UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS (US) LLC,
Petitioner,

v.

CIPLA LTD,
Patent Owner.

Case IPR2020-00371
Patent No. 9,901,585

PETITIONER'S NOTICE OF APPEAL

Pursuant to 37 C.F.R. §§ 90.2(a) and 90.3, and 35 U.S.C. §§ 141 and 142, and 28 U.S.C. § 1295(a)(4)(A), Petitioner GlaxoSmithKline Consumer Healthcare Holdings (US) LLC ("Petitioner") provides notice that it appeals to the United States Court of Appeals for the Federal Circuit from the Decision Denying Institution of *Inter Partes* Review in Case No. IPR2020-00371 entered July 31, 2020 (Paper 7), and from all underlying orders, decisions, rulings, and opinions.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), the issues on appeal are anticipated to include, but are not limited to, whether the USPTO's discretionary denial of institution in IPR2020-00371 was improper as based upon an improperly promulgated or inappropriately applied rule and whether the discretionary denial of institution in the underlying IPR should be vacated. *See* 35 U.S.C. § 316(a)(2), 5 U.S.C. § 706(2)(D); 5 U.S.C. § 553; 5 U.S.C. § 706(2)(C).

A copy of the decision being appealed is attached to this Notice.

Pursuant to 35 U.S.C. § 142 and 37 C.F.R. § 90.2(a), this Notice is being filed with the Director of the United States Patent and Trademark Office, and a copy of this Notice is being concurrently filed with the Patent Trial and Appeal Board. In addition, a copy of this Notice and the required docketing fees are being filed with the Clerk's Office for the United States Court of Appeals for the Federal Circuit via CM/ECF.

Respectfully submitted,

Dated: October 1, 2020

By: */ Charles E. Lipsey /*
Charles E. Lipsey, Lead Counsel
Reg. No. 28,165

CERTIFICATE OF SERVICE AND FILING

The undersigned certifies that on this 1st day of October 2020, in addition to being filed and served electronically through the Board's E2E system, a true and correct copy of the foregoing **PETITIONER'S NOTICE OF APPEAL** was filed and served on the Director of the United States Patent and Trademark Office via hand delivery at the following address:

Director of the United States Patent and Trademark Office
c/o Office of the General Counsel
Madison Building East, Room 10B20
600 Dulany Street
Alexandria, VA 22314

The undersigned also hereby certifies that on this 1st day of October 2020, a true and correct copy of the foregoing **PETITIONER'S NOTICE OF APPEAL** and the filing fee were filed with the Clerk's Office of the United States Court of Appeals for the Federal Circuit via CM/ECF.

The undersigned also hereby certifies that on this 1st day of October 2020, a true and correct copy of the foregoing **PETITIONER'S NOTICE OF APPEAL** was served electronically via email on counsel of record for the Patent Owner as follows:

Brandon M. White
Nathan K. Kelley
Perkins Coie LLP
700 13th St., NW, Suite 600
Washington, DC 2005

White-ptab@perkinscoie.com
Kelley_nathan-ptab@perkinscoie.com

Emily J. Greb
Perkins Coie LLP
33 East Main Street, Suite 201
Madison, WI 53703
Greb-ptab@perkinscoie.com

dymista@perkinscoie.com

/ William Esper /
William Esper
Legal Assistant
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP

Trials@uspto.gov
571-272-7822

Paper 7
Date: July 31, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLAXOSMITHKLINE
CONSUMER HEALTHCARE HOLDINGS (US) LLC,
Petitioner,

v.

CIPLA LTD.,
Patent Owner.

IPR2020-00371
Patent 9,901,585 B2

Before ZHENYU YANG, CHRISTOPHER M. KAISER, and MICHELLE N. ANKENBRAND, *Administrative Patent Judges.*

ANKENBRAND, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 325(d)

I. INTRODUCTION

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC ("Petitioner") requests an *inter partes* review of claims 1–30 of U.S. Patent Number 9,901,585 B2, ("the '585 patent," Ex. 1004). Paper 1 ("Pet."). Cipla Ltd. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

Based on the particular circumstances of this case, we exercise our discretion under 35 U.S.C. § 325(d) and do not institute an *inter partes* review of the challenged claims.

