. The corticosteroid and carrier are described as potentially blended together. *Id.* at 7:52–60. The '061 patent describes that the corticosteroid may also be “intimately associated”² with the adhesive agent, such that the corticosteroid may be surrounded or encapsulated by the adhesive agent, or the corticosteroid may be disposed on the surface of the

² The '061 patent states that “‘intimately associated’, as used herein to describe the spatial relationship between two or more components of a composition refers to components that are intimately mixed, such as, for example, in mixtures, coatings and matrices.” Ex. 1001, 5:29–33.

adhesive agent, and that the corticosteroid may be mixed or granulated with the adhesive agent. *Id.* at 8:58–67.

The carrier and adhesive are “pharmaceutically acceptable excipients.” *Id.* at 3:61–4:4.

The '061 patent describes that ODTs may be manufactured by: forming a first preblend (1) of the pharmaceutically acceptable carrier and micronized corticosteroid (and a glidant) and mixing for 10 minutes; forming a second preblend (2) of filler, disintegrant, sweetener, more microgranules of corticosteroid and more carrier, and the preblend 1, and mixing for 10 minutes; forming a final compressible blend of preblend 2, lubricant, more rapidly dispersing granules (microgranules of corticosteroid) and mixing for 30–40 minutes to acceptable uniformity; and, finally, forming tablets by compressing the final compressible blend. *Id.* at 12:63–13:61.

The '061 patent concludes with thirty claims, of which claims 1, 19, and 30 are independent claims; claim 1 is reproduced below:

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;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 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

wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701>method for disintegration time.

Ex. 1001, 31:28–34:25 (claims).

D. PETITIONER’S ASSERTED GROUNDS FOR UNPATENTABILITY

Petitioner asserts the following grounds for unpatentability:

Ground	Claims Challenged	35 U.S.C. § ³	Reference(s)/Basis
1	1–30	103	Perrett ⁴
2	1, 2, 4–11, 17–20, 22, 29, 30	103	Dohil2009 ⁵
3	1–30	103	Dohil2009, Venkatesh ⁶

Pet. 16. In support of these grounds for unpatentability, Petitioner submits, *inter alia*, the Declaration of Alan F. Parr, PhD. Ex. 1070. In support of its positions here, Patent Owner submits, *inter alia*, the Declaration of Martyn Davies, PhD. Ex. 2001. The qualifications of the witnesses to testify as to the subject matter of their declarations stand uncontested.

³ The priority date of the ’061 patent is uncontested to be September 6, 2013, which is after the relevant AIA revisions to the Patent Act took effect on March 16, 2013. 35 U.S.C. § 100 (note); *see* Ex. 1001, code (60). Therefore, AIA § 103 applies.

⁴ Stephen Perrett et al., US 2011/0081411 A1, published April 7, 2011 (Ex. 1057, “Perrett”).

⁵ Ranjan Dohil et al., US 2009/0191275 A1, published July 30, 2009 (Ex. 1058, “Dohil2009”).

⁶ Gopi M. Venkatesh et al., US 2005/0232988 A1, published Oct 20, 2005 (Ex. 1020, “Venkatesh”).

II. DISCUSSION

A. DISCRETIONARY DENIAL

Patent Owner contends that we should exercise our discretion to deny the Petition under 35 U.S.C. § 325(d). Prelim. Resp. 5–23; Prelim. Sur-Reply. According to Patent Owner, prior art asserted and arguments presented in the Petition are the same as, or cumulative of, art and arguments previously presented to the Office. Prelim. Resp. 8–20. Patent Owner also argues that Petitioner has not shown the Office erred in a manner material to patentability of challenged claims. *Id.* at 20–23. Petitioner concedes Perrett, Dohil2009, and Venkatesh were all considered by the Office previously, but argues they were not considered as they are presented here, and also argues that the Examiner erred in considering the references during prosecution. Pet. 74–77; Prelim. Reply 1–5.

In determining whether to deny institution under § 325(d), we use the following two-part framework:

- (1) 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; and
- (2) if either condition of [the] first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*”). The *Becton, Dickinson* factors provide useful insight into how to apply the framework under 35 U.S.C. § 325(d). *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)).

Under § 325(d), the art and arguments must have been previously presented to the Office during proceedings, such as examination of the underlying patent application, pertaining to the challenged patent. *Advanced Bionics*, Paper 6 at 7. Previously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (“IDS”), in the prosecution history of the challenged patent. *Id.* at 7–8.

1. 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

Under the first part of the *Advanced Bionics* framework, we consider “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.” *Id.* at 8. We evaluate *Becton, Dickinson* factors (a), (b), and (d) to determine whether Petitioner has demonstrated material error. *Id.* at 10. Those factors are:

- (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; [and]
- (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.

Becton, Dickinson, IPR2017-01586, Paper 8 at 17–18.

With respect to the first part of the *Advanced Bionics* analysis, we address “whether the same or substantially the same art . . . w[as] previously

presented to the Office.” *Advanced Bionics*, 7–8 (stating that “[p]reviously presented art includes . . . art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS)”). Patent Owner contends

All Grounds in the Petition rely on one of two primary references: Perrett or Dohil2009. These references are identical to or substantially the same as (and cumulative of) references that were considered during the prosecution of the ’061 patent, as well as the ’071 and ’961 patents. The third Ground relies on secondary reference Venkatesh, which is also identical to or substantially the same as (and cumulative of) references that were considered during the prosecution of the ’061 patent and related applications. Petitioner’s arguments are also cumulative of the Examiner’s arguments made during prosecution of the ’061 patent and related applications.

Prelim. Resp. 8.

More specifically, Patent Owner argues that Perrett was considered and relied on by the Examiner during prosecution of the ’061 patent, in combination with other prior art, in rejecting the claims. *Id.* at 9 (citing Ex. 1056, 160–164 (prosecution history)). Patent Owner further argues that “Petitioner’s arguments [here] based on Perrett overlap with arguments previously considered by the Examiner,” identifying that the Examiner cited Perrett as teaching an ODT with a corticosteroid (at claimed dosages) to treat esophageal inflammation (and also, particle size of 1–50 μm leads to uniform adsorption of the drug; although the Examiner cited another reference, Ramalho, for teaching the bulk of the claim limitations). Patent Owner argues that Petitioner relies upon Perrett similarly here. *Id.* at 10. Patent Owner also points out that Perrett, in the form of an identical disclosure in WO2011/041509 (Ex. 1063), is cited and (allegedly) distinguished from the invention in the ’061 patent’s Specification. *Id.* at 11 (citing Ex. 1001, 3:5–22).

Patent Owner also points to the prosecution history of the “grandparent” patent to the ’061 patent, i.e., US 10,471,071 B2 (“the ’071 patent”), and argues that Perrett is merely cumulative of prior art and the related arguments presented by the Examiner during its prosecution. Prelim. Resp. 12 (citing *Becton, Dickinson*, at 23; *Johnson & Johnson Surgical Vision, Inc. v. Alcon, Inc.*, IPR2021-00899, Paper 16 at 2 (PTAB Nov. 9, 2021); *Microsoft Corp. v. IPA Techs., Inc.*, IPR2019-00839, Paper 9 at 13–18 (PTAB Nov. 8, 2019); *Cultec, Inc. v. Stormtech LLC*, IPR2017-00777, Paper 7 at 8–11, 13 (PTAB Aug. 22, 2017) (informative)—(each supporting the position that earlier, related applications’ prosecution record and prior art applied therein may be relevant to our analysis under 35 U.S.C. § 325(d)). According to Patent Owner, “[d]uring prosecution of the ’071 patent, the Examiner relied on Perrett for the disclosure of an ODT comprising a corticosteroid blended with microgranules of an excipient which also serves as a carrier. Ex. 1068, 85.” *Id.* at 13.

