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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.

IPR2020-00368
Patent 8,163,723 B2

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

YANG, *Administrative Patent Judge*.

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

INTRODUCTION

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC ("Petitioner") filed a Petition (Paper 1 ("Pet.")), seeking an *inter partes* review of claims 1–28 of U.S. Patent No. 8,163,723 B2 (Ex. 1002, "the '723 patent"). Cipla Ltd. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

For the reasons provided below, we exercise our discretion under 35 U.S.C. § 325(d) and deny institution of an *inter partes* review.

Related Matters

According to the parties, the '723 patent is the subject of *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.); and *Meda Pharmaceuticals, Inc. v. Apotex Inc*., No. 1:14-cv-01453-LPS (D. Del.). Pet. 56; Paper 5, 1. All three cases have been dismissed by stipulation. Pet. 56; Paper 5, 1.

The parties also identify *Argentum Pharmaceuticals LLC v. Cipla Ltd.*, IPR2017-00807 (PTAB) ("the Argentum IPR") as a related matter. Pet. 56; Paper 5, 1. The Argentum IPR challenged the parent of the '723 patent, U.S. Patent No. 8,168,620 B2 (Ex. 1001, "the '620 patent"). There, the Board instituted trial but terminated it prior to issuing a final written decision. Pet. 56, 58; Paper 5, 1.

Petitioner concurrently filed three other petitions, challenging patents related to the '723 patent: IPR2020-00369 (challenging the '620 patent), 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 (Ex. 1004, "the '585 patent").

The '723 Patent

The '723 patent discloses and claims pharmaceutical compositions comprising azelastine (or its pharmaceutically acceptable salt) and fluticasone (or its pharmaceutically acceptable ester) in a dosage form suitable for nasal administration. *See generally* Ex. 1002. It teaches that azelastine is an antihistamine useful for treating allergy-related conditions. *Id.* at 1:30–33 (stating "it is known to use the antihistamine azelastine (usually as the hydrochloride salt) as a nasal spray against seasonal or perennial allergic rhinitis"). It also teaches that it was known in the art to treat allergic rhinitis with corticosteroids, "which will suppress nasal and ocular inflammatory conditions." *Id.* at 1:35–37. The '723 patent lists fluticasone as a corticosteroid "known for nasal use." *Id.* at 1:37–38.

According to the '723 patent, "[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 1:43–47.

The '723 patent states that the inventors found that, "very surprisingly, azelastine . . . can advantageously be combined with a steroid . . . to provide a stable, very effective combination product or formulation" for nasal treatment. *Id.* at 1:48–57. Such a combination, according to the '723 patent, "can provide, in a single administration or dosing regime, 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 1:58–62.

The '723 patent discloses that the pharmaceutical compositions are preferably in the form of nasal drops, eye drops, nasal sprays, nasal inhalation solutions, aerosols, or insufflation powders. *Id.* at 2:16–18. Of these, the '723 patent states that a nasal spray is a particularly preferred form. *Id.* at 2:24–26. The '723 patent also teaches that the formulations may contain pharmaceutically acceptable excipients, such as preservatives, stabilizers, auxiliary substances, isotonization agents, thickening agents, and buffers. *Id.* at 2:32–3:65.

Illustrative Claim

Claim 1 is the only independent claim and is reproduced below:

> 1. A method for the prophylaxis or treatment in a mammal of a condition for which administration of one or more anti-histamines and/or one or more steroids is indicated, comprising intranasal administration to said mammal of a therapeutically effective amount of a pharmaceutical composition comprising (a) azelastine, or a pharmaceutically acceptable salt thereof; and (b) pharmaceutically acceptable ester of fluticasone.

The Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claims Challenged	35 U.S.C. §	References
1–28	103(a)	PDR 1999,[1] Segal[2]
1–28	103(a)	Cramer,[3] PDR 1999

In support of its patentability challenge, Petitioner relies on the Declarations of Maureen D. Donovan, Ph.D. (Ex. 1058) and Robert P. Schleimer, Ph.D. (Ex. 1062).

[1] Physicians' Desk Reference (53rd ed. 1999) (Ex. 1010).
[2] WO 98/48839 A1, published Nov. 5, 1998 (Ex. 1012).
[3] EP 0 780 127 A1, published June 25, 1997 (Ex. 1011).

DISCUSSION

Patent Owner asks us to exercise our discretion under 35 U.S.C. § 325(d) and deny this Petition. Prelim. Resp. 20–28. Patent Owner argues that "[t]he Office has already evaluated—and rejected—Petitioner's arguments." *Id.* at 20. According to Patent Owner, Cramer and Segal were addressed by the Examiner during prosecution, and while PDR 1999 was not previously considered, "its teachings are cumulative of information already considered (and rejected) by the Office." *Id.* at 21. We find Patent Owner's arguments persuasive.

Under § 325(d),

> In determining whether to institute or order a proceeding under . . . chapter 31, 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.

In evaluating whether to exercise our discretion under § 325(d), we weigh the following non-exclusive factors ("*BD* factors"):

> (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 prior art or arguments.

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