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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.
Petitioner,

v.

UNITED THERAPEUTICS CORP.[1]
Patent Owner.

Case IPR2017-01621
Patent 9,358,240 B2

Before LORA M. GREEN, ERICA A. FRANKLIN, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

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

[1] Further to Patent Owner's request, we have changed the case caption in order to reflect that United Therapeutics Corporation is the assignee of record with respect to US Patent No. 9,399,507 B2. Prelim Resp. 1 n.1.

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I. INTRODUCTION

Watson Laboratories, Inc. ("Petitioner" or "Watson") filed a Petition requesting an *inter partes* review of claims 1–9 of U.S. Patent No. 9,358,240 B2 (Ex. 1001, "the '240 patent"). Paper 2 ("Pet."). United Therapeutics Corp. ("Patent Owner" or "UTC") filed a Preliminary Response to the Petition. Paper 5 (Prelim. Resp.).

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 and Patent Owner identify the following proceedings as relating to the '240 patent: *United Therapeutics Corp. v. Watson Laboratories, Inc.* Case No. 15-cv-05723 (D.N.J.) and IPR2017-01622, which challenges the patentability of U.S. Patent No. 9,339,507 ("the '507 patent"). *Id.* The '240 patent and the '507 patent share a common parent and provisional application. *Id.* Patent Owner also identifies US Patent Application No. 15/011,999, a pending continuation application with common priority to the '240 and '507 patents, as related to this proceeding. Paper 3, 2.

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B. The '240 Patent (Ex. 1001)

The '240 patent issued June 7, 2016, identifying Horst Olschewski, Robert Roscigno, Lewis J. Rubin, Thomas Schmehl, Werner Seeger, Carl Sterritt, and Robert Voswinckel as co-inventors. Ex. 1001. The patent discloses "methods and kits for therapeutic treatment . . . involving administering treprostinil using a metered dose inhaler and related kits." *Id.* at 1:15–19.

The '240 patent teaches that pulmonary hypertension is "a condition associated with an elevation of pulmonary arterial pressure (PAP) over normal levels." *Id.* at 2:6–8. "Pulmonary hypertension has been implicated in several life-threatening clinical conditions, such as adult respiratory distress syndrome ('ARDS') and persistent pulmonary hypertension of the newborn ('PPHN')." *Id.* at 2:37–40. "Pulmonary hypertension may also ultimately result in a potentially fatal heart condition known as 'cor pulmonale,' or pulmonary heart disease." *Id.* at 2:48–51. According to the '240 patent, "currently there is no treatment for pulmonary hypertension that can be administered using a compact inhalation device, such as a metered dose inhaler." *Id.* at 2:53–55.

The '240 patent discloses that "[t]he inventors discovered that a therapeutically effective dose of treprostinil can be administered in a few single inhalations using a compact inhalation device, such as a metered dose inhaler." *Id.* at 5:8–11. The '240 patent further discloses that "such administering does not cause significant side effects." *Id.* at 5:12–13.

C. Challenged Claims

Petitioner challenges claims 1–9 of the '240 patent. Claim 1, the only independent claim, is reproduced below:

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> 1. A method of treating pulmonary hypertension comprising:
>
> administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of a formulation comprising 200 to 1000 μg/ml of treprostinil or a pharmaceutically acceptable salt thereof
>
> with a pulsed ultrasonic nebulizer that aerosolizes a fixed amount of treprostinil or a pharmaceutically effective salt thereof per pulse,
>
> said pulsed ultrasonic nebulizer comprising an opto-acoustical trigger which allows said human to synchronize each breath to each pulse,
>
> said therapeutically effective single dose event comprising from 15 μg to 90 μg treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 18 breaths.

Ex. 1001, 18:2–17.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–9 of the '240 patent on the following grounds (Pet. 6):

References	**Basis**	**Claims Challenged**
Voswinckel,[2] Patton,[3] and Ghofrani[4]	§ 103(a)	1–9

[2] Robert Voswinckel, et al., *Inhaled Treprostinil Sodium (TRE) for the Treatment of Pulmonary Hypertension,* Abstract #1414, CIRCULATION, 110, 17, Supplement (Oct. 2004): III–295 (Ex. 1003, "Voswinckel").
[3] Patton et al., WO 93/00951, published Jan. 21, 1993 (Ex. 1012, "Patton").
[4] Hossein Ardeschi Ghofrani, Robert Voswinckel, et al., *Neue Therapieoptionen in der Behandlung der pulmonalarteriellen Hypertonie*, 30(4) HERTZ 296–302 (2005) (Ex. 1005, "Ghofrani"). Ghofrani was originally published in German. All citations herein are to the English translation of Ghofrani provided by Petitioner (Ex. 1005).

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References	Basis	Claims Challenged
Voswinckel, Patton, and the OptiNeb User Manual[5]	§ 103(a)	1–9
Voswinckel, Ghofrani and the EU Community Register[6]	§ 103(a)	1–9

Petitioner submits the Declaration of Dr. Maureen D. Donovan (Ex. 1002), the Declaration of Dr. Scott Bennett (Ex. 1013), two Affidavits of Christopher Butler (Ex. 1014 and 1015), and the Declaration of Dr. DeForest McDuff (Ex. 1055) in support of institution of *inter partes* review. Patent Owner submits the Declaration of Dr. Richard Dalby (Ex. 2001), the Declaration of Dr. Werner Seeger (Ex. 2020), the Declaration of Dr. Hossein A. Ghofrani (Ex. 2026), the Declaration of Dr. Frank Reichenberger (Ex. 2027), and the Declaration of Dr. Friedrich Grimminger (Ex. 2028) to support their arguments in opposition to institution.

II. ANALYSIS

A. 35 U.S.C. § 315(b)

We first consider arguments raised in Patent Owner's Preliminary Response challenging whether Petitioner timely filed the Petition. Prelim. Resp. 13–20. Patent Owner initially filed a complaint against Petitioner alleging infringement of patents other than the '240 patent in the United States District Court for the District of New Jersey on July 22, 2015.

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[5] Opti-Neb-ir® Operating Instructions, Model ON-100/2-2.4 MHz (2005) (Ex. 1006, "OptiNeb"). OptiNeb was originally published in German. Pet. 17, n. 6. All citations herein are to the English translation of OptiNeb provided by the Petitioner (Ex. 1006).

[6] Annexes to Commission Decision C(2005)3436 of 05 September 2005, http://ec.europa.eu/health/documents/communityregister/2005/2005090510259/anx_10259_en.pdf (Annex III–Ventavis Labelling and Package Leaflet) (Ex. 1009, "EU Community Register" or "Annex III").

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