

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. FALK PHARMA GMBH,
Petitioner,

v.

ELLODI PHARMACEUTICALS, L.P.,
Patent Owner.

Case No. IPR2024-01197
Patent No. 8,771,729 B2

PATENT OWNER'S PRELIMINARY RESPONSE
37 C.F.R. § 42.107

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List of Patent Owner's Exhibits

Exhibit No.	Description
2001	U.S. Patent Application Publication No. US 2009/0191275 A1 to Dohil, et al. ("Dohil 2009")
2002	U.S. Patent Application Publication No. US 2009/0169620 A1 to Venkatesh, et al. ("Venkatesh 2009")
2003	U.S. Patent Application Publication No. US 2009/0131386 A1 to Phillips ("Phillips")
2004	Prosecution History for U.S. Patent No. 10,632,069

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.107(a), Ellodi Pharmaceuticals, L.P. (“Patent Owner” or “Ellodi”) submits this Preliminary Response to the Petition for *Inter Partes* Review (“Petition” or “Pet.”) of claims 1-40 (the “Challenged Claims”) of U.S. Patent No. 8,771,729 B2 (“the ’729 patent”) filed by Dr. Falk Pharma GmbH (“Petitioner”) on July 22, 2024. The Board mailed its notice of filing date accorded to the Petition on July 29, 2024 (Paper 3). This Preliminary Response is timely filed.

It is Petitioner’s burden to show—by the Petition and its supporting evidence—that there is a reasonable likelihood that at least one of the Challenged Claims is unpatentable. 37 C.F.R. § 42.108(c); *see also* 35 U.S.C. § 314. Petitioner fails to meet its burden of proof because of fatal procedural deficiencies. More specifically, Petitioner relies on references that are materially indistinct from references that formed the basis of a rejection and that were overcome during prosecution of the ’729 patent. Moreover, Petitioner not only fails to identify any flaws in the Examiner’s analysis of the materially indistinct references, it expressly ratifies it by making the same arguments as the Examiner during prosecution with substantially the same art.

II. BACKGROUND

A. The ’729 Patent (Ex. 1001)

The ’729 patent is directed to orally disintegrating solid pharmaceutical

compositions containing a topically administered corticosteroid for the treatment of conditions associated with inflammation of the upper portion of the gastrointestinal tract. (Ex. 1001, 1:11-24.) One condition, eosinophilic esophagitis (EoE), is an inflammatory condition of the esophagus. (Ex. 1001, 1:24-26.) Prior treatments for EoE included corticosteroid formulations designed for inhalation that instead applied to the back of the throat, (Ex. 1001, 1:30-41), as well as oral administration of systemically active corticosteroids (Ex. 1001, 1:42-50.) These treatments posed undesirable side effects, including candidiasis infection and suppression of immune function. (*Id.*) The orally disintegrating solid pharmaceutical composition claimed in the '729 patent solves these problems by topically administering a corticosteroid that has no significant systemic glucocorticoid or mineralocorticoid activity after oral administration (i.e. a corticosteroid that has no significant systemic activity) to the upper gastrointestinal tract, including the esophagus, because it disintegrates within 60 seconds. (Ex. 1001, 1:56-67.) This mitigates the undesirable side effects of traditional EoE treatments. (Ex. 1001, 1:56-67, 3:62-66.)

B. Prosecution of the '729 Patent (Ex. 1031)

The '729 patent issued from U.S. Patent Application No. 12/896,005 (“the '005 Application”). (Ex. 1001, cover.) Patent Owner filed the '005 Application on October 1, 2010. (Ex. 1001, cover.) During prosecution, the Examiner rejected the as-filed claims for obviousness over US 2009/0169620 (“Venkatesh 2009”) in view

of US 2005/0009848 (“Brantl”) and Venkatesh 2009 in view of Brantl, and in further view of US 2007/0059361 (“Rawas-Qalaji”). (Ex. 1031, 85-96.) The Examiner argued that Venkatesh 2009 teaches a solid pharmaceutical composition in the form of an orally disintegrating tablet (ODT) that disintegrates within 60 seconds or less and Brantl teaches the administration of topical corticosteroids. (*Id.*) Patent Owner responded to the Examiner’s rejection, asserting that Venkatesh 2009 does not teach the topical administration of corticosteroids and, in Brantl, corticosteroids are optional. (Ex. 1031, 71-76.)

The Examiner subsequently withdrew this rejection but made another rejection for obviousness over US 2009/0131386 (“Phillips”) in view of Venkatesh 2009 and Rawas-Qalaji. (Ex. 1031, 42-54.) The Examiner argued that Phillips teaches solid pharmaceutical compositions for the treatment of inflammation of the gastrointestinal tract. (*Id.*) Patent Owner responded to the Office Action, arguing that Phillips is directed primarily to liquid dosage forms and does not teach an orally disintegrating solid pharmaceutical composition that can disintegrate within 60 seconds. (Ex. 1031, 30-34.) Patent Owner also amended claim 1 to recite an orally disintegrating solid pharmaceutical composition with the disintegration time and US <701> Disintegration Test. (Ex. 1031, 25.) The Examiner withdrew the rejection based on Phillips and allowed the claims, noting that Phillips did not disclose the disintegration time. (Ex. 1031, 19.)

III. THE BOARD SHOULD EXERCISE ITS DISCRETION TO DENY INSTITUTION UNDER 325(D)

It is well-settled that the Board has discretion whether to institute an *inter partes* review. 35 U.S.C. §§ 314(a), 325(d). When exercising this discretion under § 325(d), the Board “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.” 35 U.S.C. § 325(d).

The Board uses a two-part framework when determining whether to exercise its discretion under § 325(d). The first question asks: “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, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential). If either condition of the first part of the framework is satisfied, the second question asks: “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims.” *Id.*

This analysis “reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9. As part of this deference, when applying the second part of the framework, “[i]f 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.” *Id.* In this way, the Board’s standard for determining whether the Office materially erred in its evaluation of the art and arguments is akin to the substantial evidence standard used in appellate review. *See In re Peterson*, 315 F.3d 1325, 1328 (Fed. Cir. 2003) (“Under the substantial evidence standard, we affirm the Board’s factual determinations if they are based upon such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.”) (internal quotation marks and citation omitted).

The two-part framework articulated in *Advanced Bionics* employs the factors provided in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017) (precedential as to § III.C.5, first paragraph). These factors include:

- (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;

- (d) the extent of the overlap between the arguments made during examination and the manner in which a petitioner relies on the prior art or a patent owner distinguishes the prior art;
- (e) whether a petitioner has pointed out sufficiently how the Office erred in evaluating 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, IPR2017-01586, Paper 8 at 17-18. *Becton* factors (a), (b), and (d) are relevant to the first question of whether the same or substantially the same art or arguments were previously presented. *Advanced Bionics*, IPR2019-01469, Paper 6 at 9-10. *Becton* factors (c), (e), and (f) relate to the second question of “whether the petitioner has demonstrated a material error by the Office.” *Id.* at 10-11.

In this case, Petitioner presents the same or substantially the same art and arguments that were previously before the Office (and successfully overcome) and fails to make a showing of material error. All Grounds in the Petition rely on one of two primary references: Dohil or Grother. These references are identical to or substantially the same as (and cumulative of) references that were considered during the prosecution of the '729 patent and three patents claiming corticosteroid-containing ODTs that relate to the '729 patent. (U.S. Patent Nos. 10,632,069, 11,246,828, and 11,266,598.) Three of the four Grounds in the Petition rely on one

of two secondary references: Venkatesh or FDA Guidance. These references are also identical to or substantially the same as (and cumulative of) references that were considered during the prosecution of the '729 patent and related applications. Petitioner's arguments are also cumulative of the Examiner's arguments made during prosecution of the '729 patent and related applications. Despite this overlap, Petitioner makes no attempt to establish that the Examiner "erred in evaluating the art or arguments" previously presented to the Office, as has "generally [been] required" for such cumulative petitions to be instituted under § 325(d). *Advanced Bionics*, IPR2019-01469, Paper 6 at 8. Accordingly, the Board should exercise its discretion not to institute *inter partes* review.

A. Grounds 1 and 3 rely on the same or substantially the same art and arguments that were considered by the Office without error

In Grounds 1 and 3, Petitioner relies on Dohil and Venkatesh. The Board should deny institution because (i) Dohil is substantially similar to Phillips (Ex. 2003) that was before the Examiner, (ii) Dohil is identical to Dohil 2009 (Ex. 2001) that was before the Examiner in related patent applications, (iii) Venkatesh is substantially similar to Venkatesh 2009 (Ex. 2002) that was before the Examiner, and (iv) the disclosures of Dohil and Venkatesh are substantially the same and cumulative of the art and arguments previously considered by the Office.

