Trials@uspto.gov
571-272-7822

Paper 10
Date: September 6, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA, LLC,
Petitioner,

v.

HOSPIRA INC.,
Patent Owner.

Case IPR2017-01055
Patent 8,338,470 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

I. INTRODUCTION

Petitioner, Fresenius Kabi USA, LLC ("Fresnius Kabi"), filed a Petition to institute an *inter partes* review of claims 1–7 of U.S. Patent No. 8,338,470 B1 (Ex. 1001, "the '470 patent") pursuant to 35 U.S.C. § 311(a). Paper 2 ("Pet."). Petitioner also filed a Motion for Joinder (Paper 4, "Mot."), seeking to be joined to *Amneal Pharmaceuticals LLC v. Hospira, Inc.*, Case No. IPR2016-01578 (the "Amneal IPR"). Patent Owner, Hospira Inc., filed a Preliminary Response under 35 U.S.C. § 313. Paper 8 ("Prelim. Resp.").

As explained below, we deny the Motion for Joinder and the Petition.

A. Related Matters

The Amneal IPR was instituted on February 9, 2017. IPR2016-01578, Paper 11. It was terminated on May 26, 2017, pursuant to a joint motion of the parties and in light of their settlement. IPR2016-01578, Paper 19.

Patent Owner has asserted the '470 patent against both Amneal and current Petitioner, Fresenius Kabi. *See Hospira, Inc. v. Amneal Pharmaceuticals LLC*, No. l:15-cv-00697 (D. Del.) (complaint served Aug. 11, 2015); *Hospira Inc. v. Fresenius Kabi USA, LLC*, 1:16-cv-00651 (N.D. Ill.) (complaint served January 15, 2016). Pet. 63; Paper 6, 2.

B. The '470 Patent

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. 14–15.

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

These are the same grounds Amneal raised in its Petition. We instituted the Amneal IPR, however, on only the third-listed ground above: "obviousness of claims 1–7 of the '470 patent over the combination of 2010 Precedex Label, De Giorgi, Eichhorn, Palmgrén, and Lavoisier." IPR2016-01578, Paper 11, 16.

II. ANALYSIS

A. The Motion for Joinder is Moot

Petitioner's Motion for Joinder seeks joinder with the Amneal IPR. Mot. 1. The Amneal IPR is no longer pending. *See* IPR2016-01578, Paper 19. Hence, there is no proceeding for Petitioner to join. Accordingly, we dismiss the Motion for Joinder as moot.

---

[4] De Giorgi, Isabella et al., *Risk and pharmacoeconomic analyses of the injectable medication process in the paediatric and neonatal intensivecare 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").

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.