II. BACKGROUND

A. Related Matters

The parties do not identify any related matters involving the '585 patent. *See* Pet. 66; Paper 4, 1–2. The parties identify the following concluded district court litigation involving U.S. Patent Number 8,168,620 ("the '620 patent"), which is related to the '585 patent: *Meda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 1:15-cv-00785-LPS (D. Del.); *Meda Pharmaceuticals Inc. v. Perrigo UK FINCO Ltd.*, No. 1:16-cv-00794-LPS (D. Del.); *Meda Pharmaceuticals, Inc. v. Apotex Inc.*, No. 1:14-cv-01453-LPS (D. Del.). Pet. 66–67; Paper 4, 1.

The parties also identify as related *Argentum Pharmaceuticals LLC v. Cipla Ltd.*, IPR2017-00807 (PTAB) ("the Argentum IPR") an instituted proceeding challenging the '620 patent that the Board terminated prior to issuing a final written decision. Pet. 67; Paper 4, 1.

Patent Owner also identifies three petitions requesting an *inter partes* review that Petitioner filed challenging patents related to the '585 patent: IPR2020-00368, challenging U.S. Patent Number 8,163,723; IPR2020-

00369, challenging the '620 patent; and IPR2020-00370, challenging U.S. Patent Number 9,259,428. Paper 4, 1–2.

B. The '585 Patent

The '585 patent, titled "Combination of Azelastine and Fluticasone for Nasal Administration," issued on February 27, 2018. Ex. 1004, codes (45), (54). The '585 patent relates to pharmaceutical formulations comprising azelastine (4-[(4-chlorophenyl)methyl]-2-(hexahydro-1-methyl-1H-azepin-4-yl)-1(2H)-phthalazinone) and a corticosteroid. *Id.* at 1:64–66, 2:15–22. The corticosteroid may include fluticasone. *Id.* at 2:46–54.

The Specification explains that it is known to use antihistamines, e.g., azelastine hydrochloride, in nasal sprays to treat allergy-related conditions. *Id.* at 1:44–49. The Specification further explains that it is also known to treat allergy-related conditions with a corticosteroid to suppress nasal inflammatory conditions. *Id.* at 1:50–53. The Specification states that "[i]t would be highly desirable, however, to provide a treatment that combines the effects of anti-histamine treatments and steroid treatments, in a pharmaceutically acceptable formulation, which is tolerated in situ, without significantly disrupting the potency of the constituent pharmaceuticals." *Id.* at 1:58–63.

According to the Specification, the applicants "found that, very surprisingly, azelastine . . . can advantageously be combined with a steroid . . . to provide a stable, very effective combination product." *Id.* at 1:64–2:6. "The combination can provide, in a single administration or dosing regime[n], the antihistaminic properties of azelastine and the anti-inflammatory (and/or other) properties of the steroid, without any significant interference between the two, or adverse reaction in situ." *Id.* at 2:7–11.

The Specification discloses that the formulation may be in the form of an aqueous solution nasal spray. *Id.* at 2:47–54. The Specification explains that "[t]he formulations preferably contain a preservative and/or stabilizer." *Id.* at 2:60–61. Preferred preservatives include edetate disodium, benzalkonium chloride, and phenyl ethyl alcohol. *Id.* at 2:61–3:12. The formulations may include further auxiliary substances: specifically surfactants, e.g., polyethoxylated sorbitan fatty acid esters (polysorbate); isotonization agents, e.g., glycerine, glucose, and sodium chloride; and thickening agents, e.g., methyl cellulose, and carboxymethyl cellulose sodium. *See id.* at 3:36–50, 3:51–54, 3:66–4:14. The Specification explains that "[i]t is also possible to add to the formulations buffer substances . . . to adjust the formulations to a pH value of 3 to 7, preferably 4.5 to 6.5." *Id.* at 4:23–28.

C. Illustrative Claim

Petitioner challenges claims 1–30 of the '585 patent, of which claims 1, 16, and 27 are independent. Pet. 1. Claim 1 of the '585 patent is illustrative of the claimed subject matter and recites:

> 1. A nasal spray formulation, comprising:
>
> from 0.001% (weight/weight) to 1% (weight/weight) of azelastine hydrochloride;
>
> from 0.0357% (weight/weight) to 1.5% (weight/weight) of fluticasone propionate;
>
> one or more preservatives;
>
> one or more thickening agents;
>
> one or more surfactants; and
>
> one or more isotonization agents.

