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Paper 28
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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.

Cases IPR2015-00990
Patent 7,056,886 B2

Before LORA M. GREEN, JACQUELINE WRIGHT BONILLA, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Coalition for Affordable Drugs II LLC ("Petitioner") filed a Petition to institute an *inter partes* review of claims 46–52 and 61–75 (Paper 1, "Pet.") of U.S. Patent No. 7,056,886 B2 (Ex. 1003, "the '886 patent"). NPS Pharmaceuticals, Inc. ("Patent Owner") filed a Patent Owner Preliminary Response. Paper 19 ("Prelim. Resp.").

Upon consideration of the above-mentioned Petition and Preliminary Response, we conclude that Petitioner has established that there is a reasonable likelihood that it will prevail with respect to at least one of the challenged claims. We institute an *inter partes* review as to claims 46–52 and 61–75 of the '886 patent.

A. Related Proceedings

The parties inform us of no related litigation between them involving the '886 patent. Pet. 4; Paper 5. Concurrent with the filing of the present Petition, Petitioner also filed a different Petition requesting *inter partes* review of claims 1–45 of the '886 patent (IPR2015-01093).

B. The '886 Patent (Ex. 1001)

The '886 patent discloses L-histidine stabilized drug formulations of glucagon-like peptide-2 ("GLP-2") and GLP-2 analogs. Ex. 1003, Abstract. The '886 patent disclosed that the GLP-2/GLP-2 analog formulations of the invention exhibit "superior stability following storage and/or exposure to elevated temperatures." *Id.* The formulations further comprise a phosphate

buffer, L-histidine (as a stabilizing amino acid), and mannitol or sucrose (as a bulking agent). *Id.* at 2:7–27.

The GLP-2 analogs may be agonists or antagonists. *Id.* at 4:19–31. "[A]ntagonists of GLP-2 analogs include any mutation or variation of the naturally occurring GLP-2 peptide which results in the inhibition of intestinotrophic activity of naturally occurring GLP-2 or GLP-2 analogs which exhibit agonist acitivity [sic]." *Id.* at 4:61–67. The GLP-2 analog known as "h[Gly2]GLP-2" is specifically disclosed. *Id.* at 5:21–32.

C. Illustrative Claims

Independent claims 46, 52, 61, and 69 are representative of the challenged claims, and are reproduced below:

> 46. A GLP-2 formulation comprising:
> (a) about 0.1 to about 50 mg/ml of a GLP-2 peptide or an analog thereof;
> (b) a phosphate buffer in an amount sufficient to adjust the pH of the formulation to a pharmaceutically tolerable level;
> (c) about 0.5 to about 1% L-histidine; and
> (d) about 2 to about 5% mannitol.
>
> 52. A GLP-2 formulation comprising:
> (a) a medically useful amount of a naturally occurring GLP-2 peptide or an analog thereof;
> (b) a phosphate buffer in an amount sufficient to adjust the pH of the formulation to a physiologically tolerable level;
> (c) L-histidine in an amount sufficient to stabilize the formulation; and
> (d) a bulking agent selected from the group consisting of mannitol and sucrose.

61. A kit comprising:

(a) a lyophilized GLP-2 formulation comprising:

(i) a GLP-2 peptide or an analog thereof;

(ii) a phosphate buffer in an amount sufficient to adjust the pH of the formulation to a pharmaceutically acceptable level;

(iii) L-histidine; and

(iv) a bulking agent selected from the group consisting of mannitol and sucrose;

(b) a vial of sterile water for reconstitution; and

(c) instructions directing reconstitution.

69. A method for treating a human or animal having a gastrointestinal disorder, disease or condition for which treatment with GLP-2 is indicated, the method comprising the step of administering a therapeutically effective amount of a GLP-2 formulation comprising:

(a) a GLP-2 peptide or an analog thereof;

(b) a phosphate buffer in an amount sufficient to adjust the pH of the formulation to a pharmaceutically tolerable level;

(c) L-histidine; and

(d) a bulking agent selected from the group consisting of mannitol and sucrose,

thereby enhancing, maintaining, or promoting the growth or functioning of the gastrointestinal tract.

Claims 47–51 depend from claim 46, directly or indirectly. Claims 62–68 depend from claim 61, directly or indirectly. Claims 70–75 depend from claim 69, directly or indirectly.

D. Asserted Grounds of Unpatentability

Petitioner challenges claims 46–52 and 61–75 of the '886 patent on the following grounds. Pet. 20–57.

Ground	References	Basis	Claim[s] challenged
1	Drucker '379,[1] Kornfelt,[2] Osterberg[3]	§ 103(a)	46–50, 52, 69–75
2	Drucker '600,[4] Kornfelt, Osterberg, and Holthuis[5]	§ 103(a)	61–67
3	Drucker '379, Kornfelt, Osterberg, and Munroe[6]	§ 103(a)	51, 75
4	Drucker '600, Kornfelt, Osterberg, Holthuis, and Munroe	§ 103(a)	68

Petitioner relies also on the Declaration of Dr. Anthony Palmieri III, Ph.D., R.Ph., in support of the proposed grounds of unpatentability. Ex. 1001 ("Palmieri Declaration" or "Palmieri Decl.").

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[1] Drucker et al., U.S. Patent No. 5,789,379, issued August 4, 1998. Ex. 1029 ("Drucker '379").
[2] Kornfelt et al., U.S. Patent No. 5,652,216, issued July 29, 1997. Ex. 1027 ("Kornfelt").
[3] Osterberg et al., *Physical state of L-histidine after freeze-drying and long-term storage*, 8 EP. J. OF PHARM. SCI. 301–308 (1999). Ex. 1030 ("Osterberg").
[4] Drucker et al., PCT Publication WO 98/52600, published November 26, 1988. Ex. 1028 ("Drucker '600").
[5] Holthuis et al., U.S. Patent No. 5,496,801, issued March 5, 1996. Ex. 1005 ("Holthuis").
[6] Munroe et al., *Prototypic G-protein coupled receptor for the intestinotrophic factor glucagon-like peptide 2*, 96 PROC. NAT'L ACAD. SCI. 1569–1573 (1999). Ex. 1022 ("Munroe").

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