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 IPR2020-00369
Patent No. 8,168,620

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. IPR2020-00369 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 IPR2020-00369 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
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Case IPR2020-00369
Patent No. 8,168,620

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:

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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.

IPR2020-00369
Patent 8,168,620 B2

Before JO-ANNE M. KOKOSKI, ZHENYU YANG, and CHRISTOPHER M. KAISER, *Administrative Patent Judges.*

KOKOSKI, *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") filed a Petition to institute an *inter partes* review of claims 1–18, 21, 22, 24–26, 28, 29, 31, 33, and 35–48 ("the challenged claims") of U.S. Patent No. 8,168,620 B2 ("the '620 patent," Ex. 1001). Paper 1 ("Pet."). Cipla Ltd. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority, acting on the designation of the Director, to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). For the reasons that follow, we exercise our discretion under 35 U.S.C. § 325(d) and deny institution of *inter partes* review.

A. Related Proceedings

Petitioner identifies the following district court proceedings involving the '620 patent: *Meda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 1:15-cv-00785-LPS (D. Del.) (dismissed on July 28, 2017); *Meda Pharmaceuticals Inc. v. Perrigo UK FINCO Ltd.*, No. 1:16-cv-00794-LPS (D. Del.) (dismissed on July 7, 2017); and *Meda Pharmaceuticals, Inc. v. Apotex Inc.*, No. 1:14-cv-01453-LPS (D. Del.) (dismissed on May 17, 2017). Pet. 62; Paper 5, 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. 62; Paper 5, 1.

Petitioner concurrently filed three other petitions, challenging patents related to the '620 patent: IPR2020-00368 (challenging U.S. Patent

No. 8,163,723 B2 (Ex. 1002)); IPR2020-00370 (challenging U.S. Patent No. 9,259,428 B2 (Ex. 1003)), and IPR2020-00371 (challenging U.S. Patent No. 9,901,585 B2 ("the '585 patent," Ex. 1004)). Paper 5, 1–2.

B. The '620 Patent

The '620 patent is titled "Combination of Azelastine and Steroids." Ex. 1001, code (54). The '620 patent relates to pharmaceutical formulations comprising azelastine and a steroid, preferably a corticosteroid such as fluticasone. *Id.* at 1:54–60, 2:18–25. The Specification explains that it is known to use antihistamines, e.g., azelastine hydrochloride, in nasal sprays to treat allergy-related conditions. *Id.* at 1:20–25. The Specification explains that it is also known to treat allergy-related conditions with a corticosteroid to suppress nasal inflammatory conditions. *Id.* at 1:26–33. According to the Specification, "[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 1:34–38.

The Specification states that the applicants "found that, very surprisingly, azelastine . . . can advantageously be combined with a steroid . . . to provide a stable, very effective combination product." *Id.* at 1:39–48. "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 1:48–53.

The Specification discloses that the formulation may be in the form of a nasal spray, and that "[t]he formulations preferably contain a preservative

and/or stabilizer." *Id.* at 2:18–25, 2:31–50. The formulations also may include, for example, surfactants, isotonization agents, and thickening agents. *See id.* at 3:21–24, 3:36–39, 5:20–30.

C. Representative Claim

Petitioner challenges claims 1–18, 21, 22, 24–26, 28, 29, 31, 33, and 35–48 of the '620 patent, of which claims 1, 21, 24, 25, 47, and 48 are independent. Pet. 1. Claim 1 is representative of the claimed subject matter, and is reproduced below.

> 1. A pharmaceutical formulation comprising:
>
> azelastine, or a pharmaceutically acceptable salt thereof, and
>
> a pharmaceutically acceptable ester of fluticasone,
>
> wherein said pharmaceutical dosage formulation is in a dosage form suitable for nasal administration.

Ex. 1001, 11:46–51.

D. The Asserted Grounds of Unpatentability

Petitioner asserts the challenged claims are unpatentable on the following grounds.

Claim(s) Challenged	35 U.S.C. §	References
1–18, 21, 22, 24–26, 28, 29, 31, 33, 35–47	103(a)	PDR 1999,[1] Segal[2]
48	103(a)	PDR 1999, Segal, Hettche[3]
1–18, 21, 22, 24–26, 28, 29, 31, 33, 35–48	103(a)	Cramer,[4] PDR 1999

[1] Physicians' Desk Reference (53rd ed. 1999) (Ex. 1010).
[2] WO 98/48839 A1, published Nov. 5, 1998 (Ex. 1012).
[3] U.S. Patent No. 5,164,194, issued Nov. 17, 1992 (Ex. 1013).
[4] EP 0 780 127 A1, published June 25, 1998 (Ex. 1011).

