

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 JOHN F. CARPENTER, PH.D.
IN SUPPORT OF PATENT OWNER'S RESPONSE

NPS EX. 2040
CFAD v. NPS
IPR2015-00990

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. SUMMARY OF QUALIFICATIONS	1
III. MATERIALS CONSIDERED	4
IV. UNDERSTANDING OF THIS PROCEEDING	4
V. LEGAL PRINCIPLES APPLIED AND LEVEL OF SKILL	6
VI. THE '886 PATENT AND THE CHALLENGED CLAIMS	7
VII. TECHNICAL BACKGROUND AND STATE OF THE ART IN 1999.....	11
VIII. THE COMMERCIAL EMBODIMENT OF THE '886 PATENT	18
IX. THE PETITIONER'S CHALLENGES - OBVIOUSNESS	23
X. SUMMARY OF NON-OBVIOUSNESS OF EACH CHALLENGED CLAIM.....	28
XI. THE FIELD OF THE INVENTION AND LEVEL OF ORDINARY SKILL IN THIS ART	34
XII. THE PRIOR ART	36
A. Drucker '379.....	36
B. Drucker '600.....	37
C. Osterberg	38
D. Kornfelt.....	39
E. Holthuis	42
F. Munroe	43
XIII. SURPRISING AND UNEXPECTED RESULTS OF THE '886 PATENT INVENTION	43
XIV. STABILIZATION OF GLUCAGON IS NOT PREDICTIVE OF STABILIZATION OF GLP-2	46
XV. HISTIDINE IS A PROBLEMATIC EXCIPIENT	51
XVI. THERE IS NO MOTIVATION TO COMBINE, AND THERE ARE CLEAR TEACHINGS AWAY FROM PETITIONER'S COMBINATIONS.....	54

I. INTRODUCTION

1. I, John Frank Carpenter, Ph.D., hereby declare as follows:

2. I have been retained by counsel for Patent Owner NPS

Pharmaceuticals, Inc. as an expert in formulation science to address topics relevant to the subject matter of this *inter partes* review proceeding involving certain claims of U.S. Patent No. 7,056,886 (Ex. 1003; the “’886 patent”). I am being compensated at the rate of \$690 per hour. My compensation is in no way dependent on the outcome of this case.

II. SUMMARY OF QUALIFICATIONS

3. My curriculum vitae is Ex. 2043.

4. I am a tenured Professor of Pharmaceutical Sciences and the Co-Director of the Center for Pharmaceutical Biotechnology at the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences.

5. I received a Bachelor of Science degree in Zoology from Duke University, a Masters of Science from Oregon State University, and a Ph.D. in Biology from the University of Louisiana, Lafayette in 1978, 1981, and 1985, respectively.

6. I was a Visiting Lecturer at the University of California, Davis from 1987-1988 and also a Postdoctoral Research Associate in Biophysics during that time at UC Davis.

7. I was a Senior Scientist at CryoLife, Inc. from 1988-1992.
8. I was an Assistant Professor of Pharmaceutical Biotechnology at the University of Colorado from 1993 to 1998; from 1998-2004, I was a tenured Associate Professor of Pharmaceutical Biotechnology at the University of Colorado Health Sciences Center; and from 2004 until present I have been a tenured Professor of Pharmaceutical Sciences at the University of Colorado Health Sciences Center.
9. Since 1993 I have been Graduate Faculty at University of Colorado Health Sciences Center.
10. Since 1997 I have been the Co-Founder and Co-Director of the Center for Pharmaceutical Biotechnology at University of Colorado.
11. Since 1997 I have also been Graduate Faculty at the University of Colorado, Boulder.
12. From 2000 to 2003, I was Associate Director of the Pharmaceutical Sciences Graduate Training Program in the Department of Pharmaceutical Sciences, University of Colorado.
13. From 2004 to 2008, I was Director of the Pharmaceutical Sciences Graduate Training Program in the Department of Pharmaceutical Sciences, University of Colorado.
14. From 2001 to 2010, I was Co-Director, NIH Training Grant,

Leadership Training in Pharmaceutical Biotechnology, University of Colorado.

15. Since 2012, I have been Director of Business Development, University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences.

16. I have published more than 250 peer-reviewed publications in the field of protein/peptide formulation, consulted for dozens of pharmaceutical companies internationally, and have been an invited lecturer at conferences, pharmaceutical companies and universities around the world.

17. I was elected a Fellow of the American Association for the Advancement of Science in 2009. I was awarded a Research Achievement Award in Biotechnology, American Association of Pharmaceutical Scientists in 2007. I was awarded the Ebert Prize, *AphA, Journal of Pharmaceutical Sciences*, in 2007. My other scientific honors and awards are listed in my *curriculum vitae*, which also includes a list of my publications, patents, grant activity, presentations, and teaching activity.

18. Over the course of my career, I have more than three decades of experience in studies including protein/peptide formulation development; protein/peptide degradation and stabilization during processing storage and administration to patients; rational development of stable lyophilized formulations; mechanisms by which excipients provide stabilization or fail to stabilize proteins/peptide during freezing, drying and storage in the dried solid; 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.