Trials@uspto.gov
571-272-7822

Paper 17
Entered: July 15, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner,

v.

UCB BIOPHARMA SPRL,
Patent Owner.

IPR2019-00400
Patent 8,633,194 B2

Before ROBERT A. POLLOCK, RYAN H. FLAX, and KRISTI L. R. SAWERT *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Apotex Inc. ("Petitioner") filed a corrected Petition for an *inter partes* review of claims 1–11 of U.S. Patent No. 8,633,194 B2 ("the '194 patent," Ex. 1001). Paper 4 ("Pet."). UCB Biopharma Sprl ("Patent Owner" or "UCB") timely filed a Preliminary Response. Paper 11 ("Prelim. Resp."). The parties further submitted an authorized Reply and Sur-Reply to the Preliminary Response. Paper 13 ("Reply"); Paper 16 ("Sur-reply").

We review the Petition, Preliminary Response, Reply, Sur-reply, and accompanying evidence under 35 U.S.C. § 314. For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has demonstrated a reasonable likelihood that at least one claim of the '194 patent is unpatentable, we institute an *inter partes* review of the challenged claims.

A. Real Parties-in-Interest

Petitioner identifies itself, Apotex Corp., Apotex Holdings Inc., and Apotex Pharmaceuticals Holdings Inc. as real parties-in-interest. Pet. 3. According to Patent Owner, its real parties-in-interest are UCB Biopharma Sprl, UCB, Inc., UCB Pharma S.A., UCB S.A., and UCB Manufacturing Inc. Paper 7, 2.[1]

[1] Although Patent Owner names only UCB entities as real parties-in-interest, we note that Petitioner's tentative FDA approval letter (Ex. 2007) and the current Orange Book listing for various Xyzal formulations (Ex. 3003) lists Sanofi Aventis US LLC as the NDA holder. Clarification by the parties is requested.

B. Related Proceedings

The '194 patent is at issue in *UCB, Inc. v. Apotex Inc.*, No. 0-18-cv-60846 (S.D. Fla.). *See* Paper 7, 2; Paper 10, 2. On April 1, 2019, Judge Cooke of the Southern District of Florida issued an Order staying that case pending our review of the '194 patent. Ex. 3001 (order granting Apotex, Inc.'s motion to stay pending *inter partes* review and administratively closing the case); Ex. 3002 (reporting same).

Patent Owner also notes the '194 patent was previously at issue in *UCB, Inc. v. Apotex Inc.*, 1:18-cv-03404 (S.D.N.Y.), which was voluntarily dismissed. Paper 7, 2.

C. Asserted Grounds of Unpatentability

Petitioner asserts two grounds of unpatentability (Pet. 7, 8):

Ground	Claims	Basis	Asserted References
1	1–11	103(a)[2]	WO '094[3] and the Handbook[4]
2	1–11	103(a)	EP '203,[5] US '558,[6] and the Handbook

[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '194 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. § 103 throughout this Decision.
[3] International Patent Application No. WO 2004/050094. Ex. 1007.
[4] AMERICAN PHARMACEUTICAL ASSOCIATION, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (Arthur H. Kibbe, Ph.D. ed., 3d ed. 2000). Ex. 1006.
[5] European Patent Application Publication No. 0605203 A2. Ex. 1004.
[6] U.S. Patent No. 5,698,558, issued Dec. 16, 1997. Ex. 1015.

In support of its patentability challenges, Petitioner relies on, *inter alia*, the Declaration of Dr. Paul A. Laskar, Ph.D. Ex. 1002.

D. The '194 Patent and Relevant Background

According to the '194 patent's Specification, "[t]he present invention is based on the unexpected recognition that a pharmaceutical composition comprising an active substance belonging to the family of substituted benzhydryl piperazines and a reduced amount of preservatives is stable during a long period of time." Ex. 1001, 1:60–64; *see also id.* at 1:64–65 (defining stability as "the capacity to resist[] . . . microbial contamination"). Such combinations can be administered orally, by spray inhalation, and nasal installation and may be formulated as drops, nasal drops, eye drops, ear drops, and oral preparations such as a syrup. *Id.* at 5:8–29.

"Preferably, the active substance is selected from the group of cetirizine, levocetirizine, and their pharmaceutically acceptable salts." *Id.* at 2:19–21. By way of background, we understand that these compounds have antihistamine activity. Cetirizine, the active ingredient in the commercially available allergy relief product Zyrtec, is a racemic mixture of (R) and (S) enantiomers; the levorotary R-enantiomer (as levocetirizine dihydrochloride) is the active ingredient in the commercially available Xyzal and Xyzal Allergy 24HR products. *See* Ex. 1001, 2:22–48; Ex. 1008, 1123;[7] Ex. 1011; Ex. 2007; and Ex. 3003.

---

[7] Jean-Paul Tillement *et al*., *Compared pharmacological characteristics in humans of racemic cetirizine and levocetirizine, two histamine H1-receptor antagonists*, 66(7) BIOCHEM. PHARMACOL. 1123–26 (2003).

The Specification suggests that compositions including cetirizine or levocetirizine can employ a wide variety of preservatives (*see, e.g.*, Ex. 1001, 3:19–44), but "[b]est results have been obtained with a mixture of methyl parahydroxybonzoate and propyl parahydroxybonzoate in a ratio of 9/1 expressed in weight" (*id.* at 3:45–48).[8] And, whereas the Specification asserts that 3 mg/ml of parahydroxybenzoate esters is "a normal concentration to preserve aqueous solutions" (*id.* at 1:64–2:4), it highlights embodiments in which

> the pharmaceutical composition contains an amount of p-hydroxybenzoate esters (methyl p-hydroxybenzoate/propyl p-hydroxybenzoate in a ratio of 9/1 expressed in weight) selected in the range of 0.0001 and 1.5 mg/ml of the composition. Preferably, it contains an amount selected in the range of 0.01 and 1.125 mg/ml. More preferably it contains an amount of preservatives selected in the range of 0.1 and 1 mg/ml.

