

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS LLC,  
Petitioner,

v.

HOSPIRA, INC.,  
Patent Owner.

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Case IPR2016-01577  
Patent 8,242,158 B1

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

YANG, *Administrative Patent Judge*.

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

## INTRODUCTION

Amneal Pharmaceuticals LLC (“Petitioner”) filed a Petition for an *inter partes* review of claims 1–4 of U.S. Patent No. 8,242,158 B1 (“the ’158 patent,” Ex. 1001). Paper 2 (“Pet.”). Hospira Inc. (“Patent Owner”) timely filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). We review the Petition under 35 U.S.C. § 314.

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–4, we institute an *inter partes* review of the challenged claims.

### *Related Proceedings*

According to the parties, Patent Owner has asserted the ’158 patent in *Hospira, Inc. v. Amneal Pharmaceuticals LLC*, No. 1:15-cv-00697 (D. Del.). Pet. 53; Paper 6, 2.

Petitioner has filed IPR2016-01578, IPR2016-01579, and IPR2016-01580, challenging related U.S. Patent Nos. 8,338,470, 8,455,527, and 8,648,106, respectively. Pet. 53; Paper 6, 2.

### *The ’158 Patent*

The ’158 patent relates to “pharmaceutical compositions comprising dexmedetomidine or a pharmaceutically acceptable salt thereof[,] wherein the composition is formulated as a liquid for parenteral administration to a subject, and wherein the composition is disposed within a sealed container as a premixture.” Ex. 1001, Abstract; *see also id.* at 1:6–8 (“The present

invention relates to patient-ready, premixed formulations of dexmedetomidine, or a pharmaceutically acceptable salt thereof.”).

Dexmedetomidine is an enantiomer of medetomidine. *Id.* at 1:22–23. Before the ’158 patent, both medetomidine and dexmedetomidine were known as  $\alpha_2$ -adrenoceptor agonists for general sedation/analgesia and the treatment of hypertension or anxiety. *Id.* at 1:14–25. According to the ’158 patent, before its invention, “dexmedetomidine ha[d] been provided as a concentrate that must be diluted prior to administration to a patient. The requirement of a dilution step in the preparation of the dexmedetomidine formulation is associated with additional costs and inconvenience, as well as the risk of possible contamination or overdose due to human error.” *Id.* at 1:48–53. The ’158 patent purportedly provides a dexmedetomidine formulation that avoids the expense, inconvenience, delay, and risk of contamination or overdose. *Id.* at 1:53–55.

*Illustrative Claim*

Claim 1, the sole independent claim, is illustrative 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 4  $\mu\text{g}/\text{mL}$  disposed within a sealed glass container.

*Asserted Grounds of Unpatentability*

Petitioner asserts the following grounds, each of which challenges the patentability of claims 1–4:

| <b>Basis</b> | <b>References</b>  |
|--------------|--|
| § 103        | Precedex Label <sup>1</sup> and Palmgrén <sup>2</sup>  |
| § 103        | The '867 patent, <sup>3</sup> Precedex Label, and Palmgrén   |
| § 103        | Precedex Label, De Giorgi, <sup>4</sup> Eichhorn, <sup>5</sup><br>Palmgrén, and Lavoisier <sup>6</sup> |

In support of their respective positions, Petitioner relies on the Declarations of Dr. James Gordon Cain (Ex. 1002) and Dr. Alpaslan Yaman (Ex. 1003), and Patent Owner relies on the Declarations of Dr. Robert Linhardt (Ex. 2005) and Dr. Michael Ramsay (Ex. 2006).

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<sup>1</sup> Prescribing Information for Precedex (dexmedetomidine hydrochloride) injection (Ex. 1007).

<sup>2</sup> Palmgrén 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 (2006) (Ex. 1017).

<sup>3</sup> Aantaa et al., U.S. Patent No. 6,716,867, issued Apr. 6, 2004 (Ex. 1006).

<sup>4</sup> De Giorgi et al., *Risk and Pharmacoeconomic Analyses of the Injectable Medication Process in the Paediatric and Neonatal Intensive Care Units*, 22 INTERNATIONAL JOURNAL FOR QUALITY IN HEALTH CARE 170–78 (2010) (Ex. 1015).

<sup>5</sup> Eichhorn, John H., *APSF Hosts Medication Safety Conference: Consensus Group Defines Challenges and Opportunities for Improved Practice*, 25 APSF NEWSLETTER 1, 3–8 (2010).

<sup>6</sup> Product sheet for Lavoisier sodium chloride 0.9% injectable solution (2009).

## ANALYSIS

### *Claim Construction*

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

The parties dispute the construction for the term “ready to use,” which appears in all challenged claims. *See* Pet. 12–13; Prelim. Resp. 8–11. According to Petitioner, an ordinary artisan “would understand the term ‘ready-to-use’ to mean ‘requiring no further dilution or reconstitution before transfer to an administration device.’” Pet. 12. Patent Owner urges that we construe the term to mean “formulated such that it is suitable for administration to a patient *upon manufacture* without dilution or reconstitution by a clinician, hospital personnel, caretaker, patient, or any other individual.” Prelim. Resp. 8–9 (emphasis added).

The ’158 patent describes “ready to use” compositions as “premixed compositions that are suitable for administration to a patient without dilution.” Ex. 1001, 3:56–59. The parties appear to agree that “ready to use” is equivalent to a “premixture.” *See* Pet. 12 n.2; Prelim. Resp. 9. According to the ’158 patent,

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