

Filed: July 24, 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 IPR2015-00990  
Patent 7,056,886

---

**PATENT OWNER'S PRELIMINARY RESPONSE**

## TABLE OF CONTENTS

|      |  |    |
|------|--|----|
| I.   | Introduction.....  | 1  |
| II.  | The Claimed Invention .....  | 3  |
| III. | The Petition Should Be Denied Because Petitioner Has Not<br>Established a Reasonable Likelihood that Any of the Challenged<br>Claims Are Obvious.....  | 5  |
| A.   | The Board Should Exercise Its Discretion under 35 U.S.C. §<br>325(d) to Deny the Petition Because It Relies on Substantially<br>the Same Art and Arguments Previously Considered by the<br>Office..... | 8  |
| 1.   | The '886 Patent Claims were Rejected During<br>Prosecution over a Combination of a GLP-2 Formulation<br>and Histidine Stabilization of Glucagon; The Rejection<br>was Overcome.....                    | 11 |
| 2.   | Petitioner Relies on Substantially the Same<br>Combinations of Prior Art and the Same Argument as the<br>Examiner Did during Prosecution.....  | 16 |
| B.   | The Petition Fails to Articulate Sufficient Motivation to<br>Combine the References to Arrive at the Claimed Invention<br>with a Reasonable Expectation of Success .....                               | 20 |
| C.   | GATTEX®, the Commercial Embodiment of the Challenged<br>Claims, Met a Long Felt Need and Is a Commercial Success .....   | 27 |
| IV.  | The Petition Should Be Denied Because Petitioner Failed to<br>Demonstrate that the '886 Patent Is not Entitled to the Benefit of Its<br>Priority Application .....                                     | 28 |
| V.   | The Petition Should Be Denied Because It Fails to Identify All Real<br>Parties-in-Interest.....  | 30 |
| VI.  | The Petition Should Be Denied because the Real Parties-In-Interest<br>Are Abusing and Misusing The IPR Process .....   | 41 |
| VII. | Conclusion .....   | 43 |

## TABLE OF EXHIBITS

| Ex.<br>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 <sup>nd</sup> ed., Chapters 5-7 & 18, pp. 111-197 & 542-597 (1993)                           |

::

| <b>Ex. No.</b> | <b>Description</b>   |
|----------------|--|
| 2029           | Voet and Voet, Biochemistry, 2 <sup>nd</sup> ed., Chapters 7 & 14, pp. 141-90 & 371-410 (1995)   |
| 2030           | Purves <i>et al.</i> , Life: The Science of Biology, 3 <sup>rd</sup> 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)   |

...

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 April 24, 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 46-52 and 61-75) are directed to formulations of GLP-2 or an analog that are stabilized with L-histidine (claims 46-52), kits containing these formulations (claims 61-68), and methods of using these formulations to treat serious intestinal diseases (claims 69-75). 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;

# 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.