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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*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

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.").

Based on these submissions, we instituted trial on the following grounds of unpatentability asserted by Petitioner:

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

[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] Thomas Osterberg & Tommy Wadsten, *Physical state of L-histidine after freeze-drying and long-term storage*, 8 EP. J. OF PHARM. SCI. 301–08 (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] Donald G. Munroe et al., *Prototypic G-protein coupled receptor for the intestinotrophic factor glucagon-like peptide 2*, 96 PROC. NAT'L ACAD. SCI. USA 1569–73 (1999) (Ex. 1022) ("Munroe").

Ground	References	Basis	Claim[s] challenged
4	Drucker '600, Kornfelt, Osterberg, Holthuis, and Munroe	§ 103(a)	68

Decision to Institute (Paper 28, "Dec.").

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 33, "PO Resp."), to which Petitioner filed a Reply (Paper 42, "Pet. Reply").

Petitioner relies on the Declarations of Anthony Palmieri III, Ph.D., R.Ph. (Exs. 1001, 1041) and Ivan T. Hoffmann (Ex. 1042) in support of the proposed grounds of unpatentability.

Patent Owner relies on the Declarations of John F. Carpenter, Ph.D. (Ex. 2040; redacted version Ex. 2148) and Gordon Rausser, Ph.D. (Ex. 2041; redacted version Ex. 2149).

Patent Owner filed a motion to exclude certain of Petitioner's evidence. Paper 51. Petitioner filed an opposition (Paper 55), and Patent Owner filed a reply (Paper 59).

Oral argument was conducted on June 23, 2016. A transcript is entered as Paper 67 ("Tr.").

This Final Written Decision is entered pursuant to 35 U.S.C. § 318(a). We conclude for the reasons that follow that Petitioner has shown by a preponderance of the evidence that claims 46–52 and 61–75 of the '886 patent are unpatentable.

A. Related Proceedings

Petitioner also filed a different Petition requesting *inter partes* review

of claims 1–45 of the '886 patent (IPR2015-01093). We also instituted *inter partes* review in IPR2015-01093, and issue a final decision therein concurrently with this Final Written Decision.

B. The '886 Patent (Ex. 1003)

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 discloses 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 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,

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