

NEPTUNE GENERICS, LLC
Petitioner

V.

CORCEPT THERAPEUTICS, INC. Patent Owner

Patent No. 8,921,348 Issued: December 30, 2014 Filed: October 29, 2013 Inventor: Joseph K. Belanoff

Title: "Optimizing mifepristone levels in plasma serum of patients suffering from mental disorders treatable with glucocorticoid receptor antagonists"

Inter Partes Review No.—not yet assigned

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,921,348 AND MANDATORY NOTICES UNDER 37 C.F.R. § 42.8



TABLE OF CONTENTS

CONTENTS

I.	Introduction	1
II.	Grounds for Standing.	1
III.	Mandatory Notices	1
a.	Real Party-In-Interest	1
b.	Notice of Related Matters	1
c.	Lead and Backup Counsel	1
d.	Service Information	2
e.	Payment of Fees	2
IV.	Threshold Requirement for <i>Inter Partes</i> Review	2
V.	Identification of Challenge	2
a.	Overview of the '348 Patent	2
VI.	Level of Skill in the Art	12
VII.	Claim Construction	12
a.	"mifepristone"	13
b.	"optimizing levels of mifepristone"	13
c.	"adjusting the daily dose of the patient"	13
d.	"a plasma sampling collection device suitable for detecting mifepristone serum levels"	14
VIII.	State of the Art at the Time of Filing of the '348 Patent	15
IX.	Detailed Explanation of the Challenge	23
a.	Ground 1: Claims 1, 2, 4, 6, and 7 of the '348 Patent are obvious under 35 U.S.C. & 103 over <i>Belanoff</i> '848	25



b	. Ground 2: Claims 1, 2, 4, 6, and 7 of the '348 Patent are unpatentable as obvious under 35 U.S.C. § 103 over <i>Belanoff 2002</i> in view of <i>Chu</i>	
	and Belanoff and Sitruk-Ware.	32
c.	Ground 3: Claim 3 of the '348 Patent is unpatentable as obvious	
	under 35 U.S.C. § 103 over Belanoff 2002, Chu and Belanoff, and	
	Sitruk-Ware in further view of Belanoff '953.	42
d	. Ground 4: Claim 5 of the '348 Patent is unpatentable as obvious	
	under 35 U.S.C. § 103 over Belanoff 2002, Chu and Belanoff and	
	Sitruk-Ware in further view of Murphy.	43
e.	Ground 5: Claim 3 of the '348 Patent is unpatentable as obvious	
	under 35 U.S.C. § 103 over Belanoff '848 in further view of Belanoff	
	953.	45
f.	Ground 6: Claim 5 of the '348 Patent is unpatentable as obvious	
	under 35 U.S.C. § 103 over Belanoff '848 in further view of Murphy	46
X.	Secondary Considerations	47
VΙ	Conclusion	50



TABLE OF AUTHORITIES

CASES

Biomarin v. Genzyme, IPR2013-00534, Paper 81, p12-13, (PTAB 2015)	26
Cuozzo Speed Technologies, LLC v. Lee, 579 U. S (2016)	12
<i>In re Aller</i> , 42 C.C.P.A. 824, 220 F.2d 454, 456 (1955)	29
<i>In re Boesch</i> , 617 F.2d 272, 276 (C.C.P.A. 1980)	29
<i>In re Geisler</i> , 116 F.3d 1465, 1470 (Fed. Cir. 1997)	29
<i>In re Kulling</i> , 897 F.2d 1147, 1149 (Fed. Cir. 1990)	29
In re Peterson, 315 F.3d 1325, 1330 (Fed. Cir. 2003)	29
KSR International Co. v. Teleflex Inc., 550 U.S. 398, 416 (2007)	26
Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1368-69 (Fed. Cir. 2007)	29
Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005)	14
Santarus, Inc. v. Par Pharm., Inc., 694 F.3d 1344, 1354 (Fed. Cir. 2012)	30
STATUTES	
35 U.S.C. § 103(a)	7
35 U.S.C. § 314(a)	2
REGULATIONS	
37 C.F.R. § 42.100(b)	12
37 C.F.R. § 42.8	1



I. Introduction

Neptune Generics, LLC ("Petitioner") requests *inter partes* review ("IPR") of claims 1-7 of U.S. Patent No. 8,921,348 ("the '348 Patent") (Exhibit 1001).

II. Grounds for Standing

Petitioner certifies that the patent for which review is sought is available for *inter partes* review, and that Petitioner is not barred or estopped from requesting an *inter partes* review on the grounds identified in the petition.

III. Mandatory Notices

a. Real Party-In-Interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner certifies that Neptune Generics, LLC has authority to direct or control (i) the timing of, filing of, content of, or any decisions or other activities relating to this Petition or (ii) any timing, future filings, content of, or any decisions or other activities relating to the future proceedings related to this Petition.

b. Notice of Related Matters

Petitioner is unaware of any other matters related to the '348 Patent.

c. Lead and Backup Counsel

Lead Counsel:	Backup Counsel:
Kenneth M. Goldman	Christopher L. May
Reg. No. 34,174	Reg. No. 53,286
MASSEY & GAIL LLP	MASSEY & GAIL LLP
50 E. Washington Street, Suite 400	1325 G Street N.W., Suite 500
Chicago, IL 60602	Washington, DC 20005
kgoldman@masseygail.com	cmay@masseygail.com



DOCKET

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.

