

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.

Petitioner

v.

UNITED THERAPEUTICS CORP.

Patent Owner

Patent No. 9,358,240

Issue Date: June 7, 2016

Title: TREPROSTINIL ADMINISTRATION BY INHALATION

Inter Partes Review No. 2017-01621

SUPPLEMENTAL PATENT OWNER RESPONSE

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	SUMMARY OF ARGUMENT	2
III.	PETITIONER HAS NOT ESTABLISHED THAT VOSWINCKEL, GHOFRANI, THE OPTINEB-IR MANUAL, OR THE EU COMMUNITY REGISTER ARE PRIOR ART	2
A.	The OptiNeb-ir Manual was not publicly accessible.	3
B.	The EU Community Register was not publicly accessible.	8
IV.	PETITIONER HAS NOT ESTABLISHED OBVIOUSNESS OVER GROUND 2 OR GROUND 3.	9
A.	Ground 2.....	10
1.	A POSA would not have been motivated to combine Voswinckel and the OptiNeb-ir Manual to achieve limitation [D].....	10
2.	A POSA would not have been motivated to combine Voswinckel, the OptiNeb-ir Manual, and Patton to achieve limitations [B] or [C].	14
B.	Ground 3.....	17
1.	A POSA would not have been motivated to combine Voswinckel and the EU Community Register to achieve limitations [B1] or [C].	17
2.	A POSA would not have had a reasonable expectation of success in combining the EU Community Register and Ghofrani regarding limitation [D].....	20
C.	Dr. Donovan’s testimony lacks credibility and relies on information outside the record.	21

D. The objective indicia of non-obviousness weigh in favor of
patentability.....23

V. CONCLUSION.....23

TABLE OF AUTHORITIES

CASES

Adobe Systems Inc v. William Grecia, IPR2018-00418 (PTAB June 21, 2018).....8

Blue Calypso, LLC v. Groupon, Inc., 815 F.3d 1331 (Fed. Cir. 2016)3, 6

Dynamic Drinkware, LLC v. Nat’l Graphics, Inc., 800 F.3d 1375 (Fed. Cir. 2015) 2

In re Cronyn, 890 F.2d 1158 (Fed. Cir. 1989).....6

In re Lister, 583 F.3d 1307 (Fed. Cir. 2009)3

SAS Institute Inc. v. Iancu, 584 U.S. ____ (2018)1

Zetec, Inc. v. Westinghouse Elec. Co., IPR2014-00384 (PTAB July 23, 2014)11, 18

STATUTES

37 C.F.R. § 42.10810

37 C.F.R. § 42.63(b)5

EXHIBIT LIST

Exhibit No.	Description
2001	Declaration of Dr. Richard Dalby
2002	<i>Oxford Dictionary of English</i> . 2 nd ed. Revised. Oxford University Press, 2005 (excerpt).
2003	Newman, Stephen P. <i>Respiratory drug delivery: essential theory and practice</i> . Respiratory Drug Delivery Online, 2009 (excerpt).
2004	Hill, N., <i>Therapeutic Options for the Treatment of Pulmonary Hypertension</i> , Medscape Pulmonary Medicine 9(2) (2005).
2005	Exhibits Accompanying First Declaration of Dr. Roham Zamanian and Amendment and Reply filed in 12/591,200 (Nov. 9, 2015) (Ex. 1162)
2006	Declaration of Dr. Edmund Elder and Exhibits Accompanying Second Declaration of Dr. Roham Zamanian Amendment and Reply filed in 12/591,200 (Feb. 2, 2016) (Ex. 1163)
2007	Finlay, Warren H. <i>The Mechanics of Inhaled Pharmaceutical Aerosols: an Introduction</i> . Academic Press, 2002 (excerpt).
2008	“Mechanical Ventilation.” <i>American Journal of Respiratory and Critical Care Medicine</i> 196(2):P3-4 (2017).
2009	Motion for Leave to File An Amended Complaint and Exhibits Filed in Civil Action No: 3:15-cv-05723 PGS-LHG
2010	Email Correspondence to Watson’s Counsel Serving Motion for Leave to File An Amended Complaint and attached Exhibits (Ex. 2009).
2011	Consent Order Entering Motion for Leave to File An Amended Complaint in Civil Action No: 3:15-cv-05723 PGS-LHG
2012	Orange Book Listing for Tyvaso® (Accessed October 3, 2017)
2013	First Notice Letter Sent June 12, 2015 by Watson Regarding Orange Book Listed Tyvaso® Patents
2014	Issue Notifications for US Patent No. 9,399,507 and US Patent No. 9,358,240
2015	FDA Form 3542, Listing US Patent No. 9,399,507 in Orange Book
2016	FDA Form 3542, Listing US Patent No. 9,358,240 in Orange Book
2017	Email Correspondence between United Therapeutics and Watson Regarding Proposed Schedule for Civil Action No: 3:15-cv-05723 PGS-LHG in view of US Patent No. 9,399,507 and US Patent No. 9,358,240

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.