In each of the ’061 and ’071 patents, Patent Owner overcame the Examiner’s rejections over Perrett. *Id.* at 11, 13 (citing Ex. 1068, 24, 38, 57).

Patent Owner also argues that

Dohil2009 is identical to and thus cumulative of U.S. Publication No. 2009/0191275 to Dohil et al., which was considered during prosecution of the ’061 patent. Ex. 1056, 121. Similarly, Venkatesh is identical to and thus cumulative of U.S. Publication No. 2005/0232988 to Venkatesh et al.,

which was also considered during the prosecution of the '061 patent. Ex. 1056, 121.⁷

Prelim. Resp. 18.

These references were cited in an IDS and they appear on the face of the '061 patent. *Id.* (citing Ex. 1001, code (56); Ex. 1056, 54). Patent Owner argues that citation in an IDS during prosecution is consideration of the prior art and a reason the Board has denied institution under § 325(d). *Id.* at 18–20 (citing numerous PTAB decisions). Further, Patent Owner argues that Venkatesh was cited in the '061 patent's Specification itself. *Id.* at 20.

Petitioner acknowledges that “Perrett, Dohil2009, and Venkatesh were submitted to the USPTO during prosecution of the '061 patent” (citing Ex. 1001, 1, 2) and that “Venkatesh is cited in the '061 patent specification” (citing Ex. 1001, 10:29–33). Pet. 74. As pointed out by Patent Owner, Petitioner argues that none of Perrett, Dohil2009, and Venkatesh were relied upon by the Examiner during prosecution “as a primary reference to reject the claims,” and the Examiner instead focused on a reference called “Ramalho” (US 2006/0051414). *Id.* We understand Petitioner's point to be that the asserted prior art here was not considered by the Examiner during prosecution in the same fashion as it is asserted here by Petitioner and “the arguments presented herein differ substantially from those presented during examination of the '061 patent.” *Id.* at 75. Petitioner acknowledges that

⁷ Why Patent Owner asserts Dohil2009 and Venkatesh are “identical and thus cumulative” of or “counterparts” to the identified patent application publications is confusing because the identified publications are the very references asserted by Petitioner. *See* Pet. 15–16, 40–73; Ex. 1020; Ex. 1058.

Perrett was applied as a “primary anticipation and obviousness reference” during the prosecution of the grandparent ’071 patent. *Id.*

Considering the facts and allegations above, we find there is no question that “the same or substantially the same art previously was presented to the Office.” *Advanced Bionics*, Paper 6 at 7–8 (“[p]reviously presented art includes . . . art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS)”). Each of Perrett, Dohil2009, and Venkatesh is listed on the face of the ’061 patent as having been submitted and considered by the Examiner. Ex. 1001, code (56) (page 2 first column). Thus, in view of the unique record before us, we proceed to part two of the *Advanced Bionics* analysis.

2. Whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims

Under the second part of the *Advanced Bionics* framework, we consider “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics*, Paper 6 at 8. “An example of a material error may include misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims.” *Id.* at 8 n.9. We evaluate *Becton*, *Dickinson* factors (c), (e), and (f) as a part of this analysis to determine whether Petitioner has demonstrated material error. *Id.* at 10. Those factors are:

- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; . . .
- (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 the prior art or arguments.

Becton, Dickinson, Paper 8 at 17–18.

Regarding Perrett, Patent Owner argues that Petitioner’s position that Perrett was not a “primary reference” during prosecution of the ’061 patent is a “mistaken assumption” as to the proper analysis under *Advanced Bionics*, part 2, because it is merely a conclusory position, and it is not disputed that Perrett was applied as a “primary reference” in the prosecution of the *grandparent* ’071 patent. Prelim. Resp. 14–15. Patent Owner also argues that whether or not the Examiner in the ’061 patent had access to an EPO decision concerning a related EPO patent (EP3041476, *see* Ex. 1062) is irrelevant to this inquiry because the claims of that case and those here are not the same. *Id.* at 15–17 (Patent Owner’s claim chart comparing and contrasting challenged claim 1 here with claim 1 of the EPO patent).

Regarding Dohil2009 and Venkatesh, Patent Owner again argues that Petitioner’s mere conclusion that these were not used as “primary references” or cited in a rejection in addressing the claims’ patentability during prosecution is not an identified error. On this second point, Patent Owner argues that a rejection is not required and consideration as evidenced by an IDS is all that is needed to show the claims were allowed over the asserted references. Prelim. Resp. 21.

Petitioner does argue, as indicated by Patent Owner, that none of Perrett, Dohil2009, and Venkatesh was a primary focus of the Examiner in rejecting the claims that issued in the ’061 patent (although Perrett was asserted and relied upon in a § 103 rejection and was the primary basis for a § 102 rejection in the *grandparent* ’071 patent). Pet. 74–75. We do not

agree that whether a reference was considered a “primary” reference during prosecution is determinative under this analysis.

Petitioner also argues that, even having the presently-asserted prior art before it, the Office erred because “*Perrett and Dohil2009 each disclose the claim elements that [Patent Owner] argued were critical to distinguishing the claims from the prior art during examination, which misled the Examiner*”—Petitioner identifies Perrett and Dohil2009 as disclosing: ODTs comprising topically acting corticosteroids, such as fluticasone and budesonide; ODTs with drug particles on the micron scale; blending processes in which a micronized corticosteroid is mixed with carriers that results in it being disposed over the surface of the excipient and adsorbed onto the carrier. *Id.* at 75–76 (emphasis added) (citing, *inter alia*, Ex. 1057 ¶¶ 39, 45, 63, 66, 85, 91, claims 19, 22; Ex. 1058 ¶¶ 19, 49, 70).

Patent Owner’s “critical” prosecution argument referenced by Petitioner is found in a Response to an Office Action (and Amendment) dated September 9, 2021, filed in prosecuting the ’061 patent, where Patent Owner argued that the prior art asserted there (Ramalho and Perrett and two other references) disclosed “no indication that the [corticosteroid] was adsorbed to the disintegrating agent (which the Examiner equates with the pharmaceutically acceptable carrier), as required by the pending claims,” and Perrett “provide[d] no guidance on formulating an [orally disintegrating tablet] in order to enhance exposure of a topically active drug (such as a corticosteroid).” Ex. 1056, 103–113; *see also* Ex. 1068, 74 (Patent Owner arguing, in prosecuting the grandparent ’071 patent, that “Perrett does not teach or suggest a corticosteroid adsorbed onto a pharmaceutically acceptable carrier as required by the present claims”).

Petitioner also argues that the Office did not have the benefit of the EPO decision of record here concerning the related EPO patent with a claim similar (but not identical) to those challenged here, where the EPO tribunal found Perrett discloses “all the claim limitations, including topically acting corticosteroids and the adsorption of such corticosteroids onto a pharmaceutical carrier.” Pet. 76 (citing Ex. 1062, 17–19, 23).

