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Paper 67
Entered: October 21, 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 IPR2015-01093
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 1–45 (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 18 ("Prelim. Resp.").

Based on these submissions, we instituted trial as to claims 1–27, 31–40, and 44–45 of the '886 patent on the following grounds of unpatentability asserted by Petitioner:

Ground	References	Basis	Claims challenged
1	Drucker '379,[1] Kornfelt,[2] Osterberg[3]	§ 103(a)	1–27, 33–35, 38, 45
2	Drucker '379, Kornfelt, Osterberg, Munroe[4]	§ 103(a)	31, 32, 44
3	Drucker '379, Kornfelt, Osterberg, Holthuis[5]	§ 103(a)	39–40

[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] 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").
[5] Holthuis et al., U.S. Patent No. 5,496,801, issued March 5, 1996. Ex. 1005 ("Holthuis").

Ground	References	Basis	Claims challenged
4	Drucker '547, [6] Kornfelt, Osterberg, Holthuis, Munroe	§ 103(a)	36–37

Decision to Institute (Paper 26, "Dec.").

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 31, "PO Resp."), to which Petitioner filed a Reply (Paper 40, "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. 2051;[7] 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 49. Petitioner filed an opposition (Paper 53), and Patent Owner filed a reply (Paper 57).

Oral argument was conducted on June 23, 2016. A transcript is entered as Paper 65 ("Tr.").

This Final Written Decision is entered pursuant to 35 U.S.C. § 318(a).

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[6] Drucker et al., PCT Publication WO 98/03547, published January 29, 1998. Ex. 1028 ("Drucker '547").

[7] We note that throughout the Patent Owner Response, reference is made to Ex. 2040, the Exhibit number for Dr. Carpenter's Declaration in related case IPR2015-00990 instead of Ex. 2051. We have interpreted those citations to Ex. 2040 to refer to Ex. 2051.

We conclude for the reasons that follow that Petitioner has shown by a preponderance of the evidence that claims 1–27, 31–40, and 44–45 of the '886 patent are unpatentable.

A. Related Proceedings

Petitioner also filed a different Petition requesting *inter partes* review of claims 46–52 and 61–75 of the '886 patent (IPR2015-00990). We also instituted *inter partes* review in IPR2015-00990, and issue a final decision therein concurrently with this Final Written Decision.

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 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 claim 1 is illustrative of the challenged claims, and is

reproduced below:

> 1. A glucagon-like peptide 2 (GLP-2) formulation comprising:
> (a) a medically useful amount of a naturally occurring GLP-2 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; and
> (d) a bulking agent selected from the group consisting of mannitol and sucrose.

Ex. 1003, 12:9–18. Claims 2–27, 31–40, and 44–45 depend from claim 1, directly or indirectly.

II. ANALYSIS

A. Claim Interpretation

We interpret claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016). Under the broadest reasonable construction standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). "Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). "Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir.

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