In support of its patentability challenge, Petitioner relies on the Declarations of Maureen D. Donovan, Ph.D. (Ex. 1057), and Robert P. Schleimer, Ph.D. (Ex. 1061).

II. ANALYSIS

Institution of *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a); 37 C.F.R. § 42.108; *see also Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("the PTO is permitted, but never compelled, to institute an IPR proceeding"). Our discretion as to whether to institute is guided by 35 U.S.C. § 325(d), which states that "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." Patent Owner contends that Petitioner's challenges rely on the same or substantially the same prior art and arguments that were already considered during the prosecution of the '620 patent, and that Petitioner fails to identify a material error in the Office's analysis. Prelim. Resp. 21–29.

When evaluating whether the same or substantially the same prior art or arguments previously were presented to the Office under § 325(d), the Board uses a two-part framework in determining whether to exercise its 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 this 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, 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 were previously 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.

After considering all of the relevant factors and the parties' arguments, we are persuaded, for the reasons set forth below, that the

Petition presents substantially the same arguments previously presented to the Office.

A. Relevant Prosecution History

The '620 patent issued from Application No. 10,518,016, filed as application No. PCT/GB03/02557 on June 13, 2003. Ex. 1001, codes (21), (22), (86). 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 that also includes the claimed excipients. *See, e.g., id.* at 606–608 (citing, *inter alia*, Cramer's Example III). In addition, Segal and Hettche were identified in Information Disclosure Statements filed by the applicants, and the Examiner identified both having been considered. *Id.* at 637, 786.

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. *See id.*

Following the response, the Examiner allowed the claims. *See* Ex. 2001, 192–199. In the Reasons for Allowability, the Examiner

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

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.* The Examiner further found that "Dr. Maus concludes that the superior results obtained with the combination of nasal fluticasone propionate and azelastine 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.

B. Same or Substantially the Same Prior Art or Arguments

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.[6] Petitioner asserts Cramer,

[6] 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 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.

Segal, PDR 1999, and Hettche against the challenged claims of the '620 patent. Petitioner admits that the Examiner cited Cramer during prosecution of the '620 patent. Pet. 63–64. Specifically, the Examiner relied on Cramer, both alone and in combination with other references, to reject pending claims in three Office Actions. Ex. 2001, 497–512, 603–622, 721–742. 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. 29–30. 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.* at 51–57. Additionally, Petitioner, like the Examiner, relies on Cramer's Example III. *Id.* at 29–30. Thus, Petitioner makes the same arguments the Office previously considered regarding Cramer.

Although Petitioner does not address whether Segal, PDR 1999, and Hettche were presented to the Office during the '620 patent's prosecution, we find that Segal and Hettche were previously presented to the Office and that PDR 1999 is cumulative of references the Examiner considered during

prosecution. Starting with Segal and Hettche, the applicant listed them on Information Disclosure Statements that the Examiner considered. Ex. 2001, 637, 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 and Hettche were asserted against the '620 patent claims in the Argentum IPR petition. The Examiner, in allowing the claims of the '585 patent (a later-issued patent related to the '620 patent), stated that "all the references cited by the Argentum Petition are of record and have been previously evaluated, or disclose information redundant to information of record." Ex. 1008, 37.[7] Petitioner admits that "the Argentum IPR was instituted based on the cited prior art and similar arguments" as in this Petition. Pet. 64. Accordingly, Segal and Hettche were previously presented to the Office and Petitioner makes the same arguments the Office previously considered regarding Segal and Hettche.

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. PDR 1999 discloses monotherapy nasal spray formulations comprising either azelastine hydrochloride or fluticasone

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

propionate, and Petitioner relies on PDR 1999 for those teachings. *See, e.g.*, Pet. 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). Cramer, which was considered by the Examiner, and declarations submitted during prosecution to traverse the rejections, described the prior-art practices of using antihistamines and corticosteroids as monotherapies. Ex. 1011, 2:19–22; Ex. 2001, 568–596. Moreover, as Patent Owner notes, these teachings were already considered by the Examiner because "the specification itself recognizes that azelastine and fluticasone as monotherapies to treat allergy-related conditions were known in the art." Prelim. Resp. 14–15 (citing Ex. 1001, 1:20–30). 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 '620 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 '620 patent.

C. 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, and does not discuss or cite to

the factors listed in the Board's precedential decision in *Becton, Dickinson*. *See generally* Pet. Nevertheless, Petitioner asserts that, during prosecution, the applicant overcame the rejections over Cramer "based solely on alleged objective indicia of nonobviousness, none of which demonstrates nonobviousness." Pet. 63–64. Petitioner is correct that the Examiner allowed the claims of the '620 patent after considering objective indicia of nonobviousness. Ex. 2001, 195–98. Petitioner, however, has not shown sufficiently that the Examiner erred in doing so.

