

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. FALK PHARMA GMBH,

Petitioner,

v.

ELLODI PHARMACETICALS, L.P.,

Patent Owner.

IPR2025-00054

Patent 11,246,828 B2

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

NEW, *Administrative Patent Judge.*

DECISION

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

I. INTRODUCTION

Petitioner Dr. Falk Pharma GmbH (“Petitioner”) has filed a Petition (Paper 1, “Pet.”) seeking *inter partes* review of claims 1–16 (all claims) of U.S. Patent 10,632,828 B2 (Ex. 1001, the “’828 patent”). Patent Owner Ellodi Pharmaceuticals, L.P. (“Patent Owner”) did not file a Preliminary Response nor was it required to do so.

Under 35 U.S.C. § 314, the Board “may not authorize an *inter partes* review to be instituted unless ... the information presented in the petition ... and any response ... shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” For the reasons we explain below, we institute *inter partes* review of claims 1–16 of the ’828 patent.

II. BACKGROUND

A. *Real Parties-in-Interest*

Petitioner identifies Dr. Falk Pharma GmbH as the real party-in-interest. Pet. 68. Patent Owner identifies Ellodi Pharmaceuticals, L.P., as the real party-in-interest. Paper 4, 1.

B. *Related Matters*

Petitioner identifies *Ellodi Pharms., L.P. v. Dr. Falk Pharma GmbH*, Case No. 24-cv-1392 (E.D. Va) and *Ellodi Pharms., L.P. v. Dr. Falk Pharma GmbH*, Düsseldorf Regional Court, Case No. 4b O 43/24, Patent Litigation Chamber, Werdener Str. 1, 40227 Düsseldorf, Germany as related matters involving the ’828 patent. Pet. 68.

Petitioner also identifies the following U.S. Patents and U.S. Patent Applications as being related to the '828 patent: U.S. Appl. Ser. Nos. 61/247,642 and 17/569,047, and U.S. Patents 8,771,729 B2, 9,486,407 B2, 9,387,167 B2, 9,849,084 B2, 10,632,069 B2, and 11,266,598 B2. Pet. 68–69.

Patent Owner identifies the following *inter partes* reviews as being related to the present case: IPR2024-01197, *Dr. Falk Pharma GmbH v. Ellodi Pharms., L.P.* (US 8,771,729 B2); IPR2025-00052, *Dr. Falk Pharma GmbH v. Ellodi Pharms., L.P.* (US 10,632,069 B2); IPR2025-00055, *Dr. Falk Pharma GmbH v. Ellodi Pharms., L.P.* (US 9,486,407 B2); and IPR2025-00056, *Dr. Falk Pharma GmbH v. Ellodi Pharms., L.P.* (US 11,260,061 B2). Paper 7, 2.

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1–16 of the '828 patent are unpatentable, based upon the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–16	103	Dohil ¹
2	1–16	103	Grother ² , FDA Guidance ³

¹ Dohil et al. (US 2007/0111978 A1, May 17, 2007) (“Dohil”) Ex. 1002.

² Grother et al. (WO 00/44351, August 3, 2000) (“Grother”) Ex. 1008.

³ U.S. Food and Drug Administration, *Guidance for Industry: Orally Disintegrating Tablets* (December 2008) (“FDA Guidance”) Ex. 1005.

Pet. 21. Petitioner also relies upon the Declaration of Dr. Alan F. Parr (the “Parr Declaration,” Ex. 1051).

D. The '828 Patent

The '828 patent is directed to orally-administered corticosteroid compositions. Ex. 1001, Abstr. The '828 patent is also directed to a method for treating a condition associated with inflammation of the gastrointestinal tract in an individual, comprising administering to an individual an orally-administered corticosteroid pharmaceutical composition. *Id.*

The '828 patent teaches that, in one embodiment, its invention is directed to solid pharmaceutical compositions comprising less than or equal to 20 mg of a corticosteroid, in which the composition has no significant systemic glucocorticoid or mineralcorticoid activity after oral administration. Ex. 1001, cols. 1–2, ll. 66–3. The '828 patent teaches, in this embodiment in the solid pharmaceutical composition disintegrates within sixty seconds in simulated saliva when tested using the USP <701> Disintegration Test, and/or which disintegrates within sixty seconds when placed in the oral cavity of a human. *Id.* at col. 2, ll. 3–7. The '828 patent teaches that “[s]uitable corticosteroids which may be included in the pharmaceutical compositions of the present invention include budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, tixocortol and salts, solvates, and esters thereof” and that “[i]n other embodiments, the compositions of the present invention comprise budesonide.” *Id.* at col. 7, ll. 20–27.