Petitioner argues that the Office erred in its understanding and application of Perrett during the prosecution of the '061 patent and in the prosecution of its grandparent '071 patent because the Examiner (the same Examiner handled each prosecution) ultimately concluded in each instance that Perrett failed to disclose the respective *adsorbed* claim limitation (i.e., “a topically acting corticosteroid . . . adsorbed onto a pharmaceutically acceptable carrier” in the '061 patent’s claim 1, and “a topically acting corticosteroid . . . adsorbed onto a pharmaceutically acceptable carrier” in the then-pending '071 patent). *See* Prelim. Reply 1–3; Ex. 1001, 31:28–41 (claim 1); Ex. 1068, 65 (claim 1 of the then-pending '071 patent).

Petitioner points to its own arguments and evidence on this issue as presented in the Petition. Prelim. Reply 1–3 (citing Pet. 20–24, citing Ex. 1001, 7:28–38, 10:5–8; Ex. 1020 ¶ 15, 21; Ex. 1057 ¶¶ 13, 19, 24, 39, 42, 45, 51–52, 63, 66–67, 89–91, claims 19, 22; Ex. 1054, 35; Ex. 1055, 383; Ex. 1070 ¶¶ 131–145). Petitioner’s first point is that the particle size and component mixing disclosed by Perrett would necessarily result in “some adsorption,” contrary to the statements and conclusions made during prosecution. Pet. 21–22.

Moreover, also contrary to what was determined by the Office during prosecution, Petitioner secondly argues that “Perrett expressly discloses and

claims [orally disintegrating tablets] 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” (as the OTDs of Perrett are argued to be manufactured similarly to the description in the ’061 patent to achieve adsorption—*see* Ex. 1001, 10:5–8 (mixing blend for adsorption). Pet. 22–23 (citing Ex. 1057 ¶ 63, claims 19, 22).

Our review of Perrett confirms it discloses OTDs where the micronized “corticosteroid [is] disposed on the surface of the adhesive agent” and the micronized “corticosteroid is disposed over the surface of an excipient” (our understanding is that an “adhesive agent” and an “excipient” can be considered a pharmaceutically acceptable carrier for the drug). *See* Ex. 1057, claims 19, 22; *see also* Ex. 1070 ¶¶ 102, 114, 134, 145 (Dr. Parr equating the pharmaceutically acceptable adhesive agent and excipient with a carrier); *cf.* Ex. 2001 ¶ 22 (Dr. Davies testifying that Dr. Parr did not conclude adhesive agents are carriers). Perrett states that “[i]n certain embodiments . . . the corticosteroid and the adhesive agent are intimately associated” where the “corticosteroid [is] surrounded or encapsulated by the adhesive agent,” or the “corticosteroid [is] disposed on the surface of the adhesive agent,” or the “corticosteroid [is] mixed or granulated with the adhesive agent,” and then follows these statements by referring to the purpose of so forming a tablet, i.e., topical administration of the drug. Ex. 1057 ¶¶ 63–64.

This evidence supports the conclusion that the Office incorrectly analyzed Perrett during prosecution. The Examiner overlooked relevant disclosure of the reference as it related to the pending claims that materially impacted patentability.

Petitioner also points to the EPO (Opposition Division) decision as evidence of the Office's error, where the foreign tribunal assessed similar (not identical) claim language ("wherein the corticosteroid . . . particles are adsorbed onto the pharmaceutically acceptable carrier") of Patent No. "EP-B-3 041 476" (Ex. 1061) in view of the PCT-equivalent of Perrett (i.e., WO2011/041509 (Ex. 1063), which the EPO called "D3"), and found the disputed, similar *adsorbed* limitation was taught by the Perrett-equivalent. *See* Pet. 13–15, 76; Ex. 1062, 17–19 (EPO tribunal discussing the Perrett-equivalent).

Of course, the Board is not bound by the EPO tribunal's decision on a separate foreign patent and, as Patent Owner points out, the claims here and in that proceeding are not identical. But, the claims considered at the EPO and here are similar and share a key limitation (adsorbed onto a pharmaceutically acceptable carrier) as noted above. Thus, the EPO tribunal's determinations are relevant evidence here.

What the EPO determined was that: (1) Perrett's disclosed process "lead[s] implicitly to at least some adsorption"; (2) the process's sinter bridges, agglomeration, and microgranules "lead[] to at least some adsorption of the drug on the carrier"; (3) adsorption is not a digital phenomenon and entirely present or absent, but there may be many different degrees that are still considered adsorption; and (4) the mixing and milling steps of Perrett lead to a type of adsorption that was covered by the claim limitation. Ex. 1062, 17–18. We agree, preliminarily, with the EPO's decision and find this evidence supports Petitioner's contention that the Office erred in analyzing Perrett in view of the similar claim limitations here.

Based on the facts and allegations noted above, we find that Petitioner has pointed out sufficiently how the Office erred in its evaluation of the asserted prior art, primarily Perrett; and we find that additional evidence and facts presented in the Petition, for example the EPO tribunal determination and its underlying facts, warrant reconsideration of the prior art or arguments. *See Becton, Dickinson*, Paper 8 at 17–18. Therefore, for the reasons above, we conclude on this record that Petitioner is correct that the Office materially erred in evaluating Perrett.

3. Summary

For the reasons discussed above, we decline to exercise our discretion under 35 U.S.C. § 325(d) to deny the Petition.

B. LEGAL STANDARDS ON PATENTABILITY

“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) (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).

An *inter partes* review may be instituted if the information presented by a petitioner in the petition, in view of the patent owner’s preliminary response and the preliminary record, shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314.

The Supreme Court, in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* (383 U.S. at 17–18) that are applied in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103(a) as follows: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art;⁸ and (4) considering objective evidence indicating obviousness or non-obviousness.⁹ *KSR*, 550 U.S. at 406.

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 416. “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious,” the answer depends on “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at 417.

C. ORDINARY LEVEL OF SKILL IN THE ART

Petitioner contends:

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

⁸ See *infra* Section II.C.

⁹ At this stage of the proceeding, there is no evidence of objective indicia of obviousness or non-obviousness.

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.

Pet. 5.

At this stage of the proceeding, Patent Owner neither contests Petitioner's proposed definition of the ordinarily skilled artisan nor provides an alternative definition. *See generally* Prelim. Resp.

For the purposes of this Decision, we accept and use Petitioner's proposed, and unopposed, definition of the ordinarily skilled artisan. It appears that Petitioner's proposed definition comports with the high level of skill in the art reflected in the prior art of record and the '061 patent, itself. *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)).

D. CLAIM CONSTRUCTION

The Board interprets claim terms in an *inter partes* review using the same claim construction standard that is used to construe patent claims in a civil action in federal district court. 37 C.F.R. § 42.100(b). In construing claims, district courts and the Board here, by default, give claim terms their ordinary and customary meaning, which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Should claim terms require express construction, sources for claim interpretation include "the words of the claims themselves, the remainder of the specification, the prosecution history [i.e., the intrinsic evidence], and

extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Id.* at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). “[T]he claims themselves [may] provide substantial guidance as to the meaning of particular claim terms.” *Id.* However, the claims “do not stand alone,” but are part of “‘a fully integrated written instrument’ . . . consisting principally of a specification that concludes with the claims,” and, therefore, the claims are “read in view of the specification.” *Id.* at 1315 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978–79 (Fed. Cir. 1995) (en banc)). Any special definition for a claim term must be set forth in the specification “with reasonable clarity, deliberateness, and precision.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Without such a special definition, however, limitations may not be read from the specification into the claims. *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Our claim construction positions herein are preliminary. Further argument by the parties is permitted (but, should be explicitly made and set forth in a designated section of briefing).