1. Part 1 (*Becton, Dickinson* Factors (a), (b), (d)): Petitioner's Reliance and Arguments Based on Dohil are Substantially the Same as Those Considered During Prosecution

During prosecution of the '729 patent, the Examiner rejected the then-pending claims after concluding that they were anticipated or rendered obvious by the Phillips reference (Ex. 1031, 42-54.) Patent Owner was able to overcome the Examiner's rejection because Phillips does not disclose a solid dosage form that disintegrates within 60 seconds, and neither does Dohil. (Ex. 1031, 19, 30-34.)

Phillips is directed to pharmaceutical compositions for the treatment of inflammation of the gastrointestinal tract (Ex. 2003, Abstract.) Phillips composition comprises a corticosteroid from about 100 ug to about 20 mg. (Ex. 2003, ¶¶[0008], [0059].) Most relevantly, Phillips teaches that the composition can be formulated into solid dosage forms and administered locally. (Ex. 2003, ¶[0083].) In particular, Phillips teaches that the dosage form can be "tablets, pills, dragees, capsules ... for oral ingestion by a patient to be treated." (Ex. 2003, ¶[0084].) These solid dosage forms are formulated such that the dosage forms substantially dissolve or disintegrate in the mouth and/or esophagus, prior to reaching the stomach. (Ex. 2003, ¶¶[0085], [0092].)

In an office action dated January 24, 2013, the Examiner rejected the claims as obvious in view of Phillips. (Ex. 1031, 42-54.) The Examiner argued that Phillips teaches that solid dosage forms containing corticosteroids can be made such that the

pharmaceutical composition interaction with the surface of the gastrointestinal tract (e.g. the mucosa and/or epithelium of a specific site of the upper gastrointestinal tract) is increased and symptoms of gastrointestinal tract inflammation is decreased. (Ex. 1031, 42-54.)

In response, Patent Owner amended claim 1 to recite that the claimed solid dosage form disintegrated within 60 seconds according to a specific test (the USP <701> Disintegration Test). (Ex. 1031, 25.) Patent Owner also argued that Phillips is directed to liquid dosage forms, with viscosity enhancing agents, and, more importantly, does not teach or suggest an orally disintegrating solid pharmaceutical composition that can disintegrate within sixty seconds. (Ex. 1031, 30-34.) Patent Owner went on to state:

Phillips also fails to recognize the difference in employing a liquid composition versus a disintegrating solid composition comprising a corticosteroid as the former provides for greater distribution and residence of the active throughout the mouth and thus broader promotion of an undesirable affect, *i.e.*, an oral yeast infection. Thus, *Phillips* provides no reason to have a rapid disintegration time, particularly one of about 60 seconds as recited in claims 1 and 27.

Thus, *Phillips*' comment that "dosage forms substantially dissolve or disintegrate in the mouth and/or esophagus" does not equate to a

suggestion that a solid composition dissolves within sixty seconds, as recited in claims 1 and 27. This is so because a dosage form can substantially dissolve or disintegrate in the mouth or esophagus in more than sixty seconds. For example, *Phillips* contains a laundry list of solid dosage forms that cannot be reasonably read as disintegrating within sixty seconds. *Phillips*' list includes capsules, which cannot reasonably disintegrate within sixty seconds because they are designed to break down enzymatically in the gastrointestinal tract, and lozenges, which are retained in the mouth for longer than sixty seconds before dissolving. Thus, despite a statement concerning the location (i.e., mouth of esophagus) of disintegration or dissolution, *Phillips* fails to disclose any particular disintegration time, and similarly fails to recognize the importance of disintegration within sixty seconds.

(Ex. 1031, 31-32 (emphasis in original)¹.)

As emphasized in Patent Owner's response, and during the Examiner-Initiated Interview, disintegration within sixty seconds is an important feature of the invention. Patent Owner pointed out that prolonged contact of corticosteroids to the mouth or throat can lead to an oral yeast infection. (Ex. 1031, 31-32, 37.) To

¹ All emphasis added unless otherwise indicated.

minimize contact with the mouth, thereby minimizing the chance of an oral yeast infection, the claims provide a composition that disintegrates within sixty seconds, decreasing both the contact between the drug and the mouth and the likelihood of developing a yeast infection. (Ex. 1031, 31-32, 37.)

The Examiner ultimately allowed the claims, finding that the disintegration time is an important limitation and providing in the Notice of Allowance that 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, the reference is silent with respect to any disintegration time.” (Ex. 1031, 19 (emphasis in original).) The Examiner found that Patent Owner had successfully rebutted any presumption of obviousness arising from Phillips’ solid dosage forms. (Ex. 1031, 19.) Patent Owner had shown the previously unrecognized importance of the claimed disintegration time for an orally disintegrating solid composition used to treat inflammation of the esophagus by demonstrating that Phillips fails to recognize the connection between the residence time of a corticosteroid in the mouth and the potential for developing yeast infections. (Ex. 1031, 31-32, 37.)

a. Dohil is cumulative of art and arguments considered during prosecution

Grounds 1 and 3 rely on primary reference Dohil alone or in combination with Venkatesh. Dohil is cumulative of the art and arguments considered and discussed by the Examiner related to Phillips.

Petitioner relies on Dohil or Dohil in combination with Venkatesh to satisfy the limitation of solid pharmaceutical compositions containing corticosteroids that dissolve rapidly in the mouth. Dohil, however, like Phillips, is primarily directed to liquid compositions and the only formulations tested and compositions exemplified in Dohil are liquid compositions. (Ex. 1002 at ¶¶[0021], [0030], [0046]-[0070].) Both Dohil and Phillips only mention solid dosage forms in passing, and neither reference mentions nor discloses a solid pharmaceutical composition that disintegrates within 60 seconds. Dohil and Phillips are the same or substantially the same in the disclosures Petitioner points to:

Claim(s) for which Petitioner cites Dohil	Petitioner's Reliance on Dohil (Ex. 1002)	Phillips (Ex. 2003) Considered During Prosecution
1 [Preamble], 3, 15, 27 [Preamble]	Petitioner argues that Dohil discloses that “[b]udesonide is provided in the form of a <i>lozenge which may be dissolved in the mouth</i> , thus reaching and coating the esophagus. The lozenge or other similar tablet, capsule, or other solid, would <i>dissolve rapidly</i>	“In certain embodiments, solid oral dosage forms (e.g., <i>tablets</i> , dragee cores, capsules, push-fit capsules, soft capsules, lozenges, etc.) are formulated such that the dosage forms

	<i>in the mouth</i> or esophagus to produce a solution that can then coat the esophagus.” Dohil further discloses “[b]udesonide, in the form of <i>a dissolving tablet</i>.” (Pet. at 19, 27, 29 (citing Ex. 1002, ¶¶[0032], [0013], [0037]) (emphasis in original).)	substantially <i>dissolve or disintegrate in the mouth</i> and/or esophagus.” (Ex. 2003, ¶[0085].)
1[i], 27[i]	“In certain embodiments, <i>1-2 mg</i> or <i>2-3 mg</i> of corticosteroid per day is administered to said individual.” “<i>0-1 mg/day, 1-2 mg/day... or 5-6 mg/day</i> of... for example, Budesonide, are administered” (Pet. at 20 (citing Ex. 1002, ¶¶[0015], [0058]).)	“In some embodiments, the amount of corticosteroid (e.g., fluticasone propionate) used in a method or in a combination disclosed herein includes, by way of non-limiting example, about 100 µg to about 20 mg, 300 µg to about 4 mg, about 50 µg to about 500 mg, about 50 µg to about 200 mg, about 50 µg to about 100 mg, about 50 µg to about 50 mg, about 250 µg to about 20 mg, about 250 µg to about 15 mg, about 250 µg to about 10 mg, about <i>250 µg to about 5 mg, 250 µg to 3 mg, or 500 µg to 3 mg, or 500 µg to 2 mg, or 1 mg to 3 mg.</i>” (Ex. 2003, ¶[0059].)