E. Representative Claim

Claim 1 is the sole independent claim of the '828 patent and recites:

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

EX1001, col. 18, ll. 50–63 (we adopt Petitioner's use of [iv] and [v] for the respective limitations. *See* Pet. 4).

III. ANALYSIS

A. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claims in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 100(b) (2020). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006)

(citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

Petitioner notes that the ’828 patent’s Specification defines “orally disintegrating tablet,” “orally dispersing tablet,” or “ODT” to refer “to a solid dosage form of the present invention, which disintegrates rapidly in the oral cavity of a patient after administration, without chewing.” Pet. 22 (citing Ex. 1001, col. 2, ll. 49–52). Petitioner points out that this definition is equivalent to that adopted by the U.S. Food and Drug Administration (“FDA”). *Id.* (citing Ex. 1005, 2; Ex. 1051 ¶ 118).

Petitioner also notes that the ’828 patent defines the claim term “about,” when referring to a numerical quantity, “includes ‘exactly’.... When the term ‘about’ is used in reference to a range of values, the term ‘about’ refers to both the minimum and maximum value of the range (e.g., ‘about 1–50 μm ’ means ‘about 1 μm to about 50 μm ’).” Pet. 22 (quoting Ex. 1001, cols. 2–3, ll. 65–6). Petitioner acknowledges that these definitions of the ’828 patent govern the definitions of these terms. Pet. 22.

We determine that no express construction of any claim term beyond the definitions provided by the Specification and, in the absence of such definitions, the ordinary and customary meaning, as understood by a person of ordinary skill in the art at the time of the invention, is necessary for the purpose of rendering this Decision. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *see also Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms ... that are in controversy,

and only to the extent necessary to resolve the controversy.”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

B. A Person of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art would have had 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. Pet. 4. Alternatively, argues Petitioner, a skilled artisan would have had a lesser degree in those fields, with at least five or more years of experience in formulation development. *Id.* at 4–5. Petitioner also contends that a person of ordinary skill in the art would also have had access to a medical doctor with a specialty in gastroenterology, and other individuals with expertise related to the above subjects. *Id.* at 5.

Petitioner’s proposed definition of the level of ordinary skill in the art appears to be consistent with the level of skill presented in the cited prior art. *See, e.g.*, Exs. 1004–1007; *see also Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself may reflect an appropriate level of skill in the art). However, at this point we reject the portion of Petitioner’s proposed definition that includes having “access to a medical doctor with a specialty in gastroenterology, and other individuals with expertise related to the above subjects,” as not reflecting the individual level of skill of a given skilled artisan. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986) (holding that “[t]he person of ordinary skill is a hypothetical *person* who is presumed to be aware of all the pertinent prior art. The actual inventor’s skill is not determinative”) (emphasis added, footnotes omitted). For the purposes of this Decision, we

adopt Petitioner's proposed definition as defining a person of ordinary skill in the art as a person who would have had:

[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.

Pet. 4–5.

C. Ground 1: Alleged Obviousness of Claims 1–16 over Dohil

1. Overview of Dohil

Dohil, U.S. Patent Application Publication No. 2007/0111978 A1, is entitled *Viscous Budesonide for the Treatment of Inflammatory Diseases of the Gastrointestinal Tract*. Ex. 1002, code (54). Dohil is directed to 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. *Id.*, Abstr. Dohil also discloses pharmaceutical compositions useful for its disclosed methods. *Id.*

Specifically, Dohil teaches the administration of a therapeutically effective amount of a topical corticosteroid, such as budesonide, for the treatment of, *inter alia*, eosinophilic esophagitis.⁴ Ex. 1002 ¶¶ 11, 15. Dohil teaches that such a therapeutically effective amount can be 1–2 mg or 2–3 mg of corticosteroid per day. *Id.* ¶ 15. Dohil also teaches that an effective dose of corticosteroid may consist of:

⁴ Dohil teaches that eosinophilic esophagitis is a disorder of the esophagus, the pathogenesis of which is poorly understood, but which may be caused by allergic or abnormal host immunological responses. Ex. 1002 ¶ 63.

