

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INITIATIVE FOR MEDICINES, ACCESS & KNOWLEDGE (I-MAK), INC.
Petitioner

v.

GILEAD PHARMASSET LLC
Patent Owner

Case No. IPR2018-00125
U.S. Patent No. 8,633,309

PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	MANDATORY NOTICES	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)).....	2
	D. Service Information (37 C.F.R. § 42.8(b)(4)).....	2
III.	REQUIREMENTS FOR REVIEW	3
	A. Grounds For Standing	3
	B. Identification of Challenge.....	3
IV.	OVERVIEW OF THE ‘309 PATENT	4
V.	FILE HISTORY OF THE ‘309 PATENT	5
VI.	PERSON OF ORDINARY SKILL IN THE ART	9
VII.	CLAIM CONSTRUCTION	9
VIII.	BACKGROUND KNOWLEDGE IN THE ART	10
	A. Nucleoside Analog Drugs Inhibited Viral Diseases.....	10
	B. Some Nucleoside Drugs Were Poor Substrates for Phosphorylation .	15
	C. Compound 1D Was a Superior Agent Against HCV, But a Poor Substrate for Phosphorylation	15
	D. ProTide Prodrugs of Nucleosides Were Well-Known to Overcome the Problem of Poor Phosphorylation	16
	E. ProTide Prodrugs Were Diastereomeric at Phosphorous and Such Diastereomers Could Possess Different Biological Activity.....	18

F.	ProTide Analogs of Compound 1D Were Active Against HCV	18
IX.	SCOPE AND CONTENT OF THE PRIOR ART	21
A.	WO 2008/121634 (“Sofia ‘634”)	21
B.	J. Med. Chem. 2006 (“Congiatu”).....	24
C.	WO 2005/003147 (“Clark ‘147”).....	25
X.	CLAIMS 1-12 ARE UNPATENTABLE	26
A.	Ground 1: Claims 1-12 Were Anticipated by Sofia ‘634.....	27
1.	Claims 1-3 (compounds).....	34
2.	Claims 4-6 (pharmaceutical compositions)	34
3.	Claims 7-12 (methods of treating hepatitis C).....	35
B.	Ground 2: Claims 1-12 Were Obvious Over Sofia ‘634 and Congiatu.....	35
1.	Claims 1-3 (compounds).....	44
2.	Claims 4-6 (pharmaceutical compositions)	45
3.	Claims 7-12 (methods of treating hepatitis C).....	46
C.	Ground 3: Claims 1-12 Were Obvious Over Clark ‘147 and Congiatu.....	46
1.	Claims 1-3 (compounds).....	46
2.	Claims 4-6 (pharmaceutical compositions)	51
3.	Claims 7-12 (methods of treating hepatitis C).....	52
XI.	CONCLUSION	52
XII.	APPENDIX – LIST OF EXHIBITS.....	54
XIII.	CERTIFICATE OF COMPLIANCE	55

XIV. CERTIFICATE OF SERVICE.....56

I. INTRODUCTION

Initiative for Medicines, Access & Knowledge (I-MAK), Inc. (“Petitioner”) requests *inter partes* review (“IPR”) of claims 1-12 of United States Patent No. 8,633,309 to Ross et al. (“the ‘309 patent”; EX1001) under the provisions of 35 U.S.C. § 311, § 6 of the Leahy-Smith America Invents Act (“AIA”), and 37 C.F.R. § 42.100 et seq. The ‘309 patent issued on January 21, 2014, and is currently assigned to Gilead Pharmasset LLC (“Patent Owner”). This petition demonstrates that claims 1-12 of the ‘309 patent are unpatentable.

The ‘309 patent claims pharmaceutical compounds, compositions and methods that were already known and obvious in light of the prior art. Specifically, the ‘309 claims a specific diastereomeric form of a specific nucleoside compound that was already known because it was the subject of a previous patent application by Patent Owner. In addition, investigating diastereomeric forms of a nucleoside compound and finding one was more active was entirely conventional and expected. Identifying a diastereomeric form that is more active than others is not inventive, but obvious.

Thus, claims 1-12 of the ‘309 patent are unpatentable and should be cancelled.

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.