Petitioner asserts that the claim language “orally disintegrating tablet” / “orally dispersing tablet” / “ODT,” “sugar alcohols,” “saccharide,” “about,” “rapidly dispersing microgranule,” and “adsorbed onto a

pharmaceutically acceptable carrier,” should be addressed for claim construction purposes. Pet. 16–19.

Patent Owner asserts that the claim language “rapidly disintegrating microgranules,” and “adsorbed onto a pharmaceutically acceptable carrier” should be addressed for claim construction purposes. Prelim. Resp. 24–29.

We address these terms below.

1. “orally disintegrating tablet” / “orally dispersing tablet” / “ODT”

The language “orally disintegrating tablet” is part of every claim of the ’061 patent, and the terms “orally dispersing tablet” and “ODT” are used in the Specification. Ex. 1001, 31:28–34:25 (claims).

Petitioner identifies that this language is defined in the Specification and that it is “equivalent to [the definition] adopted by the FDA,” but Petitioner does not specifically request any interpretation of the language. Pet. 17.

Patent Owner makes no mention of this claim language having any specific meaning or needing construction. See Prelim. Resp. 24–29.

“When the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term.” *Multiform Dessicants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998). The Specification expressly states that “[t]he terms ‘orally disintegrating tablet’, ‘orally dispersing tablet’, or ‘ODT’ refer to a solid dosage form of the present invention, which disintegrates rapidly in the oral cavity of a patient after administration, without chewing.” Ex. 1001, 5:12–15.

At this stage of the proceeding, we interpret the language “orally disintegrating tablet” / “orally dispersing tablet” / “ODT” to have the meaning as expressly set forth in the Specification, as noted above.

2. “sugar alcohol”

The term “sugar alcohol” appears in claims 12, 13, 15, 16, and 24–27. Ex. 1001, 31:28–34:25 (claims).

Petitioner asserts that this term is defined in the Specification and refer[s] 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.

Pet. 17.

Patent Owner makes no mention of this claim language having any specific meaning or requiring construction. *See* Prelim. Resp. 24–29.

We do not agree with Petitioner that the Specification expressly defines the term “sugar alcohol,” based on the specific language quoted above. At this stage of the proceeding, we find it unnecessary to expressly interpret this claim language.

3. “saccharide”

The language “saccharide” appears in claims 12, 13, 15, 16, and 24–27. Ex. 1001, 31:28–34:25 (claims).

Petitioner argues “[t]he ’061 patent states that ‘[t]he term ‘saccharide’ is synonymous with the term ‘sugars’ [and] includes monosaccharides such as glucose, fructose, the [*sic*] lactose, and ribose and disaccharides such as

sucrose, lactose, maltose, trehalose, and cellobiose.’ EX1001 9:36-40.”

Pet. 17.

Patent Owner makes no mention of this claim language having any specific meaning or requiring construction. *See* Prelim. Resp. 24–29.

We do not agree with Petitioner that the Specification expressly defines the term “saccharide,” based on the specific language quoted above. At this stage of the proceeding, we find it unnecessary to expressly interpret this claim language.

4. “about”

The term “about” appears in claims 1, 5, 8–11, 16–22, 27, and 28. Ex. 1001, 31:28–34:25 (claims).

Petitioner argues:

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.

Pet. 17–18.

Patent Owner makes no mention of this claim language having any specific meaning or requiring construction. *See* Prelim. Resp. 24–29.

Although the quote above appears to be a reasonable way to interpret and is informative as to the breadth of “about,” we do not agree with Petitioner that the Specification expressly defines the term “about,” based on the specific language quoted above. At this stage of the proceeding, we find it unnecessary to expressly interpret this claim language.

5. “rapidly dispersing microgranule”

The term “rapidly dispersing microgranule” appears in claims 12, 16, 24, and 27. Ex. 1001, 31:28–34:25 (claims).

Petitioner states:

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.

Pet. 18.

Patent Owner states “[w]ith regard to ‘rapidly disintegrating microgranules,’ Patent Owner construes this term to have its plain and ordinary meaning, which requires no construction, and reserves the right to respond to any proposed construction by Petitioner. Pet., 18.” Prelim. Resp. 24.

At this stage of the proceeding, we find it unnecessary to expressly interpret this claim language.

6. “adsorbed onto a pharmaceutically acceptable carrier”

The term “adsorbed onto a pharmaceutically acceptable carrier” is recited by claim 1 (and recited in a similar way by claim 30); and the term “adsorbed” is recited by claim 19. Ex. 1001, 31:28–34:25 (claims).

Petitioner asserts that “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.’” Pet. 18–19 (citing Ex. 1001; Ex. 1054, 35; Ex. 1055, 380; Ex. 1056; Ex. 1060, 41; Ex. 1070 ¶¶ 119–122).

Patent Owner argues that Petitioner’s proposed definition of this term “does not reflect the ordinary usage of the term.” Prelim. Resp. 24. Patent Owner “proposes ‘adsorbed onto a pharmaceutically acceptable carrier’ to mean ‘the adhesion of the corticosteroid onto the surface of a pharmaceutically acceptable carrier.’” *Id.* at 24–29 (citing Ex. 1001, 3:36–37, 3:61–65, 4:4–15, 10:5–8, 13:3–61; Ex. 1054, 34; Ex. 1055, 380; Ex. 1057 ¶¶ 17, 63, claims 19, 22; Ex. 1060, 41; Ex. 2001 ¶¶ 71–75, 79–81, 83; Ex. 2002, 18, 361).

In response to Patent Owner’s position, Petitioner argues it is “overly narrow” because, as evidenced by the EPO tribunal’s decision on the related foreign patent, “adsorbed is ‘broad and covers different degrees and mechanisms of adsorption.’” Prelim. Reply 5 (citing Ex. 1062, 15–18).

The dispute here concerns the meaning of “adsorbed” (or adsorption). The ’061 patent uses the term repeatedly, but never defines it, which supports the contention that there was a known, ordinary and customary meaning for the term of which those of ordinary skill in the art would have been aware. For example, the ’061 patent describes, in relation to preparing the invention’s tablets, the forming of a “mixture . . . suitable for *adsorption* of the drug,” as follows:

The pharmaceutically acceptable carrier used in the mixture of the present invention is *suitable for adsorption* of the drug, it should have the properties of an excellent carrier for dry blends providing blend flowability and workability and preventing the segregation. It may concur in providing corticosteroid content uniformity. It is selected from the group consisting of microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, or amorphous magnesium aluminum silicate (commercially available as VEEGUM™ or NEUSILIN™). . . .

The presence of this carrier in admixture with the active also ensures reproducibility of preparations of the composition of the invention (in particular with the applied technology of direct tableting). In one embodiment of the present invention a low dose corticosteroid blend with the carrier showing high blend uniformity, low segregation potential and excellent flowability is disclosed. This blend is particularly suitable for producing a rapidly disintegrating diluted corticosteroid composition. In one embodiment of the invention the blend comprises fluticasone propionate **adsorbed on** silicified microcrystalline cellulose, and rapidly dispersing microgranules.

Ex. 1001, 7:28–60 (emphasis added). The '061 patent further states, “[t]he **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**.” *Id.* at 10:5–8 (emphasis added). These passages from the '061 patent discuss, but do not explain or define, adsorption, and describe blending corticosteroid and a carrier excipient into a mixture, which adsorbs the corticosteroid onto the carrier.

