Filed: January 20, 2016

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 RESPONSE

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The Patent Trial and Appeal Board ("PTAB"), on October 23, 2015, implemented this Inter Partes Review ("IPR") of certain claims of U.S. Patent No. 7,056,886 ("the '886 patent"). Pursuant to 35 U.S.C. §§ 314 and 316((a)(8) and 37 C.F.R. §42.120, Patent Owner NPS Pharmaceuticals, Inc. submits this Patent Owner's Response and requests issuance of a final written decision under 35 U.S.C. § 318 (a) and issuance and publication of a certificate under 35 U.S.C. § 318 (b) confirming the patentability of the challenged claims.

I. Introduction

The'886 patent inventor discovered GLP-2/GLP-2 analog formulations "exhibiting superior stability following storage and/or exposure to elevated temperatures." Ex. 1003, Abstract. The challenged claims (46-52 and 61-75) are directed to formulations of GLP-2 or an analog that are stabilized, particularly when lyophilized (*i.e.*, six months at ambient temperature, 18 months at 4^{o}C with less than about 5% peptide degradation) at a pharmaceutically acceptable pH (*i.e.*, a pH that can be administered without patient reactions that preclude further administration) by a combination of L-histidine, phosphate buffer, and mannitol (46-51) or mannitol or sucrose (52), kits containing the latter formulations (61-68), and methods of use to treat serious intestinal diseases (69-75). This invention resulted in the first successfully marketed GLP-2 analog product approved for treating short bowel syndrome - GATTEX®.

The PTAB instituted this IPR because:

> [t]he information relied upon in the Petition tend[ed] to suggest that L-histidine has a stabilizing effect on peptide drugs generally, indicating that properties of L-histidine peptides affecting peptide association (and, therefore, peptide stabilization) are relevant in a manner distinct from properties of L-histidine affecting biological activity of the peptides.
>
> * * * * *
>
> [the Petitioner showed] sufficiently that a person of ordinary skill in the art would have had a reasonable expectation of success in formulating GLP-2 in combination with L-histidine and sucrose or mannitol to create a lyophilized storage stable formulation in view of the guidance set forth in the prior art.
>
> * * * * *
>
> [t]he information set forth in the Petition [was] sufficient to establish that buffered pharmaceutical formulations of GLP-2 analogs were known and that Osterberg and Kornfelt suggests that the use of L-histidine in combination with an excipient such as mannitol or sucrose in protein formulations was a predictable variation within the technical grasp of a person of ordinary skill in the art done for the purposes of protein stabilization.

Paper 28, 19, 22-23. These conclusions are incorrect and arise from incomplete and unreliable expert testimony. The PTAB relied upon Petitioner's alleged expert Dr. Anthony Palmieri, who provided an uninformed and less than expert explanation of the prior art, particularly Kornfelt *et al.*, U.S. Patent No. 5,652,216 ("Kornfelt")

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