Trials@uspto.gov
571-272-7822

Paper 11
Entered: August 21, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner,

v.

CIPLA LTD.,
Patent Owner.

Case IPR2017-00807
Patent 8,168,620 B2

Before BRIAN P. MURPHY, ZHENYU YANG, and KRISTI L. R. SAWERT, *Administrative Patent Judges.*

SAWERT, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Argentum Pharmaceuticals LLC ("Petitioner") filed a Petition for an *inter partes* review of claims 1, 4–6, 24–26, 29, and 42–44 of U.S. Patent No. 8,168,620 B2 ("the '620 patent," Ex. 1001). Paper 2 ("Pet."). Cipla Ltd. ("Patent Owner") timely filed a Preliminary Response. Paper 7 ("Prelim. Resp.").

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a); *see also* 37 C.F.R. §§ 42.4, 42.108.

For the reasons provided below, we determine that Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a) as to claims 1, 4–6, 24–26, 29, and 42–44 of the '620 patent, and we institute an *inter partes* review of those claims.

A. Related Proceedings

The parties identify the following district court actions as related matters under 37 C.F.R. § 42.8(b)(2): *Meda Pharms. Inc. v. Apotex Inc.*, 14-cv-01453 (D. Del.); *Meda Pharms. Inc. v. Teva Pharms.*, 15-cv-00785 (D. Del.); *Meda Pharms. Inc. v. Perrigo UK Finco Ltd.*, 16-cv-00794 (D. Del.). Pet. 1; Paper 9, 1. Patent Owner also identifies U.S. Patent Application Nos. 15/070,839 and 13/284,836 as claiming or potentially claiming priority to the '620 patent. Paper 4, 1; Paper 9, 1.

B. Real Parties-in-Interest

Petitioner identifies Argentum Pharmaceuticals LLC, Intelligent Pharma Research LLC, APS GP LLC, APS GP Investors LLC, and KVK-TECH, Inc. as real parties-in-interest under 37 C.F.R. § 42.8(b)(1). Pet. 1. Patent Owner identifies Cipla Limited, Meda Pharmaceuticals Inc., Meda AB, Mylan N.V., Mylan Inc., Mylan Pharmaceuticals, Inc., and Mylan Specialty L.P. as real parties-in-interest under 37 C.F.R. § 42.8(b)(1). Paper 9, 1.

C. The '620 Patent

The '620 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. 1001. The '620 patent teaches that azelastine is an antihistamine useful for treating allergy-related conditions. "Thus, for example, it is known to use the antihistamine azelastine (usually as the hydrochloride salt) as a nasal spray against seasonal or perennial allergic rhinitis . . . ." *Id.* at 1:21–24. The '620 patent 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 1:26–28. The '620 patent lists fluticasone as a corticosteroid "known for nasal use." *Id.* at 1:28–30.

"It would be highly desirable, however," the '620 patent continues, "to provide a treatment that combines the effects of anti-histamine treatments and steroid treatments, in a pharmaceutically acceptable formulation." *Id.* at 1:34–36. The '620 patent teaches that these

formulations should be "tolerated in situ, without significantly disrupting the potency of the constituent pharmaceuticals." *Id.* at 1:37–38. The '620 patent then 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 1:39–48. The combination of azelastine and a steroid such as fluticasone, the '620 patent explains, "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 1:48–53.

The '620 patent teaches that the disclosed pharmaceutical compositions are preferably in the form of nasal drops, eye drops, nasal sprays, nasal inhalation solutions, aerosols, or insufflation powders. *Id.* at 2:14–16. Of these, the '620 patent states that a nasal spray is a particularly preferred form. *Id.* at 2:23–25. The '620 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 2:31–4:3.

D. Challenged Claims

Petitioner challenges claims 1, 4–6, 24–26, 29, and 42–44 of the '620 patent. Pet. 2. Claims 1 and 25 are independent and illustrative of the claimed subject matter:

> 1. A pharmaceutical formulation comprising:
> azelastine, or a pharmaceutically acceptable salt thereof,
> and
> a pharmaceutically acceptable ester of fluticasone,
> wherein said pharmaceutical formulation is in a dosage form suitable for nasal administration.
>
> 25. A nasal spray formulation comprising (i) azelastine, or a pharmaceutically acceptable salt thereof, (ii) a pharmaceutically acceptable ester of fluticasone, and (iii) a pharmaceutically acceptable carrier or excipient therefor.

Ex. 1001, 11:46–51, 13:24–27.

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.