Id. at 3:49–56; *see also id.* at 9:38–11:7 (Example 4 including oral levocetirizine solution having 9/1 ratio of methyl p-hydroxybenzoate/propyl p-hydroxybenzoate which comprise 0.75 mg/ml of the composition).

E. Challenged Claims

The '194 patent includes 12 claims. Of these, Petitioner challenges claims 1–11, of which only claim 1 (reproduced below) is independent:

---

[8] The Laskar Declaration indicates that the methyl parahydroxybenzoate and propyl parahydroxybenzoate recited in the '194 patent's claim 1 (*see infra* Section E) are also known as methylparaben and propylparaben, respectively, and generically as "parabens." *See, e.g.*, Ex. 1002 ¶¶ 53, 54, 80 n.14 (citing Ex. 1006, 340, 450).

> 1. A liquid pharmaceutical composition comprising (i) levocetirizine or a pharmaceutically acceptable salt of levocetirizine, and (ii) a preservative mixture consisting essentially of a mixture of methyl parahydroxybenzoate and propyl parahydroxybenzoate in a ratio of 9/1 expressed in weight, said mixture being present in an amount of more than 0 and up to 0.75 mg/ml of the composition, wherein said composition is substantially free of bacteria.

Ex. 1001, 13:6–13. Among the dependent claims before us, claim 4 recites that "the composition is in the form of oral solutions, nasal drops, eye drops or ear drops"; claim 11 is limited to "an oral solution comprising 0.50 mg/ml levocetirizine dihydrochloride, 0.675 mg/ml methyl p-hydroxybenzoate, and 0.075 mg/ml propyl p-hydroxybenzoate"; and claims 8–10 are cast as methods of making the composition according to claim 1. *Id.* at 13:19–21, 14:5–22.

F. Relevant Prosecution History

During the prosecution leading to the issuance of the '194 patent, the Examiner rejected claims as obvious over the combination of Dietrich, DeLongueville, Doron, Gilliland I, Gilliland II, and Routlege. Ex. 1013, 454–463; Exs. 2001–2006 (references cited in full at Prelim. Resp., i). In response, Applicants initially amended claim 1 to recite

> 1. A liquid pharmaceutical composition comprising (i) levocetirizine or a pharmaceutically acceptable salt of levocetirizine, and (ii) a preservative mixture consisting essentially of a mixture of methyl parahydroxybenzoate and propyl parahydroxybenzoate in a ratio of 9/1 expressed in weight, said mixture being present in an amount of more than 0 and up to **1.125** mg/ml of the composition, wherein said composition is substantially free of bacteria.

See Ex. 1013, 492, 495 (emphasis added). In conjunction with its amendment, Applicants submitted a Declaration of named inventor Domenico Fanara, asserting that "[t]the combined parabens in typical pharmaceutical preparations is at least about 2 mg/ml, as shown by an accepted pharmaceutical treatise (see, Remington, The Science and Practice of Pharmacy, 21st ed., 2005, pp. 748-749, Ex. B, hereinafter 'the Remington treatise')." *Id.* at 536, ¶ 7. Mr. Fanara testified, however, that "[i]n the course of developing liquid pharmaceutical formulations of levocetirizine and its salts, we were surprised to discover that levocetirizine itself can act as an anti-microbial." *Id.* at ¶ 8. Mr. Fanara also submitted evidence purporting to show the antibacterial efficacy of levocetirizine solutions having 0.375 mg/ml or 0.750 mg/ml of parabens consisting of methyl paraben (MP) and propyl paraben (PP) in a 9/1 ratio. *See id.* at 536–37, ¶¶ 10–11. Upon distinguishing the specific teachings of DeLongueville, Doron, Gilliland I, and Gilliland II, Mr. Fanara stated that the combination of those references "does not teach or suggest that a pharmaceutical formulation could be prepared that is maintained substantially free of bacteria and having the a [sic] total of MP and PP of no greater than 1.125 mg/ml, and no other preservative." *Id.* at 537–38, ¶¶ 12–17.

A subsequent Interview Summary Record shows that the Examiner was not persuaded by Applicants' argument that Remington taught a combined paraben concentration of at least about 2 mg/ml. *Id.* at 571. Rather, the Examiner found that "Remington discloses that parabens are common preservatives used in liquid pharmaceutical dosage forms and their typical concentrations levels range from about 0.1% [1 mg/ml] and up."

Based on this reading of Remington—and Gilliland II's teaching that methyl paraben and propyl paraben have synergistic effects in combination—the Examiner determined that one of ordinary skill in the art at the time of the invention "would expect that MP/PP [methyl paraben and propyl paraben] in a dose of about 1 mg/ml and slightly below would be . . . antimicrobial in view of the prior art," but "would not expect that amounts of MP/PP much less than 1 mg/ml would be effective." *Id.* The Examiner further indicated that claims reciting a combined paraben concentration of 0.75 mg/ml would be patentable, as follows:

> A review of the data provided in the Declaration demonstrate that compositions containing levocetrizine (sic) and MP/PP with ratio of 9/1 and total concentration of 0.675 mg/ml and 0.375 have antimicrobial effects. This is deemed to be surprising and unexpected. Examiner noted that one of ordinary skill in the art would not expect to have antimicrobial effects at these concentrations based on the art of record, however based on the art of record the upper limit of MP/PP amount of 1 mg/ml in claim 5 and 1.125 mg/mg in claim 1 would not be unexpected. The upper limit of claim 15 of 0.75 mg/ml is also considered to be unobvious in view of the prior art. Examiner suggests incorporating the upper limit of claim 15 (i.e.[,] 0.75 mg/ml) as the upper limit in claim 1 to make the instant claims allowable.

Id. In light of the above, claim 1 was amended to recite the combined paraben concentration of 0.75 mg/ml, as issued. *Id.* at 590, 612.

II. ANALYSIS

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed.

Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

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 nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

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

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

A. Person of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus. Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner contends that a person of ordinary skill in the art as of the relevant date would have

> (i) a Pharm. D. or Ph.D. in chemistry, biochemistry, pharmacy, pharmaceutics, or in a related field, and at least two years of relevant experience in developing and formulating aqueous pharmaceutical formulations; (ii) a master's degree in the same fields and at least five years of the same relevant experience; or (iii) a bachelor's degree in the same fields and at least seven years of the same relevant experience.

Pet. 6 (citing Ex. 1002, ¶ 32–33). Patent Owner does not presently dispute Petitioner's proposed definition of the skilled artisan. Prelim. Resp. 2 n.1. And as Petitioner's proposed definition is not inconsistent with the cited

prior art, we adopt it for the purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

B. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b).[9] Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* Furthermore, at this stage in the proceeding, we need only construe the claims to the extent necessary to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the

[9] The Office has changed the claim construction standard in AIA proceedings to replace the broadest reasonable interpretation ("BRI") standard with the same claim construction standard used in a civil action in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018). The change applies to petitions filed on or after November 13, 2018. *Id.* Because the present Petition was filed on December 13, 2018, we construe the claims in accordance with the federal district court standard, now codified at 37 C.F.R. § 42.100(b).

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

Petitioner refers us to the express definition of certain terms at columns 2 and 3 of the '194 patent's Specification and contends that no further construction is necessary. Pet. 6; *see also* Ex. 1001, 2:22–3:48 (defining, e.g., cetirizine, levocetirizine, pharmaceutically acceptable salts, and preservatives). UCB agrees that no construction is necessary at this time. Prelim. Resp. 2 n.1. At this stage of the proceeding, we agree with the parties that no terms require express construction. We, nonetheless, emphasize that we apply the common and ordinary meaning to "substantially free of bacteria," a term not expressly defined in the '194 patent. We understand "substantially free of bacteria" to mean having, at most, a low, but clinically acceptable, level of bacteria, which would have been its ordinary meaning to the skilled artisan because the claimed composition is a pharmaceutical, but the term "substantially" leaves some flexibility from absolute sterility. To the extent either party disagrees with our present understanding of this term, we invite further briefing on the topic in the Patent Owner Response and Petitioner's Reply.

C. Obviousness in view of WO '094 and the Handbook (Ground 1)

As Ground 1, Petitioner challenges claims 1–11 as obvious in view of WO '094 and the Handbook. Pet. 19–43. Petitioner's challenge includes a detailed claim chart mapping the teachings of these references to each element of claim 1. *Id.* at 19–21. UCB states that it has "has previewed its substantive arguments," at pages 19–24 of its Preliminary Response, but

focuses largely on arguments for denying institution under 35 U.S.C. §§ 325(d) and 314(a), which we address in section II(E), below. *See* Sur-Reply 4. We begin our analysis with an overview of the references asserted under Ground 1.

1. Overview of WO '094 (Exhibit 1007)

WO '094 is directed to the use of levocetirizine for the treatment of persistent allergic rhinitis, wherein: "[a] preferred daily dosage provides from about 0,0005 mg to about 2 mg of levocetirizine or a pharmaceutically acceptable salt thereof, per kg of body weight per patient . . . . [and] may be administered once per day of treatment, or divided into smaller dosages." Ex. 1007, Abstract, 1:10–27, 2:35–3:2.

WO '094 further discloses that levocetirizine compositions may be formulated as, for example, aerosols, solids, creams, and liquids, including oral solutions such as syrups and drops. *Id.* at 4:8–29. Such dosage forms "may be prepared according to conventional methods used by pharmacists," and include "substances conventionally used as preserving, stabilizing, moisture-retaining, and emulsifying agents." *Id.* at 3:16–26. In one preferred embodiment, WO '094 discloses a syrup formulation of "levocetirizine dihydrochloride, methyl- and propylparaben, saccharinum, and purified water." *Id.* at 4:33–35.

2. Overview of the Handbook (Exhibit 1006)

The Handbook teaches that methylparaben and propylparaben are "widely used as . . . antimicrobial preservative[s] in cosmetics, food

products, and pharmaceutical formulations." Ex 1006, 340, 450.[10] According to the Handbook, antimicrobial activity and solubility vary inversely with increasing paraben chain length. *Id.* at 340, 341. "A mixture of parabens is thus frequently used to provide effective preservation," moreover, "[a]ctivity may be improved by using a combination of parabens, since additive effects occur." *Id.*[11]

The Handbook teaches that methylparaben and propylparaben "are affirmed GRAS Direct Food Substances in the US at levels up to 0.1% [1 mg/ml]"[12] and "[i]ncluded in the FDA Inactive Ingredients Guide (IM, IV, and SC injections, inhalations, ophthalmic preparations, oral capsules, solutions, suspensions and tablets, otic, rectal, topical, and vaginal preparations)." *Id.* at 342, 452. The Handbook teaches, for example, that "[m]ethylparaben (0.18%) [1.8 mg/ml] together with propylparaben (0.02%)

---

[10] Where possible, we refer to page numbers as published in the cited documents.

[11] Although the Handbook teaches the additive benefits of parabens in combination, we do not immediately discern the basis of Petitioner's assertion that such effects are synergistic. *See* Pet. 17, 23, 26, 29, 51; Ex. 1002 ¶¶ 85, 94, 102, 146. We, nevertheless, note that the '194 patent's Applicants did not dispute the Examiner's finding that combinations of parabens have synergistic antibacterial effects. *See* Ex. 1013, 339–40.

[12] The Laskar Declaration explains that the percentages of methyl- and propylparabens in a solution may be converted from w/v percent to milligrams per ml by multiplying the % value by a factor of 10. Ex. 1002 ¶¶ 71–73. Thus, for example, "0.015% w/v of methylparaben corresponds to 0.15 mg/ml." *Id.* ¶ 72. Patent Owner does not presently object to this calculation. *See, e.g.*, Prelim. Resp. 23–24 (discussing percentage in the Handbook in terms of mg/ml); Pet. 27 n.14. Bracketed amounts reflect that conversion.

