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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.

IPR2020-00370
Patent 9,259,428 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 1–30 ("the challenged claims") of U.S. Patent No. 9,259,428 B2 ("the '428 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 '428 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. 63–64; 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 U.S. Patent No. 8,168,620 B2 ("the '620 patent," Ex. 1001), which is related to the '428 patent. Pet. 63–64; Paper 5, 1. The Board terminated the proceeding prior to issuing a final written decision.

Petitioner concurrently filed three other petitions, challenging patents related to the '428 patent: IPR2020-00368 (challenging U.S. Patent

No. 8,163,723 B2 ("the '723 patent," Ex. 1002)); IPR2020-00369 (challenging the '620 patent), and IPR2020-00371 (challenging U.S. Patent No. 9,901,585 B2 ("the '585 patent," Ex. 1004)). Paper 5, 1–2.

B. The '428 Patent

The '428 patent is titled "Combination of Azelastine and Fluticasone for Nasal Administration." Ex. 1003, code (54). The '428 patent relates to pharmaceutical formulations comprising azelastine and fluticasone, which can be used to minimize or prevent allergic reactions. *Id.* at 1:32–34, 7:19–45. The Specification explains that it is known to use antihistamines, e.g., azelastine hydrochloride, in nasal sprays to treat allergy-related conditions. *Id.* at 1:41–46. The Specification explains that it is also known to treat allergy-related conditions with a corticosteroid such as fluticasone to suppress nasal inflammatory conditions. *Id.* at 1:47–54. 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 1:55–59.

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 1:60–2:2. "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 2:2–7.

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. Preferred preservatives include edetate disodium, benzalkonium chloride, and phenyl ethyl alcohol. *Id.* at 2:55–3:7. 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 3:30–43, 3:44–47, 3:57–4:5. 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 4:14–19.

The Specification further teaches "a method for the prophylaxis or treatment in a mammal, such as a human, of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated." *Id.* at 7:30–33. The method of treatment comprises administration of a therapeutically effective amount of a pharmaceutical formulation containing azelastine and fluticasone described in the Specification. *Id*. at 7:33–45.

C. Representative Claim

Petitioner challenges claims 1–30 of the '428 patent, of which claims 1, 14, and 28 are independent. Pet. 1. Claim 1 is representative of the claimed subject matter, and is reproduced below.

> 1. A method for the treatment of seasonal allergic rhinitis, comprising administration of a therapeutically effective amount of 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. 1003, 11:51–61.

D. The Asserted Grounds of Unpatentability

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

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

In support of its patentability challenge, Petitioner relies on the Declarations of Maureen D. Donovan, Ph.D. (Ex. 1059), and Robert P. Schleimer, Ph.D. (Ex. 1063).

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

[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, 1998 (Ex. 1011).

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