Ex. 1004, 11:62–12:3.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–30 of the '585 patent based on the following grounds:

Claims Challenged	35 U.S.C. §[1]	References/Basis
1–30	103(a)	PDR 1999,[2] Segal[3]
1–30	103(a)	Cramer,[4] PDR 1999

Petitioner supports the Petition with the testimony of Maureen D. Donovan, Ph.D. (Ex. 1060) and Robert P. Schleimer, Ph.D. (Ex. 1064).

III. ANALYSIS

A. Discretionary Denial under 35 U.S.C. § 325(d)

Patent Owner argues that we should exercise our discretion to deny the Petition under 35 U.S.C. § 325(d) because Petitioner presents substantially the same prior art and arguments the Office previously considered during the prosecution of the '585 patent and the related '620 patent, and fails to identify a material error in the Office's analysis. Prelim. Resp. 20–28.

Section 325(d) provides that in determining whether to institute an *inter partes* review, "the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." We use a two-part

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[1] Because the claims at issue have an effective filing date before March 16, 2013, the effective date of the applicable provisions of the Leahy Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) ("AIA"), we apply the pre-AIA version of 35 U.S.C. § 103 in this decision.
[2] Physicians' Desk Reference, *Flonase (fluticasone propionate)* entry 1112–1124 and *Astelin (azelastine hydrochloride)* entry 3191–3192 (53rd ed. 1999) (Ex. 1010).
[3] WO 98/48839 A1, published Nov. 5, 1998 (Ex. 1012).
[4] EP 0 780 127 A1, published June 25, 1997 (Ex. 1011).

framework in determining whether to exercise discretion under § 325(d), specifically:

> (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6, 8 (PTAB Feb. 13, 2020) (precedential). In applying the two-part framework, we consider several non-exclusive factors, including: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art; (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph). If, after review of factors (a), (b), and (d), we determine that the same or substantially the same art or arguments previously were presented to the Office, then factors (c), (e), and (f) relate to whether the petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics*,

Paper 6 at 10. "At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence or record unless material error is shown." *Id.* at 9.

For the reasons set forth below, under the facts and circumstances of this case, we exercise our discretion under § 325(d) to deny institution of a trial. Before turning to the two-part framework, we briefly discuss the asserted references and the relevant prosecution history of the '585 and '620 patents.

1. Asserted references

Below, we provide a brief summary of the references that Petitioner asserts against the challenged claims of the '585 patent.

a) PDR 1999 (Ex. 1010)

Petitioner relies on PDR 1999 for its disclosure of nasal spray compositions containing either fluticasone propionate, marketed under the brand name Flonase, or azelastine hydrochloride, marketed under the brand name Astelin. *See, e.g.*, Pet. 4–5. The flonase prescribing information describes the commercially available "FLONASE Nasal Spray 50 mcg [as] an aqueous suspension of microfine fluticasone propionate for topical administration to the nasal mucosa by means of a metering, atomizing spray pump." Ex. 1010, 1122. The formulation contains 0.05% w/w fluticasone propionate. *Id.* The "FLONASE Nasal Spray also contains microcrystalline cellulose and carboxymethylcellulose sodium, dextrose, 0.02% w/w benzalkonium chloride, polysorbate 80, and 0.25% w/w phenylethyl alcohol, and has a pH between 5 and 7." *Id.*

The Astelin prescribing information describes the commercially available "Astelin® (azelastine hydrochloride) Nasal Spray, 137 micrograms

(mcg), [as] an antihistamine formulated as a metered Spray solution for intranasal administration." Ex. 1010, 3191. "Astelin® Nasal Spray contains 0.1% azelastine hydrochloride in an aqueous solution at pH 6.8 ± 0.3. It also contains benzalkonium chloride (125 mcg/mL), edetate disodium, hydroxypropyl methyl cellulose, citric acid, dibasic sodium phosphate, sodium chloride, and purified water." *Id.*

b) Cramer (Ex. 1011)

Cramer describes "novel nasal spray compositions comprising a safe and effective amount of a glucocorticosteroid and an antihistamine." Ex. 1011, 2:5–6. Cramer teaches the "[g]lucocorticoid agents most useful to the present invention include those selected from the group consisting of beclomethasone, flunisolide, triamcinolone, fluticasone, mometasone, budesonide, pharmaceutically acceptable salts thereof." *Id.* at 3:15–18. The glucocorticoid concentration in the compositions may range "from about 0.001% to about 0.2%, more preferably from about 0.01% to about 0.1%." *Id.* at 3:19–20. Cramer teaches useful antihistamines "include cetirizine, loratadine, azelastine and the like . . . at a concentration of from about 0.01% to about 4.0%, more preferably from about 0.01% to about 1%." *Id.* at 3:24–30.