[0.2 mg/ml] has been used for the preservation of various parenteral pharmaceutical formulations." *Id.* at 340, 450 (same). The Handbook, however, notes:

> Although parabens have also been used as preservatives in injections and ophthalmic preparations they are now generally regarded as being unsuitable for these types of formulations due to the irritant potential of the parabens. These experiences may depend on immune responses to enzymatically formed metabolites of the parabens in the skin.

Id. at 342.

Despite this caution, the Handbook discloses additional information regarding concentrations of methylparaben and propylparaben suitable for particular applications, including "IM, IV, SC injections" and "Ophthalmic preparations." *Id.* at 340, 450. With respect to methylparaben, for example, it indicates 0.065–0.25 % [0.65–2.5 mg/ml], 0.015–0.2 % [0.15–2.0 mg/ml], 0.033 % [0.3 mg/ml], and 0.015–0.2 % [0.15–2.0 mg/ml] for injectable, oral, nasal, and ophthalmic solutions, respectively. *Id.* at 340. The Handbook similarly indicates 0.005–0.2 % [0.05–2.0 mg/ml], 0.01–0.2 % [0.1–2.0 mg/ml], 0.017 % [0.17 mg/ml], and 0.005–0.01 % [0.05–0.1 mg/ml] of propylparaben for injectable, oral, nasal, and ophthalmic solutions, respectively. *Id.* at 450.

3. Analysis

Noting that WO '094 discloses a preferred oral syrup formulation of "levocetirizine dihydrochloride, methyl- and propylparaben, saccharinum, and purified water," Petitioner argues that one of ordinary skill in the art would have been motivated to further modify this formulation. Pet. 22

(quoting Ex. 1007, 4:34–35). Petitioner argues that because WO '094 is silent as to the ratio and amounts of methyl- and propylparabens in the formulation, the skilled artisan would have looked to the Handbook for guidance. *Id.* at 22–23. With respect to the former, Petitioner points to the 9/1 ratio expressly taught by the Handbook for non-oral (e.g., injectable) formulations. *Id.* at 23 (quoting Ex. 1006 at 340) ("[m]ethylparaben (0.18%) [1.8 mg/ml] together with propylparaben (0.02%) [0.2 mg/ml] has been used for the preservation of various parenteral pharmaceutical formulations"). Petitioner further relies on the declaration testimony of its expert, Dr. Laskar, in arguing that the 9/1 ratio is not limited to parenteral formulations, but is "widely used across a variety of dosage forms" for topical and oral applications. *Id.* at 23–24 (citing Ex. 1002 ¶ 88).

Although the 9/1 ratio disclosed in the Handbook for parenteral formulations contemplates a combined paraben concentration of 2.0 mg/ml, Petitioner points to the Handbook's teaching to use 0.015–0.2% [0.15–2.0 mg/ml] methylparaben in oral solutions and suspensions. Pet. 27 (citing Ex. 1006, 340, Table 1). According to Dr. Laskar, this amount of methylparaben applied to a 9/1 ratio of methyl-to-propylparaben, equates to from 0.167 mg/ml–2.22 mg/ml total parabens (specifically, from (0.15 mg/ml methylparaben + 0.017 mg/ml propylparaben) to (2.0 mg/ml methylparaben + 0.22 mg/ml propylparaben)). *Id.* at 27–28; *see* Ex. 1002 ¶¶ 96–101.[13] Petitioner further argues that one of ordinary skill in the art

[13] We note that the 0.017 mg/ml–0.22 mg/ml range of propylparaben in Dr. Laskar's calculation overlaps with the Handbook's 0.1–0.2 mg/ml range

would be motivated to use lower amounts of parabens "within the workable ranges reported in the Handbook for oral solutions and suspensions" to minimize their irritant potential and as "common sense notion . . . to use as little of a particular compound as possible to achieve the desired effect." *Id.* at 29–30 (citing Ex. 1002 ¶¶ 102–103). Accordingly, Petitioner asserts that the prior art would have led the skilled artisan to the claimed composition, having the recited parabens "present in an amount of more than 0 and up to 0.75 mg/ml of the composition," as set forth in the '194 patent's claim 1.

With respect to the requirement that "said composition is substantially free of bacteria," we note Dr. Laskar's testimony that "[n]owhere does the prior art teach that bacteria presence and/or growth was a problem for the known levocetirizine compositions." Ex. 1002 ¶ 106. Moreover, claim 1 does not recite any requirement for the level of resistance to bacterial contamination provided by the invention, nor require that the composition is at any point exposed to bacteria, merely that it is "substantially free of bacteria."

Further, and although the intrinsic preservative effect of levocetirizine may have been a motivating factor for the named inventors (*see* Ex. 1001, 1:51–54, 60–65; Ex. 1013, 455, 536 ¶¶ 8–9), on the present record we do not find unreasonable Petitioner's argument that this inherent property of

---

for oral solutions and suspensions. *See* Ex. 1006, 450. The parties may wish to explore, however, why one of ordinary skill in the art would base the 9/1 calculation upon the Handbook's range for methylparaben rather than for propylparaben, and whether that would result in a similar overlap. *See also* Pet. 43 n.17.

levocetirizine is insufficient to confer patentability. *See* Pet. 30–32 (citing e.g., *Ex parte Obiaya*, 227 USPQ 58, 60 (BPAI 1985) ("The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious."). Accordingly, we are not persuaded on this record that the "substantially free of bacteria" limitation meaningfully distinguishes the claim over the prior art.

As noted above, Patent Owner merely "previews" its substantive arguments in the Preliminary Response (*see* Sur-Reply 4 (citing Prelim. Resp. 19–24)), arguing, *inter alia*, that Petitioner has not sufficiently established that one of ordinary skill in the art would choose "a syrup formulation containing methylparaben and propylparaben over other 'preferred' non-paraben containing formulations"; that the "Handbook's reference to [parabens'] "irritant potential" provides only minimal motivation"; that "there would be no reason to *lower* the amount of parabens because the goal of a safe formulation had already been achieved with higher paraben amounts"; and that each of the exemplary formulations cited by Petitioner "contains at least 2 mg/ml total parabens, far higher than the 0.75 mg/ml total parabens required by the claims." Prelim. Resp. 19–24 (emphasis omitted).

