Filed on behalf of Petitioner Coalition For Affordable Drugs II LLC

By: Jeffrey D. Blake, Esq.

MERCHANT & GOULD P.C.

191 Peachtree Street N.E., Suite 4300

Atlanta, GA 30303

jblake@merchantgould.com

Main Telephone: (404) 954-5100

Main Facsimile: (404) 954-5099

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS II LLC Petitioner

V.

NPS PHARMACEUTICALS, INC.
Patent Owner

Case No. To be assigned Patent 7,056,886

DECLARATION OF ANTHONY PALMIERI III, Ph.D., R.Ph. FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,056,886 (CLAIMS 46-52 and 61-75) UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 et seq.



TABLE OF CONTENTS

I.	INTI	RODUCTION			
II.	QUA	JALIFICATIONS			
III.		COMPENSATION, PRIOR TESTIMONY, AND RELATIONSHIP TO THE PARTIES			
IV.	SUM	IMARY OF OPINION			
V.	LEGAL STANDARDS				
	A.	Claim Construction	8		
	B.	Obviousness	8		
	C.	A Person of Ordinary Skill in the Art	8		
VI.	CON	ICURRENT LITIGATION	9		
VII.	DETAILED OPINION				
	A.	Person of Ordinary Skill in the Art	9		
	B.	How the Challenged Claims Are to Be Construed	10		
	C.	Relevant Time Frame for Analysis of the '886 Patent	12		
	D.	Overview of the State of the Art Prior to December 29, 2000 and the Cited Prior Art	13		
	E.	Cited Art Applied is Prior Art to the '886 Patent	15		
	F.	Claims 46-52 and 69-75 Are Unpatentable Because They Would Have Been Obvious Over Drucker '379 in view of			



Declaration of Anthony Palmieri III, Ph.D. *Inter Partes* Review of U.S. Patent No. 7,056,886

Kor	Cornfelt, Osterberg, and Munroe			16	
1.	Each of the Limitations of Claims 46-52 and 69-75 Are Found in Drucker '379, Kornfelt, Osterberg, and				
	Mur	iroe		16	
	a.	Independent Claim 46			
		i.	A GLP-2 Formulation was Known	30	
		ii.	About 0.1 to About 50 mg/ml of A GLP-2 Peptide Or An Analog Thereof was Known	30	
		iii.	A Phosphate Buffer In An Amount Sufficient to Adjust the pH Of The Formulation To A Pharmaceutically Tolerable Level was Known	32	
		iv.	About 0.5 to About 1% L-histidine and About 2% to About 5% Mannitol Would Be Obvious to Use	34	
	b.	Inde	pendent Claim 52	41	
		i.	A GLP-2 Formulation was Known	42	
		ii.	A Medically Useful Amount of a Naturally Occurring GLP-2 Peptide or an Analog Thereof was Known	42	
		iii.	A Phosphate Buffer in an Amount Sufficient to Adjust the pH of the Formulation to a Physiologically Tolerable Level was Known	44	
		iv.	L-Histidine in an Amount Sufficient to Stabilize the Formulation Would be Obvious to Use	46	



Declaration of Anthony Palmieri III, Ph.D. *Inter Partes* Review of U.S. Patent No. 7,056,886

	V.	Group Consisting of Mannitol and Sucrose is Obvious	48		
c.	Independent Claim 69				
	i.	A Method for Treating a Human or Animal having a Gastrointestinal Disorder, Disease or Condition for Which Treatment with GLP-2 is Indicated Including Administering a Therapeutically Effective Amount of a GLP-2 Formulation was Known	54		
	ii.	A GLP-2 Peptide or an Analog Thereof was Known	57		
	iii.	A Phosphate Buffer in an Amount Sufficient to Adjust the pH of the Formulation to a Pharmaceutically Tolerable Level was Known	57		
	iv.	L-histidine Would be Obvious to Use	59		
	V.	A Bulking Agent Selected from the Group Consisting of Mannitol and Sucrose Would be Obvious to Use	60		
	vi.	Enhancing, Maintaining, or Promoting the Growth or Functioning of the Gastrointestinal Tract Was Known	62		
d.	Clair	ms 47-72	67		
e.	Clair	Claim 48.			
f.	Clair	Claims 49 and 70			
σ	Clair	Claims 50 and 71			



Declaration of Anthony Palmieri III, Ph.D. *Inter Partes* Review of U.S. Patent No. 7,056,886

		h.	Clair	ns 51 and 75	69	
		i.	Clair	ns 73 and 74	70	
G.	Claims 61-68 Are Unpatentable Because They Would Have Been Obvious Over Drucker '600 in view of Kornfelt, Holthuis, Osterberg, and Munroe					
	1.			Limitations of Claims 61-68 Are Found in 00, Kornfelt, Osterberg, and Munroe	72	
		a.	Inde	pendent Claim 61	81	
			i.	A Kit Including a Lyophilized GLP-2 Formulation was Known	82	
			ii.	A GLP-2 Peptide or an Analog Thereof was Known	83	
			iii.	A Phosphate Buffer in an Amount Sufficient to Adjust the pH of the Formulation to a Pharmaceutically Acceptable Level was Known	83	
			iv.	L-histidine Would be Obvious to Use	85	
			V.	A Bulking Agent Selected from the Group Consisting of Mannitol and Sucrose Would be Obvious to Use	87	
			vi.	A Vial of Sterile Water for Reconstitution Would be Obvious to Use	88	
			vii.	Instructions Directing Reconstitution were Known, or Alternatively, Obvious to Use	89	
	b. Claims 62 and 63				95	



DOCKET

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.

