# Filed on behalf of Petitioner Coalition For Affordable Drugs II LLC

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## 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

\_\_\_\_\_\_

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

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DECLARATION OF ANTHONY PALMIERI III, Ph.D., R.Ph. FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,056,886 (CLAIMS 1-45) UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 et seq.



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

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		1. Grounds 1 and 2: Each of Claims 1-27, 33-35, 38, and 45 are obvious over Drucker '379 and further in view of Kornfelt and			



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Drucker '37	Each of Claims 31, 32, and 44 are Obvious over 79 and further in view of Kornfelt, Osterberg, and
	Independent Claim 1
i.	A GLP-2 formulation was known45
ii.	A medically useful amount of a naturally occurring GLP-2 was known
iii.	A phosphate buffer in an amount sufficient to adjust the pH of the formulation to a physiologically tolerable level was known
iv.	The use of L-histidine was known49
V.	The use of mannitol and sucrose as a bulking agent was known
b. De	pendent Claims 8, 10, 12, 14, 16, 18, 20, and 2251
i.	The concentration of GLP-2 peptide was known51
ii.	The concentration of L-histidine was known53
iii.	The claimed concentration of mannitol was known
	ependent Claims 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 5, 27, and 45
d. De	ependent Claims 2. 4. and 656



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		e.	Dependent Claims 24 and 26	57
		f.	Dependent Claims 33, 34, and 35	57
		g.	Dependent Claim 38.	.58
		rucker '379 a	Each of Claims 31-32 and 44 are Obvious in View of and further in view of Kornfelt, Osterberg, and	.59
	3.		Claims 28-30 and 39-43 are Obvious in View of Drucke Celt, Osterberg, and Holthius.	
	4.		Each of Claims 36 and 37 are Obvious in View of Drucket, Osterberg, and Drucker '574	
	5.	There was a	Reason to Combine the Cited References	73
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I, Dr. Anthony Palmieri III, hereby state the following:

### I. INTRODUCTION

- 1. I have been retained to provide technical assistance related to the filing of a Petition for *Inter Partes* Review of U.S. Patent No. 7,056,886 ("the '886 Patent") (Ex. 1003). I am working as a private consultant on this matter and the opinions presented here are my own.
- 2. I have been asked to prepare a written report including comments related to the Petition regarding whether certain claims of the '886 Patent are unpatentable because they would have been obvious in view of the documents cited herein. This Declaration sets forth the bases and reasons for my opinions, including the additional materials and information relied upon in forming those opinions and conclusions. I have reviewed Exhibits 1003-1031 set forth in the table below.

EXHIBIT	DESCRIPTION
1001	Declaration of Dr. Anthony Palmieri III, Ph.D., R.Ph.
1002	CV of Dr. Palmieri
1003	U.S. Patent No. 7,056,886 to Isaacs



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