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Paper 11
Date: February 3, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACUTICALS LLC,
Petitioner,

v.

HOSPIRA INC.,
Patent Owner.

Case IPR2016-01580
Patent 8,648,106 B2

Before MICHAEL J. FITZPATRICK, SHERIDAN K. SNEDDEN, and ZHENYU YANG, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner, Amneal Pharmaceuticals LLC filed a Petition to institute an *inter partes* review of claims 1–9 of U.S. Patent No. 8,648,106 B2 (Ex. 1001, "the '106 patent") pursuant to 35 U.S.C. § 311(a). Paper 2 ("Pet."). Patent Owner, Hospira Inc., filed a Preliminary Response under 35 U.S.C. § 313. Paper 9 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). Upon consideration of the Petition and Preliminary Response, and for the reasons explained below, we determine that the information presented does not show a reasonable likelihood that Petitioner would prevail with respect to any claim challenged in the Petition. *See* 35 U.S.C. § 314(a); 37 C.F.R § 42.108. The Petition is denied.

A. Related Matters

Patent Owner has asserted the '106 patent in *Hospira, Inc. v. Amneal Pharmaceuticals LLC*, No. 1:15-cv-00697 (D. Del.). Pet. 74; Paper 4, 2.

Petitioner has filed petitions for *inter partes* reviews of U.S. Patent Nos. 8,338,470 B1, 8,455,527 B1, and 8,242,158 B1, which are related to the '106 patent. Pet. 6–7; *see also* Cases IPR2016-01578, IPR2016-01579, IPR2016-01577.

B. The '106 Patent

4-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole is known shorthand as medetomidine. Ex. 1001, 1:26–27. It is a racemic mixture of two

enantiomers: levomedetomidine and dexmedetomidine. *Id.*; Ex. 2005 ¶25.[1] The '106 patent focuses on the latter enantiomer, dexmedetomidine, and "relates to patient-ready, premixed formulations of dexmedetomidine, or a pharmaceutically acceptable salt thereof, that can be used, for example, in perioperative care of a patient or for sedation." Ex. 1001, 1:19–22.

The '106 patent acknowledges that, before the claimed invention, both medetomidine and dexmedetomidine were known to be α_2-adrenoceptor agonists and used as antihypertensive, sedative, and analgesic agents. *Id.* at 1:28–50. The '106 patent also acknowledges prior patents disclosing medical administration of dexmedetomidine, including via epidural, parenteral, intravenous, oral, hypodermic, and transmucosal routes. *Id.* at 1:34–60 (citing various U.S. patents).

C. The Challenged Claims

Of the challenged claims, claim 1 is independent. It is illustrative and reproduced below.

> 1. A ready to use liquid pharmaceutical composition for parenteral administration to a subject, comprising dexmedetomidine or a pharmaceutically acceptable salt thereof disposed within a sealed glass container, wherein the liquid pharmaceutical composition when stored in the glass container for at least five months exhibits no more than about 2% decrease in the concentration of dexmedetomidine.

D. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

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[1] Exhibit 2005 is a declaration by Robert Linhardt, Ph.D.

References	Basis[2]	Claims
2010 Precedex Label (Ex. 1007)[3] and Palmgren (Ex. 1017)[4]	§ 103(a)	1–9
Aantaa (Ex. 1006),[5] 2010 Precedex Label, and Palmgren	§ 103(a)	1–9
2010 Precedex Label, De Giorgi (Ex. 1015),[6] Eichhorn (Ex. 1016),[7] Palmgren, and Lavoisier (Ex. 1018)[8]	§ 103(a)	1–9

Pet. 11–12.

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[2] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, which was enacted September 16, 2011, made amendments to 35 U.S.C. §§ 102 and 103. AIA § 3(b) and (c). Those amendments became effective eighteen months later on March 16, 2013. *Id.* at § 3(n). Because the application from which the '106 patent issued was filed before March 16, 2013, any citations herein to 35 U.S.C. §§ 102 and 103 are to their pre-AIA versions.

[3] The 2010 Precedex Label is an FDA-approved label for Precedex, which is the commercial or brand name for dexmedetomidine-HCl. Ex. 1007, l. 7. Petitioner alleges it was published September 2010.

[4] Palmgren, Joni J. et al., *Drug adsorption to plastic containers and retention of drugs in cultured cells under in vitro conditions*, 64 EUROPEAN JOURNAL OF PHARMACEUTICS AND BIOPHARMACEUTICS 369–78 (June 29, 2006).

[5] U.S. Patent No. 6,716,867 B1, issued April 6, 2004.

[6] De Giorgi, Isabella et al., *Risk and pharmacoeconomic analyses of the injectable medication process in the paediatric and neonatal intensive care units*, vol. 22 no. 3 INTERNATIONAL JOURNAL FOR QUALITY IN HEALTH CARE 170–78 (2010).

[7] Eichhorn, John H., *APSF Hosts Medication Safety Conference: Consensus Group Defines Challenges and Opportunities for Improved* Practice, vol. 25 no. 1 THE OFFICIAL JOURNAL OF THE ANESTHESIA PATIENT SAFETY 1, 3–8 (Spring 2010).

[8] Lavoisier product sheet for NaCl 0.9% injectable solution (June 2009).

II. ANALYSIS

A. Claim Construction

"A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). Pursuant to that standard, the claim language should be read in light of the specification, as it would be interpreted by one of ordinary skill in the art. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Thus, we generally give claim terms their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning 'is the meaning that the term would have to a person of ordinary skill in the art in question.'" (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc))). A patentee, however, may rebut this presumption by acting as his own lexicographer, providing a definition of the term in the specification with "reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

The parties propose express constructions for two limitations, "dexmedetomidine" and "ready to use," both of which appear in claim 1 and are incorporated by the remainder of the claims of the '106 patent. We need not construe these limitations, however, as a different limitation of claim 1 is dispositive of the Petition. That limitation is "wherein the liquid pharmaceutical composition when stored in the glass container for at least five months exhibits no more than about 2% decrease in the concentration of dexmedetomidine." As explained below, none of Petitioner's grounds show

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