During the prosecution of the '620 patent, the applicant submitted several declarations from inventor Geena Malhotra as evidence supporting unexpected stability of the claimed formulation and the inoperability of Cramer's Example III. Ex. 2001, 336–39, 568–70, 698–700. The applicant also submitted declarations from Mr. Nikhil Chopra, Joachim Maus, M.D., and Sujeet Rajan, M.D. to support the assertions of commercial success, unexpected results, and long-felt need, respectively. *Id.* at 328–34, 358–64, 458–62.

After considering those declarations, the Examiner allowed the claims. *See id.* at 192–99. As set forth above, in the Reasons for Allowability, the Examiner discussed the Chopra, Maus, and Rajan declarations in detail. *Id.* at 195–98. The Examiner: (1) found that the Chopra declaration supports the commercial success of the combination product, and that it filled a long-felt and unmet need; (2) found that the Rajan declaration supports that the combined product met a long-felt but unmet need; and (3) agreed with Dr. Maus that the results obtained when using the combined azelastine-fluticasone product would have been unexpected. *Id.* at 196–197. Accordingly, the Examiner concluded that "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.

Petitioner argues that there are no "unexpected results supportive of nonobviousness" because, during prosecution, the applicant did not compare "the claimed invention to the closest prior art." Pet. 59. Before turning to Petitioner's arguments, we note that Petitioner cites about 60 paragraphs of Dr. Schleimer's declaration to support its contentions, but the discussion in the mentions only four of those paragraphs (paragraphs 603–606). *See id.* at 59–60. "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 paragraphs on which Petitioner's arguments rely.

According to Petitioner, "the closest prior art is a pharmaceutical nasal formulation comprising both azelastine and fluticasone, such as those taught by *Cramer* and *Segal*." Pet. 59. 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, such as those taught by *Cramer* and *Segal*, or to co-administration of commercially available azelastine hydrochloride nasal spray and fluticasone propionate nasal spray." *Id.* at 60. Dr. Schleimer testifies similarly. Ex. 1061 ¶¶ 604–606.

Even if we agreed with Petitioner that the applicant did not compare the claimed invention to the closest prior art, Petitioner has not shown sufficiently on this record that the Examiner erred in allowing the challenged claims. The Examiner did not allow the claims solely based on the applicant's showing of unexpected results; the Examiner also found persuasive the applicant's commercial success and long-felt need evidence, including the Chopra and Rajan declarations. Ex. 2001, 195–198.

Petitioner does not discuss either of these declarations, and does not mention commercial success. With respect to long-felt but unmet need, Petitioner only states that "Cipla has not shown that the claimed invention satisfied a long-felt but unmet need, for at least the reason that Cipla has not shown that any such need that was not already satisfied by co-administration of commercially available azelastine hydrochloride and fluticasone propionate nasal sprays." Pet. 61. This conclusory attorney argument is not supported by any evidence, and is not enough to show that the Examiner committed any material error.

Moreover, Petitioner's argument is substantially similar to one made in the Argentum IPR that the Examiner already considered during prosecution of the related '585 patent. 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."). There, the Examiner determined that 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.* Petitioner, however, does not attempt to explain how the Examiner erred in that determination.

Petitioner also does not discuss the Maus declaration,[8] which the Examiner found persuasive. *See, e.g.*, Ex. 1008, 41 (describing the Maus declaration as reviewing several studies, including "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").

Accordingly, the record demonstrates that the Examiner determined the claims were nonobviousness based on the totality of the evidence. Petitioner has not demonstrated a material error by the Office in the prior consideration of the same or substantially the same art or arguments presented in the Petition.

III. CONCLUSION

The Petition 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 '620 patent. Petitioner does not demonstrate that the Examiner materially erred in considering such. Accordingly, in light of the circumstances of this case, we exercise our discretion and deny institution of a trial under 35 U.S.C. § 325(d).[9]

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[8] Petitioner also argues that a declaration by inventor Geena Malhotra does not support nonobviousness. Pet. 54. But, as Petitioner acknowledges, "the Examiner did not cite [the Malhotra] declaration in issuing the patents." *Id.* Thus, we do not find Petitioner's arguments directed to the Malhotra declaration as relevant in determining whether Petitioner shows that the Examiner erred in a manner material to patentability.

[9] Patent Owner argues that we should deny institution for several other reasons. Prelim. Resp. 5–11, 29–62. Because we deny the Petition under § 325(d), we do not reach those additional arguments.

IV. ORDER

In consideration of the foregoing, it is hereby

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

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