Trials@uspto.gov
571-272-7822

Paper No. 9
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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 IPR2017-01054
Patent 8,242,158 B1

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

PER CURIAM.

Opinion Concurring filed by *Administrative Patent Judge* FITZPATRICK.

DECISION
Denying *Inter Partes* Review; Dismissing Motion for Joinder
37 C.F.R. §§ 42.108, 42.122

INTRODUCTION

On March 8, 2017, Fresenius Kabi USA, 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."). Petitioner concurrently filed a Motion for Joinder (Paper 4, "Mot."), seeking to be joined to *Amneal Pharmaceuticals LLC v. Hospira, Inc.*, Case No. IPR2016-01577 (the "Amneal IPR"). Hospira Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 8 ("Prelim. Resp."). We review the Petition under 35 U.S.C. § 314.

For the reasons provided below, we dismiss the Motion for Joinder and deny the Petition.

A. 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.), and *Hospira Inc. v. Fresenius Kabi USA, LLC*, 1:16-cv-00651 (N.D. Ill.) Pet. 54; Paper 6, 2.

The '158 patent is also the subject of the Amneal IPR. In that case, we instituted trial on February 9, 2017 (IPR2016-01577, Paper 11), but terminated it on May 19, 2017, because the parties settled their dispute (IPR2016-01577, Paper 19).

B. 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 α_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.

C. 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 μg/mL disposed within a sealed glass container.

D. Asserted Grounds of Unpatentability

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

Basis	References
§ 103	Precedex Label[1] and Palmgrén [2]
§ 103	The '867 patent,[3] Precedex Label, and Palmgrén
§ 103	Precedex Label, De Giorgi,[4] Eichhorn,[5] Palmgrén, and Lavoisier[6]

In support of their respective positions, Petitioner relies on the Declarations of Dr. James Gordon Cain (Ex. 1002) and Dr. Alpaslan Yaman (Ex. 1003).

ANALYSIS

A. The Motion for Joinder is Moot

Petitioner seeks joinder with the Amneal IPR. Mot. 1. The Amneal IPR has been terminated. *See* IPR2016-01577, Paper 19. Hence, there is no

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[1] Prescribing Information for Precedex (dexmedetomidine hydrochloride) injection (Ex. 1007).
[2] 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).
[3] Aantaa et al., U.S. Patent No. 6,716,867, issued Apr. 6, 2004 (Ex. 1006).
[4] 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).
[5] Eichhorn, John H., *APSF Hosts Medication Safety Conference: Consensus Group Defines Challenges and Opportunities for Improved* Practice, 25 APSF NEWSLETTER 1, 3–8 (2010).
[6] Product sheet for Lavoisier sodium chloride 0.9% injectable solution (2009).

pending proceeding for Petitioner to join. Accordingly, we dismiss the Motion for Joinder as moot.

B. The Petition is Time-Barred under 35 U.S.C. § 315(b)

Section 315(b) bars institution of *inter partes* review when the petition is filed more than one year after the petitioner is served with a complaint alleging infringement of the patent. 35 U.S.C. § 315(b). The one-year time bar, however, does not apply to a request for joinder. *Id.* (last sentence). The decision to grant joinder is discretionary. *Id.* § 315(c).

Petitioner concedes that it was served with a complaint alleging infringement of the '158 patent more than one year before it filed its Petition. Pet. 2 n.1, *see also id.* at 54 ("The Complaint alleging infringement of the '158 patent against Fresenius Kabi was filed and served on January 15, 2016."). Despite the late filing, Petitioner argues that it "is not barred from bringing this Petition . . . as [it] concurrently seeks joinder with IPR2016-01577." *Id.* at 2 n.1.

As discussed above, Petitioner's Motion for Joinder is dismissed as moot because there is no instituted *inter partes* review for Petitioner to join. Thus, the Petition is statutorily barred, and no *inter partes* review may be instituted. 35 U.S.C. § 315(b).

ORDER

Accordingly, it is

ORDERED that the Motion for Joinder is *dismissed* as moot.

FURTHER ORDERED that the Petition for *inter partes* review of claims 1–4 of the '158 patent is *denied*.

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