

By: Jeffrey D. Blake, Esq.
Matthew L. Fedowitz, Esq.
MERCHANT & GOULD P.C.
191 Peachtree Street N.E., Suite 4300
Atlanta, GA 30303
jblake@merchantgould.com
mfedowitz@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 IPR 2015-01093
U.S. Patent No. 7,056,886

DECLARATION OF IVAN T. HOFMANN, CPA/CFF, CLP

CFAD Exhibit 1042

TABLE OF CONTENTS

I.	Introduction.....	1
II.	Qualifications.....	2
III.	Documents Considered.....	6
IV.	Compensation	6
V.	Summary Of Opinions.....	7
VI.	Case Background	11
VII.	The Requirements Of Objective Indicia Of Nonobviousness.....	13
VIII.	NPS and the Rausser Declaration Have Not Established That Gattex [®] Satisfied a Long-Felt But Unmet Need	14
	A. The Rausser Declaration Does Not Argue That a Nexus Exists Between the Claimed Inventions of the '886 Patent and the Fulfillment of a Purported Long-Felt But Unmet Need.....	14
	B. The Rausser Declaration Fails to Show That Any Purported Long-Felt But Unmet Need Is Met By Gattex [®]	16
IX.	There Is No Nexus Between the Performance of Gattex [®] and the Claimed Inventions of the '886 Patent.....	20
	A. The Rausser Declaration Fails to Demonstrate How the Particular Ingredients Recited in the Claims of the '886 Patent Led to the Purported Commercial Success of Gattex [®]	20
	B. The Rausser Declaration Fails to Apportion the Performance of Gattex [®] to the Patents Which Purportedly Cover Gattex [®]	21
	C. The Rausser Declaration Fails to Demonstrate that the '886 Patent Drives Sales of Gattex [®]	23

**CONTAINS HIGHLY CONFIDENTIAL INFORMATION
FILED UNDER SEAL**

D.	The Rausser Declaration Conflates FDA Approval with Commercial Success and Nexus	25
E.	The Rausser Declaration Fails to Address the Importance of Marketing of Gattex®	27
F.	The Rausser Declaration Inappropriately Dismisses the Impact of Patient Assistance Programs on the Performance of Gattex®	30
G.	ODE/NCE Exclusivity	36
X.	NPS And Dr. Rausser Have Not Established Commercial Success Of Gattex®	38
A.	The Performance of Gattex®	38
B.	The Analysis of Pricing in the Rausser Declaration is Misleading	39
C.	The Rausser Declaration’s Analysis of Forecasts Fails to Provide Evidence of Commercial Success	42
D.	The Discussion of NPS’s Stock Price in the Rausser Declaration is Flawed and Misleading	43
E.	The Discussion of Shire’s Acquisition of NPS in the Rausser Declaration is Flawed and Does Not Establish Commercial Success of Gattex®	49
1.	Future Desired Sales and Profits Do Not Reflect Commercial Success of a Product	49
2.	The Rausser Declaration Fails to Appropriately Apportion Any Purported Commercial Success Related to the NPS Acquisition to the ’886 Patent	52

**CONTAINS HIGHLY CONFIDENTIAL INFORMATION
FILED UNDER SEAL**

I, Ivan T. Hofmann, hereby declare as follows:

I. INTRODUCTION

1. I have been retained by Petitioner Coalition for Affordable Drugs II, LLC (“CFAD”) to provide analysis in the above-captioned *inter partes* review (“IPR”) concerning U.S. Patent No. 7,056,886 (“the ’886 Patent”). The ’886 Patent is entitled “GLP-2 Formulations,” and the challenged claims of the ’886 Patent are directed to stabilized formulations of glucagon-like peptide 2 (“GLP-2”) or analogs thereof. [EX. 1003.] The ’886 Patent is assigned on its face to NPS Allelix, Corp., a subsidiary of NPS Pharmaceuticals, Inc. (“NPS”). [EXS. 1003; 1075.]

2. I have been asked by counsel for CFAD to review and respond to assertions regarding alleged objective indicia of nonobviousness relating to the ’886 Patent that were raised in NPS’s Patent Owner Response (the “POR”), and in the Declaration of Gordon Rausser, Ph.D. under 37 C.F.R §1.68 in Support of Patent Owner’s Response to the Petition (the “Rausser Declaration”). My declaration specifically focuses on the asserted objective indicia known as (1) long-felt but unmet need and (2) commercial success as they relate to the pharmaceutical product Gattex[®], which I understand NPS alleges is the commercial embodiment of certain claims of the ’886 Patent. [POR, p. 59.]

II. QUALIFICATIONS

3. I am a Managing Director at Gleason IP, a division of Gleason & Associates, P.C. (“Gleason”). Gleason is an economic, accounting, and financial consulting firm which provides services primarily in the areas of Valuation, Litigation Support, Intellectual Property, Forensic Accounting and Financial Reorganization. I am the leader of the Intellectual Property Practice. Prior to joining Gleason, I worked for the global firm of Deloitte & Touche, LLP.

4. I graduated *magna cum laude* from the University of Notre Dame in 1994, with a Bachelor of Business Administration degree and a double major in Economics and Accounting. I am a Certified Public Accountant (“CPA”). I am also Certified in Financial Forensics (“CFF”). I am a member of the Licensing Executives Society (“LES”) and have received my Certified Licensing Professional (“CLP”) designation, which is granted by the LES to professionals with demonstrated knowledge and experience in the areas of intellectual property and licensing. I have attended and instructed numerous continuing education seminars since the completion of my formal education and have been a speaker on numerous occasions on a variety of financial, economic, accounting, intellectual property, and valuation topics. I have presented to various bar associations and

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.