

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. and APOTEX CORP.

Petitioners

V.

ELI LILLY & COMPANY

Patent Owner

Inter Partes Review No.: IPR2016-01190

Patent No. 7,772,209
Filed: July 11, 2007
Issued: August 10, 2010
Inventor: Clet Niyikiza

Title: ANTIFOLATE COMBINATION THERAPIES

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 7,772,209**

TABLE OF CONTENTS

TABLE OF AUTHORITIES	iii
TABLE OF EXHIBITS	vii
I. INTRODUCTION	1
II. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a))	1
III. MANDATORY NOTICES (37 C.F.R. § 42.8)	2
A. Real Parties-in-Interest (37 C.F.R. § 42.8(b)(1))	2
B. Related Matters (37 C.F.R. § 42.8(b)(2))	2
C. Lead and Back-Up Counsel (37 C.F.R. § 42.8(b)(3)) and Service Information (37 C.F.R. § 42.8(b)(4))	3
IV. PAYMENT OF FEES (37 C.F.R. § 42.15(a) and § 42.103)	3
V. IDENTIFICATION OF CHALLENGE	4
A. Overview of U.S. Patent No. 7,772,209	4
1. The ‘209 Patent Specification	4
2. The ‘209 Patent Claims	6
3. The ‘209 Prosecution History	7
B. Claim Construction of Challenged Claims	12
1. “Patient”	13
2. “Methylmalonic acid lowering agent”	13
3. “An effective amount of pemetrexed disodium”	13
4. “An effective amount of folic acid and an effective amount of a methylmalonic acid lowering agent”	14
5. “Toxicity”	14
6. “Antifolate” and “antifolate drug”	14

C.	Statement of Precise Relief Requested for Each Claim Challenged	15
1.	Claims for Which Review is Requested	15
2.	Statutory Grounds of Challenge	15
D.	Overview of the State of the Art and Motivation to Combine	16
1.	Summary of the Petition’s Prior Art References.....	20
E.	Level of Ordinary Skill in the Art.....	24
VI.	DETAILED EXPLANATION OF THE CHALLENGE	25
A.	Ground 1: Claims 1–22 of U.S. Patent No. 7,772,209 are obvious under 35 U.S.C. § 103(a) over <i>Niyikiza</i> in view of the ‘974 <i>Patent</i> and in further view of <i>EP 005</i> and the knowledge of one of ordinary skill in the art.	25
1.	Independent Claims 1 and 12 are obvious over <i>Niyikiza</i> in view of the ‘974 <i>Patent</i> and in further view of <i>EP 005</i> and the knowledge of one of ordinary skill in the art.....	25
2.	Dependent Claims 2–10 and 14–21 are obvious.	39
3.	Dependent Claims 11, 13, and 22 are obvious.	48
B.	The S.D. of Indiana Decision Finding that Teva Did Not Establish by Clear and Convincing Evidence that Certain Claims of the ‘209 Patent are Obvious is Not Relevant to this Proceeding.....	51
VII.	ANY SECONDARY CONSIDERATIONS ARE INSUFFICIENT TO OVERCOME THE OBVIOUSNESS OF CLAIMS 1–22.	54
VIII.	CONCLUSION.....	60

TABLE OF AUTHORITIES

FEDERAL CASES

<i>Abbott Labs v. Andrx Pharms., Inc.</i> , 452 F.3d 1331 (Fed. Cir. 2006)	49
<i>Bayer Schering Pharma AG v. Barr Labs., Inc.</i> , 575 F.3d 1341 (Fed. Cir. 2009).....	39
<i>Dow Chem. Co. v. Sumitomo Chem. Co.</i> , 257 F.3d 1364 (Fed. Cir. 2001)	31
<i>Dystar Textilfarben GmbH v. C.H. Patrick Co.</i> , 464 F.3d 1356 (Fed. Cir. 2006)	50
<i>Ethicon, Inc. v. Quigg</i> , 849 F.2d 1422 (Fed. Cir. 1988)	51
<i>Ex parte Gelles</i> , 22 USPQ2d 1318 (Bd. Pat. App. & Inter. 1992).....	54, 57, 60
<i>Galderma Labs., L.P. v. Tolmar, Inc.</i> , 737 F.3d 731 (Fed. Cir. 2013).....	54
<i>Geo M. Martin Co. v. Alliance Mach. Sys. Int’l LLC</i> , 618 F.3d 1294 (Fed. Cir. 2010)	60
<i>In re Aller</i> , 220 F.2d 454 (CCPA 1955).....	34
<i>In re Am. Acad. of Sci. Tech. Ctr.</i> , 367 F.3d 1359 (Fed. Cir. 2004).....	12
<i>In re Applied Materials, Inc.</i> , 692 F.3d 1289 (Fed. Cir. 2012)	34, 39, 45
<i>In re Cipro Cases I & II</i> , 61 Cal. 4th 116 (Cal. 2015)	51
<i>In re Cuozzo Speed Techs., LLC</i> , 778 F.3d 1271 (Fed. Cir. 2015)	12

<i>In re Dill</i> , 604 F.2d 1356 (CCPA 1979)	57
<i>In re Glatt Air Techniques, Inc.</i> , 630 F.3d 1026 (Fed. Cir. 2011)	31
<i>In re Graves</i> , 69 F.3d 1147 (Fed. Cir. 1995)	31
<i>In re Icon Health & Fitness, Inc.</i> , 496 F.3d 1374 (Fed. Cir. 2007)	26, 32
<i>In re Klosak</i> , 455 F.2d 1077 (CCPA 1973)	57
<i>In re Merchant</i> , 575 F.2d 865 (CCPA 1978)	57
<i>In re Peterson</i> , 315 F.3d at 1329	35, 43, 48
<i>In re Preda</i> , 401 F.2d 825 (CCPA 1968)	31
<i>In re Swanson</i> , 540 F.3d 1368 (Fed. Cir. 2008)	51
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	39, 44, 50
<i>Leapfrog Enters. Inc. v. Fisher-Price Inc.</i> , 485 F.3d 1157 (Fed. Cir. 2007)	55
<i>Nat’l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.</i> , 357 F.3d 1319 (Fed. Cir. 2004)	20
<i>Newell Cos., Inc. v. Kenney, Mfg. Co.</i> , 864 F.2d 757 (Fed. Cir. 1988)	55
<i>NPF Ltd. v. Smart Parts, Inc.</i> , 187 Fed. App’x 973 (Fed. Cir. 2006)	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.