At this stage of the proceeding, UCB has not advanced expert testimony addressing Petitioner's arguments and Dr. Laskar's underlying declaration testimony. Based on the record presently before us, we find Petitioner's argument reasonable and generally credit Dr. Laskar's

unopposed declaration testimony regarding the scope and content of the prior art and the unpatentability of the challenged claims. Accordingly, we find that Petitioner has satisfied the burden of showing that there is a reasonable likelihood that at least claim 1 of the '194 patent would have been obvious over the combination of WO '094 and the Handbook.

We have also reviewed Petitioner's contentions with respect to dependent claims 2–11, and determine that the Petition provides the requisite showing, at this stage of the proceeding, that the combination of WO '094 and the Handbook discloses the subject matter of these claims. *See* Pet. 32–43. Patent Owner does not offer, at this stage, any arguments addressing Petitioner's substantive showing. *See* Sur-Reply 4 (citing Prelim. Resp. 19–24). We determine, based on the current record, that the Petition shows a reasonable likelihood that Petitioner would prevail with respect to the contention that claims 2–11 would also have been obvious based on the combination of WO '094 and the Handbook as set forth with respect to Ground 1.

D. Obviousness in view of EP '203, US '558, and the Handbook (Ground 2)

As Ground 2, Petitioner challenges the '194 patent's claims 1–11 as obvious in light of EP '203, US '558, and the Handbook. Pet. 43–63. Petitioner's challenge again includes a detailed claim chart mapping the teachings of these references to each element of claim 1. *Id.* at 45–46. As the teachings of the Handbook are discussed in section II(C)(2), above, we begin our analysis with an overview of EP '203 and US '558.

1. Overview of EP ’203 (Exhibit 1004)

EP ’203 discloses an “antiallergic composition for ophthalmic or nasal use, comprising cetirizine or a salt thereof as an active ingredient.” Ex. 1004, Abstract. The reference discloses that such compositions “may further contain any conventional additives in suitable amounts, which are used in ordinary ophthalmic or nasal solutions, e.g., preservatives such as p-hydroxybenzoates . . . . The amount of additive to be used can be determined by those skilled in the art within the same range as adopted for ordinary ophthalmic or nasal solutions.” Ex. 1004, 3:52–57.

Example 5 of EP ’203 discloses:

> An ophthalmic composition . . . in solution form according to the following formulation:

Ingredient	Amount
Cetirizine hydrochloride	0.3 g
α-cyclodextrin	0.8 g
Polyvinyl alcohol	0.2 g
Sodium acetate	0.1 g
Propylene glycol	2.0 g
Methylparaben	0.2 g
Propylparaben	0.1 g
Sodium hydroxide	q.s.
Distilled water	ad 100 ml

Id. at 11:22–42. The above-disclosed “formulation” comprises a table

setting forth amounts of cetirizine hydrochloride, methylparaben, propylparaben and other ingredients.

2. Overview of the US ’558 (Exhibit 1015)

US ’558 teaches the use of “optically pure (-) cetirizine for the treatment of seasonal and perennial allergic rhinitis in humans while avoiding the concomitant liability of adverse effects associated with the racemic mixture of cetirizine.” Ex. 1015, Abstract, 1:11–33, 3:47–62. Cetirizine is a racemic mixture of isomers where “the active compound is the (-) isomer of 2-[4-[(4-chlorophenyl)phenylmethyl]-1-piperazinyl) ethoxyacetic acid, hereinafter referred to as cetirizine.” *Id.* at 1:40–43. US ’558 states that “[t]he prefixes d and 1 or (+) and (-) are employed to designate the sign of rotation of plane-polarized light by the compound, with (-) or 1 meaning that the compound is levorotatory. A compound prefixed with (+) or d is dextrorotatory.” *Id.* at 1:53–56.

Accordingly, US ’558 teaches that cetirizine comprises a mixture of (+) and (-) isomers, where the active, (-) isomer is levocetirizine.

3. Analysis

Petitioner contends that one of ordinary skill in the art would have focused on Example 5 of EP ’203, which comprises an ophthalmic solution of cetirizine in combination with methylparaben and propylparaben. Pet. 43–44 (citations omitted). Because US ’588 teaches that cetirizine comprises two isomers, of which only levocetirizine, the (-) isomer, is active, Petitioner reasonably asserts that one of ordinary skill in the art would have been motived to use levocetirizine in place of cetirizine in such

formulations. *Id.* at 46–48 (citations omitted). Petitioner further argues that one of ordinary skill in the art would have been motivated to look to the Handbook for guidance regarding the amount of parabens in various liquid formulations. *Id.* at 50. According to Petitioner, and for essentially the same reasons as set forth with respect to Ground 1, discussed above, the skilled artisan would have arrived at the claimed ratio and amounts of methyl- and propylparaben set forth in independent claim 1. *See id.* at 48–52.

At this stage of the proceeding, UCB has not advanced expert testimony addressing Petitioner's arguments and Dr. Laskar's underlying declaration testimony. Based on the record presently before us, we find Petitioner's argument reasonable and generally credit Dr. Laskar's unopposed declaration testimony regarding the scope and content of the prior art and the unpatentability of the challenged claims. Accordingly, we find that Petitioner has satisfied the burden of showing that there is a reasonable likelihood that at least claim 1 of the '194 patent would have been obvious over the combination of WO '094, US '558, and the Handbook.

We have also reviewed Petitioner's contentions with respect to dependent claims 2–11, and determine that the Petition provides the requisite showing, at this stage of the proceeding, that the combination of WO '094 and the Handbook discloses the subject matter of these claims. *See* Pet. 53–63. Patent Owner does not offer, at this stage, any arguments addressing Petitioner's substantive showing. *See* Sur-Reply 4 (citing Prelim. Resp. 19–24). We determine, based on the current record, that the Petition shows a

reasonable likelihood that Petitioner would prevail with respect to the contention that claims 2–11 would also have been obvious based on the combination of WO '094, US '558, and the Handbook as set forth with respect to Ground 2.

