

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

---

U.S. Patent No. 8,334,270

---

**DECLARATION OF JOSEPH M. FORTUNAK, Ph.D.**

## TABLE OF CONTENTS

I.	QUALIFICATIONS .....	1
II.	SCOPE OF WORK.....	7
III.	OVERVIEW OF THE '270 PATENT .....	8
IV.	FILE HISTORY OF THE '270 PATENT .....	9
V.	LEGAL STANDARDS .....	9
VI.	PERSON OF ORDINARY SKILL IN THE ART .....	12
VII.	CLAIM CONSTRUCTION.....	12
VIII.	BACKGROUND KNOWLEDGE IN THE ART .....	13
	A. The Use of Nucleoside Analogs As Antiviral Agents And Their Mechanism of Action Were Known.....	13
	B. Anti-Viral Nucleosides Must Be Converted Into Their Triphosphates To Be Active, Monophosphorylation Was The Rate-Limiting Step In Such Conversion, and 5'-Phosphate Prodrugs Enabled Nucleosides To Overcome This Limitation .....	18
	C. The Means Were Available to Determine Which Nucleosides Were Kinase Dependent.....	23
	D. Narrowing The Selection Of Options For The Phosphoramidate Prodrug.....	23
	E. Phosphoramidates Improved Nucleosides.....	24
	F. The '270 Patent Acknowledges This Common Knowledge .....	25
IX.	SCOPE AND CONTENT OF THE PRIOR ART .....	27
	A. Sofia .....	28
	B. Ma .....	29

C.	Clark ‘147.....	30
D.	Clark 2005.....	31
E.	Perrone.....	32
F.	McGuigan ‘327.....	33
X.	PRIOR ART REFERENCES DISCLOSE OR SUGGEST EACH OF THE CLAIMED FEATURES OF CLAIMS 1, 2, 10-18 AND 20-25 OF THE ‘270 PATENT.....	34
A.	Claims 1, 2, 10-18, and 20-25 Were Anticipated By Sofia And Obvious Over Sofia and Perrone.....	35
1.	Claims 1, 2, 16-18 (compound).....	35
2.	Claims 10-12 and 20-22 (compositions comprising compound).....	44
3.	Claims 13-15 and 23-25 (methods of treating viral infections).....	45
B.	Claims 1, 2, 10-18 and 20-25 Were Obvious Over Ma and Perrone.....	46
1.	Claims 1, 2, 16-18 (compound).....	47
2.	Claims 10-12 and 20-22 (compositions comprising compound).....	55
3.	Claims 13-15 and 23-25 (methods of treating viral infections).....	56
C.	Claims 1, 2, 10-18 and 20-25 Were Obvious Over Clark ‘147, Clark 2005 and Perrone.....	57
1.	Claims 1, 2, 16-18 (compound).....	58
2.	Claims 10-12 and 20-22 (compositions comprising compound).....	72
3.	Claims 13-15 and 23-25 (methods of treating viral infections).....	73
D.	Claims 1, 2, 10-18, 20-25 Were Obvious Over Clark ‘147, Clark 2005 and McGuigan ‘327.....	74
1.	Claims 1, 2, 16-18 (compound).....	74

2. Claims 10-12 and 20-22 (compositions comprising compound)86

3. Claims 13-15 and 23-25 (methods of treating viral infections)86

XI. CONCLUSION .....87

XII. APPENDIX – LIST OF EXHIBITS.....89

I, Joseph M. Fortunak, declare as follows:

## **I. QUALIFICATIONS**

1. My name is Joseph M. Fortunak. 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., 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,

# 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.