Trials@uspto.gov
571.272.7822

Paper No. 11
Entered: February 15, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEPTUNE GENERICS, LLC
Petitioner,

v.

CORCEPT THERAPEUTICS, INC.
Patent Owner.

Case IPR2018-01494
Patent 8,921,348 B2

Before CHRISTOPHER G. PAULRAJ, ROBERT A. POLLOCK, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

# DECISION
Granting Institution of *Inter Partes* Review
*35 U.S.C. § 314(a)*

# I. INTRODUCTION

Neptune Generics, LLC ("Petitioner" or "Neptune") filed a Petition requesting an *inter partes* review of claims 1–7 of U.S. Patent No. 8,921,348 B2 (Ex. 1001, "the '358 patent").[1] Paper 1 ("Pet."). Corcept Therapeutics, Inc. ("Patent Owner" or "Corcept") filed a Preliminary Response to the Petition. Paper 9 (Prelim. Resp.).[2]

Institution of an *inter partes* review is authorized by statute only 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; *see* 37 C.F.R. §§ 42.4, 42.108. Upon considering the Petition, the Preliminary Response, and the cited evidence, we conclude that Petitioner has satisfied the burden under 35 U.S.C. § 314(a) to show that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims.

## *A. Related Proceedings*

Petitioner represents that it is unaware of any other matters related to the '348 patent. Patent Owner identifies *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 18-cv-03632-SDW (D.N.J. Mar. 15, 2018) as relating to the '348 patent. Paper 4, 1.

## *B. The '348 Patent (Ex. 1001)*

The '348 patent issued December 30, 2014, identifying Joseph K. Belanoff as the inventor. Ex. 1001. The patent discloses "a method for

---

[1] Petitioner identifies Neptune Generics, LLC as the real party in interest. Pet. 1.

[2] Patent Owner identifies Corcept Therapeutics, Inc. as the real party in interest. Paper 4, 1.

optimizing levels of mifepristone in a patient suffering from a mental disorder amenable to treatment by mifepristone." *Id.* at Abstract.

The '348 patent teaches that "[i]t has surprisingly been discovered that administration of the same dose of mifepristone can produce widely varying blood serum levels in different patients," which can result in "some patients not receiving an efficacious dose of mifepristone." *Id.* at 1:28–32. "[T]he blood serum levels can differ by as much as 800% from one patient to another. Thus a method for ensuring that blood serum levels of mifepristone remain in an efficacious and safe range is needed." *Id.* at 1:33–36.

According to the '348 patent, the disclosed invention provides a method for optimizing mifepristone levels by treating the patient and then "testing the serum levels of the patient to determine whether the blood levels of mifepristone are greater than 1300 ng/ml [] and adjusting the daily dose of the patient to achieve mifepristone blood levels greater than 1300 ng/mL." *Id.* at 1:40–49.

### *C. Challenged Claims*

Petitioner challenges claims 1–7 of the '348 patent. Claim 1 is representative and is reproduced below:

> 1. A method for optimizing levels of mifepristone in a patient suffering from a disorder amenable to treatment by mifepristone, the method comprising:
>
> treating the patient with seven or more daily doses of mifepristone over a period of seven or more days;
>
> testing the serum levels of the patient to determine whether the blood levels of mifepristone are greater than 1300 ng/mL; and
>
> adjusting the daily dose of the patient to achieve mifepristone blood levels greater than 1300 ng/mL.

Ex. 1001, 16:26–35.

### *D. The Prosecution History*

We provide a discussion of the prosecution history of the '348 patent for context given that one of the prior art references asserted in this proceeding (Belanoff '953[3]) was cited by the Examiner during prosecution.

The application that issued as the '348 patent (Application No. 14/065,792), was filed on October 29, 2013 with 8 original claims. Ex. 1002, 142. During prosecution, the Examiner entered an obviousness-type double patenting rejection. *Id.* at 45–48. Patent Owner overcame this rejection by filing a terminal disclaimer. *Id.* at 20–32. No other rejections were entered.

The application that issued as the '348 patent was a continuation of Application No. 12/199,144 ("the '144 application"), which has now issued as US Patent 8,598,149. The claims at issue in this application are very similar to those in the issued '348 patent.[4] Accordingly, the '144 patent is informative as to the reasons why the Examiner allowed the '348 patent.

---

[3] Belanoff, US Patent No. 9,964,953, issued Nov. 15, 2005 (Ex. 1010, "Belanoff '953").

[4] Claim 1 of the '144 application, as originally filed, reads as follows:

> 1. A method for optimizing levels of mifepristone in a patient suffering from a mental disorder amenable to treatment by mifepristone, the method comprising:
>
> treating the patient with seven or more daily doses of mifepristone over a period of seven or more days;
>
> testing the serum levels of the patient to determine whether the blood levels of mifepristone are greater than 1300 ng/mL; and
>
> adjusting the daily dose of the patient to achieve mifepristone blood levels greater than 1300 ng/mL.

Ex. 1003, 233 (emphasis added to reflect differences as compared to claim 1 of the '348 patent).

In an Office Action mailed August 3, 2011, the Examiner rejected the pending claims of the '144 application as obvious under 35 U.S.C. § 103(a) over the combination of the Medical Encyclopedia of Medline,[5] Sarkar,[6] and Belanoff '953. The Examiner found that the Medical Encyclopedia of Medline taught that "[t]herapeutic drug levels are usually performed to look for the presence and the amount of specific drug in the blood" and that "[w]ith most medications, a certain level of drug is needed in the blood stream to obtain the desired therapeutic effect." Ex. 1003, 163. The Examiner found that Belanoff '953 disclosed that mifepristone was useful for treating acute stress disorder and taught dosages of 1 to 10 mg/kg, which translates to 75–750 mg for an average adult weighing 75 kg. *Id.* The Examiner found that Sarkar taught that serum concentrations for a 100–200 mg dose of mifepristone ranged from 1933.2–2276.88 ng/ml. *Id.*

Based on the combination of the Medical Encyclopedia, Sarkar, and Belanoff '953, the Examiner concluded that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the serum level of mefipristone [sic] in patients suffering from Acute Stress Disorder." *Id.* The Examiner explained:

> One of ordinary skill in the art would have been motivated to optimize the serum level of mefipristone [sic] in patients suffering from Acute Stress Disorder. Adjusting the therapeutic serum levels to obtain a therapeutic effect is well-known in the art. Since both the serum concentration and the dosage of mifepristone useful in treating the Acute Stress Disorder are

---

[5] U.S. National Library of Medicine, Medical Encyclopedia: Therapeutic Drug Levels, http://www.nlm.nih.gov/medlineplus/ency/article/003430.htm, ("Medical Encyclopedia of Medline").

[6] Sarkar, *Mifepristone: Bioavailability, Pharmacokinetics, and Use-Effectiveness,* 101(2) European Journal of Obstetrics and Gynecology and Reproductive Biology, 113-120 (2002) ("Sarkar").

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.