10 to 400 ug/kg of body [mass] per day, or for example, in the range of 20 to 300 ug/kg per day, or for example in the range of 30 to 200 ug/kg per day, or for example in the range of 30 to 100 ug/kg per day, or for example in the range of 35 to 100 ug/kg per day, or for example in the range of 30–50 ug/kg per day, or for example in the range of 40–100 ug/kg/day, or for example in the range of 40–60 ug/kg/day, or in an illustrative embodiment in the range of 35–60 ug/kg/day.

Id. ¶ 31.

Dohil further teaches that:

In other illustrative embodiments of the invention, the Budesonide is provided in the form of a lozenge which may be dissolved in the mouth, thus reaching and coating the esophagus. The lozenge or other similar tablet, capsule, or other solid, wo[u]ld dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus.

Ex. 1002 ¶ 32.

2. Obviousness of claims 1–16 over Dohil

a. Principles of law

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of non-obviousness, if present. *KSR*, 550 U.S. at 406.

“[W]hen a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR*, 550 U.S. at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). But, in analyzing the obviousness of a combination of prior art elements, it can also be important to identify a reason that would have prompted one of skill in the art “to combine ... known elements in the fashion claimed by the patent at issue.” *Id.* at 418.

“[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” *In re Preda*, 401 F.2d 825, 826 (C.C.P.A. 1968). Moreover, a precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *KSR*, 550 U.S. at 418. Rather, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness over a combination of references must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (quotations and citations omitted).

b. Petitioner's arguments

i. Independent claim 1

(a) Preamble: “An orally dispersing tablet comprising”

Petitioner argues that, if the preamble is limiting, Dohil discloses the recited orally dispersing tablet. Pet. 22. Petitioner points to, e.g., Dohil’s teaching that “[b]udesonide ... in the form of a lozenge which may be dissolved in the mouth, thus reaching and coating the esophagus. The lozenge or other similar tablet, capsule, or other solid, would dissolve rapidly in the mouth or esophagus to produce a solution that can then coat the esophagus.” *Id.* at 23–24 (quoting Ex. 1002 ¶ 32). Petitioner argues that Dohil further discloses “[b]udesonide, in the form of a dissolving tablet.” *Id.* at 24 (quoting Ex. 1002 ¶ 13; also citing *id.* ¶ 37 (disclosing “dissolving tablets”; Ex. 1051 ¶ 119).

Petitioner argues that those of ordinary skill in the art would have understood that Dohil’s lozenges and tablets that dissolve rapidly in the oral cavity do so without chewing. Pet. 24 (citing Ex. 1051 ¶ 117; Ex. 1005, 1). Petitioner asserts that Dohil’s lozenges and tablets are orally dispersing tablets that dissolve rapidly in the mouth without chewing and therefore satisfies the preamble. *Id.*

(b) Limitation 1(i): “about 0.5 mg to about 5 mg of budesonide”

Petitioner argues that Dohil discloses that “[b]udesonide is provided in the form of a lozenge which may be dissolved in the mouth.” Pet. 24 (citing Ex. 1002 ¶ 32). According to Petitioner, Dohil teaches that “[i]n certain embodiments, 1–2 mg [or 2–3 mg] of corticosteroid per day is

administered to said individual.” *Id.* (quoting Ex. 1002 ¶¶ 15, 31, also citing *id.* ¶ 58 (“0–1 mg/day, 1–2 mg/day, 2–3 mg/day, 3[–]4 mg/day, 4–5 mg/day [of] ... for example, Budesonide, are administered”)). Petitioner contends that the patients in the study disclosed by Dohil were dosed with topically administered budesonide at 0.5, 1, or 2 mg/day. *Id.* (citing Ex. 1002 ¶¶ 58, 53, Table 1. Petitioner additionally argues that Dohil teaches that “[i]n one illustrative example, the dose is provided once a day.” *Id.* at 24–25 (quoting Ex. 1002 ¶ 31). Petitioner asserts that Dohil thus teaches a lozenge or tablet containing a daily dose of budesonide at, e.g., 0.5 mg, 1 mg, 2 mg, and/or 3 mg. *Id.* at 25 (citing Ex. 1051 ¶¶ 121–126).

