

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 IPR2018-00119
Patent 7,964,580

**PATENT OWNER GILEAD PHARMASSET LLC'S
PRELIMINARY RESPONSE**

TABLE OF CONTENTS

I. INTRODUCTION1

II. THE SOFIA '580 PATENT3

 A. Hepatitis C and the previous treatments.4

 B. Many researchers tried to develop anti-HCV drugs but failed.5

 1. Changes to nucleoside structure can have significant and unpredictable impacts on activity and toxicity.6

 2. Persons of ordinary skill in this field understood that the effectiveness of prodrugs was unpredictable and nucleoside-specific.9

 C. Sofosbuvir was a “game-changing” treatment for HCV.11

 D. The Sofia '580 patent claims12

III. ARGUMENT13

 A. The Sofia Abstract and Ma are not prior art.13

 1. I-MAK has done no analysis under 35 USC § 112.15

 2. Claims 1-14 are entitled to the March 30, 2007 filing date of the '315 provisional application.16

 B. The Sofia Abstract does not anticipate claims 1-14.20

 C. Claims 1-14 are not obvious.23

 1. Claims 1-14 are patentable over the Sofia Abstract plus Perrone.28

 a. I-MAK fails to establish a motivation to combine the Sofia Abstract with Perrone.29

 b. I-MAK fails to establish a reasonable expectation of success.31

c. I-MAK fails to establish that a person of skill would have chosen the (phenyl)(isopropyl-L-alaninyl)phosphate group disclosed in Perrone.33

2. Claims 1-14 are patentable over Ma plus Perrone.....34

 a. Ma does not suggest experimenting with RO2433 but rather teaches developing PSI-6130.34

 b. I-MAK fails to establish a motivation to combine Ma with Perrone.37

 c. I-MAK fails to establish a reasonable expectation of success.....39

D. Dr. Fortunak’s opinions are conclusory and insufficient to support institution40

IV. PRESERVATION OF RIGHTS UNDER *OIL STATES*41

V. CONCLUSION.....42

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LIST OF EXHIBITS

Exhibit No.	Exhibit Description
GIL 2001	Carroll et al. <i>Nucleoside Analog Inhibitors of Hepatitis C Virus Replication</i> . Infectious Disorders – Drug Targets, 2006
GIL 2002	Chung, M.D. et al. <i>Curing Chronic Hepatitis C – The Arc of a Medical Triumph</i> . The New England Journal of Medicine, 2014.
GIL 2003	Tucker, Miriam E. <i>FDA Approves ‘Game Changer’ Hepatitis C Drug Sofosbuvir</i> . Medscape, 2013.
GIL 2004	HARVONI® label
GIL 2005	Norton, Amy. <i>Hepatitis C Killing More Americans than HIV: Studies</i> . Reuters, 2012.
GIL 2006	Secrist III et al. <i>Clofarabine: From Design to Approval</i> . Modified Nucleosides: in Biochemistry, Biotechnology and Medicine, 2008.
GIL 2007	<i>America’s Overspend: How the Pharmaceutical Patent Problem is Fueling High Drug Prices</i> . I-MAK, 2017.
GIL 2008	I-MAK: Our People
GIL 2009	Lawitz et al. <i>Development of Sofosbuvir for the Treatment of Hepatitis C Virus Infection</i> . Annals of the New York Academy of Sciences, 2014.
GIL 2010	Ninburg, Michael. <i>Hepatitis C Deserves the Attention</i> . Seattlepi.com, 2007.
GIL 2011	Pollack, Andrew. <i>F.D.A. Approves Pill to Treat Hepatitis C</i> . The New York Times, 2013.
GIL 2012	Rockoff, Jonathan D. <i>FDA Approves Gilead’s Hepatitis C Drug</i> . The Wall Street Journal, 2013.
GIL 2013	United States Provisional Application Serial No. 60/909,315
GIL 2014	United States Provisional Application Serial No. 60/982,309
GIL 2015	Sofia et al. <i>Discovery of a β-D-2’-Deoxy-2’-β-C-methyluridine Nucleotide Prodrug (PSI-7977) for the Treatment of Hepatitis C Virus</i> . Journal of Medicinal Chemistry Article, 2010.
GIL 2016	RESERVED
GIL 2017	Meier, C. <i>Pro-Nucleotides – Recent Advances in the Design of Efficient Tools for the Delivery of Biologically Active Nucleoside Monophosphates</i> . Synlett, 1997
GIL 2018	RESERVED

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GIL 2019	Krise et al. <i>Prodrugs of Phosphates, Phosphonates, and Phosphinates</i> . Advanced Drug Delivery Review, 1996.
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