Cramer teaches "[p]referred nasal dosage forms are solutions, suspensions and gels, which normally contain sodium chloride in a major amount of water (preferably purified water) in addition to the antihistamine and glucocorticoid." *Id.* at 3:45–47. Cramer teaches the compositions may include "[m]inor amounts of other ingredients such as pH adjusters (e.g., an acid such as HCl), emulsifiers or dispersing agents, buffering agents,

preservatives, wetting agents and jelling agents (e.g., methylcellulose)." *Id.* at 3:47–49. "Most preferably, the nasal composition is isotonic." *Id.* 3:49.

Cramer describes a specific example of a pharmaceutical composition as Example III, reproduced below.

Component	Wgt%
triamcinolone acetonide	0.050
azelastine HCl	0.070
polysorbate 80	0.050
glycerin	2.000
hydroxypropyl methyl cellulose	1.000
sodium chloride	0.900
ethylenediamine tetraacetic acid	0.050
benzalkonium chloride	0.020
distilled water	q.s. to vol.

Id. at 6:26–42. Cramer teaches that the composition is used to provide relief from allergy symptoms and "substantially similar results are also obtained using, in whole or in part, equivalent amounts of other glucocorticoid agents such as fluticasone, mometasone, budesonide, pharmaceutically acceptable salts thereof and mixtures thereof." *Id.* at 6:43–46.

c) Segal (Ex. 1012)

Segal describes "topically applicable nasal compositions comprising a therapeutically effective amount of a topical anti-inflammatory agent and a therapeutically effective amount of at least one agent suitable for topical

nasal administration and selected from the group consisting of . . . an antihistamine." Ex. 1012, 2:10–15. Segal discloses that the topical anti-inflammatory agent is a corticosteroid, e.g., fluticasone propionate. *Id.* at 2:23–26. Segal also discloses suitable antihistamines, including azelastine. *Id.* at 3:19–20. Segal teaches that "[t]he use of an additional therapeutic agent in combination with an anti-inflammatory agent provides additive and synergistic effects in the treatment of nasal and sinus conditions." *Id.* at 3:9–12.

Segal teaches "[t]he compositions of the present invention can be conveniently administered nasally to a human subject in dosage unit form to elicit the desired therapeutic effect of the anti-inflammatory agent and the additional therapeutic agents described above. The compositions may be administered in the form of a nasal spray." *Id.* at 4:20–23. Segal describes "nasal sprays containing a water buffered aqueous solution as a carrier." *Id.* at 4:4–7. "The compositions are preferably isotonic," e.g., sugars and sodium chloride, and may contain additional agents, including a humectant, e.g., glycerin, pharmaceutically acceptable preservatives, and pH adjusters. *Id.* at 4:5–14.

2. Relevant prosecution history

The '585 patent issued from Application No. 15/070,839, which claims priority through a series of parent applications to Application No. 10/518,016, filed as application No. PCT/GB03/02557 on June 13, 2003, now the '620 patent. Ex. 1004, at [21], [60]. We discuss the prosecution of both the '620 patent and the '585 patent below.

During the prosecution of the '620 patent, the Examiner rejected the claims as anticipated by Cramer or as having been obvious over Cramer

combined with other references. *See* Ex. 2001, 497–512, 603–622, 721–742.[5] For example, the Examiner found that Cramer discloses a nasal spray composition containing azelastine and fluticasone in the claimed amounts, further including the claimed excipients. *See, e.g.*, *id.* at 606–608 (citing, *inter alia*, Cramer's Example III).

In response, the applicant filed three declarations from inventor Ms. Geena Malhotra as evidence supporting unexpected stability of the claimed formulation and the inoperability of Cramer's Example III. *See id.* at 336–339, 568–570, 698–700. After a non-final rejection of the claims as anticipated by Cramer, the applicant amended the claims and filed additional declarations from Mr. Nikhil Chopra, Joachim Maus, M.D., and Sujeet Rajan, M.D. *See id.* at 254–283, 328–334, 358–364, 458–462. The additional declarations supported the applicant's assertions of commercial success, unexpected results, and long-felt need, respectively. *See id.*

Following the response, the Examiner allowed the claims. *See id.* at 192–199. In the Reasons for Allowability, the Examiner discussed in detail the Chopra, Maus, and Rajan declarations supporting objective evidence of non-obviousness. *See id.* at 195–198. The Examiner found "the Chopra Declaration supports that the product of the invention has been a commercial success for both the inventors and the copiers . . . [and] that the product of the invention has filled a long-felt, but unmet need for an improved treatment for allergic rhinitis." *Id.* at 196. The Examiner found Dr. Rajan's declaration "also supports that the invention fills a long unmet need." *Id.* And the Examiner found that "Dr. Maus concludes that the superior results obtained with the combination of nasal fluticasone propionate and azelastine

[5] We cite to the page numbers that Patent Owner added to Exhibit 2001.