A scientific dictionary definition in the record for the term “adsorption” is “[t]he **surface retention** of solid, liquid, or gas molecules, atoms, or ions by a solid or liquid, as opposed to absorption, the penetration of substances into the bulk of the solid or liquid.” Ex. 1060, 41 (McGraw-Hill Dictionary of Scientific and Technical Terms, published 2003) (emphasis added). A standard dictionary definition in the record of the term “adsorption” is “the **adhesion** in an extremely thin layer of molecules (as of gases, solutes, or liquids) **to the surfaces** of solid bodies or liquids with which they are in contact.” Ex. 2002, 18 (Merriam-Webster’s Collegiate Dictionary, published 2006) (emphasis added). Each of these definitions refers to retention or adhesion of a particle to the surface of another thing.

An explanation, but not a definition, of adsorption is provided by a reference of record, Hong Wen, *Adsorption at Solid Surfaces: Pharmaceutical Applications*, Encyclopedia of PHARMACEUTICAL TECHNOLOGY 3rd ed., Vol. 1 (2008), as follows:

Adsorption could generally be classified as physical adsorption and chemical adsorption.□ Forces involved in adsorption include van der Waals force, hydrogen bonding or electrostatic force in physical adsorption, and covalent chemical bonds in chemical adsorption. Adsorption could occur between solid and solid, solid and liquid, or solid and gas. In pharmaceutical development, these adsorptions could take place during different processing stages, and affect the properties of the final products.

Ex. 1054, 34; *see also* Prelim. Reply 6 (discussing Wen).

Based on the use of the disputed language in the Specification of the '061 patent (intrinsic record) and the explanation of this language in the contemporary literature, including dictionaries and encyclopedias, as discussed above, we conclude for the purposes of this Decision that the claim language “adsorbed onto a pharmaceutically acceptable carrier” means “adhered to or retained on a surface of a pharmaceutically acceptable carrier.”

7. Summary on Claim Construction

At this stage of the proceeding, we expressly construe only the claim terms noted above. We determine that no other express construction of any claim term is necessary for purposes of rendering this Institution Decision. *See Nidec Motor Corp.*, 868 F.3d at 1017.

If either party intends to further argue claim construction at trial, they should do so in a clearly designated section of their briefing so as to expressly identify such arguments. *See, e.g.*, 37 C.F.R. § 42.104(b)(3)

(content of petition); *see also* Board’s Consolidated Trial Practice Guide (CTPG), 84 Fed. Reg. 64,280 at 46, 48–45 (Nov. 2019).¹⁰ Claim construction arguments should not be relegated to patentability arguments on the facts.

E. PETITIONER’S ASSERTED PRIOR ART

We review and summarize the relevant portions of Petitioner’s asserted prior art references below. There is currently no dispute that each constitutes prior art.

1. Perrett (Ex. 1057)

Perrett, titled “ORALLY ADMINISTERED CORTICOSTEROID COMPOSITIONS,” is the April 7, 2011 publication of U.S. Application 12/896,005, which was filed on October 1, 2010, and indicates priority to Provisional 61/247,642, filed October 1, 2009. Ex. 1057, codes (21), (22), (43), (54), (60).

Perrett discloses:

The present invention is directed to orally administered corticosteroid compositions. The present invention also provides a method for treating a condition associated with inflammation of the gastrointestinal tract in an individual. The method comprises administering to an individual in need thereof a pharmaceutical composition of the present invention.

Id. at Abstract. Perrett further states that its

invention is directed to a solid pharmaceutical composition comprising less than or equal to 20 mg of a corticosteroid, wherein the composition has no significant systemic glucocorticoid or mineralcorticoid activity after oral administration, wherein the solid pharmaceutical composition

¹⁰ Available at www.uspto.gov/TrialPracticeGuideConsolidated. Familiarity with the Trial Practice Guide is expected.

disintegrates within 60 seconds in simulated saliva when tested using the USP <701> Disintegration Test.

Id. ¶ 7. This rapid disintegration refers to the Perrett composition being an “orally disintegrating tablet,” “orally dispersing tablet,” or “ODT.” *Id.* ¶ 15. The objective of the Perrett ODT is to “provide local effects through topical contact with a diseased tissue,” such as inflammation of the esophagus, using a corticosteroid, such as budesonide or fluticasone, as examples. *Id.* ¶¶ 19, 25, 39.

The corticosteroid can be provided in the ODT in a dose from about 0.01 mg to about 90 mg. *Id.* ¶ 40. The drug particles can be microgranules of corticosteroid combined with an adhesive agent or a film-forming binder, granulated to be about 1 nm to about 300 µm in size or, for example, no larger than 30 µm, 300 µm, or 400 µm. *Id.* ¶¶ 42, 45, 66–67. The ODT can include a sugar alcohol, e.g., a saccharide, as a disintegrant. *Id.* ¶ 43. The ODT can also include a variety of other excipients, such as fillers, diluents, glidants, disintegrants, binders, lubricants, glidants, flavoring agents, taste-masking agents, carriers, dispersants, adhesive agents, antifungal agents, and antiviral agents. *Id.* ¶¶ 48–56, 62.

Perrett discloses a variety of adhesive agents including, for example, polyvinylpyrrolidone, methylcellulose, and sodium carboxymethylcellulose. *Id.* ¶ 62. Perrett discloses a variety of film-forming binders including, for example, corn starch, hydroxypropyl methylcellulose, and methylcellulose. *Id.* ¶ 69. Perrett’s ODT may include microcrystalline cellulose as a filler/diluent. *Id.* ¶ 70.

Perrett discloses:

In certain embodiments of the solid pharmaceutical compositions of the present invention, the corticosteroid and the

adhesive agent are intimately associated. In one such embodiment the solid pharmaceutical composition comprises corticosteroid surrounded or encapsulated by the adhesive agent. In another such embodiment the solid pharmaceutical composition comprises corticosteroid disposed on the surface of the adhesive agent. In still other embodiments, the solid pharmaceutical composition comprises corticosteroid mixed or granulated with the adhesive agent.

Id. ¶ 63.

Perrett discloses manufacturing an ODT by, for example:

(1) granulating crystalline corticosteroid (sized 5–50 μm) and a diluent, such as microcrystalline cellulose, with a polymeric binder; (2) granulating sugar alcohols to be no larger than 30 μm with a disintegrant; (3) blending these two blends further with excipients like flavoring agents, sweetener, microcrystalline cellulose; and (4) compressing this into tablets. *Id.* ¶ 89. The initial granulation blending can occur for about 3–5 minutes to mix ingredients. *Id.* ¶ 91.

Perrett includes a claim that recites “the corticosteroid is disposed over the surface of an excipient,” and another claim that recites “the corticosteroid is disposed on the surface of said adhesive agent.” *Id.* at claims 19, 22.

2. Dohil2009 (Ex. 1058)

Dohil2009, titled “VISCOUS BUDESONIDE FOR THE TREATMENT OF INFLAMMATORY DISEASES OF THE GASTROINTESTINAL TRACT,” is the July 30, 2009 publication of U.S. Application 12/269,693, which was filed on November 12, 2008, and indicates priority as early as November 12, 2005, whereon Provisional Application 60/735,340 was filed. Ex. 1010, codes (21), (22), (43), (54), (60), (63).

Regarding its invention, Dohil2009 states:

Provided herein are methods for preventing or alleviating the symptoms of and inflammation associated with inflammatory diseases and conditions of the gastrointestinal tract, for example, those involving the esophagus. Also provided herein are pharmaceutical compositions useful for the methods of the present invention.

