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

PETITION FOR INTER PARTES REVIEW



TABLE OF CONTENTS

I.	INTF	TRODUCTION				
II.	MANDATORY NOTICES					
	A.	Real Parties-in-Interest (37 C.F.R. § 42.8(b)(1))	1			
	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					
	A.	Grounds For Standing	2			
	B.	Identification of Challenge	3			
IV.	OVE	ERVIEW OF THE '159 PATENT4				
V.	FILE	HISTORY OF THE '159 PATENT	6			
VI.	PERS	ERSON OF ORDINARY SKILL IN THE ART7				
VII.	CLA	CLAIM CONSTRUCTION				
VIII.	BAC	KGROUND KNOWLEDGE IN THE ART	9			
	A.	GS-7977 Was A Known And Promising Antiviral Agent for Treatin	_			
	B.	Crystalline Forms of GS-7977 Were Known	.10			
	C.	Tablet and Capsule Formulations Comprising Pharmaceutical Excipients Were Known	.14			
	D.	Tablet And Capsule Formulations Comprising Crystalline GS-7977 And Pharmaceutical Excipients Were Known				



	E.		7977 Was Known to Be in Human Clinical Trials at a 400mg y Dose	17	
	F.		nod of Treating HCV Using A Tablet Or Capsule Comprising talline GS-7977 And A Pharmaceutical Excipient Was Known	ı.19	
IX.	SCOPE AND CONTENT OF THE PRIOR ART				
	A.	Ross	'645	20	
	B.	Ross	'257	23	
X.	EAC	H CLA	AIM OF THE '159 PATENT IS UNPATENTABLE	26	
	A.		inds 1 and 2: Claims 1-37 Were Anticipated By And Obvious Ross '645	26	
		1.	Claims 1 and 2 (composition comprising compound and excipient)	27	
		2.	Claims 3-12 (pharmaceutical composition comprising at least one pharmaceutically acceptable excipient)		
		3.	Claims 13-15 (composition comprising at least one pharmaceutically acceptable excipient by specific weight)	35	
		4.	Claims 16-17 (unit dosage form comprising 400mg of crystalline GD-7977)	37	
		5.	Claims 18-27 (unit dosage form comprising at least one pharmaceutical excipient)	38	
		6.	Claims 28-29 (unit dosage form comprising at least one pharmaceutically acceptable excipient by specific weight)	41	
		7.	Claim 30 (unit dosage form comprising a capsule or tablet)	42	
		8.	Claims 31-32 (process for preparing a tablet composition comprising the unit dosage form where GS-7977 is 400mg).	43	
		9.	Claims 33-37 (method of treatment comprising administering the composition)	g 44	



		Grounds 3 and 4: Claims 1-37 Were Anticipated By And Obvious Over Ross '25745				
	1.	Claims 1 and 2 (composition comprising compound and excipient)	45			
	2.	Claims 3-12 (pharmaceutical composition comprising at least one pharmaceutically acceptable excipient)				
	3.	Claims 13-15 (composition comprising at least one pharmaceutically acceptable excipient by specific weight)	54			
	4.	Claims 16-17 (unit dosage form comprising 400mg of crystalline GS-7977)	56			
	5.	Claims 18-27 (unit dosage form comprising at least one pharmaceutical excipient)	57			
	6.	Claims 28-29 (unit dosage form comprising at least one pharmaceutically acceptable excipient by specific weight)	60			
	7.	Claim 30 (unit dosage form comprising a capsule or tablet)	61			
	8.	Claims 31-32 (process for preparing a tablet composition comprising the unit dosage form where GS-7977 is 400mg)	62			
	9.	Claims 33-37 (method of treatment comprising administering the composition)	_			
XI.	CONCLUS	ION	64			
XII.	APPENDIX	X-LIST OF EXHIBITS	65			
XIII.	CERTIFICA	ATE OF COMPLIANCE	66			
XIV.	CERTIFICA	ATE OF SERVICE	67			



I. INTRODUCTION

Initiative for Medicines, Access & Knowledge (I-MAK), Inc. ("Petitioner") requests *inter partes* review ("IPR") of claims 1-37 of United States Patent No. 8,889,159 to Cleary et al. ("the '159 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 '159 patent issued on November 18, 2014, and is currently assigned to Gilead Pharmasset LLC ("Patent Owner"). This petition demonstrates that claims 1-37 are unpatentable.

The '159 patent claims a composition and unit dosage forms for the treatment of hepatitis C virus ("HCV") infection that were anticipated by and obvious in light of the prior art. Specifically, the '159 claims compositions and unit dosage forms comprising GS-7977, a known crystalline form of a known anti-HCV drug, and at least one excipient, but such compositions and unit dosage forms were known as a result of the previous disclosure of the crystalline form of the drug. Thus, claims 1-37 of the '159 patent are unpatentable and should be cancelled.

II. MANDATORY NOTICES

A. Real Parties-in-Interest (37 C.F.R. § 42.8(b)(1))

The real parties-in-interest for this petition are Initiative for Medicines, Access & Knowledge (I-MAK), Inc., and the Laura and John Arnold Foundation.



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