HCl would have been unexpected at the time of filing of the application. On the basis of this information and declaration, the examiner concurs in this conclusion." *Id.* at 197 (internal citation omitted). Accordingly, the Examiner concluded "the invention [of the '620 patent] is unexpectedly and surprisingly unobvious over, different from, and superior to the prior art of record." *Id.* at 198.

During the prosecution of the '585 patent, the Examiner rejected the claims as anticipated by Cramer, or as having been obvious over Cramer with additional optional references. Ex. 1008, 4–5.[6] In so doing, the Examiner incorporated by reference the Office's "explanation of disclosures of the prior art and rationales for combing the disclosures of [the] references" as set forth in the '620 patent's prosecution, among others. *Id.* at 5. In other words, the Examiner relied on the Office's previous findings and conclusions regarding Cramer, including Cramer's disclosure of a nasal spray containing azelastine and fluticasone, as well as Cramer's Example III. *See, e.g.*, Ex. 2001, 501–502.

In a response filed August 1, 2017, the applicant argued that one of Dr. Malhotra's declarations submitted during the '620 patent's prosecution established that Cramer's Example III was inoperable. *See id.* at 20–23. The applicant further argued that the Chopra, Maus, and Rajan declarations submitted during the '620 patent's prosecution were evidence of secondary considerations that the claimed formulations were nonobvious. *See id.* at 23–27. The applicant also submitted an Information Disclosure Statement

[6] We cite to the page numbers that Petitioner added to Exhibit 1008.

("IDS") listing the Argentum IPR petition, which asserted Segal, Hettche,[7] Phillipps,[8] and Flonase Label[9] against challenged claims of the '620 patent, all of which the Examiner considered. Ex. 1008, 36–37 ("The references provided in the Information Disclosure were evaluated for their disclosure in view of the claims of the instant application."); Ex. 3001, 2 (August 1, 2017, IDS, first entry, titled "Petition for Inter Partes Review on U.S. Patent No. 8,168,620, No. IPR2017-00807 filed February 2, 2017, Argentum Pharmaceuticals LLC v. Cipla Ltd., 73 pages").

Following the Response, the Examiner allowed the claims. *Id.* at 36–42. The Examiner addressed the Argentum IPR petition, explaining "[w]ith regard to obviousness, all the references cited by the Argentum Petition are of record and have been previously evaluated, or disclose information redundant to information of record." *Id.* at 37. The Examiner further stated:

> With regard to the Declaration by Maus, the Argentum Petition asserts that the relevant comparator for the inventive formulation is concurrent use of fluticasone propionate nasal spray and azelastine nasal spray. The assertion is not persuasive because at the time of the invention, the field as a whole was divided as

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[7] US 5,164,194, issued Nov. 17, 1992 (Ex. 1013). Hettche teaches a "medicament for nasal use . . . which contains as [an] active ingredient azelastine or a physiologically acceptable salt." *Id.* at Abstract.

[8] US 4,335,121, issued June 15, 1982 (Ex. 1009). Phillipps discloses topical nasal sprays comprising fluticasone propionate formulated with one or more pharmaceutical carriers or excipients. *Id.* at 32:46–50, 32:57–60, 36:7–10.

[9] FLONASE® (fluticasone propionate) Nasal Spray, 50 mcg Product Information (Dec. 1998) (Ex. 1010). The Flonase Label discloses an aqueous suspension of microfine fluticasone propionate that also contains microcrystalline cellulose and carboxymethylcellulose sodium, dextrose, 0.02% w/w benzalkonium chloride, polysorbate 80, and 0.25% w/w phenylethyl alcohol. *Id.* at 1122.

> to whether oral or nasal administration of antihistamine was better.

Id. at 37. The Examiner considered arguments against the Chopra Declaration, finding that "[t]he Argentum Petition also argues that evidence of commercial success requires evidence of relative product pricing and marketing. Careful analysis of the Chopra data refutes the argument." *Id.* at 38.

