

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIODELIVERY SCIENCES INTERNATIONAL, INC.
Petitioner

v.

RB PHARMACEUTICALS LIMITED
Patent Owner.

Case IPR2014-00998
Patent 8,475,832

**PATENT OWNER PRELIMINARY RESPONSE
PURSUANT TO 37 C.F.R. § 42.107**

TABLE OF CONTENTS

	Page
I. INTRODUCTION AND BACKGROUND	2
II. THE '832 PATENT	7
III. CLAIM CONSTRUCTION	10
IV. THE PETITION SHOULD BE REJECTED AS REDUNDANT OVER THE '325 IPR AND BECAUSE PETITIONER HAS NOT DEMONSTRATED A REASONABLE LIKELIHOOD OF PREVAILING ON ANY OF THE PROPOSED GROUNDS FOR UNPATENTABILITY	20
A. The Board Should Decline to Institute a Second Trial Because the Petitioner Already Presented the Same Art and Arguments in the '325 IPR	20
1. The Board Has Routinely Denied Duplicative Proceedings	21
2. Petitioner Admits That It Has Recycled Previous Art and Arguments	24
a. Ground 1, obviousness over Euro-Celtique, mirrors Ground 10 in the '325 IPR.....	25
b. Grounds 2-4 rely on the EMEA Study Report, which was previously presented to the Board and relied upon by Petitioner and the Board in the '325 IPR	27
c. Petitioner's reliance on WO 03/030883 in Ground 3 uses substantially the same art and arguments as in the '325 IPR.....	29
d. Petitioner's reliance on Yang in Ground 4 uses the same art and arguments as in the '325 IPR	31
3. Instituting Trial on These Duplicative Grounds Would Not Be in the Interests of Justice	32
B. Euro-Celtique Fails to Teach or Suggest a Specific Embodiment Within the Scope of Claim 15	34

TABLE OF CONTENTS

(continued)

	Page
C. Petitioner Fails to Set Forth Any Evidence Explaining How the Prior Art Could Be Used to Obtain the Specific Claimed Film Formulations.....	38
1. Euro-Celtique fails to teach or suggest how to produce a film providing the claimed Cmax and AUC ranges	40
2. Each of the secondary references proposed by Petitioner fail to teach or suggest how to produce a film providing the claimed Cmax and AUC ranges.....	44
3. Dr. Çelik fails to explain how to produce a film providing the claimed Cmax and AUC ranges.....	47
V. CONCLUSION.....	50

TABLE OF AUTHORITIES

Page(s)

CASES

<i>3D-Matrix Ltd. v. Menicon Co., Ltd.</i> , IPR2014-00398.....	40, 44
<i>Ariad Pharms., Inc. v. Eli Lilly & Co.</i> , 598 F.3d 1336 (Fed. Cir. 2010) (en banc)	37
<i>Butamax Advanced Biofuels LLC v. Gevo, Inc.</i> , IPR2013-00539	47
<i>Ex Parte Cima Labs Inc.</i> , No. 2009-3071, 2009	18
<i>Ferring B.V. v. Watson Labs., Inc.</i> , No. 3:11cv481, 2013 U.S. Dist. LEXIS 17536 (D. Nev. Feb. 6, 2013).....	17, 18
<i>Garmin Int’l, Inc. v. Cuozzo Speed Tech., LLC</i> , IPR2012-00001	15
<i>In re O’Farrell</i> , 853 F.2d 894 (Fed. Cir. 1988)	39, 43, 46, 48
<i>In re Rosuvastatin Calcium Patent Litigation</i> , 703 F.3d (Fed. Cir. 2012)	39
<i>Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.</i> , IPR2013-00324.....	21
<i>Medichem, S.A. v. Rolabo, S.L.</i> , 437 F.3d 1157 (Fed. Cir. 2006)	43, 48
<i>Medtronic, Inc. v. Nuvasive, Inc.</i> , IPR2014-00487	23
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (en banc)	14
<i>Prism Pharma Co., Ltd. v. Choongwae Pharma Corp.</i> IPR2014-00315 (8 July 2014)	23
<i>Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms., Inc.</i> , 748 F.3d 1354 (Fed. Cir. 2014)	39, 46

...

TABLE OF AUTHORITIES

(continued)

Page(s)

SAS Institute, Inc. v. ComplementSoft, LLC,
IPR2013-00581passim

Unilever, Inc. v. Procter & Gamble Co.
IPR2014-00506 (7 July 2014)23, 26

Vitronics Corp. v. Conceptronic, Inc.,
90 F.3d 1576 (Fed. Cir. 1996)15

STATUTES

35 U.S.C. § 313 1

35 U.S.C. § 314(a)21

35 U.S.C §§ 314(a)20, 50

35 U.S.C. § 316(b)21, 33

35 U.S.C. § 325(d)passim

OTHER AUTHORITIES

37 C.F.R. § 42.1(b).33

37 C.F.R. § 42.100(b)14

37 C.F.R. § 42.107 1

37 C.F.R. § 42.108(a).....27

37 C.F.R. § 42.108(b)20

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.