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Paper 35
Entered: February 10, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEPTUNE GENERICS, LLC,
Petitioner,

v.

CORCEPT THERAPEUTICS, INC.,
Patent Owner.

IPR2018-01494
Patent 8,921,348 B2

Before TINA E. HULSE, ROBERT A. POLLOCK, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

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

Following our Institution Decision, Patent Owner filed a Response to the Petition (Paper 24, "PO Resp."), Petitioner filed a Reply to Patent Owner's Response (Paper 29, "Reply"), and Patent Owner filed a Sur-Reply (Paper 30, "Sur-Reply"). On November 19, 2019, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 34 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Based on the record before us, we conclude that Petitioner has not demonstrated by a preponderance of the evidence that claims 1–7 of the '348 patent are unpatentable.

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[1] Petitioner identifies Neptune Generics, LLC; Niagara Funding Co, LLC; GKC Partners II, LP; GKC General Partner II, LP; Burford Capital Ireland DAC; GKC PII Holdings, LLC; Burford Capital Investment Management LLC; Burford Capital Holdings (UK) Limited; and Burford Capital Limited as the real parties in interest (collectively, "RPI"). Paper 6, 2–3. Petitioner further represents that GKC Partners II, LP is now known as BCIM Partners II, LP, GKC General Partner II, LP is now known as BCIM General Partner II, LP, and GKC PII Holdings, LLC is now known as BCIM PII Holdings, LLC. Paper 28, 3.

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

A. Related Proceedings

Petitioner represents that it is unaware of any other matters related to the '348 patent. Pet. 1. Patent Owner identifies *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 18-cv-03632-SDW (D.N.J. Mar. 15, 2018), and *Corcept Therapeutics, Inc. v. Sun Pharma Global FZE et al.*, No. 19-cv-15678-SDW-CLW (D.N.J. July 22, 2019) as relating to the '348 patent. Paper 4, 1; Paper 27, 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 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 been surprisingly 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 with seven or more doses for a period of seven or more days 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 over claims 1–7 of US Patent 8,598,149 ("the '149 patent"). *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 issued as the '149 patent. The claims at issue in the '144 application are very similar to

[3] Belanoff, US Patent No. 6,964,953, issued Nov. 15, 2005 (Ex. 1010, "Belanoff '953").

those in the issued '348 patent.[4] Accordingly, the '144 application is informative as to the reasons why the Examiner allowed 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

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[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).

[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").

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