Trials@uspto.gov
571.272.7822

Paper No. 19
Entered: November 20, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.
Petitioner,

v.

CORCEPT THERAPEUTICS, INC.
Patent Owner.

PGR2019-00048
Patent 10,195,214 B2

Before JAQUELINE WRIGHT BONILLA, *Deputy Chief Administrative Patent Judge*, ROBERT A. POLLOCK, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

DECISION
Granting Institution of Post Grant Review
35 U.S.C. § 324(a)

I. INTRODUCTION

On May 7, 2019, Teva Pharmaceuticals USA, Inc., ("Petitioner") filed a Petition for Post Grant Review of claims 1–13 of U.S. Patent No. 10,195,214 B2 ("the '214 patent").[1] Paper 2 ("Pet."). On August 23, 2019, Corcept Therapeutics, Inc. ("Patent Owner") filed a Preliminary Response to the Petition.[2] Paper 8 ("Prelim. Resp."). On September 23, 2019, with the authorization of the Board, Paper 14, Petitioner filed a Reply to Patent Owner's Preliminary Response. Paper 15 ("Reply"). On October 3, 2019, also with the authorization of the Board, Patent Owner filed a Sur-Reply to Petitioner's Reply. Paper 17 ("Sur-reply").

Institution of post grant review is authorized by statute only when "the information presented in the petition . . . demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 324(a) (2012); *see* 37 C.F.R. § 42.4 (2012). Upon considering the Petition, the Preliminary Response, and the cited evidence, we conclude that Petitioner has satisfied the burden under 35 U.S.C. § 324(a) to show that it is more likely than not that at least one of the claims challenged in the petition is unpatentable.

A. Related Proceedings

Petitioner and Patent Owner represent that the '214 patent was asserted in district court in *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 18-3632 (SDW) (CLW) (D.N.J.). Pet. 65; Paper 5, 1. Petitioner additionally identifies pending U.S.

---

[1] Petitioner identifies Teva Pharmaceutical USA Inc. as the real party in interest. Pet. 65.

[2] Patent Owner identifies Corcept Therapeutics, Inc. as the real party in interest. Paper 5, 1.

Patent Application Nos. 16/219,564 and 15/627,368 as relating to the '214 patent. Pet. 65.

B. The '214 Patent (Ex. 1001)

The '214 patent, entitled "Concomitant Administration of Glucocorticoid Receptor Modulators and CYP3A Inhibitors," issued February 5, 2019, identifying Joseph K. Belanoff as the inventor. Ex. 1001, code (54), (45), (72). The '214 patent discloses "methods of treating diseases including Cushing's syndrome and hormone-sensitive cancers by concomitant administration of a glucocorticoid receptor antagonist (GRA) and steroidogenesis inhibitors, and by concomitant administration of a GRA and CYP3A inhibitors." Ex. 1001, Abstract.

The '214 patent teaches that Cushing's syndrome is a disorder caused by dysregulation of cortisol. *Id*. at 1:27–37. "Clinical manifestations of Cushing's syndrome include abnormalities in glucose control, requirement for anti-diabetic medication, abnormalities in insulin level, abnormal psychiatric symptoms, cushingoid appearance, acne, hirsutism, and increased or excessive body weight, and other symptoms." *Id*. at 37–42.

The '214 patent discloses that "[o]ne effective treatment of cortisol dysregulation is to block the binding of cortisol to cortisol receptors, or to block the effect of cortisol binding to cortisol receptors." *Id*. at 1:43–45. The '214 patent also discloses that "[m]ifepristone binds to cortisol receptors, and acts to block such binding and to block the effect of cortisol on tissues." *Id*. at 1:45–49.

According to the '214 patent, "[a]nother effective treatment of cortisol dysregulation is to reduce the synthesis of cortisol, e.g., by reducing or blocking steroid synthesis." *Id*. at 1:50–53. "CYP3A enzymes play

important roles in the synthesis of steroid hormones such as cortisol." *Id*. at 1:61–62. The '214 patent discloses a number of drugs that inhibit CYP3A including, *inter alia*, ketoconazole, itraconazole, and clarithromycin. *Id*. at 1:63–2:12.

The '214 patent teaches that "[t]he simultaneous, or nearly simultaneous (e.g., concomitant) presence of two drugs in a subject may alter the effects of one or the other, or both, drugs." *Id*. at 2:64–66. More specifically, "[c]oncomitant administration of different drugs often leads to adverse effects since the metabolism and/or excretion of each drug may reduce or interfere with the metabolism and/or excretion of the other drug(s), thus increasing the effective concentrations of those drugs as compared to the effective concentrations of those drugs when administered alone." *Id*. at 3:15–22. In addition, "the risk of . . . toxic effects is believed to be increased when other drugs are concomitantly administered." *Id*. at 3:24–29.

The '214 patent discloses that "CYP3A inhibitors such as, e.g., ketoconazole, may be concomitantly administered with glucocorticoid receptor modulators (GRMs) such as the GR antagonik [sic, antagonist] (GRA) mifepristone." *Id*. at 3:47–50; *see id*. at 4:1–21. For example, the '214 patent asserts that "concomitant administration of ketoconazole and mifepristone surprisingly does not increase the risk of ketoconazole toxicity in the patient, and is believed to be safe for the patient." *Id*. at 4:51–55.

C. Challenged Claims

Petitioner challenges claims 1–13 of the '214 patent. Claim 1 is representative and is reproduced below.

1. A method of treating Cushing's syndrome in a patient who

is taking an original once-daily dose of 1200 mg or 900 mg per day of mifepristone, comprising the steps of:

reducing the original once-daily dose to an adjusted once-daily dose of 600 mg mifepristone,

administering the adjusted once-daily dose of 600 mg mifepristone and a strong CYP3A inhibitor to the patient,

wherein said strong CYP3A inhibitor is selected from the group consisting of ketoconazole, itraconazole, nefazodone, ritonavir, nelfmavir, indinavir, boceprevir, clarithromycin, conivaptan, lopinavir, posaconazole, saquinavir, telaprevir, cobicistat, troleandomycin, tipranivir, paritaprevir and voriconazole.

Ex. 1001, 68:2–16.

D. The Asserted Ground of Unpatentability

Petitioner challenges the patentability of claims 1–13 of the '214 patent on the following grounds:

Claim(s) Challenged	**35 U.S.C. §**	**Reference(s)/Basis**
1–13	103(a)	Korlym Label,[3] Lee[4]
1–13	103(a)	Korlym Label, Lee, and FDA Guidance[5]

Petitioner submits the Declaration of Dr. David J. Greenblatt (Ex. 1002) in support of institution of post grant review.

[3] Corcept Therapeutics Inc., *Korlym™ (mifepristone) 300 mg Tablets*, (2012) (Ex. 1004, "Korlym Label").
[4] Lee et al., Office of Clinical Pharmacology Review NDA 20687 (Addendum, Korlym™, Mifepristone) (2012) (Ex. 1005, "Lee").
[5] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), *Guidance for Industry, Drug Interaction Studies — Study Design, Data Analysis, and Implications for Dosing and Labeling*, (2006) (Ex. 1041, "FDA Guidance").

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.