Id. at Abstract.

Dohil2009 discloses treatments for inflammation conditions, such as eosinophilic esophagitis, including oral administration of a corticosteroid topically in a dissolving tablet. *Id.* ¶¶ 4, 9, 12, 19. The corticosteroid is, for example, budesonide or fluticasone propionate, and is provided with at least one excipient to deliver it to the esophagus, such as starch. *Id.* ¶¶ 12–13, 49. The corticosteroid can be provided as microparticles having a diameter less than 10 μm , at a dose of about 0.01 mg to about 20 mg (i.e., selected to be “therapeutically effective”). *Id.* ¶¶ 19, 42, 55–56. Dohil2009 discloses that, in the lozenge, capsule, or tablet embodiments, the, e.g., tablet “would dissolve rapidly in the mouth” to “then coat the esophagus.” *Id.* ¶ 62. Dohil2009 states that, in addition to the drug, the composition can contain a variety of suitable pharmaceutically acceptable excipients. *Id.* ¶ 69.

Dohil2009 discloses forming tablets by: combining corticosteroids with solid excipients, optionally grinding to a mixture, and further processing the mixture of granules by adding auxiliaries such as fillers (e.g., sugars), disintegrating agents, sweeteners, viscosity enhancers (e.g., silicon dioxide or magnesium aluminum silicate), mucoadhesive agents, binders, lubricants, solvents, flavoring agents, antioxidants, buffering agents. *Id.* ¶¶ 70–87, 92–93.

3. Venkatesh (Ex. 1020)

Venkatesh, titled “ORALLY DISINTEGRATING TABLETS AND METHODS OF MANUFACTURE,” is the October 20, 2005 published version of U.S. Application 10/827,106, which was filed on April 19, 2004. Ex. 1020, codes (21), (22), (43), (54).

Venkatesh states that its invention relates to:

A tablet that rapidly disintegrates in the oral cavity comprising a compressed blend of rapidly dispersing microgranules 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 a taste-masked microcapsule containing at least one drug, the microcapsule being prepared by granulating a pharmaceutically acceptable formulation comprising at least one drug in a therapeutically effective amount and at least one polymeric binder that improves resilience of the microgranules, wet milling the granulated mass, and microencapsulating the milled granules to provide microcapsules.

Id. at Abstract.

Venkatesh discloses that such a tablet is “orally disintegrating,” and that it does so “rapidly . . . in the buccal cavity with a smooth creamy mouthfeel,” “(no grittiness).” *Id.* ¶¶ 1–2, 15. By “rapidly disintegrate,” Venkatesh states it means “preferably less than 60 seconds.” *Id.* ¶ 16. Venkatesh discloses that it achieves such tablet properties by using milled/micronized drug particles of less than 50 µm or 25 µm or 20 µm, blended with a polymeric binder such as starch and hydroxypropyl methylcellulose. *Id.* ¶¶ 15, 18. Other potential excipients for the tablet include sugar alcohol/saccharide, a disintegrant, flavorant, colorant, and sweetener. *Id.* ¶ 18, 26–30. The active agent or drug can be “any therapeutic active agent.” *Id.* ¶ 25.

F. GROUND 1—ASSERTED OBVIOUSNESS OVER PERRETT

Under Ground 1, Petitioner asserts, that claims 1–30 would have been obvious over Perrett and, thus, are unpatentable. Pet. 2–3, 12–16, 20–40 (citing Ex. 1001, 7:28–38, 9:65–67, 10:5–8; Ex. 1005, 3; Ex. 1019, 320; Ex. 1020, Abstract, ¶¶ 2, 13, 15, 18–24, 30, 42, 89; Ex. 1054, 35, 43; Ex. 1055, 383; Ex. 1057 ¶¶ 7, 15, 19, 24–25, 27, 30, 39–55, 60, 63, 66–67, 70, 72, 77, 79–92, claims 18, 19, 22; Ex. 1061; Ex. 1062, 5, 15, 17–19, 21–24; Ex. 169, 139–140; Ex. 1070 ¶¶ 100–104, 129, 131–147, 149, 151, 153, 155–156, 158–160, 162–163, 165, 167, 170, 173, 176, 179–180, 182–183, 185, 187, 189, 191–193, 195, 215, 227, 231, 233–236, 240–241, 243–244, 246).

Patent Owner opposes Petitioner’s assertions under Ground 1. Prelim. Resp. 1–2, 4–5, 28–43 (citing Ex. 1001, 2:30–3:39, 3:61–4:15, 10:5–8, 10:51–67, 13:3–61, 14:58–15:2; Ex. 1054, 35; Ex. 1056, 46, 111–112; Ex. 1057 ¶¶ 17, 63, 91, claims 19, 22; Ex. 1062, 15; Ex. 2001 ¶¶ 44, 46–47, 83, 94–104, 109–113).

We review and summarize the parties’ positions on Ground 1 below.

1. Petitioner’s Positions

Petitioner asserts “[Patent Owner] previously disclosed and claimed ODTs containing budesonide and fluticasone with particle sizes on the micron scale in . . . Perrett,” which “is prior art to the ’061 patent, and . . . share[s] a common inventor, Gopi Venkatesh. [The] ’061 patent merely recycles the same subject matter [Patent Owner] previously disclosed in Perrett.” Pet. 2. Further,

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].

Pet. 12–13.

Petitioner maps the teachings of Perrett to the limitations of independent claim 1, as follows.

Regarding claim 1’s preamble, if it is a limitation, Petitioner asserts Perrett discloses orally disintegrating tablets (ODTs). Pet. 20 (citing Ex. 1057 ¶¶ 15, 42, 82; Ex. 1070 ¶ 129).

Regarding claim 1’s limitation requiring “a topically acting corticosteroid or pharmaceutically acceptable salt or ester thereof, adsorbed onto a pharmaceutically acceptable carrier,” Petitioner asserts that Perrett discloses its ODTs have a topically acting corticosteroid (e.g., budesonide or fluticasone propionate), which is prepared for tableting by granulating crystalline corticosteroid into microgranules of about 5–50 µm with a diluent/filler (e.g., microcrystalline cellulose) and then blending the drug particles, a filler/diluent/binder (e.g., mannitol, crospovidone, microcrystalline cellulose, starches) for 3–5 minutes. *Id.* at 20–21 (citing Ex. 1057 ¶¶ 51–52, 89–91).

Petitioner asserts that, as evidenced by the ’061 patent’s disclosure, these fillers/diluents/binders are pharmaceutically acceptable carriers. *Id.* at 21 (citing Ex. 1001, 7:28–38). Petitioner asserts that the ordinarily skilled artisan would have understood that Perrett’s process for preparing the tablet

formulation, like the '061 patent's described process, would result in at least some of the corticosteroid being adsorbed onto such a carrier, due in part to the micro-particle size of the drug and the blending of the components. *Id.* at 21–23 (citing Ex. 1001, 10:5–8 (“repeatedly mixing corticosteroid and carrier so that the blend is adsorbed onto the carrier”); Ex. 1020 ¶ 21; Ex. 1054, 35; Ex. 1055, 383; Ex. 1057 ¶¶ 45, 66–67, 89; Ex. 1070 ¶¶ 131–145). Petitioner points out that Perrett respectively claims that “the corticosteroid is disposed over the surface of an excipient” (such carriers are excipients). *Id.* at 22–23 (citing Ex. 1057 ¶ 63, claims 12, 22).