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

Petitioner argues that Dohil teaches that “[b]udesonide is provided in the form of a lozenge” or “other similar tablet” which will “dissolve rapidly in the mouth or esophagus.” Pet. 25 (quoting Ex. 1002 ¶ 32). Petitioner asserts that Dohil further teaches that, “[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.” *Id.* (quoting Ex. 1002 ¶ 37). According to Petitioner, it was known in the art that the rapid dissolution of the lozenge or tablet would be desirably aided by at least one disintegrating agent. *Id.* at 25–26 (citing, e.g., Ex. 1018, 446–447).

Petitioner explains that disintegrating agents were known to assist ODT disintegration in saliva, which facilitates the dispersal of the tablet in the oral cavity. Pet. 26 (citing Ex. 1019, 310 (explaining that Mouth Dissolving Tablets (“MTDs”) were known that “contain agents to enhance

the rate of tablet disintegration in the oral cavity and are more appropriately termed as fast-disintegrating tablets, as they may take about one minute to disintegrate completely”); also citing Ex. 1051 ¶¶ 127–131).

- (d) Limitation 1(iii): “sucralose, mannitol, magnesium stearate, polyvinyl pyrrolidone, polyethylene glycol, or combinations thereof”

Petitioner argues that Dohil discloses that sucralose, mannitol, magnesium stearate, polyvinylpyrrolidone, and polyethylene glycol should be included as excipients in its formulations. Pet. 26–27 (citing Ex. 1002 ¶¶ 14, 37, 39, 40). Petitioner contends that a person of ordinary skill in the art would have been motivated to include any one of these five ingredients as well as combinations of all five ingredients in Dohil’s formulation, and with a reasonable expectation of success, based on Dohil’s disclosure to formulate ODTs with these ingredients. *Id.* at 27 (citing E. 1051 ¶ 133).

- (e) Limitation 1[iv]: “wherein upon administration a therapeutically effective amount of budesonide is deposited topically in the upper gastrointestinal tract”

Petitioner argues that Dohil discloses a lozenge or tablet that “comprises a therapeutically effective amount of corticosteroid to prevent or alleviate esophageal inflammation. In certain embodiments, 1–2 mg or 2–3 mg of corticosteroid per day is administered to said individual.” Pet. 32 (citing Ex. 1002 ¶ 15). Petitioner contends that Dohil further teaches a lozenge or tablet containing a daily dose of budesonide containing, e.g., 0.5 mg, 1 mg, 2 mg, and/or 3 mg. *Id.* (citing Ex. 1051 ¶ 158). Petitioner argues that a person of ordinary skill in the art would therefore understand

that a dose of, e.g., 0.5 mg to 1 mg of corticosteroid per day is a therapeutically effective amount of the corticosteroid. *Id.*

Petitioner notes that Dohil teaches that, upon administration of the lozenge or tablet, it “dissolve[s] rapidly in the mouth or esophagus to produce a solution” of budesonide that is deposited topically in the upper gastrointestinal tract by “coat[ing] the esophagus.” Pet. 32 (quoting Ex. 1002 ¶ 32). Petitioner points to Dohil’s repeated disclosures that its formulations are designed to topically deposit a therapeutically effective amount of budesonide in the “upper gastrointestinal tract,” and “to the esophagus.” *Id.* (citing Ex. 1002 ¶¶ 10, 13, 37, 41; Ex. 1051 ¶ 159).

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

Petitioner argues that Dohil teaches 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. 33 (citing Ex. 1002 ¶ 32). Petitioner asserts that was desirable for the disintegration time of rapidly dissolving lozenge and tablets vary “from several seconds to about a minute.” *Id.* (citing Ex. 1018, 434; Ex. 1051 ¶ 162).

