

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

FUSTIBAL LLC,  
Petitioner,

v.

BAYER HEALTHCARE LLC,  
Patent Owner.

---

Case No: IPR2016-01490  
Patent No. 8,637,553

---

**PATENT OWNER PRELIMINARY RESPONSE**

**TABLE OF CONTENTS**

I.	INTRODUCTION .....	1
II.	BACKGROUND ON REGORAFENIB .....	4
III.	THE PERSON OF ORDINARY SKILL IN THE ART .....	6
IV.	CLAIM CONSTRUCTION .....	6
	ARGUMENT .....	7
I.	TRIAL SHOULD NOT BE INSTITUTED ON GROUND 1 (ANTICIPATION) FOR ANY CLAIM OF THE '553 PATENT. ....	7
A.	Ground 1 Should Not Be Instituted Pursuant to Section 325(d).....	7
B.	The Petition Does Not Establish a Reasonable Likelihood that the Petitioner Would Prevail on Its Anticipation Challenge to Claim 13. ....	8
1.	Riedl Does Not Anticipate As a Matter of Law. ....	9
2.	The Petition Reflects that Its Arguments Are Premised on Obviousness, Not Anticipation. ....	17
3.	The Petition's Anticipation Arguments Are Unsupported by Evidence.....	19
C.	The Petition Does Not Establish a Reasonable Likelihood that the Petitioner Would Prevail on Its Anticipation Challenge to the Remaining Claims. ....	20
II.	TRIAL SHOULD NOT BE INSTITUTED ON ANY OF GROUNDS 2-5 (OBVIOUSNESS) FOR ANY CLAIM OF THE '553 PATENT.....	21
A.	Grounds 2-5 Suffer from Several Flaws that Render Them Deficient as a Matter of Law.....	22
1.	The Petition Fails to Perform Any Lead Compound Analysis.....	22

2.	The Logic of the Petition’s Obviousness Analysis is Flawed and Inconsistent.....	25
3.	Grounds 2–5 Are Unsupported by Evidence Concerning the Understanding of the POSA.....	33
4.	The Legal Authority Cited in the Petition Does Not Support Instituting Trial.....	34
B.	Ground 2 Fails Because Riedl Has Already Been Considered by the Office.....	36

**TABLE OF AUTHORITIES**

**FEDERAL CASES**

*Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991 (Fed. Cir. 2006) ..... 10, 11

*Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293  
(Fed. Cir. 2007)..... 34

*Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967  
(Fed. Cir. 2014)..... 23, 26

*Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331 (Fed. Cir. 2009) ..... 18

*Daiichi Sankyo Co. v. Matrix Labs.*, 619 F.3d 1346 (Fed. Cir. 2010)..... 23, 25, 30

*Eisai Co. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008) ..... 26, 27

*Eli Lilly & Co. v. Bd. of Regents of Univ. of Wash.*, 334 F.3d 1264  
(Fed. Cir. 2003)..... 10

*Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, No. IP 99-38-C H/K,  
2001 WL 1397304 (S.D. Ind. Oct. 29, 2001) ..... 26

*Impax Labs. v. Aventis Pharm. Inc.*, 468 F.3d 1366 (Fed. Cir. 2006) ..... 10, 11, 15

*In re Armodafinil Patent Litig. Inc.*, 939 F. Supp. 2d 456 (D. Del.  
2013) ..... 36

*In re Cyclobenzaprine Hydrochloride Extended-Release Capsule  
Patent Litig.*, 676 F.3d 1063 (Fed. Cir. 2012) ..... 31

*In re Petering*, 301 F.2d 676 (C.C.P.A. 1962)..... 10, 11

*In re Ruschig*, 343 F.2d 965 (C.C.P.A. 1965)..... 11

*Institut Pasteur & Universite Pierre et Marie Curie v. Focarino*, 738  
F.3d 1337 (Fed. Cir. 2013) ..... 25

*KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) ..... 26

*Leo Pharm. Prods. v. Rea*, 726 F.3d 1346 (Fed. Cir. 2013)..... 26

<i>Net MoneyIN, Inc. v. VeriSign, Inc.</i> , 545 F.3d 1359 (Fed. Cir. 2008).....	16, 18
<i>Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.</i> , 520 F.3d 1358 (Fed. Cir. 2008) .....	27
<i>Otsuka Pharm. v. Sandoz, Inc.</i> , 678 F.3d 1280 (Fed. Cir. 2012).....	passim
<i>Perricone v. Medicis Pharmaceutical Corp.</i> , 432 F.3d 1368 (Fed. Cir. 2005) .....	16, 17
<i>Pfizer, Inc. v. Apotex, Inc.</i> , 480 F.3d 1348 (Fed. Cir. 2007).....	35
<i>Pfizer Inc. v. Mylan Pharm. Inc.</i> , 71 F. Supp. 3d 458, 468–69 (D. Del. 2014), <i>aff'd per curiam</i> , 628 F. App'x 764 (Fed. Cir. 2016) .....	36
<i>Pfizer Inc. v. Teva Pharm. USA, Inc.</i> , 555 F. App'x 961 (Fed. Cir. 2014) .....	25
<i>Procter &amp; Gamble Co. v. Teva Pharm. USA, Inc.</i> , 566 F.3d 989 (Fed. Cir. 2009) .....	22, 24, 26
<i>Takeda Chem. Indus. v. Alphapharm Pty.</i> , 492 F.3d 1350 (Fed. Cir. 2007) .....	passim
<i>Takeda Pharm. Co. v. Handa Pharm., LLC</i> , Nos. C-11-00840 JCS et al., 2013 WL 9853725 (N.D. Cal. Oct. 17, 2013) .....	36
<i>Taltech Ltd. v. Esquel Enters.</i> , 604 F.3d 1324 (Fed. Cir. 2010).....	11
<i>Vanda Pharm. Inc. v. Roxane Labs., Inc.</i> , Nos. CV 13-1973-GMS, 14-757-GMS, 2016 WL 4490701 (D. Del. Aug. 25, 2016).....	31
<i>Vizio, Inc. v. Int'l Trade Comm'n</i> , 605 F.3d 1330 (Fed. Cir. 2010).....	16, 18
<i>Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.</i> , 231 F.3d 1339 (Fed. Cir. 2000).....	23

### OTHER AUTHORITIES

37 C.F.R. § 42.2 .....	19, 33
37 C.F.R. § 42.63 .....	19
28 U.S.C. § 1746.....	20, 33

# 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.