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Paper 11
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC,
Petitioner,

v.

HOSPIRA, INC,
Patent Owner.

Case IPR2016-01578
Patent 8,338,470 B1

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

Opinion for the Board filed by *Administrative Patent Judge* SNEDDEN.

Opinion Concurring filed by *Administrative Patent Judge* FITZPATRICK.

SNEDDEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Amneal Pharmaceuticals LLC ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1–7 (Paper 2; "Pet.") of US 8,338,470 B1 (Ex. 1001; "the '470 patent"). Hospira, Inc. ("Patent Owner") filed a Patent Owner Preliminary response. Paper 9 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. We thus institute an *inter partes* review of claims 1–7 of the '470 patent.

A. Related Proceedings

Patent Owner has asserted the '470 patent in *Hospira, Inc. v. Amneal Pharmaceuticals LLC*, No. 1:15-cv-00697 (D. Del.). Pet. 61; Paper 6, 2.

Petitioner has sought *inter partes* review for related patents in the following proceedings: Case IPR2016-01577 (U.S. Patent No. 8,242,158 B2), Case IPR2016-01579 (U.S. Patent No. 8,455,527 B2), and Case IPR2016-01580 (U.S. Patent No. 8,648,106 B2).

B. The '470 patent (Ex. 1001)

The '470 patent relates to ready-to-use liquid pharmaceutical compositions of dexmedetomidine for parenteral administration to a subject. Ex. 1001, Abstract, 26:22–27. Dexmedetomidine is an enantiomer of medetomidine (or racemic 4-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole). *Id.* at 1:20–30. The '470 patent describes the invention as "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." *Id.* at 1:13–16.

The '470 patent defines the terms "premix" or "premixture" as follows:

> The terms "premix" or "premixture" as used herein refers to a pharmaceutical formulation that does not require reconstitution or dilution prior to administration to a patient.

Id. at 3:51–53.

The '470 patent defines the term "ready to use" as follows:

> [T]he compositions of the present invention can be formulated as "ready to use" compositions which refer to premixed compositions that are suitable for administration to a patient without dilution. For example, in certain embodiments, the compositions of the present invention are "ready to use" upon removing the compositions from a sealed container or vessel.

Id. at 3:59–65.

The '470 patent discloses that the dexmedetomidine compositions may be disposed in a container. *Id.* at 9:11–13. The '470 patent discloses that the containers may be glass vials, ampoules, syringes, and plastic flexible containers, such as polyvinyl chloride (PVC), VisIV, polypropylene, and CR3 containers. *Id.* at 9:17–29.

The '470 patent discloses numerous suitable concentrations for the premixed dexmedetomidine compositions. *Id.* at 7:64–8:16.

C. Illustrative Claims

Petitioner challenges claims 1–7 of the '470 patent. Independent claim 1 is illustrative of the challenged claims and is reproduced below:

> 1. A ready to use liquid pharmaceutical composition for parenteral administration to a subject, comprising dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 0.005 to about 50 μg/mL disposed within a sealed glass container.
>
> Claims 2–7 depend from claim 1, either directly or indirectly.

D. The Asserted Grounds

Petitioner challenges claims 1–7 of the '470 patent on the following grounds. Pet. 13–14.

Ground	Reference[s]	Basis	Claims challenged
1	2010 Precedex Label[1] and Palmgrén[2]	§ 103	1–7
2	Aantaa,[3] 2010 Precedex Label, and Palmgrén	§ 103	1–7

[1] 2010 Precedex™ Label (Ex. 1007, "2010 Precedex Label").
[2] Palmgrén, 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) (Ex. 1017, "Palmgrén").
[3] Aantaa et al., U.S. Patent No. 6,716,867, issued Apr. 6, 2004 (Ex. 1006, "Aantaa").

Ground	Reference[s]	Basis	Claims challenged
3	2010 Precedex Label, De Giorgi,[4] Eichhorn,[5] Palmgrén, Lavoisier[6]	§ 103	1–7

Petitioner supports its challenge with the Declarations of James Cain, MD, MBA, FAAP (Ex. 1002) and Alpaslan Yaman, Ph.D. (Ex. 1003).

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, 2144–46 (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) (quoting *Phillips v. AWH Corp*, 415 F.3d 1303, 1312 (Fed. Cir. 2005)).

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[4] 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) (Ex. 1015, "De Giorgi").

[5] 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) (Ex. 1016, "Eichhorn").

[6] Lavoisier Sodium Chloride Product Sheet, June 2009 (Ex. 1018, "Lavoisier").

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