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

---

[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).

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.