

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. IPR2018-00390
U.S. Patent No. 8,889,159

DECLARATION OF JOSEPH M. FORTUNAK, Ph.D.

TABLE OF CONTENTS

I.	QUALIFICATIONS	1
II.	SCOPE OF WORK.....	6
III.	OVERVIEW OF THE ‘159 PATENT	8
IV.	FILE HISTORY OF THE ‘159 PATENT	10
V.	LEGAL STANDARDS	11
VI.	PERSON OF ORDINARY SKILL IN THE ART	13
VII.	CLAIM CONSTRUCTION	14
VIII.	BACKGROUND KNOWLEDGE IN THE ART	14
	A. GS-7977 Was A Known And Promising Antiviral Agent for Treating HCV.....	14
	B. Crystalline Forms of GS-7977 Were Known.....	16
	C. Tablet and Capsule Formulations Comprising Pharmaceutical Excipients Were Known.....	19
	D. Tablet And Capsule Formulations Comprising Crystalline GS-7977 And Pharmaceutical Excipients Were Known.....	20
	E. GS-7977 Was Known to Be in Human Clinical Trials at a 400mg Daily Dose	23
	F. Method of Treating HCV Using A Tablet Or Capsule Comprising Crystalline GS-7977 And A Pharmaceutical Excipient Was Known.....	24
IX.	SCOPE AND CONTENT OF THE PRIOR ART.....	25
	A. Ross ’645	25
	B. Ross ’257	28

X.	PRIOR ART REFERENCES DISCLOSE OR SUGGEST EACH OF THE CLAIMED FEATURES OF EACH CLAIM OF THE '159 PATENT	31
A.	Claims 1-37 Were Anticipated By And Obvious Over Ross '645	31
1.	Claims 1 and 2 (composition comprising compound and excipient).....	32
2.	Claims 3-12 (pharmaceutical composition comprising at least one pharmaceutically acceptable excipient)	36
3.	Claims 13-15 (composition comprising at least one pharmaceutically acceptable excipient by specific weight).....	40
4.	Claims 16-17 (unit dosage form comprising 400mg of crystalline GD-7977)	42
5.	Claims 18-27 (unit dosage form comprising at least one pharmaceutical excipient)	43
6.	Claims 28-29 (unit dosage form comprising at least one pharmaceutically acceptable excipient by specific weight).....	45
7.	Claim 30 (unit dosage form comprising a capsule or tablet)....	47
8.	Claims 31-32 (process for preparing a tablet composition comprising the unit dosage form where GS-7977 is 400mg) ...	47
9.	Claims 33-37 (method of treatment comprising administering the composition).....	48
B.	Claims 1-37 Were Anticipated By And Obvious Over Ross '257	50
1.	Claims 1 and 2 (composition comprising compound and excipient).....	50
2.	Claims 3-12 (pharmaceutical composition comprising at least one pharmaceutically acceptable excipient)	54
3.	Claims 13-15 (composition comprising at least one pharmaceutically acceptable excipient by specific weight).....	59

4.	Claims 16-17 (unit dosage form comprising 400mg of crystalline GS-7977)	60
5.	Claims 18-27 (unit dosage form comprising at least one pharmaceutical excipient)	61
6.	Claims 28-29 (unit dosage form comprising at least one pharmaceutically acceptable excipient by specific weight).....	64
7.	Claim 30 (unit dosage form comprising a capsule or tablet)....	65
8.	Claims 31-32 (process for preparing a tablet composition comprising the unit dosage form where GS-7977 is 400mg) ...	66
9.	Claims 33-37 (method of treatment comprising administering the composition).....	67
XI.	CONCLUSION.....	68
XII.	APPENDIX-LIST OF EXHIBITS	70

I. QUALIFICATIONS

1. I am a Professor of Chemistry and Pharmaceutical Sciences at Howard University, in Washington, D.C., where I regularly teach courses in Organic Chemistry to undergraduate students. I also teach courses in drug discovery, drug development, pharmaceutical chemistry, pharmaceutical sciences, and green chemistry/chemical synthesis to PharmD and PhD students in Chemistry and Pharmacy.

2. I received my Bachelor of Science in Chemistry from Purdue University in 1976, and my Doctorate in Philosophy in Organic Chemistry from the University of Wisconsin-Madison in 1981. After earning my Ph.D., I was a postdoctoral fellow and a research assistant professor at Cambridge University in the United Kingdom from 1981-1983.

3. My career has spanned both the industrial and academic sectors, including senior managerial and academic appointments.

4. From 1983-1993, I worked at SmithKline Beecham Pharmaceutical Corp. (GlaxoSmithKline), and served as Associate Senior Research Investigator, Senior Research Investigator and Assistant Director. During that time, I was primarily responsible for inventing processes to synthesize active pharmaceutical ingredients (“APIs”) for investigational new drugs, including the drugs halofantrine, ropinerole, topotecan and eprosartan, which the U.S. Food and Drug

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.