1[ii], 27[ii]	Dohil discloses “[i]f desired, disintegrating agents may be added, such as the cross-linked polyvinylpyrrolidone, agar, or alginic acid or a salt thereof such as sodium alginate.” (Pet. at 21 (citing Ex. 1002, ¶[0037]) (emphasis in original).)	“Disintegrating agents are optionally added, such as the cross-linked polyvinylpyrrolidone, agar, or alginic acid or a salt thereof such as sodium alginate.” (Ex. 2003, ¶[0085].)
1[iv], 2, 27[iii]	Dohil discloses that “[t]he lozenge or other similar tablet, capsule, or other solid, would dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus.” Pet. at 23, 26 (citing Ex. 1002, ¶[0032]).)	“In specific embodiments, following oral administration of a composition described herein to the esophagus (e.g., following initial swallowing or drinking of the composition)...the corticosteroid or composition administered is present within the esophagus (e.g., as measured by gamma scintigraphy) after at least 5 seconds, 10 seconds, 15 seconds, 20 seconds, 25 seconds, 30 seconds, 40 seconds, 45 seconds, 50 seconds...” (Ex. 2003, ¶[0037].)
1[v], 35, 36	Upon administration of Dohil’s lozenge or tablet, it “dissolve[s] rapidly in the mouth or esophagus to produce a solution” of budesonide that is deposited topically in the upper	“In some embodiments, the effective amount of the composition delivered to the esophagus is an amount sufficient to coat or at least partially coat the

	gastrointestinal tract by “<i>coat[ing] the esophagus.</i>” (Pet. at 25, 33 (citing Ex. 1002, ¶[0032]).)	<i>esophagus</i>, and deliver the composition to the affected areas, including by way of example only, the lower esophagus” (Ex. 2003, ¶[0060].)
4, 5, 6	Dohil discloses that its tablets are beneficially “formulated with at least one excipient to <i>deliver a viscous form</i> of the corticosteroid to the esophagus.” Dohil’s excipients “may be, for example, selected from the group consisting of...hydroxypropylmethyl-cellulose, <i>sodium carboxymethyl-cellulose (CMC)</i>, and <i>polyvinylpyrrolidone (PVP: povidone).</i>” (Pet. at 27-28 (citing Ex. 1002, ¶¶[0013], [0014], [0037]) (first emphasis added).)	“In some embodiments, the <i>viscosity enhancing agent</i> is selected from, by way of non-limiting example, microcrystalline cellulose, <i>carboxymethyl cellulose sodium</i> and a combination thereof. ” (Ex. 2003, ¶[0010].) “Disintegrating agents are optionally added, such as the <i>cross-linked polyvinylpyrrolidone</i>, agar, or alginic acid or a salt thereof such as sodium alginate.” (Ex. 2003, ¶[0085].)
7	Dohil discloses that “[s]uitable excipients are, in particular, fillers such as sugars, including <i>lactose, sucrose... or sorbitol....</i>” (Pet. at 28-29 (citing Ex. 1002, ¶¶[0037], [0014]) (emphasis in original).)	“Suitable excipients include, by way of non-limiting example, fillers such as sugars or starches, including dextrose, <i>lactose</i>, maltodextrin, <i>sucrose</i>, sucralose, mannitol, or <i>sorbitol</i>; cellulose preparations, for

		example, maize starch, wheat starch, rice starch, potato starch, or a combination thereof.” (Ex. 2003, ¶[0085].)
20, 21	Dohil further discloses “combining the corticosteroids with solid excipients, <i>optionally grinding a resulting mixture, and processing the mixture of granules...</i> to obtain tablets or dragee cores.” Dohil further discloses that the “[d]ragee cores are provided with <i>suitable coatings</i>,” that include adhesive excipients of “<i>polyvinylpyrrolidone</i>.” (Pet. at 29-30 (citing Ex. 1002, ¶¶[0013], [0037], [0039]) (second and third emphases added).)	“In certain embodiments, pharmaceutical preparations for oral use are obtained by combining an aqueous formulation of a corticosteroid (e.g., fluticasone propionate) with solid excipients, <i>optionally grinding a resulting mixture, and processing the mixture of granules</i>, after adding suitable auxiliaries, if desired, to obtain tablets or dragee cores.” (Ex. 2003, ¶[0085].) “Dragee cores are provided <i>with suitable coatings</i>. In some embodiments, concentrated sugar solutions are used for this purpose, which optionally contain gum arabic, talc, <i>polyvinylpyrrolidone...</i>” (Ex. 2003, ¶[0087].)

29-34	“The methods of the present invention are useful, for example, for preventing and <i>alleviating the symptoms and inflammation of eosinophilic esophagitis... esophageal inflammation</i> secondary to caustic/irritant ingestion, <i>persistent/recurrent esophageal strictures of any cause</i> and including caustic/irritant ingestion, pill-induced esophagitis, systemic diseases, congenital diseases, Epidermolysis bullosa, and post-surgery inflammation. The present methods are also useful for preventing or <i>alleviating symptoms and inflammation associated with other diseases or conditions of the gastrointestinal tract, for example, the upper gastrointestinal tract</i>, where it is beneficial to target a particular target site, rather than provide systemic therapy. (Pet. at 31-32 (citing Ex. 1002, ¶[0010]) (emphasis in original).)	“The methods of the present invention are useful, for example, for treating, preventing and <i>alleviating inflammation and/or symptoms and associated with eosinophilic esophagitis</i>, inflammatory bowel diseases involving the esophagus... systemic diseases, congenital diseases, Epidermolysis bullosa, ... and post-surgery inflammation. The present methods are also useful for treating, preventing or <i>alleviating symptoms and/or inflammation associated with other diseases or conditions of the gastrointestinal tract, for example, the upper gastrointestinal tract</i>, where it is beneficial to target a particular target site, rather than provide systemic therapy.” (Ex. 2003, ¶[0023].)
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As is apparent from the chart, Dohil is the same or substantially the same as Phillips, which was cited by the Examiner. Both references disclose solid dosage forms that dissolve in the mouth. (Compare Ex. 2003 (Phillips), ¶[0085] (“In certain

embodiments, solid oral dosage forms (e.g., tablets, ...) are formulated such that the dosage forms substantially dissolve or disintegrate in the mouth and/or esophagus.”) with Ex. 1002 (Dohil), ¶[0032] (“...a *lozenge which may be dissolved in the mouth*, thus reaching and coating the esophagus. The lozenge...would *dissolve rapidly in the mouth* or esophagus to produce a solution that can then coat the esophagus.”).) As such, Dohil is not materially different from Phillips and discloses substantially the same information already considered by the Office. These references are merely cumulative art. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 18-19 (concluding that references used in the petition, which were relied on in the same manner as the examiner relied on a reference during prosecution, disclosed information already considered by the Office therefore were the same or substantially the same as the prior art that was previously presented to the Office). *Becton* factors (a) and (b) thus support a finding that the first part of the *Advanced Bionics* framework has been met, as Petitioner relies on substantially the same prior art that was previously presented to the Office. *See id.* at 19.

b. Petitioner’s obviousness arguments based on Dohil mimic the Examiner’s arguments based on Phillips

Under § 325(d), denial is appropriate when a petitioner’s prior art challenges “are similar” to the arguments “raised by the Examiner” during prosecution, even if based on art not previously presented to the Office. *Xilinx, Inc. v. Analog Devices*,

Inc., IPR2021-00294, Paper 9 at 27 (P.T.A.B. June 10, 2021) (“*Xilinx*”). Here, Petitioner offers the same obviousness arguments based on Dohil that the Examiner raised for the same limitations based on Phillips.

For example, Petitioner argues that Dohil discloses a lozenge or tablet that is formulated with particular excipients such that it will dissolve rapidly in the mouth or esophagus that will then coat the esophagus. (Petition at 19.) The Examiner, during prosecution, however, relied on Phillips as teaching a solid corticosteroid composition, using pharmaceutically acceptable excipients, that dissolve or disintegrate in the mouth and/or esophagus. (Ex. 1031, 43 (citing Ex. 2003, ¶[0085]).) Thus, Petitioner’s argument mimics the Examiner’s argument of Phillips’ disclosure of a solid composition that dissolves in the mouth or esophagus.

The Examiner’s argument was not sufficient to find the claims obvious over Phillips, and Petitioner’s identical arguments are not sufficient here. Patent Owner argued that Phillips does not disclose the claimed disintegration time of 60 seconds as measured using USP <701> Disintegration Test and the Examiner agreed. (Ex. 1031, 31-32, 19.) Dohil similarly does not disclose the claimed disintegration time of 60 seconds as measured using USP <701> Disintegration Test. The Examiner’s conclusion that the ’179 patent was allowable over Phillips is equally applicable to Dohil.

In fact, the Examiner raised similar arguments in the prosecution of a child

patent application (U.S. Patent No. 10,632,069) in view of US 2009/0191275 (“Dohil 2009”) which is a continuation-in-part from Dohil. (Ex. 2004.) Specifically, the Examiner argued that Dohil 2009 discloses a lozenge formulated with the corticosteroid budesonide which dissolves in the mouth, coating the esophagus. (Ex. 2004, 54.) The terminal disclaimer of the ’069 patent over the ’729 patent shows the close relationship of the ’069 patent to the ’729 patent. (Ex. 2004, 7.) Thus, the analysis of Dohil 2009 in the ’069 patent’s prosecution is relevant here.