In the Reasons for Allowance, the Examiner found that the Chopra Declaration supported commercial success, the Chopra and Rajan Declarations supported the invention filling a long-felt need, and the Maus Declaration supported superior unexpected results. *See id.* at 39–42 (making similar findings regarding the applicant's objective evidence to those the Examiner made during the '620 patent's prosecution). Accordingly, the Examiner found that the claims that issued as the '585 patent "are narrower than the independent claims allowed as US Patent No. 8168620" and that "the invention is unexpectedly and surprisingly unobvious over, different from, and superior to the prior art of record." *Id.* at 42.

3. Whether the same or substantially the same prior art or arguments previously were presented to the Office

We first consider whether Petitioner asserts the same or substantially the same prior art or arguments that previously were presented to the Office. *Advanced Bionics*, Paper 6 at 8. We conclude that Petitioner asserts not only substantially the same prior art, but also substantially the same arguments that previously were presented to the Office.[10] Petitioner asserts Cramer,

[10] Under *Advanced Bionics*, either the same or substantially the same prior art previously must have been presented to the Office or the same or substantially the same arguments previously must have been presented to the

Segal, and PDR 1999 against the challenged claims of the '585 patent. Petitioner admits that the Examiner cited Cramer during prosecution of the '585 patent. Pet. 68. Indeed, as set forth above, the Examiner rejected all pending claims "as anticipated by, or in the alternative[,] . . . as obvious over the disclosure of Cramer, optionally further in view of [additional references]." Ex. 1008, 4–5. Thus, Cramer previously was presented to the Office.

Further, as explained above, the Examiner rejected the claims after finding that Cramer teaches nasal spray compositions comprising azelastine and fluticasone in the recited amounts and suggests pharmaceutically acceptable salt forms, including hydrochloride and propionate. *See, e.g.*, Ex. 2001, 606–608. The Examiner also found that Cramer's composition may contain certain excipients, such as those recited in the claims. *Id.* at 606–607 (citing, *inter alia*, Cramer's Example III). Petitioner relies on the same teachings. For example, Petitioner asserts that Cramer discloses nasal spray formulations comprising fluticasone and azelastine or pharmaceutically acceptable salt forms of each. Pet. 31. Petitioner also asserts that Cramer's formulations may contain other ingredients, i.e., excipients, such as emulsifiers, pH adjusters, buffering agents, preservatives, wetting agents, and jelling agents. *Id.* And, like the Examiner, Petitioner points to Cramer's Example III. *Id.* at 31–32. Thus, Petitioner makes the same arguments the Office previously considered regarding Cramer.

Office to reach the second part of the framework, i.e., a showing of error material to patentability. *Advanced Bionics*, Paper 6 at 8. Here, however, both conditions of the first part of the framework are satisfied. Thus, we discuss both.

Although Petitioner does not address whether Segal and PDR 1999 were presented to the Office during the '585 patent's prosecution, we find that Segal previously was presented to the Office and that PDR 1999 is cumulative of references the Examiner considered during prosecution. Starting with Segal, the applicant listed it on an IDS that the Examiner considered. Ex. 2001, 786; *see Advanced Bionics*, Paper 6 at 7–8 (explaining that previously presented art includes "art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent"). Segal also was asserted against the '620 patent claims in the Argentum IPR petition that the Examiner reviewed and discussed during the '585 patent's prosecution. *See* Ex. 1008, 36–39 (Notice of Allowability discussing in detail the Argentum IPR petition); Ex. 3001, 2 (listing the Argentum IPR petition). And Petitioner admits that the Petition contains "similar arguments" to those in the Argentum IPR. Pet. 68. Accordingly, Segal previously was presented to the Office and Petitioner makes the same arguments the Office previously considered regarding Segal.