E. Discretion under §§ 314(a) and 325(d)

In the Preliminary Response, UCB directs substantially all of its argument to whether the Board should exercise discretion to deny the Petition under 35 U.S.C §§ 325(d) and 314(a). *See* Prelim. Resp. 1–2, 7–33. We granted the parties additional briefing to further explore these issues. Petitioner, thus, filed a Reply to the Preliminary Response (Paper 13) and UCB filed a responsive Sur-Reply (Paper 16). Having considered the relevant record, we do not find Patent Owner's arguments with respect to discretionary denial persuasive for the reasons set forth below.

1. Discretion under § 325(d)

UCB requests that we deny the Petition under § 325(d) because "the Office thoroughly vetted the claims through multiple rejections bearing no material difference [from] the arguments Petitioner now presents." Prelim. Resp. 7. For the reasons discussed below, we do not find Patent Owner's arguments persuasive.

Under § 325(d), we have discretion to deny a petition that presents the same or substantially the same prior art or arguments as previously presented to the Office. 35 U.S.C. § 325(d). In evaluating whether the factual predicate under § 325(d) is met, the Board has considered a number of non-exclusive factors, including, for example:

a) the similarities and material differences between the asserted art and the prior art involved during examination;

b) the similarities and material differences between the cumulative nature of the asserted art and the prior art evaluated during examination;

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

d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguished the prior art;

e) whether Petitioner has pointed out sufficiently how the Examiner erred in its consideration of the asserted prior art; and

f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the asserted prior art or arguments.

Becton, Dickinson and Co. v. B. Braun Melsungen AG, IPR2017-01586, slip op. at 17–18 (PTAB Dec. 15, 2017) (Paper 8) (informative) ("the *Becton Dickinson* factors"). These factors were adopted and applied in our precedential decision *NHK Spring Co. v. Intri-Plex Technologies, Inc.*, Case IPR2018-00752, slip op. at 11–12 (PTAB Sept. 12, 2018) (Paper 8).

Becton Dickinson factors (a)–(d) relate to whether—and to what extent—the Examiner considered and relied upon the prior art and arguments asserted in the Petition. UCB first argues that during prosecution, the Examiner marked as considered WO '094, EP '203, and the Handbook, whereas the fourth asserted reference, US '558, was "unnecessary for the Examiner to consider . . . because the Examiner relied on closer references."

Prelim. Resp. 5, 9. Undercutting this argument, however, Patent Owner admits "Petitioner's references were not evaluated during prosecution." *Id.* at 9. As Petitioner points out, the Board has consistently declined to exercise its discretion under § 325(d) based on the mere citation of references in an IDS that were not applied by the Examiner. *See* Reply 2; Pet. 65–66 (collecting cases). We see no reason to deviate from that practice here.

UCB also asserts that Petitioner's references are merely cumulative to those expressly relied on by the Examiner, and that the arguments predicated on those references "bear no material difference [from] the bases for rejection during prosecution." Prelim. Resp. 8–22. With respect to the former, UCB reasonably argues that many of the teachings of Dietrich, DeLongueville, Doron, Gilliland 2, and Routledge can be found in the references asserted by Petitioner. *See, e.g., id.* at 13–17. We do note, however, that unlike WO '094, none of the references considered by the Examiner expressly discloses a formulation comprising levocetirizine with both methyl- and propylparaben, which weighs somewhat against denying institution. *See, e.g.*, Reply 3–6; Ex. 1013, 410 ("Delongueville does not teach a specific embodiment containing levocetirizine and the required mixture of methyl parahydroxybenzoate and propyl parahydroxybenzoate (although each of these components is separately taught) . . .").

We find more relevant the Handbook's guidance regarding suitable amounts and ranges of methyl- and propylparabens for particular pharmacologic applications, including oral, nasal, ophthalmic and other preparations. *See* section II(C)(2), above. The Handbook discloses, for

example, that solutions for oral use may comprise as little as 0.15 mg/ml methylparaben and/or propylparaben in the range of 0.1–2.0 mg/ml. *Id.* Such values are relied on by Petitioner's expert, Dr. Laskar, with respect to the obviousness of methyl- and propylparabens "in an amount of more than 0 and up to 0.75 mg/ml." *See, e.g.*, Ex. 1002 ¶¶ 95–103. We do not discern that comparable arguments and calculations were previously before the Examiner. And, although UCB argues that Petitioner relies on a similar motivation to reduce the total amount of parabens as was argued before the Examiner, Patent Owner does not adequately address the weight we should accord the ranges set forth in the Handbook. *See* Prelim. Resp. 19–22. This weighs against our discretionarily denying institution.

Considering the prosecution history of the '194 patent, we find that Petitioner's reliance on the teachings of the Handbook weighs heavily in favor of institution, and that the Examiner did not fully consider its teachings regarding acceptable amounts of parabens in aqueous pharmacological compositions.[14] As discussed in Section I(F), above, Applicants relied on the declaration of named inventor Domenico Fanara in distinguishing the claimed invention over the DeLongueville, Doron, Gilliland I, and Gilliland II references (individually and in combination). UCB now asserts that Doron discloses a combination of methyl- and propylparabens at 0.45 mg/ml resulting in "reduced growth of the bacteria tested" with as little as 0.45

[14] We also credit Petitioner's argument that the Examiner failed to consider "the proposition that there was no teaching in the art of an existing problem with bacteria in known solutions of levocetirizine." *See* Reply 7.

mg/ml of methyl- and propylparabens. Prelim. Resp. 16 (citing Ex. 1013, 407–419). The relevance of any such teaching, however, was vigorously disputed during prosecution. According to Dr. Fanara:

> Doron discloses compositions that significantly reduce E.coli, but at paraben concentration that are 37% and 248% greater than the concentrations used in our invention.[15] As one skilled in the art, this reference suggests to me that at the MP/PP ratios of Doron, a much greater total concentration of parabens is necessary to achieve a composition that remains substantially free of bacteria than was achieved with our invention.