Dohil 2009 contains the exact same disclosures that Petitioner points to in Dohil. (Ex. 2001.) As in the prosecution of the ’729 patent, the Patent Owner pointed out to the Examiner during prosecution of the related ’069 patent that Dohil 2009 does not disclose a disintegration time of 60 seconds. (Ex. 2004, 11.) Patent Owner amended the claims to recite that the claimed orally dispersing tablet disintegrates within 60 seconds according to a specific test (the USP <701> Disintegration Test). (Ex. 2004, 14.) The Examiner subsequently allowed the claims of the ’069 patent with this limitation. (Ex. 2004, 6-7.) The Examiner’s conclusion that the ’069 patent was allowable over Dohil 2009 is equally applicable to Dohil. Thus, substantially the same art and arguments have already been considered and need not be reexamined by the Board, thereby wasting the Board’s resources. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 9 (describing § 325(d) as reflecting “a commitment to defer to previous Office evaluations of the evidence”).

c. Venkatesh is cumulative of art and arguments considered during prosecution

Venkatesh, relied on in Ground 3, is cumulative of the art and arguments considered and discussed by the Examiner related to Venkatesh 2009 (Ex. 2002.) Venkatesh discloses an orally disintegrating tablet made up of rapidly dispersing microgranules and taste-masked microcapsules, as well as disintegrating within 60 seconds as measured using USP <701> Disintegration Test. (Ex. 1020, ¶¶[0016], [0037].)

Petitioner relies on Venkatesh for the obviousness of formulating an orally disintegrating tablet made up of rapidly dispersing microgranules and taste-masked microcapsules, as well as disintegrating within 60 seconds. (Petition at 52-57.) Even assuming that Venkatesh makes these disclosures, it is cumulative of Venkatesh 2009, which was considered and discussed by the Examiner. In an office action dated June 6, 2012, the Examiner rejected the claims of the '729 patent as obvious over Venkatesh 2009, in view of Brantl. (Ex. 1031, 85-96.) The Examiner argued that Venkatesh 2009 teaches a solid pharmaceutical composition that dissolves orally, comprising a therapeutically effective amount of a drug, a binder polymer, a sugar alcohol and/or saccharide, and a disintegrant. (Ex. 1031, 85-86 (citing Ex. 2002, Abstract, ¶¶[0002], [0006], claims 1-23).) Further, the Examiner noted that the corticosteroids are disclosed. (Ex. 1031, 86 (citing Ex. 2002, ¶[0029]).)

In response, Patent Owner argued that Venkatesh 2009 does not teach an orally disintegrating tablet for topically active drugs or a composition comprising a corticosteroid where the corticosteroid is deposited topically in the upper gastrointestinal tract. (Ex. 1031, 71-76.) The Examiner subsequently withdrew his rejection based on Venkatesh 2009. (Ex. 1031, 41.)

Like Venkatesh, Venkatesh 2009 discloses orally disintegrating tablets formulated with rapidly dispersing microgranules and taste-masked microcapsules that disintegrates within 60 seconds. (Ex. 2002, Abstract, ¶¶[0002], [0006], claims 1-23). The following chart shows the similar disclosure between Venkatesh and Venkatesh 2009:

Claim(s) for which Petitioner cites Venkatesh	Petitioner's Reliance on Venkatesh (Ex. 1020)	Venkatesh 2009 (Ex. 2002) Considered During Prosecution
	Venkatesh discloses “<i>orally disintegrating tablets and a method for their manufacture.</i>” Venkatesh's orally disintegrating tablet rapidly <i>disintegrates in the buccal cavity within “preferably less than 60 seconds.”</i> Venkatesh's orally disintegrating tablets can be formulated using “<i>any</i>	“The compositions of the present invention are <i>orally disintegrating tablet compositions</i> comprising a therapeutically effective amount of at least one drug such as temazepam, 0.5-3% of an ODT binder polymer, a sugar alcohol and/or saccharide, and a disintegrant.” (Ex. 2002, Abstract.) “When using the USP <701 >

	<i>therapeutic active agent indicated for oral administration.”</i> (Pet. at 52 (citing Ex. 1020, ¶¶[0001], [0016], [0025]).)	Disintegration Test, <i>the rate of disintegration of ODT compositions is faster than that of conventional, non-ODT compositions, for example 60 seconds or less, 30 seconds or less, 20 seconds or less, or 10 seconds or less.”</i> (Ex. 2002, ¶[0082].) The term “drug”, “active” or “active pharmaceutical ingredient” as used herein <i>includes a pharmaceutically acceptable and therapeutically effective compound suitable for treating diseases</i>, symptoms of diseases, and medical conditions” (Ex. 2002, ¶[0027]; <i>see also</i> ¶[0029] (listing corticosteroids).)
8	This technique uses “a conventional rotary tablet press equipped <i>with an external lubrication system to pre-lubricate the dies and punches.”</i> (Pet. at 53, 58 (citing Ex. 1020, ¶¶[0017], [0008], [0018], [0024].)	“(d) compressing the blend of step (c) into tablets using e.g. a conventional rotary tablet press equipped <i>with an external lubrication system to pre-lubricate the dies and punches.”</i> (Ex. 2002, ¶[0078].)
16	Venkatesh discloses that “this invention relates to pharmaceutical compositions comprising <i>rapidly dispersing</i>	“The average particle size of the <i>sugar alcohol and/or saccharide as well as rapidly dispersing microgranules</i> should be such that upon disintegration in the

	<i>microgranules of a disintegrant and sugar alcohol or a saccharide.</i> “For use in an orally disintegrating tablet, the particle size of most of the taste-masked microcapsules should be less than 400 um or less to <i>avoid gritty mouthfeel.</i>” “An ideal orally disintegrating tablet formulation rapidly disintegrates in the buccal cavity dispersing the contents and has a pleasant taste and smooth <i>creamy mouthfeel</i> (no grittiness)...” (Pet. at 54-55, 59-60 (citing Ex. 1020, ¶¶ [0001], [0012] [0002])).)	oral cavity, the composition provides a <i>smooth mouthfeel (no aftertaste or gritty or chalky taste or texture).</i>” (Ex. 2002, ¶[0045].) “For bitter tasting drugs, the ODT formulation may require a taste-masking polymer to improve the taste characteristics of the formulation, and to provide a <i>‘creamy’ mouthfeel.</i>” (Ex. 2002, ¶[0004].)
17	“One embodiment of this invention relates to pharmaceutical compositions comprising rapidly dispersing microgranules of a disintegrant and <i>sugar alcohol or a saccharide whose average particle size is not more than 30 um,</i> resilient (hard, flexible, less-friable) microgranules	“(b) granulating one or more <i>sugar alcohols, saccharides, or mixtures thereof, each having an average particle diameter of not more than about 30 μm.</i>” (Ex. 2002, ¶[0078].)

	of bitter active pharmaceutical ingredients effectively taste masked by coacervation, and other pharmaceutically acceptable excipients in the form of tablets which rapidly disintegrate in the buccal cavity.” (Pet. at 56, 61 (citing Ex. 1020, ¶[0014]).)	
18	“In accordance with the one embodiment of the invention, milled/micronized drug particles (e.g., average particle diameter less than about 50 μm, preferably less than about 25 μm)” (Pet. at 57, 62 (citing Ex. 1020, ¶[0015]).)	“The drug crystals can have an average particle size ranging from about 1 μm to about 200 μm, for example about 1-25 μm, about 1-50 μm, about 1-100 μm, about 1-150 μm, about 25-50 μm, about 25-150 μm, about 50-100 μm, about 50-150 μm, about 100-150 μm, or about 100-200 μm.” (Ex. 2002, ¶[0034].)
20	“(d) blending dispersible microgranules of step (a) with taste-masked microcapsules of step (c), and other acceptable ingredients such as a flavoring agent, a coloring agent, a sweetener and additional disintegrant in sufficient quantities to provide a therapeutically effective unit dose...” (Pet. at 64 (citing Ex. 1020, ¶[0023]).)	“(c) blending the drug microgranules of step (a) with one or more flavoring agents, a sweetener, microcrystalline cellulose, additional disintegrant, and the rapidly-dispersing microgranules of step (b)...” (Ex. 2002, ¶[0078].)

