

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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COALITION FOR AFFORDABLE DRUGS II LLC  
Petitioner

v.

NPS PHARMACEUTICALS, INC.  
Patent Owner

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Case IPR2015-01093  
Patent 7,056,886

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

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## **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

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