

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.
Petitioner

v.

UNITED THERAPEUTICS, INC.
Patent Owner

Patent No. 9,339,507
Issue Date: July 13, 2017
Title: TREPROSTINIL ADMINISTRATION BY INHALATION

Inter Partes Review No. 2017-01622

PATENT OWNER PRELIMINARY RESPONSE

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	SUMMARY OF ARGUMENT.....	1
III.	BACKGROUND	2
IV.	CLAIM CONSTRUCTION	6
	A. Person of Ordinary Skill in the Art (“POSA”).....	7
	B. Claim Terms	9
	1. “pulsed”.....	9
	2. “opto-acoustical trigger”	10
	3. “single event dose”.....	12
V.	THE PETITION SHOULD BE DENIED ON ALL GROUNDS BECAUSE IT WAS NOT TIMELY FILED.....	13
	A. The Amended Complaint was served on June 17, 2016.....	14
	B. The holding in <i>TRW</i> should not be applied to these facts.....	15
VI.	GROUND 1, 2, AND 3 SHOULD BE DENIED BECAUSE NONE OF GHOFRANI, THE OPTI-NEB MANUAL, OR THE EU COMMUNITY REGISTER HAVE BEEN QUALIFIED AS PRIOR ART.	21
	A. Ghofrani is not prior art “by another.”	21
	B. Petitioner has not demonstrated that the Opti-Neb Manual and the EU Community Register were publically accessible.....	24
	1. Petitioner has not demonstrated public accessibility of the Opti-Neb Manual.	24

2.	Petitioner has not demonstrated public accessibility for the EU Community Register	29
C.	Conclusion.....	33
VII.	THE PETITION SHOULD BE DENIED BECAUSE IT FAILS TO DEMONSTRATE A REASONABLE LIKELIHOOD OF SUCCESS ON GROUNDS 1, 2, AND 3.	33
A.	The testimony of Dr. Donovan reflects improper hindsight.	33
1.	Dr. Donovan cherry-picks a breathing rate and inhalation times to arrive at the claimed doses using the Opti-Neb Manual.	34
2.	Dr. Donovan selects specific portions in the EU Community Register regarding Vent-Neb while ignoring other portions inconsistent with her conclusions.....	36
3.	The Donovan Declaration has a number of other instances of conclusory or unsupported assertions.....	39
4.	Conclusion	40
B.	None of the Grounds 1-3 present a <i>prima facie</i> case of obviousness	40
1.	Ground 1 – Voswinckel in view of Chaudry, Patton, and Ghofrani	45
2.	Ground 2 – Voswinckel in view of Chaudry, Patton, and the Opti-Neb Manual	47
3.	Ground 3 –Voswinckel in view of Chaudry, Ghofrani, and the EU Community Register	50
C.	Conclusion.....	52
VIII.	CONCLUSION.....	52

TABLE OF AUTHORITIES**CASES**

<i>Actavis, Inc. v. Research Corp. Techs., Inc.</i> , IPR2014-01126 (PTAB Jan. 9, 2015)	29
<i>Activision Blizzard, Inc. v. Acceleration Bay, LLC</i> , IPR 2015-01964 (PTAB Mar. 29, 2017)	24
<i>Advanced Cardiovascular Sys. v. Medtronic, Inc.</i> , 265 F.3d 1294 (Fed.Cir.2001) 10	
<i>Blue Calypso, LLC v. Groupon, Inc.</i> , 815 F.3d 1331 (Fed. Cir. 2016)	24, 26
<i>Cuozzo Speed Technologies, LLC v. Lee</i> , 136 S. Ct. 2131(2016)	6
<i>In re Antonie</i> , 559 F.2d 618 (CCPA 1977)	39
<i>In re Cronyn</i> , 890 F.2d 1158 (Fed. Cir. 1989).....	26
<i>In re Hall</i> , 781 F.2d 897 (Fed. Cir. 1986).....	24
<i>In re Katz</i> , 687 F.2d 450 (CCPA 1982)	21
<i>In re Smith</i> , No. 2016-2303 (Fed. Cir. Sept. 26, 2017)	11
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	40
<i>Kyocera Wireless Corp. v. Int'l Trade Comm'n</i> , 545 F.3d 1340 (Fed. Cir. 2008)..	24
<i>Lacks Industries, Inc. v. McKechnie Vehicle Components USA, Inc.</i> , 322 F.3d 1335 (Fed. Cir. 2003).....	21
<i>Motorola Mobility LLC v. Arnouse</i> , IPR2013-00010 (PTAB Jan. 30, 2013)	18
<i>Murphy Bros. v. Michetti Pipe Stringing</i> , 526 U.S. 344 (1999)	19
<i>Mylan Labs. Ltd. v. Aventis Pharma S.A.</i> , IPR2016-00627 (PTAB Aug. 23, 2016)	34
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)	6, 9
<i>Riverwood Int'l Corp. v. R.A. Jones &Co., Inc.</i> , 324 F.3d 1346 (Fed. Cir. 2003)..	21

<i>ServiceNow, Inc., v. Hewlett-Packard Co.</i> , IPR2015-00716 (PTAB Aug. 26, 2015)	21
<i>Straight Path IP Group Inc. v. Sipnet EU S.R.O.</i> , 806 F.3d 1356 (Fed. Cir. 2015) .9, 10	
<i>Synopsys, Inc. v. Mentor Graphics Corp.</i> , 814 F.3d 1309 (Fed. Cir. 2016)	33
<i>Trs. of Columbia Univ. v. Illumina, Inc.</i> , 620 F. App'x 916 (Fed. Cir. 2015)	34
<i>TRW Automotive US LLC v. Magna Electronics, Inc.</i> , IPR2014-00293 (PTAB June 27, 2014)	15, 18, 19, 20
<i>Zetec, Inc. v. Westinghouse Elec. Co.</i> , IPR2014-00384 (PTAB July 23, 2014)	48, 50

STATUTES

21 U.S.C. § 355(b)	19
35 U.S.C. § 102(a)	24
35 U.S.C. § 271(e)(2)(A)	18
35 U.S.C. § 286	20
35 U.S.C. § 311(b)	24
35 U.S.C. § 313	1
35 U.S.C. § 315(a)	20
35 U.S.C. § 315(b)	13, 14
37 C.F.R. § 42.100(b)	6
37 C.F.R. § 42.107	1
37 C.F.R. § 42.108	33
37 C.F.R. § 42.108(c).....	34

RULES

Fed. R. Civ. P. 5.1(b)(2)(E)	14
------------------------------------	----

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.