21	“(c) microencapsulating these resilient granules (mean size: 200 um or less) by coacervation in cyclohexane containing ethylcellulose to produce effectively taste-masked microcapsules with a desired particle size distribution (average particle Size of not more than 400 um, typically not more than 300 um) wherein the average membrane thickness is in the range of 30% to 50% by weight of the coated granules...” (Pet. at 64-65 (citing Ex. 1020 ¶[0022]) (emphasis in original).)	“In another embodiment, step (a) is microencapsulating drug crystals by fluidized bed coating or coacervation, for example with a taste-masking or seal coating composition.” (Ex. 2002, ¶[0070].) “(b) taste-masking core particles by microencapsulation, e.g. by solvent coacervation or fluid-bed coating with a water insoluble polymer such as ethylcellulose, or with a mixture of a water-insoluble functional polymer and a water-soluble/gastrosoluble pore-former (e.g., ethylcellulose and sodium chloride or calcium carbonate at a ratio ranging from about 50/50 to 95/5) to produce pleasant-tasting microparticles with a desired particle size distribution” (Ex. 2002, ¶[0079]; <i>see also, id.</i> at Example 5.)
22	“In accordance with the one embodiment of the invention, milled/micronized drug particles ... are blended with a water soluble ductile polymeric binder such as modified starch and hydroxypropyl methylcellulose with a viscosity of 100 cps or	“In yet another embodiment, step (a) is forming drug-layered beads by coating an inert core, such as sugar spheres, with a solution or dispersion of the drug and a drug-layering binder such as PVP.” (Ex. 2002, ¶[0070].)

	higher, alone or in combination with a widely used <i>binder such as PVP (polyvinylpyrrolidone)</i> , hydroxypropylcellulose and hydroxypropyl methylcellulose with a viscosity of 15 cps or less.” (Pet. at 65 (citing Ex. 1020, ¶[0015]).)	
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As is apparent from the chart, Venkatesh is the same or substantially the same as Venkatesh 2009, which was cited by the Examiner. Like Venkatesh, Venkatesh 2009 does not disclose an orally disintegrating tablet to administer a topically active corticosteroid that has no significant systemic activity to upper gastrointestinal tract, and otherwise contains the same disclosures. As such, Venkatesh is not materially different from Venkatesh 2009 and discloses substantially the same information already considered by the Office. These references are merely cumulative art. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 18-19 (concluding that references used in the petition, which were relied on in the same manner as the examiner relied on a reference during prosecution, disclosed information already considered by the Office therefore were the same or substantially the same as the prior art that was previously presented to the Office). *Becton* factors (a), (b) and (d) thus support a finding that the first part of the *Advanced Bionics* framework has been met, as

Petitioner relies on substantially the same prior art and arguments that were previously presented to the Office. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 19.

d. Petitioner's obviousness arguments based on Venkatesh mimic the Examiner's arguments based on Venkatesh 2009

Petitioner makes the same obviousness arguments based on Venkatesh that the Examiner raised for the same limitations based on Venkatesh 2009. For example, Petitioner argues that Venkatesh discloses an orally disintegrating tablet made up of rapidly dispersing microgranules and taste-masked microcapsules, as well as disintegrating within 60 seconds. (Petition at 52-57.) The Examiner, during prosecution, however, relied on Venkatesh 2009 as teaching an orally disintegrating tablet comprising a corticosteroid, a binder, a sugar alcohol and/or saccharide, and a disintegrant. (Ex. 1031, 85-96.) Thus, Petitioner's argument mimics the Examiner's argument of Venkatesh 2009's disclosure of an orally disintegrating tablet made up of rapidly dispersing microgranules and taste-masked microcapsules that disintegrates within 60 seconds.

The Examiner's argument was not sufficient to find the claims obvious over Venkatesh 2009, and Petitioner's identical arguments are not sufficient here. Patent Owner argued that Venkatesh 2009 does not disclose an orally disintegrating tablet for topically active drugs that are administered to the upper gastrointestinal tract.

(Ex. 1031, 71-76.) The Examiner recognized this feature of the inventive claim and withdrew the rejection based on Venkatesh 2009. (Ex. 1031, 41.) Venkatesh similarly does not teach the claimed corticosteroid that is administered topically in the upper gastrointestinal tract. The Examiner's conclusion that the '179 patent was allowable over Venkatesh 2009 is equally applicable to Venkatesh.

2. Petitioner fails to meet its burden to demonstrate that the Office erred in a manner material to the patentability of the Challenged Claims

Turning to the second part of the *Advanced Bionics* framework, Petitioner fails to show that the Office erred in a manner material to the patentability of the Challenged Claims. Where, as here, the same or substantially overlapping disclosures were before the Patent Office, it is incumbent on the petitioner to offer a particularized explanation of how the Office erred. Accordingly, the Board should exercise its discretion to deny institution under § 325(d).

Petitioner's conclusory statements regarding the "new" references relied on in the Petition are incorrect and inadequate to carry their burden of showing material error. First, Petitioner attempts to divorce the Examiner's arguments on Dohil 2009 during the prosecution of child patents, but disregards that Phillips makes substantially the same disclosures and was considered during prosecution of the '729 patent. Petitioner does not address the arguments made during prosecution or attempt to distinguish its own arguments from the ones made by the Examiner. As explained

above, the Examiner's arguments related to Phillips are directly relevant here, and Petitioner has failed to show material error.

Similarly, Venkatesh makes substantially the same disclosures as Venkatesh 2009, which was considered during the prosecution of the '729 patent. Further, Petitioner admits that Venkatesh is cited in the specification of the '729 patent. The Examiner was thus aware of the disclosures of Venkatesh relevant to the '729 patent. *Universal Imaging Indus., LLC, v. Lexmark Int'l, Inc.*, IPR2019-01387, Paper 7 at 17-18 (P.T.A.B. Feb. 27, 2020) (denying institution under § 325(d) where the challenged patent discussed the prior art in its background section because, inter alia, "[i]t is reasonable to assume that the Examiner read the Specification and understood these statements as part of examining the [challenged] patent") (citing MPEP §§ 608.01(c), 2129).

Second, Petitioner's argument that the Examiner did not have the benefit of the EPO decision is inapplicable here and completely irrelevant. (Petition at 70-71.) The EPO revoked EP2482822 as obvious over Dohil. (Ex. 1004.) In particular, the EPO found that Dohil is the closest prior art to EP2482822 and found that it would have been obvious to a skilled artisan to formulate the lozenge or tablet in Dohil to have the claimed disintegration time of 60 seconds. (Ex. 1004, ¶ 36.) Petitioner argues that because the EPO found a European patent obvious over Dohil, the Board ought to come to the same conclusion. (Petition at 14.) However, the Petitioner failed

to mention that the claims in EP2482822 are different from the claims in the '729 patent. More importantly, the Board is not bound by EPO, which analyzed different claims under a different set of rules. Nor does Petitioner point to any authority requiring the Board be bound to the EPO decision. Further, the EPO decision is not prior art and therefore irrelevant.

Regarding *Becton* factor (f), the Petition does not present new evidence that warrants reconsideration of the same prior art. Petitioner's expert declaration is not enough; the declaration just repeats arguments in the Petition and the expert fails to support his testimony with objective evidence. *See NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 at 16-17 (P.T.A.B. Sept. 12, 2018) (precedential) (“[T]he declaration does not persuade us that we should reconsider Braunheim, the AAPA, or Petitioner's arguments because the declaration is substantially similar to the Petition...and Dr. Bogy fails to support his testimony with objective evidence.”) (footnote omitted). Specifically, neither Petitioner nor its expert address the prosecution history or the fact that the teachings of the asserted art are substantially the same as the art already considered. In particular, Petitioner and its expert fail to address that Dohil, like Phillips, does not teach a solid dosage form that disintegrates in 60 seconds. Likewise, Petitioner and its expert do not address that like Venkatesh 2009 considered during prosecution, Venkatesh does not teach the topical administration of a corticosteroid. Petitioner and its expert do not

acknowledge Patent Owner’s arguments made in prosecution, or the Examiner’s withdrawals of rejections based on substantially the same evidence/arguments. Petitioner merely states that because the art is new and was not considered (which is not correct, as several child applications were granted over Dohil), and its expert “mapped” the claims for the Board, the Office materially erred. *See Becton, Dickinson*, IPR2017-01586, Paper 8 at 24-25 (declining institution on a reference where “Petitioner has not . . . addressed the evidence and argument presented by Patent Owner” but instead “[m]ainly . . . asserts that it presents new testimonial evidence that has not been considered by the Office”).

Petitioner has not demonstrated the “misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims.” *Advanced Bionics*, IPR2019-01469, Paper 6 at 8 n.9. Petitioner failed to meet its burden of showing material error and is foreclosed from raising new arguments concerning error in a reply. *KOA Corp. v. Vishay Dale Elecs., LLC*, IPR2019-00201, Paper 30 at 77 (P.T.A.B. May 7, 2020) (“A reply that raises a new issue or belatedly presents evidence may not be considered.”).

Each of the *Advanced Bionics* factors weigh in favor of denying institution of Grounds 1 and 3 under § 325(d).

B. Grounds 2 and 4 rely on the same or substantially the same art and arguments that were considered by the Office without error

In Grounds 2 and 4, Petitioner relies on Grother, FDA Guidance, and Venkatesh. The Board should deny institution because all three references are substantially similar to Venkatesh 2009 that was before the Examiner and the disclosures of the three references are substantially the same and cumulative of the art and arguments previously considered by the Office.