Turning next to PDR 1999, we acknowledge that it was not before the Examiner during prosecution, but we agree with Patent Owner that the teachings in PDR 1999 do not differ "in any material way from the art and arguments already considered and overcome during prosecution." Prelim. Resp. 24. In other words, the disclosures in PDR 1999 are substantively the same as the disclosures in other references the Examiner considered and evaluated during prosecution, including the references asserted in the Argentum IPR. *See* Ex. 1008, 37 ("[A]ll the references cited by the

Argentum Petition are of record and have been previously evaluated, or disclose information redundant to information of record."). Petitioner concedes as much, stating that "the Argentum IPR was instituted based on the cited prior art and similar arguments." Pet. 68. Further, as explained above, PDR 1999 discloses monotherapy nasal spray formulations comprising either azelastine hydrochloride or fluticasone propionate and Petitioner relies on PDR 1999 for those teachings, as well as for disclosing certain excipients the challenged claims require. *See, e.g.*, Pet. 4–5; *see also* Ex. 1010, 1122 (PDR 1999 entry for Flonase, fluticasone propionate nasal spray), 3191 (PDR 1999 entry for Astelin, azelastine hydrochloride nasal spray). The Argentum IPR asserted similar references with essentially the same teachings, including Hettche, which discloses a nasal medicine that contains azelastine or a physiologically acceptable salt of azelastine, and Phillipps and Flonase Label, which each disclose nasal spray formulations comprising fluticasone propionate and other pharmaceutical carriers or excipients. *See* Argentum IPR, Paper 11 at 14–22; Ex. 1013, Abstract; Ex. 1009, 32:46–50, 32:57–60, 36:7–10; Ex. 1010, 1. Thus, PDR 1999 is cumulative of the art the Examiner considered during prosecution and Petitioner makes the same arguments that the Office previously considered when evaluating the '585 patent claims.

Given the foregoing, we determine that the Petition presents not only substantially the same prior art, but also the same arguments that were previously presented to the Office during prosecution of the '585 patent.

4. Error material to patentability

Because we find that the "same or substantially the same prior art or arguments previously were presented to the Office," we turn to whether

Petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics*, Paper 6 at 8, 10; *see Becton, Dickinson*, Paper 8 at 24. We conclude that Petitioner does not demonstrate an error material to patentability.

Petitioner does not explicitly allege error in the Examiner's previous consideration of the prior art or arguments. Indeed, Petitioner does not discuss or even cite to our precedential *Becton, Dickinson* factors. *See generally* Pet. Nevertheless, Petitioner asserts that the '585 patent applicant overcame the Examiner's rejection of its claims over Cramer "based solely on alleged objective indicia of nonobviousness," Pet. 68, and that the applicant's "alleged evidence does not demonstrate nonobviousness." *Id.* at 63. Accordingly, we focus on the arguments Petitioner provides as to objective indicia of nonobviousness.

Petitioner is correct that the Examiner allowed the '585 patent claims after considering objective indicia of nonobviousness. *See, e.g.*, Ex. 1008, 23–27, 36–42. As set forth above, the applicant's objective evidence of nonobviousness was extensive, as was the Examiner's analysis of that evidence. *See supra* § III.A.2; Ex. 1008, 23–27, 36–42.

Petitioner argues that the applicant failed to show "unexpected results supportive of nonobviousness" during prosecution because the applicant did not compare "the claimed invention to the closest prior art." Pet. 64 (citing Ex. 1064 ¶¶ 473–531). Before turning to Petitioner's arguments, we note that Petitioner cites for support more than 50 paragraphs of Dr. Schleimer's declaration, but the Petition's discussion mentions only three of those paragraphs, i.e., paragraphs 476–478. "A brief must make all arguments accessible to the judges, rather than ask them to play archeologist with the

record." *DeSilva v. DiLeonardi*, 181 F.3d 865, 866–67 (7th Cir. 1999); *see also* 37 C.F.R. § 42.22(a)(2) (2018) (Petitioner must "includ[e] a detailed explanation of the significance of the evidence including material facts"). Further, "[a]rguments must not be incorporated by reference from one document into another document." 37 C.F.R. § 42.6(a)(3) (2018). Accordingly, we consider only the three paragraphs on which Petitioner's arguments rely.

Petitioner contends that "the closest prior art is a pharmaceutical nasal formulation comprising both azelastine and fluticasone," such as those that Cramer and Segal teach. *Id.* Thus, Petitioner asserts that the applicant did not show unexpected results because it did not present "results comparing the claimed invention to a pharmaceutical nasal formulation comprising both azelastine and fluticasone . . . or to co-administration of commercially available azelastine hydrochloride nasal spray and fluticasone propionate nasal spray." *Id.* Dr. Schleimer testifies similarly. Ex. 1064 ¶¶ 476–478.

