

Filed on behalf of: Celgene Corporation

Filed: December 11, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC.,
Petitioner

v.

CELGENE CORPORATION,
Patent Owner

Case IPR2018-01509
U.S. Patent No. 7,189,740

PATENT OWNER PRELIMINARY RESPONSE

TABLE OF CONTENTS

TABLE OF CONTENTSi

TABLE OF AUTHORITIESiv

TABLE OF ABBREVIATIONS..... viii

LIST OF EXHIBITS.....ix

I. INTRODUCTION1

II. THE BOARD SHOULD DENY THE PETITION UNDER 35 U.S.C. § 314(a) BECAUSE INSTITUTION WOULD RESULT IN AN INEFFICIENT USE OF BOARD RESOURCES.....7

 A. The Timing of the Petition and the Advanced Nature of the Corresponding District Court Litigation Render Institution Inefficient7

 B. Institution Would Upset the Careful Balance Struck by the Hatch-Waxman Act.....9

III. THE BOARD SHOULD DENY THE PETITION UNDER 35 U.S.C. § 314(a) BECAUSE IT LACKS THE REQUIRED SPECIFICITY.....12

IV. THE BOARD SHOULD DENY THE PETITION UNDER 35 U.S.C. § 325(d) BECAUSE IT PRESENTS SUBSTANTIALLY THE SAME ART AND ARGUMENTS PREVIOUSLY CONSIDERED BY THE OFFICE15

 A. The '740 Patent Prosecution History17

 B. The '717 Patent Prosecution History19

 C. The '120 Patent Prosecution History21

 D. Petitioner Relies on Cumulative Art and Repeats the Same Arguments Already Overcome During Prosecution22

V. SCOPE AND CONTENT OF THE ASSERTED REFERENCES25

 A. List 200126

 B. Thomas 2000a27

 C. The '230 Patent29

D.	Celgene Press Release 5/8/2001 and Celgene Press Release 8/28/2001	29
VI.	LEVEL OF ORDINARY SKILL IN THE ART	31
VII.	CLAIM CONSTRUCTION.....	32
VIII.	STATE OF THE ART.....	32
A.	TNF- α Was Not a Known or Effective Target for Treating MDS	33
1.	The Art Shows Significant Uncertainty Regarding the Pathology of MDS and the Appropriate Target for Treatment	34
2.	TNF- α Inhibitors Did Not Work in Treating MDS	37
B.	Lenalidomide Was Not Known as the “Next Generation” Thalidomide.....	38
1.	Thalidomide and Lenalidomide are Distinct Compounds with Different Structures.....	39
2.	The Art Disclosed Different Categories of Thalidomide Analogs, Including IMiDs and SelCiDs, and, if Anything, Would Have Led a POSA to Use a SelCiD to Treat MDS.....	42
3.	The Compound Now Known as Lenalidomide Was One of the Least Potent TNF- α Inhibitors.....	43
C.	Even Accepting Petitioner’s Arguments as True, the Art Taught Away From the Claimed Inventions Because What Petitioner Contends Were Known to Be IMiDs Caused Cytopenias, the Primary Symptoms that Manifest in MDS Patients	45
1.	Thalidomide Did Not Cause Cytopenias	46
2.	CC-5013 Was Known to Cause Cytopenias	47
IX.	PETITIONER DOES NOT DEMONSTRATE A REASONABLE LIKELIHOOD THAT CLAIMS 1–6, 11–12, OR 14–34 WOULD HAVE BEEN OBVIOUS IN VIEW OF PETITIONER’S TWO ASSERTED GROUNDS	48
A.	Petitioner’s Hindsight-Driven Approach Does Not Fill in the Missing Gaps in the Prior Art and Ignores the State of the Art.....	49

B.	Neither List 2001 Nor Thomas 2000a Teaches or Suggests the Treatment of MDS with Lenalidomide	50
C.	Neither the '230 Patent Nor the Alleged Press Releases Cure the Shortfalls of List 2001 or Thomas 2000a.....	51
D.	A POSA Would Not Have Had Any Motivation to Treat MDS with the Compound Now Known as Lenalidomide, or Any Reasonable Expectation of Success	52
1.	A POSA Would Not Have Had Any Motivation to Combine List 2001 or Thomas 2000a with the Cited Secondary References.....	52
2.	A POSA Would Have Had No Expectation of Success in Treating MDS with What is Now Known as Lenalidomide	54
3.	The Art Taught Away From the Use of Thalidomide Analogs for Treating MDS Because They Caused the Main Symptoms of MDS	55
E.	The Dependent Claims are Patentable Over Grounds 1 and 2 for the Same Reasons as Claim 1.....	56
X.	SECONDARY CONSIDERATIONS SUPPORT	
	NONOBVIOUSNESS.....	56
A.	Unexpected Results	56
B.	Long-Felt But Unresolved Need	58
XI.	CONCLUSION	59

TABLE OF AUTHORITIES

	Page
CASES	
<i>Abbott Labs. v. Young</i> , 920 F.2d 984 (D.C. Cir. 1990).....	9
<i>Apotex Inc. v. Celgene Corp.</i> , IPR2018-00685, Paper 8 (PTAB Sept. 27, 2018).....	30
<i>Applications in Internet Time, LLC v. RPX Corp.</i> , 897 F.3d 1336 (Fed. Cir. 2018)	11
<i>Ariosa Diagnostics v. Verinata Health, Inc.</i> , IPR2013-00276, Paper 43 (PTAB Oct. 23, 2014).....	13
<i>Becton, Dickinson & Co. v. B. Braun Melsungen AG</i> , IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017)	15, 17
<i>Belden Inc. v. Berk-Tek LLC</i> , 805 F.3d 1064 (Fed. Cir. 2015)	52
<i>Boston Sci. Corp. v. Johnson & Johnson</i> , 647 F.3d 1353 (Fed. Cir. 2011)	40, 53
<i>Coal. for Affordable Drugs VI LLC v. Celgene Corp.</i> , IPR2015-01169, Paper 22 (PTAB Nov. 16, 2015).....	41, 53
<i>Comcast Cable Commc'ns, LLC v. Veveo, Inc.</i> , IPR2017-00932, Paper 10 (PTAB Sept. 7, 2017).....	31
<i>DeSilva v. DiLeonardi</i> , 181 F.3d 865 (Fed. Cir. 1999)	13
<i>Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.</i> , 800 F.3d 1375 (Fed. Cir. 2015)	29

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.