1. Part 1 (*Becton, Dickinson* Factors (a), (b), (d)): Petitioner's Reliance and Arguments Based on Grother are Substantially the Same as Those Considered During Prosecution

During prosecution the '729 patent, the Examiner rejected the then-pending claims after concluding that they were anticipated or rendered obvious by the Venkatesh 2009 reference (Ex. 1031, 85-96.)

As explained above, Venkatesh 2009 is directed to a solid pharmaceutical composition in the form of an orally disintegrating tablet. Venkatesh 2009 further teaches that the ODT compositions disintegrate in about 60 seconds or less when evaluated using the USP <701> Disintegration Test. (Ex. 2002, ¶¶[0081], 0082], [0085].)

In an office action dated June 6, 2012, the Examiner rejected the claims of the '729 patent as obvious over Venkatesh 2009, in view of Brantl. (Ex. 1031, 85-96.) The Examiner argued that Venkatesh 2009 teaches a solid pharmaceutical

composition that dissolves orally, comprising a therapeutically effective amount of a drug, a binder polymer, a sugar alcohol and/or saccharide, and a disintegrant. (Ex. 1031, 85-86 (citing Ex. 2002 Abstract, ¶¶[0002], [0006], and claims 1-23).) Further, the Examiner noted that the corticosteroids are disclosed. (Ex. 1031, 86 (citing Ex. 2002 ¶[0029])).)

In response, Patent Owner argued that Venkatesh 2009 does not teach an ODT for topically active drugs. Specifically, Patent Owner stated that

Venkatesh [2009] does not particularly highlight that drugs should be used relative to whether they have or do not have significant systemic activity. See paras. [0027]-[0030]. Of the corticosteroids listed, only one, beclomethasone, does not have significant systemic activity yet the several other corticosteroids listed do have such activity (*e.g.*, hydrocortisone, prednisone, prednisolone, methylprednisolone, betamethasone, dexamethasone). See para. [0029] (more specifically, page 3, col. 1). *Venkatesh* [2009] makes no comment on any preference for choosing corticosteroids from the laundry list, and does not provide direction for selecting beclomethasone in particular from the list of corticosteroids.

(Ex. 1031, 72 (emphasis in original).) As emphasized in Patent Owner's remarks, Venkatesh 2009 does not teach a composition comprising a corticosteroid wherein

upon administration the corticosteroid is deposited topically in the upper gastrointestinal tract. (Ex. 1031, 71-72.)

The Examiner withdrew the rejection, finding Patent Owner's argument that Venkatesh 2009 does not teach the administration of a corticosteroid that is deposited topically in the upper gastrointestinal tract persuasive. (Ex. 1031, 41.) The Examiner found that Patent Owner had successfully rebutted any presumption of obviousness arising from Venkatesh 2009's ODT composition. (Ex. 1031, 41.) Patent Owner had shown non-obviousness of topical administration by demonstrating that Venkatesh 2009 fails to recognize the distinction between drugs that have and do not have significant systemic activity, and failed to recognize that an ODT can be used to topically administer a topically active drug to the upper gastrointestinal tract.

a. Grother is cumulative of art and arguments considered during prosecution

Grounds 2 and 4 rely on primary reference Grother in combination with the FDA Guidance or the FDA Guidance and Venkatesh. Grother is cumulative of the art and arguments considered and discussed by the Examiner related to Venkatesh 2009. Just like Venkatesh 2009, Grother discloses both systemic and topical corticosteroids with no recognition of difference in activity or teaching to select a

topical corticosteroid. Further, Grother, like Venkatesh 2009, does not teach topical administration to the esophagus.

Grother is directed to a specific ODT formulation containing starch to facilitate oral disintegration and further discloses disintegration in less than or equal to 60 seconds. (Ex. 1008, Abstract.) Grother discloses that “[a]ny drug may be used as the active ingredient in the composition of the present invention,” (Ex. 1008, 15:19-20, 18:15-18 (listing corticosteroids).)

Petitioner relies on Grother and the FDA Guidance or Grother, FDA Guidance and Venkatesh to satisfy the limitation of solid pharmaceutical compositions that dissolve within 60 seconds in the mouth. (Petition at 34-51, 58-68.) While Grother does disclose an orally dissolving tablet, there is no teaching to use an orally disintegrating tablet to administer a topically active corticosteroid that has no significant systemic activity to upper gastrointestinal tract. Instead, Grother contains a laundry list of drugs, most of which are systemically active, and states that that “[a]ny drug may be used as the active ingredient in the composition of the present invention.” (Ex. 1008, 15:19-20.) Like Venkatesh 2009, Grother does not differentiate between systemic and topical corticosteroids. In fact, Grother and Venkatesh 2009 are the same or substantially the same in the disclosures Petitioner points to:

Claim(s) for which Petitioner cites Grother	Petitioner's Reliance on Grother (Ex. 1008)	Venkatesh 2009 (Ex. 2002) Considered During Prosecution
1 [Preamble], 15, 27 [Preamble]	Grother discloses “<i>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.</i>” Grother discloses that “<i>[a]ny drug may be used as the active ingredient in the composition</i> of the present invention.” (Pet. at 34-35 (citing Ex. 1008, Abstract, 12:10-19, 15:19-20); <i>see also</i> 18:15-18 (listing corticosteroids).)	“When using the USP <701 > Disintegration Test, <i>the rate of disintegration of ODT compositions is faster than that of conventional, non-ODT compositions, for example 60 seconds or less, 30 seconds or less, 20 seconds or less, or 10 seconds or less.</i>” (Ex. 2002, ¶[0082].) “The term ‘drug’, ‘active’ or ‘active pharmaceutical ingredient’ as used herein <i>includes a pharmaceutically acceptable and therapeutically effective compound suitable for treating diseases</i>, symptoms of diseases, and medical conditions” (Ex. 2002, ¶[0027].)
1[i], 27[i], 28, 38-40	Grother discloses that “the <i>active ingredient is generally present in an amount from 0.2 to 95%, normally 1 to 20%, by weight of the composition</i> of the dried dosage form.” “[T]he dose of water soluble drugs is generally limited to an <i>upper value of about 60mg per dosage form.</i>”	“Thus, in a specific embodiment, the ODT compositions of the present invention are prepared by granulating <i>a composition comprising about 10-15% by weight temazepam...</i>” (Ex. 2002, ¶[0077].) “Therapeutically effective amounts of temazepam <i>range from 5-50mg of temazepam/unit dose</i>, for example 5, 7.5, 10, 12.5, 15, 17.5, 20, 22.5, 25, 27.5, 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, or 50 mg temazepam/unit

	(Pet. at 36, 50-51 (citing Ex. 1008, 21:16-18, 26:22-27:1); <i>see also id.</i> Table 1).)	dose.” (Ex. 2002, ¶[0031].)
1[ii], 27[ii]	Grother discloses “[a] range of <i>modified starches</i> ,” including “ <i>pregelatinized starches</i> ,” and “ <i>oxidized starches</i> ” containing “carboxyl group.” (Pet. at 37-38 (citing Ex. 1008 5:10-6:5).)	“Specific examples of disintegrants include e.g. alginic acid or alginates, microcrystalline cellulose, hydroxypropyl cellulose and other cellulose derivatives, croscarmellose sodium, crospovidone, polacrillin potassium, sodium starch glycolate, <i>starch, pregelatinized starch, carboxymethyl starch</i> (e.g. Primogel® and Explotab®) etc.” (Ex. 2002, ¶[0050].)
1[iii], 3	“ <i>Any drug may be used as the active ingredient in the composition</i> of the present invention.” (Pet. at 38 (citing Ex. 1008, 15:19-20, 18:15-18 (listing corticosteroids)).)	“The term ‘drug’, ‘active’ or ‘active pharmaceutical ingredient’ as used herein <i>includes a pharmaceutically acceptable and therapeutically effective compound suitable for treating diseases</i> , symptoms of diseases, and medical conditions” (Ex. 2002, ¶[0027]; <i>see also id.</i> ¶[0029] (listing corticosteroids).)
1[iv], 2, 27[iii]	Grother discloses “fast dispersing solid dosage forms that preferably <i>dissolve in the oral cavity within sixty (60), more preferably within thirty (30), most preferably within ten (10) seconds.</i> ” “[T]he term ‘fast dispersing dosage form	“When using the USP <701 > Disintegration Test, the <i>rate of disintegration</i> of ODT compositions is faster than that of conventional, non-ODT compositions, for example <i>60 seconds or less, 30 seconds or less, 20 seconds or less, or 10 seconds or less.</i> ” (Ex. 2002, ¶[0082].)

