Trials@uspto.gov
571-272-7822

Paper No. 11
Entered: February 9, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC,
Petitioner,

v.

HOSPIRA, INC.,
Patent Owner.

Case IPR2016-01577
Patent 8,242,158 B1

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

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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.

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.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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), and Patent Owner relies on the Declarations of Dr. Robert Linhardt (Ex. 2005) and Dr. Michael Ramsay (Ex. 2006).

---

[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).

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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,

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.