Ex. 1013, 539, ¶ 16.

UCB does not allege that any of Dietrich, DeLongueville, Gilliland I, Gilliland II, or Routlege suggests the pharmacological use of parabens "in an amount of more than 0 and up to 0.75 mg/ml," as claimed in the '194 patent. At best, UCB points to the Examiner's prosecution statement:

> There is a specific reason to keep the paraben amounts low, below 1 mg/ml, which is based on the recognition of estrogenic activity and the argument for reassessment of safety levels taught by Routledge, that is suggestive of levels lower than the GRAS levels, even though regulations permit higher levels.

Prelim. Resp. 16–17 (citing Ex. 1013, 416). But the Examiner also pointed to Routledge's disclosure of "around 1% bacterial growth" with 0.9 mg/ml total parabens, which does not necessarily suggest the lower amounts claimed. *See* Ex. 1013, 416. In contrast to this evidence, the Handbook sets

[15] As indicated in paragraph 17 of Dr. Fanara's declaration, the then-pending claims recited 1.125 mg/ml total parabens.

forth substantially lower limits for methyl- and propylparabens in numerous pharmacological dosage forms.

We find Petitioner's reliance on the Handbook particularly noteworthy in view of Dr. Fanara's assertion of unexpected results as compared to the "typical" amounts of combined parabens taught in Remington, and the Examiner's subsequent determination—based on Remington and Gilliland II—that a claim reciting an upper limit of 0.75 mg/ml parabens would be unobvious over the prior art. *See* Ex. 1013, 536, ¶¶ 7–11, 571; Section I(F), above. Whereas the Examiner appears to have grounded his assessment on Remington's disclosure of typical paraben levels of at least 1 mg/ml, the Handbook provides substantially lower limits for methyl and propylparabens for a variety of pharmaceutical uses. *See supra* Sections I(F) and II(C)(2). Accordingly, and in addition to its relevance to *Becton Dickinson* factors (a)–(e), Petitioner's citation to the Handbook provides additional facts and evidence warranting reconsideration of the arguments and findings made in prosecution as indicated by factor (f).[16]

For the reasons set forth above, we decline to exercise our discretion under § 325(d).

---

[16] In addressing *Becton Dickinson* factor (e), Petitioner appears to contend that the Examiner erred in evaluating the '194 patent's Applicants' evidence of unexpected results because testing was done with levocetirizine *dihydrochlroride*, but not with levocetirizine *hydrochloride*. Absent expert testimony or other evidence of relevant functional differences between solutions made using different crystalline forms or salts levocetirizine, we give little weight to this argument.

2. Discretion under § 314(a)

UCB further requests that we deny institution under § 314(a) in light of the parallel district court litigation between the parties in the Southern District of Florida. Prelim. Resp. 27–33; *see* Section I(B), above. According to UCB, the litigation began in April 2018 after its receipt of Petitioner's March 18 Paragraph IV Certification pursuant to the Hatch-Waxman Act, fact discovery began in June 2018, and opening expert reports were served in late March 2019. Prelim. Resp. 28–29. In April 2019, upon Petitioner's request and in light of the December 13, 2018 filing of the instant Petition, the District Court stayed proceedings "pending resolution of Defendant's petition before the Patent Trial and Appeal Board." Ex. 3001; *see also* Ex. 3002 (notification from the U.S. District Court of the Southern District of Florida regarding the Court's "Order Granting Defendant's Motion to Stay Pending Inter Partes Review and Administratively Closing Case").

We have discretion to deny a petition for *inter partes* review under § 314(a). *See* 35 U.S.C. § 314(a) (stating "[t]he Director may not authorize an *inter partes* review to be instituted unless . . . ."); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion."); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("First of all, the PTO is permitted, but never compelled, to institute an IPR proceeding." (citing 35 U.S.C. § 314(a))).

In a precedential decision, the Board articulated a non-exhaustive list of factors to be considered in evaluating whether to exercise discretion under

35 U.S.C. § 314(a) to deny a petition that challenges a patent that was previously challenged before the Board. *General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, slip op. 15–16 (PTAB Sept. 6, 2017) (Paper 19) (precedential). These factors are:

> 1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
>
> 2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;
>
> 3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition;
>
> 4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
>
> 5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;
>
> 6. the finite resources of the Board; and
>
> 7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.

Id. "The *General Plastic* factors, alone or in combination, are not dispositive, but part of a balanced assessment of all relevant circumstances in the case, including the merits." Trial Practice Guide Update, available at https://go.usa.gov/xU7GP (referenced at 83 Fed. Reg. 39,989 (Aug. 13, 2018)), at 10. Accordingly, and although the *General Plastic* factors expressly presume an earlier petition, we have also considered the posture of

related district court proceedings under § 314(a), as Patent Owner requests here. *See, e.g.*, *NHK*, slip. op. at 19–20 ("find[ing] that the advanced state of the district court proceeding is an additional factor that weighs in favor of denying the Petition under § 314(a)").

In *NHK*, the panel denied institution under 35 U.S.C. § 325(d), finding the asserted prior art and arguments to be the same or similar to those overcome during prosecution. *NHK* at 18. The panel also found that the "same prior art . . . and arguments" were being advanced in a parallel district court proceeding set for trial within about seven months from institution and before any final decision would issue as an additional reason to deny institution under 35 U.S.C. § 314(a). *Id.* at 19; *see also Mylan Pharms, Inc. v. Bayer Intellectual Prop. Gmbh*, IPR2018-01143, slip op. at 12–14 (PTAB December 3, 2018) (Paper 13) (denying institution under § 314(a) in light of "the advanced stage of the copending district court case and the extensive overlap of the asserted prior art, expert testimony, and claim construction"). This proceeding is different in both respects.