	(FDDF)’ refers to compositions which <i>disintegrate/disperse within 1 to 60 seconds, preferably 1 to 30 seconds, more preferably 1 to 10 seconds and particularly 2 to 8 seconds, of being placed in the oral cavity.</i> (Pet. at 39 (citing Ex. 1008 Abstract, 13:19-22).)	<i>“disintegration on contact with saliva in the oral cavity in about 60 seconds</i> forming a smooth, easy-to-swallow suspension with a pleasant taste (no grittiness or aftertaste), meeting the specification of not more than 60 seconds, more particularly not more than 30 seconds in the <USP 701> Disintegration Test” (Ex. 2002, ¶[0088].)
1[v], 35-36	Grother discloses “a pharmaceutical composition for oral administration in the form of a fast dispersing dosage form <i>designed to release an active ingredient rapidly in the oral cavity.</i>” (Pet. at 41, 49-50 (citing Ex. 1008, 3:18-20, 1:10-11) (emphasis in original).)	“The terms ‘orally disintegrating tablet’, ‘orally dispersible tablet’, ‘fast dissolving tablet’, or ‘ODT’ refer to a <i>solid dosage form which disintegrates rapidly in the oral cavity of a patient after administration.</i>” (Ex. 2002X, ¶[0023].)
4, 5, 6	“The fast dispersing dosage form according to the invention <i>may also contain, in addition to the active ingredient and modified starch, other matrix forming agents and secondary components.</i> Matrix forming agents suitable	“Examples of <i>suitable fillers, diluents and/or binders</i> include...methylcellulose polymers (such as, e.g., Methocel A. Methocel A4C, Methocel A15C, Methocel A4M), hydroxyethylcellulose, sodium carboxymethylcellulose, carboxymethylhydroxyethylcellulose and other cellulose derivatives...or <i>modified starches</i> (including potato

	for use in the present invention include materials derived from animal or vegetable proteins, such as non-mammalian gelatins, dextrans and soy, wheat and psyllium seed proteins; gums such as acacia, guar, agar, and xanthan; polysaccharides; alginates; carboxymethylcelluloses; carrageenans; dextrans; pectins; synthetic polymers such as polyvinylpyrrolidone; and polypeptide/protein or polysaccharide complexes such as gelatin-acacia complexes.” Pet. at 43-44 (citing Ex. 1008, 14:7-15).)	starch, maize starch and rice starch)...” (Ex. 2002, ¶[0048].)
7	Grother also discloses that “[m]atrix forming agents suitable for use in the present invention include sugars such as <i>mannitol</i>, dextrose, <i>lactose</i>....” (Pet. at 44-45 (citing Ex. 1008, 14:16-21, 14:22-23) (emphasis in original).)	“Sugar alcohols suitable for use in the orally disintegrating tablet compositions of the present invention <i>include any pharmaceutically acceptable sugar alcohols</i>. A <i>non-limiting list of suitable sugar alcohols includes</i>, e.g. <i>mannitol</i>, sorbitol, xylitol, maltitol, lactitol, erythritol, isomalt, hydrogenated starch hydrolysates, and maltol. Saccharides suitable for use in the

		orally disintegrating tablet compositions of the present invention <i>include any pharmaceutically acceptable saccharides</i>. A <i>non-limiting list of suitable saccharides includes</i>, e.g. <i>lactose</i>, sucrose, and maltose.” (Ex. 2002, ¶¶[0042]-[0043].)
9-11	“<i>Anti-fungal agents</i>: amphotericin, butoconazole nitrate, <i>clotrimazole</i>, econazole nitrate, <i>fluconazole</i>, flucytosine, griseofulvin, <i>itraconazole</i>, ketoconazole, miconazole, natamycin, <i>nystatin</i>, sulconazole nitrate, terbinafine HCl, terconazole, tioconazole, undecenoic acid.” (Pet. at 45-46 (citing Ex. 1008, 17:1-4) (emphasis in original).)	“The term ‘drug’, ‘active’ or ‘active pharmaceutical ingredient’ as used herein <i>includes a pharmaceutically acceptable and therapeutically effective compound suitable for treating diseases</i>, symptoms of diseases, and medical conditions” (Ex. 2002, ¶[0027]; <i>see also id.</i> ¶[0029] (listing antifungal agents).)
19	Grother discloses that “[a] further technique is to dose a <i>non-aqueous solution of the active ingredient onto preformed placebo FDDF units</i>.” (Pet. at 63 (citing Ex. 1008, 27:11-14).)	“Because coating the drug-containing particles (e.g., temazepam crystallites, microgranules or drug-layered beads) with a <i>water-insoluble polymer may reduce the release-rate of the drug, the taste-masking coating can also include a pore-former</i>.” (Ex. 2002, ¶[0068].)

20	Grother discloses that the “solid dosage form is obtainable by removing a solvent from a mixture comprising said active ingredient, <i>said modified starch and said matrix forming agent.</i>” (Pet. at 48, 63 (citing (Ex. 1008, 12:17-19).)	“In another embodiment, the ODT compositions of the present invention are prepared by: (a) preparing drug containing microgranules by granulating crystalline drug having an average particle size of about 1-50 μm and <i>one or more diluents/fillers</i> such as lactose, mannitol, microcrystalline cellulose and mixtures thereof, <i>with a polymeric binder</i> in a high-shear granulator or a fluid-bed coater; (b) granulating one or more sugar alcohols, saccharides, or mixtures thereof, each having an average particle diameter of not more than about 30 μm, <i>with a disintegrant</i> such as crospovidone, using water or an alcohol-water mixture in a conventional granulator, and drying the granulate in fluid-bed equipment or a conventional oven to produce ‘rapidly-dispersing microgranules’ with an average particle size of not more than about 400 μm; (c) blending the drug microgranules of step (a) with one or more flavoring agents, a sweetener, microcrystalline cellulose, additional disintegrant, and the rapidly-dispersing microgranules of step (b); and (d) compressing the blend of step (c) into tablets using e.g. a conventional rotary tablet press equipped with an external lubrication system to pre lubricate the dies and punches.” (Ex. 2002X, ¶[0078].)
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22	“One or more matrix forming agents may be incorporated into the solution or suspension prior to solidification.” (Pet. at 65 (citing Ex. 1008, 14:22-23).)	“In yet another embodiment, step (a) is forming drug-layered beads by coating an inert core, such as sugar spheres, with a solution or dispersion of the drug and a drug-layering binder such as PVP.” (Ex. 2002, ¶[0070].)
23	“The resulting tablet has an open porous matrix that dissolves rapidly on contact with saliva.” (Pet. at 66 (citing Ex. 1008, 32:15-17).)	“Pore-formers include gastrosoluble pore-formers which are insoluble in water and saliva, but are readily soluble under acidic conditions, such as those found in the stomach, and water-soluble pore-formers.” (Ex. 2002, ¶[0068].)
24	Grother discloses that “[t]he preferred matrix forming agent is mannitol.” (Pet. at 67 (citing Ex. 1008, 13:12).)	“In one embodiment, step (a) above, forming drug particles, is granulating the drug with other excipients (e.g., a sugar alcohol such as mannitol.)” (Ex. 2002, ¶[0070].)
37	Grother discloses that known excipients “include microcrystalline cellulose, corn starch and lactose.” (Pet. at 68 (citing Ex. 1008, 10:9-10).)	“Specific examples of disintegrants include e.g. alginic acid or alginates, microcrystalline cellulose, hydroxypropyl cellulose and other cellulose derivatives, croscarmellose sodium, crospovidone, polacrillin potassium, sodium starch glycolate, starch, pregelatinized starch, carboxymethyl starch (e.g. Primogel® and Explotab®) etc.”

		(Ex. 2002, ¶[0050].) “Saccharides suitable for use in the orally disintegrating tablet compositions of the present invention <i>include any pharmaceutically acceptable saccharides. A non-limiting list of suitable saccharides includes</i>, e.g. <i>lactose</i>, sucrose, and maltose.” (Ex. 2002, ¶[0043].)
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As is apparent from the chart, Grother is the same or substantially the same as Venkatesh 2009, which was cited by the Examiner. Like Venkatesh 2009, Grother discloses a laundry list of drugs, with no preference or direction towards choosing a topical corticosteroid versus a systemic one, and neither reference suggests that an orally disintegrating tablet can be used to topically deposit a corticosteroid in the upper gastrointestinal tract. As such, Grother is not materially different from Venkatesh 2009 and discloses substantially the same information already considered by the Office. These references are merely cumulative art. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 18-19 (concluding that references used in the petition, which were relied on in the same manner as the examiner relied on a reference during prosecution, disclosed information already considered by the Office therefore were the same or substantially the same as the prior art that was previously presented to the Office). *Becton* factors (a) and (b) thus support a finding that the first part of the

Advanced Bionics framework has been met, as Petitioner relies on substantially the same prior art that was previously presented to the Office. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 19.

b. Petitioner’s obviousness arguments based on Grother mimic the Examiner’s arguments based on Venkatesh 2009

Under § 325(d), denial is appropriate when a petitioner’s prior art challenges “are similar” to the arguments “raised by the Examiner” during prosecution, even if based on art not previously presented to the Office. *Xilinx*, IPR2021-00294, Paper 9 at 27. Here, Petitioner offers the same obviousness arguments based on Grother that the Examiner raised for the same limitations based on Venkatesh 2009.

