

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC

Petitioner,

v.

CELGENE CORP.

Patent Owner.

CASE NO. IPR2018-01507

Patent No. 8,404,717

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 8,404,717**

TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	GROUNDS FOR STANDING	1
III.	IDENTIFICATION OF CHALLENGE AND STATEMENT OF THE PRECISE RELIEF REQUESTED	2
IV.	THRESHOLD REQUIREMENT FOR INTER PARTES REVIEW	2
V.	STATEMENT OF REASONS FOR THE RELIEF REQUESTED.....	3
A.	Summary of the Argument.....	3
B.	The '717 Patent and Its Prosecution	5
1.	The '717 Patent.....	5
2.	The Prosecution of the '717 Patent	6
C.	The Person of Ordinary Skill in the Art.....	7
D.	Claim Construction	9
E.	Scope and Content of the Prior Art.....	9
1.	Background on MDS and Its Related Transfusion- Dependent Anemia (TDA)	9
2.	TNF α Was a Known Target for MDS.	12
a.	Shetty 1996.....	12
3.	Thalidomide Clinical Trials Showed Promise, Including in Inhibiting TNF α	13
a.	Raza 2000b	13
b.	Raza 2000d.....	14
c.	Raza 2001	15
d.	Thomas 2000a	16
4.	Revimid (Lenalidomide) Was a Known Compound with Increased Potency over Thalidomide.	17
a.	Thomas 2000a (continued).....	18
b.	Corral 1999b.....	18
c.	Marriott 2001.....	19

TABLE OF CONTENTS
(CONTINUED)

d.	Celgene Press Release 8/28/2001.....	20
e.	The '230 Patent	21
5.	Clinical Trials of Revimid in MM and MDS	23
a.	List 2001	23
b.	Ritter 2001	24
c.	Celgene Press Release 5/8/2001.....	25
d.	Celgene Press Release 6/7/2001.....	26
F.	The Law of Obviousness	27
G.	Ground 1: Claims 1–10 Were Unpatentable As Obvious over List 2001 in View of the '230 Patent and Celgene Press Releases 5/8/2001 and 8/28/2001.....	28
1.	Independent Claim 1 Was Obvious.....	29
2.	Dependent Claim 10 Was Obvious.	33
3.	Dependent Claims 2, 4, 6, and 8 Were Obvious.	33
4.	Dependent Claims 3, 5, 7, and 9 Were Obvious	34
H.	Ground 2 Claims 1–10 Were Unpatentable As Obvious Over Thomas 2000a in view of the '230 Patent, the Celgene 5/8/2001 and 8/28/2001 Press Releases.....	35
1.	Independent Claim 1 Was Obvious.....	35
2.	Claim 10 Was Obvious.....	38
3.	Dependent Claims 2–9 Were Obvious.	38
I.	The POSA Was Motivated to Combine the Prior Art Teachings.	39
J.	Any Secondary Considerations Fail to Overcome the Showing of Obviousness.....	44
1.	Revlimid Sales Do Not Save the '717 Patent.....	44
a.	There Is No Nexus Between the Claims and Secondary Considerations of Nonobviousness.	44

TABLE OF CONTENTS
(CONTINUED)

b.	Any Commercial Success of Revlimid Is Attributable to Celgene’s Extensive Marketing Efforts and REMS Program.....	46
2.	The Claimed Methods Produced No Unexpected Results.....	47
3.	The ’717 Patent Satisfied No Long-Felt but Unmet Need.	47
4.	Copying Is Irrelevant.	48
VI.	MANDATORY NOTICES	49
A.	Real Parties-In-Interest (37 C.F.R. § 42.8(b)(1)).....	49
B.	Related Matters (37 C.F.R. § 42.8(b)(2))	49
C.	Identification of Counsel (37 C.F.R. § 42.8(b)(3)) and Service Information (37 C.F.R. § 42.8(b)(4)).....	50
D.	Service Information (37 C.F.R. § 42.8(b)(4)).....	50

LIST OF EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 8,404,717, titled Methods of Treating Myelodysplastic Syndromes Using Lenalidomide
1002	File History for U.S. Patent No. 8,404,717
1003	Declaration of Mark Levin, M.D., in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 8,404,717
1004	Alan F. List et al., <i>Rational Approaches to Design of Therapeutics Targeting Molecular Markers: Targeting Angiogenesis in Hematologic Malignancies</i> , HEMATOLOGY, 2001 AM. SOC. HEMATOLOGY (ASH) EDUC. PROGRAM BOOK 443 (2001)
1005	Deborah A. Thomas, M.D. & Hagop M. Kantarjian, M.D., <i>Current Role of Thalidomide in Cancer Treatment</i> , 12 CURRENT OPINION IN ONCOLOGY 564 (2000)
1006	U.S. Patent No. 6,281,230, titled Isoindolines, Method of Use, and Pharmaceutical Compositions
1007	Press Release, Celgene Corp., Celgene Advances Immunomodulatory Drug (IMiD™) Clinical Program (Feb. 29, 2000)
1008	Press Release, Celgene Corp., PR Newswire, Positive Interim Results Presented at the VIIIth International Myeloma Workshop on Celgene Corporation's Lead IMiD™ (REVIMID™) (May 8, 2001)
1009	Press Release, Celgene Corp., PR Newswire, Initial Phase I Solid Tumor Data on Celgene's Lead Imid™, Revimid™ (June 7, 2001)
1010	Press Release, Celgene Corp., PR Newswire, Celgene Corporation Awarded Additional Patent Protection for Lead IMiD™, REVIMID™; Comprehensive Patent Protection for REVIMID Includes Coverage of the Active Ingredient, Pharmaceutical Compositions, and Therapeutic Uses (Aug. 28, 2001)

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.