Petitioner argues that it would have been obvious to a person of ordinary skill in the art to formulate Dohil’s rapidly dissolving lozenge or tablet to disintegrate within 60 seconds when tested using the USP <701> Disintegration Test. Pet. 34. According to Petitioner, the knowledge of those of skill in the art is represented by, for example, the FDA’s Guidance

for Industry on ODTs. *Id.* Petitioner points out that the FDA Guidance explains that ODTs “disintegrate[] rapidly, usually within a matter of seconds.” *Id.* (quoting Ex. 1005, 2). Petitioner also notes that the FDA recommends that ODTs have “an *in-vitro* disintegration time of approximately 30 seconds or less, when based on the United States Pharmacopeia (USP) disintegration test method or alternative (see section IV).” *Id.* (quoting Ex. 1005, 2). Petitioner argues that the FDA Guidance further “recommend[s] that applicants use the USP method for disintegration testing,” specifically “USP 29, <701> Disintegration” *Id.* (citing Ex. 1005, 3 n.3).

Petitioner argues that a skilled artisan would have been motivated to follow the FDA Guidance in formulating Dohil’s rapidly dissolving lozenge or tablet containing budesonide. Pet. 34. Petitioner contends that the FDA Guidance provides the agency’s thinking and recommendations on the topic of orally dissolving tablets. *Id.* (citing Ex. 1005, 1). Petitioner argues that the FDA regulates the use of pharmaceutical compositions in the United States, and that Dohil’s formulations were intended to “be used in therapy for human patients,” and the initial testing of its formulations was conducted within the United States. *Id.* (citing Ex. 1002 ¶¶ 28, 49). Petitioner contends that a person of ordinary skill in the art, seeking to formulate budesonide into an orally disintegrating tablet, would have been motivated to follow the FDA Guidance that such a tablet should disintegrate within 30 seconds or less when tested using the USP <701> Disintegration Test. *Id.* at 34–35 (citing Ex. 1051 ¶¶ 163–164; also citing *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1291–92 (Fed. Cir. 2013) (holding that “[t]he potential for FDA approval also may properly be considered, as it was here,

in determining whether one of ordinary skill would be motivated to develop a drug product”).

Petitioner additionally argues that a person of ordinary skill in the art would have had a reasonable expectation of success, based on Dohil’s detailed description of how to formulate budesonide into a rapidly disintegrating lozenge or tablet. Pet. 35 (citing Ex. 1002 ¶¶ 27–41). According to Petitioner, formulating orally disintegrating tablets that dissolve within “several seconds to about a minute” would have been a routine exercise by 2009, the time of filing of the ’828 patent. *Id.* (citing Ex. 1018, 434; Ex. 1005, 2; Ex. 1020 ¶¶ 1, 16, 18). Petitioner contends that, at that time, there were many orally disintegrating systems and products that were commercially available, which would have bolstered a skilled artisan’s expectation of success. *Id.* (citing Ex. 1017, 179–181; Ex. 1018, 436–439; Ex. 1051 ¶ 165).

c. Analysis

After considering the as-yet uncontested evidence and arguments presented in the Petition, we determine that Petitioner has demonstrated a reasonable likelihood of success at trial in proving that at least one challenged claim of the ’828 patent is unpatentable. In particular, because Petitioner has demonstrated a reasonable likelihood that at least claim 1 is rendered obvious over Dohil in view of the understanding of a person of ordinary skill in the art, as argued in Ground 1, we institute *inter partes* review with respect to claim 1.

Furthermore, because we determine that Petitioner has demonstrated a reasonable likelihood of success at trial in showing that at least one claim is

unpatentable on at least one of the stated Grounds, we institute *inter partes* review of all challenged claims of the '828 patent, based on all of the grounds identified in the Petition. *See* 37 C.F.R. § 42.208(a); *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 371 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition”)

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term. Thus, our view with regard to any conclusion reached in the foregoing could change upon consideration of Patent Owner’s merits response and completion of the record.

In keeping with our mission of resolving patentability disputes in a just, speedy, and efficient manner, we exercise our discretion to institute *inter partes* review as set forth in the following Order.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED, pursuant to 35 U.S.C. § 314(a), that the Petition for *inter partes* review of challenged claims 1–16 of U.S. Patent 11, 246,828 B2 is GRANTED with respect to institution on all grounds in the Petition; 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 '828 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of trial.

IPR2025-00054
Patent 11,246,828 B2

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