For example, the Examiner noted that Venkatesh 2009 teaches a solid form of an orally disintegrating tablet that dissolves rapidly in the mouth and/or esophagus. (Ex. 1031, 85-86.) Petitioner likewise argues that Grother discloses a fast-dispersing solid composition that disintegrates in the oral cavity. (Petition at 34-35.) Petitioner’s argument mimics the Examiner’s argument of Venkatesh 2009’s disclosure of a solid composition that dissolves in the mouth or esophagus.

The Examiner’s argument was not sufficient to find the claims obvious over Venkatesh 2009, and Petitioner’s identical arguments are not sufficient here. Patent Owner argued that Venkatesh 2009 does not teach the claimed topical administration of the corticosteroid to the upper gastrointestinal tract and the Examiner recognized

this feature of the inventive claim. (Ex. 1031, 71-75, 41.) Grother similarly does not teach claimed topical administration of the corticosteroid to the upper gastrointestinal tract. The Examiner's conclusion that the '179 patent was allowable over Venkatesh 2009 is equally applicable to Grother.

c. FDA Guidance is cumulative of art and arguments considered during prosecution

FDA Guidance, relied on in Grounds 2 and 4, is cumulative of the art and arguments considered and discussed by the Examiner related to Venkatesh 2009. (Ex. 1005; Ex. 1031, 86.) Petitioner relies on the FDA Guidance specifically for the USP <701> Disintegration Test. (Petition at 23, 26, 39-40.) In particular, Petitioner argues that a POSA would have been motivated to follow the FDA Guidance in formulating Grother's orally disintegrating tablet to disintegrate within 60 seconds using the USP <701> Disintegration Test. (Petition at 39-40.) The use of the USP <701> Disintegration Test is cumulative of Venkatesh 2009, which was considered and discussed by the Examiner. (Ex. 1031, 87.) Venkatesh 2009 states in its disclosure that the ODT compositions disintegrate within 60 seconds using the USP <701> Disintegration Test. (Ex. 2002, ¶[0085].) In an office action dated June 6, 2012, the Examiner rejected the claims of the '729 patent as obvious over Venkatesh 2009, in view of Brantl. (Ex. 1031, 85-96.) The Examiner clearly reviewed Venkatesh 2009 and its disclosure regarding the USP <701> Disintegration Test.

(Ex. 1031, 87.) Nevertheless, the Examiner subsequently withdrew his rejection based on Venkatesh 2009. (Ex. 1031, 41.)

As is apparent from the prosecution history, the FDA Guidance is cumulative of Venkatesh 2009, which was cited by the Examiner. Specifically, Venkatesh 2009 cites to the USP <701> Disintegration Test, and the FDA Guidance simply points to the USP <701> Disintegration Test, stating that orally disintegrating tablets should disintegrate within 60 seconds as measured by the test. (Ex. 2002, ¶[0085]; Ex. 1005). As such, the FDA Guidance is not materially different from Venkatesh 2009 and discloses substantially the same information already considered by the Office. These references are merely cumulative art. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 18-19 (concluding that references used in the petition, which were relied on in the same manner as the examiner relied on a reference during prosecution, disclosed information already considered by the Office therefore were the same or substantially the same as the prior art that was previously presented to the Office).

d. Venkatesh is cumulative of art and arguments considered during prosecution

As described above, Venkatesh is cumulative of the art and arguments considered by the Examiner. (*See supra* Sections III.A.c-d.) Petitioner cites Venkatesh in Ground 4 for the same limited purpose as Ground 3.

Becton factors (a), (b), and (d) thus support a finding that the first part of the

Advanced Bionics framework has been met, as Petitioner relies on substantially the same prior art that was previously presented to the Office. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 19.

2. Petitioner fails to meet its burden to demonstrate that the Office erred in a manner material to the patentability of the Challenged Claims

Petitioner has not shown that the Office erred in a manner material to the patentability of the Challenged Claims. Where, as here, the same or substantially overlapping disclosures were before the Patent Office and expressly relied on by the Examiner, it is incumbent on the Petitioner to offer a particularized explanation of how the Office erred. Accordingly, the Board should exercise its discretion to deny institution under § 325(d).

Petitioner's conclusory statements regarding the "new" references relied on in the Petition are incorrect and inadequate to carry their burden of showing material error. First, Petitioner's argument that the Examiner did not have the benefit of the FDA Guidance is incorrect. (Petition at 70-71.) The guidance simply states that orally disintegrating tablets should disintegrate within 60 seconds as measured using the USP <701> Disintegration Test. (Ex. 1005.) Patent Owner submitted the USP <701> Disintegration Test during the prosecution of the '729 patent and Venkatesh 2009 similarly teaches orally disintegrating tablets that disintegrate within 60 seconds as measured using the USP <701> Disintegration Test. (Ex. 1031, 70-71.)

The Examiner was therefore well aware of the USP <701> Disintegration Test. (Ex. 1031, 41.) Petitioner does not address the arguments made during prosecution or attempt to distinguish its own arguments from the ones made by the Examiner. 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. (Petition at 70-71.)

Regarding *Becton* factor (f), similar to the grounds above, Petitioner does not present new evidence that warrants reconsideration of the same prior art. Petitioner's expert declaration repeats arguments in the Petition and the expert fails to support his testimony with objective evidence. *See NHK*, IPR2018-00752, Paper 8 at 16-17 (“[T]he declaration does not persuade us that we should reconsider Braunheim, the AAPA, or Petitioner's arguments because the declaration is substantially similar to the Petition...and Dr. Bogy fails to support his testimony with objective evidence.”) (footnote omitted). Specifically, neither Petitioner nor its expert address the prosecution history or the fact that the teachings of the asserted art are substantially the same as the art already considered. In particular, Petitioner and its expert fail to address that neither Grother nor Venkatesh, like Venkatesh 2009, teach the topical administration of a corticosteroid to the upper gastrointestinal tract. Further, Petitioner and its expert entirely ignore the fact that the USP <701> Disintegration Test was part of the record. (Ex. 1031, 71.) The FDA Guidance simply refers to the

USP <701> Disintegration Test, which itself was in front of the Examiner during prosecution. (Ex. 1031, 41.) Petitioner and its expert do not acknowledge Patent Owner's arguments and amendments made in prosecution, or the Examiner's withdrawals of rejections based on substantially the same evidence/arguments. Petitioner merely states that because the art is new and was not considered, and its expert "mapped" the claims for the Board, the Office materially erred. *See Becton, Dickinson*, IPR2017-01586, Paper 8 at 25 (declining institution on a reference where "Petitioner has not . . . addressed the evidence and argument presented by Patent Owner" but instead "[m]ainly . . . asserts that it presents new testimonial evidence that has not been considered by the Office").

Petitioner has not demonstrated the "misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims." *Advanced Bionics*, IPR2019-01469, Paper 6 at 8 n.9. Petitioner failed to meet its burden of showing material error and is foreclosed from raising new arguments concerning error in a reply. *KOA Corp.*, IPR2019-00201, Paper 30 at 77 ("A reply that raises a new issue or belatedly presents evidence may not be considered.").

Each of the *Advanced Bionics* factors weigh in favor of denying institution of Grounds 2 and 4 under § 325(d).

IV. CONCLUSION

For the reasons set forth above, *inter partes* review of claims 1-40 of the '729 patent should be denied.

Date: October 29, 2024

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CERTIFICATE OF COMPLIANCE WITH WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), I certify that this preliminary response complies with the type-volume limits of 37 C.F.R. § 42.24(c)(1) because it contains 10,777 words, according to the word-processing system used to prepare this petition, excluding the parts of this preliminary response that are exempted by 37 C.F.R. § 42.24(c) (including the table of contents, a table of authorities, an exhibits list, a listing of facts, a certificate of service or this certificate of word count, or appendix of exhibits).

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**CERTIFICATION OF SERVICE
UNDER 37 C.F.R. §§ 42.6(e), 42.105(a)**

I, Sanya Sukduang, hereby certify that on October 29, 2024, the foregoing Patent Owner's Preliminary Response and Exhibits 2001–2004 pursuant to 37 C.F.R. § 42.8 were served electronically via email on the following counsel of record for Petitioner as follows:

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