First, as discussed in section II(E)(1), above, we do not find persuasive Patent Owner's arguments that we should deny the Petition under § 325(d). To the contrary, the merits of the case weigh heavily in favor of granting institution. *See Sprint Spectrum L.P. et al. v. Intellectual Ventures II LLC*, IPR2018-01770, slip op. at 59 (PTAB April 12, 2019) (Paper 18) (considering merits in §314 analysis).

Second, and quite unlike the situation in *NHK*, the related district court proceeding here is stayed and administratively closed pending resolution of this *inter partes* review. Ex. 3001; Ex. 3002. Thus, as

presently postured, the district court trial will not occur before we issue a final decision in this case and, indeed, is predicated on the issuance of our final decision.[17] Accordingly, the procedural posture of the related district court litigation weighs against exercising our discretion to deny institution under § 314(a).

UCB further notes that, although Petitioner's 30-month stay of FDA market approval ends in September 2020—several months after the likely date of our final decision——"if the losing party seeks rehearing and appeal . . . the status of the '194 patent would remain in flux well past the end of the 30-month regulatory stay." Prelim. Resp. 30. UCB argues that, under this scenario, it "will be forced to seek a preliminary injunction at the District Court where the merits of the case will have to be reviewed because the Hatch-Waxman Act empowers only District Courts to issue such injunctions." *Id.* (citation omitted). While this may, as UCB contends, create some degree of judicial inefficiency, that is, nonetheless, entirely speculative. *See id.* at 29. Moreover, The Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284, 329 (2011) does not guarantee increased judicial efficiency in resolving patent disputes in each case, and no litigant is required to adopt a strategy that increases judicial efficiency at a

[17] Although Patent Owner notes that the district court has asked for updates on this *inter partes* review, any implication that this presages an earlier resumption of the district court proceeding would be pure speculation, which we accord little weight. *See* Prelim. Resp. 28; Ex. 3001 ("The Parties shall file a status report with respect to the *inter partes* review process no later than July 1, 2019, and every 90 days thereafter until the *inter partes* review process has concluded.").

cost of reducing its likelihood of prevailing in the dispute. In addition, as UCB makes clear, the issuance of preliminary injunctions is within the purview of the district court and we in no way presume to manage the court's docket. Accordingly, we do not find Patent Owner's argument availing.

Referencing *General Plastic* factors 3 through 5, UCB further argues that we should deny institution because Petitioner knew about the asserted references at least as of the time it filed its Paragraph IV certification in March 2018—some nine months before filing its Petition. Prelim. Resp. 31–33. We do not find Patent Owner's argument persuasive.

As an initial matter, 35 U.S.C § 315(b) provides a petitioner with one year to file a petition upon being served with a complaint alleging infringement in district court and, absent evidence of some improper tactical advantage, delaying filing the petition to any time before that one-year cutoff is not improper. *See Amazon.com, Inc. v. CustomPlay, LLC*, Case IPR2018-01496, slip op. at 6–7 (PTAB Mar. 7, 2019) (Paper 12) ("Thus, the fact that the Petition was filed near (but before) the end of the § 315(b) period does not, by itself, support denial of institution."); *Ericsson Inc. v. Intellectual Ventures II LLC*, IPR2018-01689, slip op. at 60 (PTAB April 16, 2019) (Paper 15) (that Petitioner knew about asserted references for four years or more "of little significance" to §314(a) analysis; "Petitioner is free to wait to file the Petition until at or near the end of the one-year period provided in 35 U.S.C. § 315(b)").

Nonetheless, even were we to presume some relevant correspondence between Petitioner's Paragraph IV Certification and the earlier-filed Petition

contemplated by the *General Plastic* factors, UCB's argument carries little weight. The crux of Patent Owner's argument appears to be that the nine months between service of its Paragraph IV letter and the filing of the Petition here, provides Petitioner with "two bites at the apple" because it has "received an advantage of nearly six months of federal court discovery, including receipt of Patent Owner's interrogatory responses that provided detailed responses to Petitioner's obviousness grounds." Prelim. Resp. 32. We discern, however, that Petitioner did not receive Patent Owner's interrogatory responses until roughly a month *after* the Petition. *See* Prelim. Resp. 28 ("Petitioner filed its petition. Petitioner . . . sought a stay . . . after another month had passed—and just days after Patent Owner provided an interrogatory response articulating its responses to Petitioner's obviousness grounds."). Initial expert reports were also not served until March 2019, several months *after* the December 13, 2018 filing of the Petition. *See* Prelim. Resp. 28. Because Petitioner did not have access to this substantive discovery before the filing of the Petition, we do not find Patent Owner's argument persuasive. *See CustomPlay*, slip op. at 7–10 (district court discovery not at a sufficiently advanced stage to support denial of institution under 314(a)).

In sum, a balanced assessment of the circumstances in this case does not weigh in favor of denying institution.

III. CONCLUSION

On this record, for the reasons provided above, Petitioner has shown a reasonable likelihood of prevailing on its assertion that at least one of the

challenged claims is unpatentable over WO '094 in view of the Handbook (Ground 1) as well as over the combination of EP '203, US '558, and the Handbook (Ground 2). Given our determination, we institute trial on all challenged claims and all grounds raised in the Petition. *See PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (indicating that a decision whether to institute an *inter partes* review "require[s] a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition").

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is granted and an *inter partes* review of U.S. Patent No. 8,633,194 B2 is instituted on the following grounds:

1) Claims 1–11 under 35 U.S.C. § 103 as obvious in view of WO '094 and the Handbook;

2) Claims 1–11 under 35 U.S.C. § 103 as obvious in view of EP '203, US '558, and the Handbook; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '194 Patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

For PETITIONER:

Jitendra Malik
Alissa Pacchioli
Joseph Janusz
Lance Soderstrom
KATTEN MUCHIN ROSENMAN LLP
jitty.malik@kattenlaw.com
alissa.pacchioli@kattenlaw.com
joe.janusz@kattenlaw.com
lance.soderstrom@kattenlaw.com

For PATENT OWNER:

James Trainor
Robert Counihan
Erica Sutter
FENWICK & WEST LLP
jtrainor@fenwick.com
rcounihan@fenwick.com
esutter@fenwick.com