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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.

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