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Paper 26
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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 IPR2015-01093
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 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.").

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 1–27, 31–40, and 44–45 of the '886 patent, but deny the Petition as to claims 28–30 and 41–43.

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 46–52 and 61–75 of the '886 patent (IPR2015-00990). *Id.*

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 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 2–45 depend from claim 1, directly or indirectly.

D. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–45 of the '886 patent on the following ground. Pet. 21–55.

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)	28–30, 39–43
4	Drucker '547, [6] Kornfelt, Osterberg, Holthuis, Munroe	§ 103(a)	36–37

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] 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").

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

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); *see also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015) ("Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA," [7] and "the standard was properly adopted by PTO regulation."). Under the broadest reasonable construction standard, claim terms are 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. 1994).

We determine that no explicit construction of any specific claim term is necessary to determine whether to institute a trial in this case. *See, e.g.*, *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011)

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[7] The Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) ("AIA").

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