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Paper No. 9
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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 IPR2017-01622
Patent 9,339,507 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 Corp. is the assignee of record with respect to US Patent No. 9,399,507 B2. Prelim Resp. 1, n. 1.

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. 9,339,507 B2 (Ex. 1001, "the '507 patent"). Paper 2 ("Pet."). United Therapeutics Corp. ("Patent Owner" or "UTC") filed a Preliminary Response to the Petition opposing institution. 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 '507 patent: *United Therapeutics Corp. v. Watson Laboratories, Inc.*, Case No. 15-cv-05723 (D.N.J.) and IPR2017-01621, which challenges the patentability of U.S. Patent No. 9,358,240 ("the '240 patent"). Pet. 4; Paper 3, 2. The '507 patent and the '240 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.

B. The '507 Patent (Ex. 1001)

The '507 patent issued May 17, 2016, identifying Horst Olschewski, Robert Roscigno, Lewis J. Rubin, Thomas Schmehl, Werner Seeger, Carl Sterritt, and Robert Voswinckel as co-inventors. Ex. 1001 (45), (75). The '507 patent discloses "methods and kits for therapeutic treatment . . . involving administering treprostinil using a metered dose inhaler and related kits." *Id.* at 1:16–19.

The '507 patent teaches that pulmonary hypertension is "a condition associated with an elevation of pulmonary arterial pressure (PAP) over normal levels." *Id.* at 2:7–9. "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 2:39–42. "Pulmonary hypertension may also ultimately result in a potentially fatal heart condition known as 'cor pulmonale,' or pulmonary heart disease." *Id.* at 2:50–53. According to the '507 patent, "[c]urrently, there is no treatment for pulmonary hypertension that can be administered using a compact inhalation device, such as a metered dose inhaler." *Id.* at 2:55–57.

The '507 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 5:4–7. The '507 patent further discloses that "such administering does not cause significant side effects." *Id.* at 5:9–10.

C. Challenged Claims

Petitioner challenges claims 1–9 of the '507 patent. Claim 1, the only independent claim, is reproduced below:

1. A kit for treating pulmonary hypertension comprising:

(i) a formulation comprising 200 to 1000 μg/ml treprostinil or a pharmaceutically acceptable salt thereof;

(ii) a pulsed ultrasonic nebulizer comprising an opto-acoustical trigger, configured to

(a) aerosolize a fixed amount of treprostinil per pulse, and

(b) deliver by inhalation a therapeutically effective single event dose of said formulation,

said single event dose comprising 15 μg to 90 μg treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 18 breaths; and

(iii) instructions for using the pulsed ultrasonic nebulizer with the formulation to treat a patient with pulmonary hypertension by delivering 15 μg to 90 μg treprostinil or a pharmaceutically acceptable salt thereof in 1 to 18 breaths to the patient in the single event dose.

Ex. 1001, 18:12–28.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–9 of the '507 patent on the following grounds (Pet. 6):

References	Basis	Claims Challenged
Voswinckel,[2] Chaudry,[3] Patton, and Ghofrani[4]	§ 103(a)	1–9
Voswinckel, Chaudry, Patton, and the OptiNeb User Manual[5]	§ 103(a)	1–9
Voswinckel, Chaudry, 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

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[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] Chaudry, US Patent Publication No. 2004/0265238 A1 issued Dec. 30, 2004 (Ex. 1004, "Chaudry").
[4] Hossein Ardeschir Ghofrani et al., *Neue Therapieoptionen in der Behandlung der pulmonalarteriellen Hypertonie*, 30 (4) HERZ 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).
[5] OptiNeb-ir Operating Instructions, Model ON-100/2-2.4 MHz (2005) (Ex. 1006, "OptiNeb"). OptiNeb was originally published in German. Pet. 18, 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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