Petitioner asserts that it was known in the field that adsorbing a therapeutic onto a carrier was beneficial and advantageous because it facilitated preparation of master batches, avoided segregation, promoted homogeneity, improved uniformity in tablets, enabled fast disintegration, and increased absorption/bioavailability, which were reasons a person of ordinary skill in the art would have chosen to adsorb the corticosteroid of Perrett onto a carrier of the reference's ODTs. *Id.* at 23 (citing Ex. 1019, 320; Ex. 1054, 35, 43). Moreover, Petitioner asserts the ordinarily skilled artisan would have reasonably expected success in doing so because adsorption was a known phenomenon when particle sizes were sub-400 μm , which Perrett's corticosteroid particles are disclosed to be. *Id.* (citing Ex. 1057 ¶¶ 45, 66–67, 89; Ex. 1070 ¶¶ 146–147).

As further evidence that Perrett teaches the adsorption limitation, Petitioner cites the EPO tribunal's decision (discussed above, *see supra* Section II.A). As discussed, the EPO tribunal considered whether the PCT-equivalent of Perrett (WO 2011/041509, Ex. 1063 (called “D3” by the EPO tribunal)) taught the claim limitation of Patent Owner's European Patent EP

3041 476 B1 (Ex. 1061) reciting “wherein the corticosteroid or pharmaceutically acceptable salt, ester, or polymorph particles are adsorbed onto the pharmaceutically acceptable carrier.” Pet. 23–24 (citing Ex. 1061, Ex. 1062, 15, 17–18). The EPO tribunal found this limitation was taught by Perrett (the Euro-equivalent) because Perrett’s disclosed blending fluticasone with carriers and granulating the drug with a carrier would result in “at least some adsorption” of the corticosteroid on the carrier. *Id.*

This limitation is, at this stage of the proceeding, of paramount importance because, as discussed below, it is the focus of Patent Owner’s opposition to institution of trial.

Regarding the next limitation of claim 1, “at least one disintegrant,” Petitioner asserts it is taught by Perrett’s disclosure of a disintegrant in its ODTs. Pet. 24 (citing Ex. 1057 ¶¶ 48, 89–90; Ex. 1070 ¶ 149).

The next limitation of claim 1 requires “about 0.5 to about 10 mg” of the corticosteroid, which Petitioner asserts Perrett teaches in disclosing ODTs having 0.01–20 mg of corticosteroid, as well as exactly about 0.5 to 10 mg. *Id.* (citing Ex. 1057 ¶¶ 40–41; Ex. 1070 ¶ 151).

The penultimate limitation of claim 1 requires that the corticosteroid “has a mean particle size of ranging from about 100 nm to about 100 µm,” which Petitioner asserts is taught by Perrett in disclosing corticosteroid particle sizes of about 1 nm to about 300 µm. *Id.* at 25 (citing Ex. 1057 ¶¶ 66–67, 89; Ex. 1070 ¶ 153).

Finally, regarding claim 1’s limitation requiring that the “tablet disintegrates within 60 seconds when tested using the USP <701> method for disintegration time,” Petitioner asserts it is expressly taught by Perrett. *Id.* (citing Ex. 1057 ¶¶ 7, 30, 60; Ex. 1070 ¶¶ 155–156).

Petitioner also addresses the limitations of claims 2–30, similarly mapping the disclosure of Perrett thereto. Pet. 25–40. Because the burden upon the Petitioner under 35 U.S.C. § 314 for institution purposes is to show a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the petition, we need not address these other claims at this time. For that matter, Patent Owner does not specifically address any claim other than claim 1 in its Preliminary Response. Institution of trial, however, is for all claims and all grounds if any. *See* 37 C.F.R. § 42.108(a).

2. Patent Owner’s Positions

In opposing Petitioner’s positions on unpatentability, Patent Owner argues “the [claim] limitation of ‘a topically acting corticosteroid or pharmaceutically acceptable salt or ester thereof, adsorbed onto a pharmaceutically acceptable carrier[.]’ . . . is not disclosed in Perrett.” Prelim. Resp 31. Patent Owner argues that, even though the ’061 patent itself identifies that Perrett’s methods were intended to achieve ODT content uniformity (a reason to adsorb drug onto carrier, according to Petitioner),¹¹ the reference does not recognize the issue of agglomeration, and although Perrett discloses that a corticosteroid is mixed with fillers/diluents/binders, Perrett is silent regarding adsorption of the drug onto a pharmaceutically acceptable carrier and no evidence supports that this adsorption would occur. *Id.* at 31–32, 34 (citing Ex. 1001, 2:30–3:33, 10:51–67; Ex. 2001 ¶¶ 94–97). Patent Owner argues that, for the claimed adsorption to occur, the

¹¹ *See* Pet. 33 (citing Ex. 1054, 35, 43 (identifying a benefit of adsorption of drugs onto carriers being achieving “excellent homogeneity . . . and . . . content uniformity of tablets” “during the mixing process.”)).

“corticosteroid must be mixed with the pharmaceutically acceptable carrier for at least ten minutes,” which is a mixing duration not disclosed in Perrett. *Id.* at 34 (citing Ex. 1001, 4:4–15, 13:3–61; Ex. 2001 ¶¶ 98–99). Patent Owner argues that Perrett does not disclose small enough corticosteroid particle sizes for adsorption onto a carrier (i.e., no larger than 100 μm). *Id.* at 34–35 (citing Ex. 2001 ¶¶ 100–101).

Patent Owner acknowledges that Perrett discloses (and claims) corticosteroid dispersed over the surface of an adhesive agent (Patent Owner does not, however, mention Perrett also claims similar relationship more generally with “an excipient”), but argues that “[n]either Petitioner nor its expert [Dr. Parr] argue that adhesive agents are pharmaceutically acceptable carriers.” Prelim. Resp. 36 (citing Ex. 2001 ¶ 104).

Patent Owner argues the “adsorption” clause of the claims is a “missing limitation” not discussed in the asserted prior art, which cannot be gap-filled by common knowledge. *Id.* at 37. Patent Owner argues that the asserted supporting evidence (e.g., Wen, Ex. 1054), for that matter, does not establish that adsorption necessarily occurs in Perrett’s process because it identifies that “many factors” may play a role in the phenomenon. *Id.* at 36–37.

Regarding Petitioner’s evidence of the EPO tribunal’s decision relating to a similar “adsorbed” limitation, Patent Owner argues that there is no support that there might be “different degrees and mechanisms of adsorption,” as determined by the EPO. *Id.* at 38–39 (citing Ex. 1062, 15).

Patent Owner also challenges Petitioner’s contention that there was “motivation,” i.e., a reason with rational underpinning, to adsorb Perrett’s corticosteroid onto a carrier because it was beneficial or advantageous in

several ways. *Id.* at 39. Patent Owner points to the '061 patent's discussion of Perrett, asserting it "calls out Perrett for not adsorbing the corticosteroid to the carrier." *Id.* (citing Ex. 1001, 3:5–18). Patent Owner argues "the '061 patent describes an otherwise unrecognized problem in Perrett and the prior art, which is the agglomeration of drug particles during the preparation of ODTs that prevents exposure of the topical corticosteroid to the inflamed esophageal tissue making prior art ODTs less efficacious," and describes the solution—adsorbing. *Id.* at 40.

