#### UNITED STATES PATENT AND TRADEMARK OFFICE

\_\_\_\_

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS II LLC, Petitioner,

v.

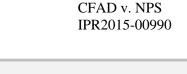
NPS PHARMACEUTICALS, INC., Patent Owner.

Case IPR2015-00990

Patent 7,056,886

\_\_\_\_

DECLARATION OF GORDON RAUSSER, Ph.D. UNDER 37 C.F.R. § 1.68 IN SUPPORT OF PATENT OWNER'S RESPONSE TO THE PETITION



NPS EX. 2149

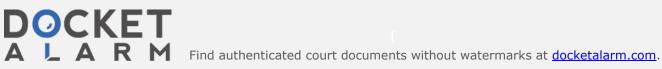


# TABLE OF CONTENTS

I.	Qı	Qualifications			
II.	Sc	ope	of Work	4	
	A.	A	ssignment	4	
	B.	D	ata and documents considered	6	
	C.	C	ompensation	7	
III.	Su	ımn	nary of Opinions	7	
IV.	Background				
	A.	S	nort bowel syndrome and SBS-IF	10	
		1.	Treatment with parenteral nutrition	13	
		2.	Drugs to increase absorptive capacity of the intestines	19	
		3.	Incidence and prevalence of SBS-IF	22	
		4.	Prognosis for SBS-IF patients	23	
	B.	G	attex®	25	
V.	Opinion 1: Gattex <sup>®</sup> addressed a long-felt, unresolved need for an SBS drug that could reduce patients' dependence on PN				
	A.	T	here was a long-felt need	27	
		1.	Medical costs of PN dependence	31	
		2.	Cost of inability to work	32	
		3.	Reducing reliance on PN can increase life-expectancy and greatly improve quality of life and economic wellbeing	34	
	B.		efore Gattex®, no medication successfully reduced BS-IF patients' dependence on PN		
	C.		attex® addressed this long-felt need by reducing SBS-IF atient dependence on PN	37	
VI.	Opinion 2: Gattex® has been a commercial success			40	
	A.	G	attex® has steadily grown its base of SBS patients	41	
	B.		attex's® ability to command a strong price in the market further evidence of commercial success	43	
	C.	G	attex® has had high sales and rapid sales growth	45	
	D.	G	attex® exceeded the pre-launch sales expectations of NPS	48	



Е.	Gattex's value contributed to a quadrupling of NPS's stock price	49
F.	Gattex® was a key value driver in Shire's \$5.2 billion acquisition of NPS	
	inion 3. There is a clear nexus between Gattex®'s mmercial success and the claims of the '886 patent	56
A.	Gattex® would not have been commercially viable if it had not been stable; therefore, all sales of Gattex® have a nexus to the '886 patent	57
B.	Gattex®'s commercial success cannot be attributed to factors unrelated to its patented properties	62
C.	Gattex® patient support program is consistent with programs offered for other similarly positioned drugs	65



1. I am an economist with expertise in intellectual property valuation and the commercial performance of pharmaceutical products. I was retained by counsel for NPS Pharmaceuticals, Inc. ("NPS") to evaluate, from an economic perspective, objective evidence regarding the non-obviousness of U.S. Patent No. 7,056,886. The claims of this patent are directed to stable formulations of GLP-2 or analogs thereof, and encompass the formulation for Gattex®,¹ a drug product used to treat patients suffering from short bowel syndrome who are dependent upon parenteral (intravenous) nutrition. This declaration addresses three types of objective evidence: 1) long-felt unmet need, 2) commercial success, and 3) nexus between commercial success and the invention claimed by the challenged patent.

### I. QUALIFICATIONS

2. I am the Robert Gordon Sproul Distinguished Professor at the University of California, Berkeley, where I teach both Economics and Statistics at the graduate and undergraduate levels. I received a Ph.D. with Highest Honors from the University of California at Davis in 1971, and in 1973 I was awarded a Postdoctoral Fellowship in Economics and Statistics at the University of Chicago. I am an elected Fellow of the American Association for the Advancement of Science (1994), the American Statistical Association (1991), and the Agricultural &

<sup>&</sup>lt;sup>1</sup> Gattex<sup>®</sup> is a registered trademark.



Applied Economics Association (1990). In 1987, I was a Fulbright Scholar in Australia.

- 3. In my academic career, I have held positions teaching economics and statistics at many universities including the University of Chicago, Harvard University, the University of California at Berkeley, University of Illinois, Iowa State University, the University of California at Davis, and Hebrew University. I served as Dean of the College of Natural Resources at the University of California, Berkeley from 1994–2000, and have three times been selected by my colleagues as Chair of my academic department. I have won 18 national awards and honors for my teaching and research.
- 4. I have published extensively in academic and professional journals on the application of statistical methods, market dynamics, industrial organization, environmental and resource economics, public policy, and futures and options. During my academic career, I have published more than 250 articles, books and book chapters. In addition, I have written more than 100 commissioned papers, governmental reports, and working papers. My upcoming book, entitled *Structuring Public-Private Research Partnerships for Success: Empowering University Partners*, is devoted to the topic of research partnerships and how they can best enhance the value of intellectual property. I am currently the Editor of the Annual Review of Resource Economics. I am a past Associate Editor of the



# 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.