Petitioner's arguments and Dr. Schleimer's testimony are substantially similar to arguments the Examiner already considered during the '585 patent's prosecution, including those made in the Argentum IPR. Ex. 1008, 37 ("With regard to the Declaration by Maus, the Argentum Petition asserts that the relevant comparator for the inventive formulation is concurrent use of fluticasone propionate nasal spray and azelastine nasal spray."). In that regard, the Examiner determined "[t]he assertion is not persuasive because at the time of the invention, the field as a whole was divided as to whether oral or nasal administration of antihistamine was better." *Id.* Yet Petitioner does not attempt to explain how the Examiner erred in that determination, or even discuss Dr. Maus's declaration, which the Examiner found persuasive. *See*

Pet. 63–66;[11] *see also* Ex. 1008, 41 (describing Dr. Maus's declaration as reviewing, *inter alia*, "a non-prior art study which concludes that there is no evidence that a combination of intranasal corticosteroids with intranasal antihistamines provides any additional therapeutic benefit, in comparison with intranasal steroids alone").

In any event, even if we agreed with Petitioner that the applicant failed to compare the claimed invention to the closest prior art, we cannot agree that Petitioner shows an error material to patentability on this record. The Examiner did not allow the '585 patent claims solely based on the applicant's showing of unexpected results. Rather, the Examiner also found persuasive the applicant's commercial success and long-felt need evidence, including the Chopra and Rajan declarations, both of which the Examiner discussed in the '585 patent's Reasons for Allowance. Ex. 1008, 39–40. Specifically, the Examiner found that the "Chopra Declaration supports that the product of the invention has been a commercial success for both the inventors and the copiers. Moreover, the Chopra Declaration also supports that the product of the invention has filled a long-felt, but unmet need for an improved treatment for allergic rhinitis." *Id.* at 40. The Examiner also found that Dr. Rajan's declaration "also supports that the invention fills a long unmet need." *Id.* (highlighting Dr. Rajan's prescribing activities both before and after the introduction of the product of the invention).

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[11] Petitioner also argues that Dr. Malhotra's declaration does not support nonobviousness. *Id.* at 65. But, as Petitioner acknowledges, "[t]he Examiner did not cite [Dr. Malhotra's] declaration in issuing the patents." *Id.* Thus, we do not find Petitioner's arguments directed to Dr. Malhotra's declaration as relevant in determining whether Petitioner shows that the Examiner erred in a manner material to patentability.

Petitioner, however, does not discuss or even mention commercial success. *See generally* Pet. And, as to long-felt but unmet need, Petitioner's analysis is one sentence; namely, that the applicant did not show "any such need that was not already satisfied by co-administration of commercially available azelastine hydrochloride and fluticasone propionate nasal sprays." *Id.* at 66. Such terse analysis is not enough to show that the Examiner erred in a manner that is material to patentability.

5. Conclusion as to § 325(d)

The Petition in this proceeding relies on the same and substantially the same references, and presents arguments that are substantially the same as those the Examiner considered and the applicant overcame during prosecution of the '585 patent. Petitioner does not demonstrate that the Examiner materially erred in considering such. Thus, under the facts and circumstances of this case, it is appropriate to exercise our discretion under § 325(d) and deny institution.

B. Patent Owner's Additional Arguments for Denial

Patent Owner asserts that we should deny institution for additional reasons unrelated to the merits of the grounds asserted in the Petition. Specifically, Patent Owner argues that we should deny institution because: (1) the Petition lacks specificity; (2) the Petition likely fails to name a real party-in-interest; and (3) instituting review would result in an inefficient use of Board resources under *General Plastic Industrial Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017) (precedential). Prelim. Resp. 5–8, 10–11, 29–32. Because we deny the Petition under § 325(d), we do not reach Patent Owner's additional arguments for denial.

IV. CONCLUSION

Taking account of the information presented in the Petition, the Preliminary Response, and the evidence of record, we exercise our discretion under § 325(d) and deny institution.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied*, and no trial is instituted.

FOR PETITIONER:

Charles E. Lipsey
Trenton A. Ward
Richard B. Racine
Joann M. Neth
Shana K. Cyr
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
charles.lipsey@finnegan.com
trenton.ward@finnegan.com
rich.racine@finnegan.com
joann.neth@finnegan.com
shana.cyr@finnegan.com

FOR PATENT OWNER:

Brandon M. White
Emily J. Greb
Nathan K. Kelley
Perkins Coie LLP
White-ptab@perkinscoie.com
Greb-ptab@perkinscoie.com
Kelley_nathan-ptab@perkinscoie.com