3. Analysis

We have considered Petitioner's assertions, Patent Owner's arguments, and the evidence of record, and find that, on the current record, Petitioner has sufficiently mapped the limitations/steps of the claims to the disclosure of Perrett, identified a reason with rational underpinning why the ordinarily skilled artisan would have modified (or simply followed) Perrett's teachings, and identified that there would have been a reasonable expectation of success. Petitioner reasonably asserts, with supporting evidence, that if Perrett's disclosed methods are followed, using Perrett's disclosed materials, it would have been reasonably expected to achieve the invention of the '061 patent's independent claim 1. Based on the evidence presented at this stage of the proceeding, Petitioner has shown under Ground 1 that there is a reasonable likelihood that at least one of the '061 patent's claims would have been obvious over Perrett.

We make the following *preliminary* determinations, none of which constitutes a final determination of any fact or the issue of patentability.

Perrett teaches an ODT having a topically acting corticosteroid, for example, fluticasone propionate, where the ODT disintegrates in the oral

cavity in as fast as 10 seconds or less, measured using the USP <701> Disintegration Test. *See, e.g.*, Ex. 1057 ¶¶ 7, 15, 19, 39, 59–60, 91. Perrett teaches that the corticosteroid can be provided at doses of about 0.01 mg to about 90 mg and as particles no larger than about 300 µm, even as small as 1 nm. *Id.* ¶¶ 40–41, 45, 66–67. Perrett teaches a not-insubstantial list of excipients (adhesive agents, diluents, disintegrants, coloring agents, lubricants, fillers, binders, sugar alcohols, carrier/dispersants), many of which would be classified a carrier for the corticosteroid, each of which is understood to be pharmaceutically acceptable. *See, e.g., id.* ¶¶ 42, 46, 48–56, 62. Examples of such excipients disclosed by Perrett include, *inter alia*, microcrystalline cellulose, corn starch, and colloidal silica. *See, e.g., id.* ¶¶ 46, 48–56, 89. None of this is reasonably disputed at this point.

Perrett discloses methods of manufacturing an ODT, one of which includes the first step of granulating crystalline corticosteroid having an average particle size of 5–50 µm with microcrystalline cellulose and a polymeric binder. *Id.* ¶ 89. An example suggests this initial granulating step involves blending the components for about 3–5 minutes. *Id.* ¶ 91. The granulated blend of corticosteroid and binder is then blended with another mix of granulated sugar alcohols and disintegrant, and also with a flavoring agent, sweetener, more microcrystalline cellulose, and more disintegrant, which is thereafter compressed into tablets. *Id.* ¶ 89. These facts are also not reasonably disputed at this point.

This process of Perrett may be compared with that described in the '061 patent as resulting in corticosteroid adsorbed onto a carrier. *See* Ex. 1001, 7:28–60, 10:5–27, 10:59–67, 13:5–14:2. The '061 patent explains that: (1) microcrystalline cellulose, but preferably silicified microcrystalline

cellulose, is an excipient suitable as a carrier for the corticosteroid; (2) blending the corticosteroid therewith is suitable for adsorption; (3) the corticosteroid “is typically micronized” to a “mean particle size of less than 10 μm ”; (4) repeated mixing the corticosteroid and carrier adsorbs the corticosteroid onto the carrier; (5) adsorbing the corticosteroid onto the carrier prior to blending with other excipients achieves desired uniformity and enhances the probability that the drug is exposed (6) and an initial blending of corticosteroid with silicified microcrystalline cellulose and colloidal silicon dioxide for 10 minutes is sufficient, before blending this mix with other excipients and then tableting. *Id.*; *see also id.* at 16:24–30, 17:5–10 (the initial blending of the corticosteroid and carrier(s) may be for 9–11 minutes). At this stage of the proceeding, we preliminarily find that Perrett’s and the ’061 patent’s methods of forming ODT tablets are substantially similar, at least in the first step of granulating corticosteroid particles and an excipient: the drug and drug particle sizes are similar, the excipients are similar, the blending and duration of blending is similar.

Petitioner also brings to our attention the EPO tribunal determination that Perrett’s method (blending its disclosed fluticasone propionate with a carrier for 3–5 minutes) would lead to some adsorption of the corticosteroid onto the carrier (e.g., mannitol, crospovidone, silicified microcrystalline cellulose, corn starch, or colloidal silica). *See* Ex. 1062, 17–18. The EPO tribunal determined that at least “some adsorption” would occur. “[A] prior art product that sometimes, but not always, embodies a claimed [invention] nonetheless teaches that aspect of the invention.” *Hewlett-Packard Co. v. Mustek Systems, Inc.*, 340 F.3d 1314, 1326 (Fed. Cir. 2003). We find, at this

point, that we agree with the EPO tribunal's decision and that it is supportive of Petitioner's challenges.

Based on the evidence, we preliminarily agree with Petitioner's position that claim 1, including the adsorption limitation, is taught or suggested by Perrett.

As noted above, we have considered Patent Owner's preliminary arguments, but are not persuaded that trial should not be instituted.

Concerning Patent Owner's arguments relating to Perrett's drug/carrier mixing occurring for only 3–5 minutes versus the '061 patent's disclosure of 10 minutes, we agree that the '061 patent describes blending “for 10 minutes,” maybe 11 minutes, but no longer, but the '601 patent does not state or suggest that 10 minutes is a threshold for adsorption of drug onto carrier (and such a blending duration is not claimed). What can be gleaned from the '061 patent is that 10 minutes is “a sufficiently long time.” Ex. 1001, 3:59–4:15. On the other hand, the '061 patent also suggests that it is not necessarily the *length of blending time*, but “repeated mixing corticosteroid and carrier” that leads to adsorption. Ex. 1001, 10:5–8. Finally, the '061 patent suggests that it may be the initial mixing of corticosteroid with a carrier (e.g., microcrystalline cellulose (one option)) that leads to adsorption and the desired ODT uniformity and topically presented corticosteroid, which is a step of forming an ODT that Perrett also discloses. Ex. 1001, claims 19, 30; Ex. 1057 ¶¶ 66–67, 89.

As to the other points made by Patent Owner, they are not persuasive on this record, but may be further developed at trial, if desired.

We have addressed only independent claim 1 above, but our institution is to all grounds and all claims.

G. GROUND 2 AND 3—ASSERTED OBVIOUSNESS OVER DOHIL2009
ALONE OR COMBINED WITH VENKATESH

Petitioner also presents Grounds 2 and 3, which assert that claims 1, 2, 4–11, 17–20, 22, 29, and 30 would have been obvious over Dohil2009, and claims 1–30 would have been obvious over Dohil2009 and Venkatesh, and are, therefore, unpatentable. Pet. 16, 40–73. Because we find sufficient reason to institute on Ground 1, we do not address the merits of these grounds. However, trial is instituted as to all grounds and all claims, which should all be addressed at trial. *See* 37 C.F.R. § 42.108(a).

III. CONCLUSION

On the record before us at this stage in the proceeding, Petitioner has demonstrated a reasonable likelihood of showing at trial that at least one challenged claim of the '061 patent is unpatentable under at least one ground. Accordingly, we institute an *inter partes* review of the challenged claims of the '061 patent on all grounds alleged by Petitioner. Our findings at this stage of the proceeding are preliminary. This decision does not reflect a final determination on the patentability of the claims.

ORDER

Accordingly, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review of claims 1–30 of the '061 patent, in accordance with each ground of challenge in the Petition, is hereby *instituted*; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '061 patent will commence on the entry date of this Decision, and notice is hereby given of the institution of a trial.

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