

Filed: August 7, 2015

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 IPR2015-01093
Patent 7,056,886

PATENT OWNER'S PRELIMINARY RESPONSE

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TABLE OF EXHIBITS

Ex. No.	Description
2001	NPS Pharmaceuticals, Inc.'s Requests for Production to Petitioner
2002	NPS Pharmaceuticals, Inc.'s Interrogatories to Petitioner
2003	NPS Pharmaceuticals, Inc.'s Topics for Examination of Petitioner
2004	General Hedge Fund Structure & Regulation
2005	RPI Diagram
2006	Form ADV Brochure of HCM (Mar. 30, 2015)
2007	Form ADV of HCM (Mar. 30, 2015)
2008	Annual Report of HCM (July 8, 2013)
2009	Amended Form D of HCOP (May 12, 2014)
2010	Amended Form D of HCP (May 12, 2014)
2011	Credes Onshore Form D (Jan. 14, 2015)
2012	Credes Onshore Delaware Secretary of State Website Printout
2013	HCMF Cayman Islands Search Report
2014	Credes Offshore Form D (Jan. 14, 2015)
2015	Credes Offshore Caymans Search Report
2016	Form D of HOF (April 9, 2015)
2017	Certificate of Formation of IPNav (Nov. 13, 2007)
2018	Certificate of Formation of nXnP (Sept. 24, 2014)
2019	Ed Silverman, <i>Innovate or Else: Kyle Bass Strikes Again and Challenges Shire Patents</i> , <u>Wall Street Journal</u> (April 2, 2015)
2020	Robert Cyran, <i>Kyle Bass Wields New Weapon in Challenging Drug Makers</i> , <u>The New York Times</u> (February 11, 2015)
2021	Joseph Walker and Rob Copeland, <i>New Hedge Fund Strategy: Dispute the Patent, Short the Stock</i> , <u>Wall Street Journal</u> (April 7, 2015)
2022	Julia La Roche, <i>Hedge Fund Manager Kyle Bass is Going After Big Pharma and Its "BS Patents,"</i> <u>Business Insider</u> (Jan. 7, 2015)
2023	Julia La Roche, <i>Hedge Fund Manager Kyle Bass is Going After Big Pharma and Its "BS Patents,"</i> <u>Business Insider Australia</u> (Jan. 8, 2015)
2024	Delaware Secretary of State Business Entity Search Printout for Coalition Entities
2025	Cayman Islands Search Report of HOM
2026	Cayman Islands Search Report of HOF
2027	GATTEX® Product Label
2028	Lehninger <i>et al.</i> , Principles of Biochemistry, 2 nd ed., Chapters 5-7 & 18, pp. 111-197 & 542-597 (1993)

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Ex. No.	Description
2029	Voet and Voet, Biochemistry, 2 nd ed., Chapters 7 & 14, pp. 141-90 & 371-410 (1995)
2030	Purves <i>et al.</i> , Life: The Science of Biology, 3 rd ed., Ch. 3, pp. 40-59 (1992)
2031	NPS Pharmaceuticals, Inc. Form10-K 2014
2032	Email from Jeff Blake to Counsel for Patent Owner
2033	Declaration of Christopher E. Kirkpatrick
2034	Declaration of Erich Spangenberg
2035	The Wall Street Journal – New Hedge Fund Strategy: Challenge the Patent, Short the Stock
2036	The Wall Street Journal – Innovate or Else: Kyle Bass Strikes Again and Challenges Shire Patents
2037	Hayman Capital Management, L.P. Form ADV Part 2A Brochure
2038	Brubaker and Drucker, Structure-Function of the Glucagon Receptor Family of G-Protein Coupled Receptors: The Glucagon, GIP, GLP-1, and GLP-2 Receptors, Receptors and Channels, vol. 8, pp. 179-188 (2002)
2039	Chaturvedi, A Report on Stability of Polypeptides and Proteins, Birla Institute of Technology and Science Pilani (Rajasthan) (August 2009)
2040	Vassilatis <i>et al.</i> , “The G protein-coupled receptor repertoires of human and mouse”, <i>Proc Natl Acad Sci USA</i> 100 (8): 4903–4908 (2003)

...

Pursuant to 35 U.S.C. § 313 and 37 C.F.R. § 42.107, Patent Owner NPS Pharmaceuticals, Inc. (“NPS” or “Patent Owner”) submits this Patent Owner’s Preliminary Response (“Response”) to the Petition for *Inter Partes* Review of U.S. Patent No. 7,056,886 (“Petition”) filed by Coalition for Affordable Drugs II LLC (“Petitioner”). Petitioner requests an *inter partes* review (“IPR”) of certain claims of U.S. Patent No. 7,056,886 (“the ’886 patent”). The Response is timely under 35 U.S.C. § 313 and 37 C.F.R. § 42.107; it is filed within three months of the mailing date of the May 7, 2015, Notice of Filing Date Accorded to Petition (Paper 6).

I. Introduction

The inventor of the ’886 patent discovered GLP-2/GLP-2 analog formulations “exhibiting superior stability following storage and/or exposure to elevated temperatures.” Ex. 1003, Abstract. The challenged claims (claims 1-45) are directed to formulations of GLP-2 or an analog that are stabilized with L-histidine. The Petition should be denied because:

1 – it asserts substantially the same grounds of unpatentability that were asserted by the Examiner during prosecution and were overcome by Patent Owner;

2 – it does not rebut the arguments made during prosecution by the Patent Owner that successfully overcame these same rejections;

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