Trials@uspto.gov
571.272.7822

Paper No. 47
Entered: June 7, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

J KYLE BASS and ERICH SPANGENBERG,
Petitioner,

v.

FRESENIUS KABI USA, LLC,
Patent Owner.

Case IPR2016-00254
Patent 8,476,010 B2

Before JACQUELINE WRIGHT BONILLA, *Vice Chief Administrative Patent Judge*, ZHENYU YANG, and TINA E. HULSE, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

J Kyle Bass and Erich Spangenberg (collectively, "Petitioner") filed a Petition requesting an *inter partes* review of claims 1, 13–15, 17, 18, 20, and 24–28 of U.S. Patent No. 8,476,010 B2 (Ex. 1001, "the '010 patent"). Paper 1 ("Pet."). Fresenius Kabi USA, LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp.").

On June 8, 2016, we instituted an *inter partes* review of claims 1, 13–15, 17, 18, 20, and 24–28 of the '010 patent on two grounds of obviousness. Paper 9 ("Dec. Inst."), 19. Patent Owner filed a Response to the Petition. Paper 28 ("PO Resp."). Petitioner filed a Reply to Patent Owner's Response. Paper 31 ("Pet. Reply").

Patent Owner filed observations on the cross-examination of Petitioner's declarant, Thomas N. Feinberg, Ph.D. Paper 36. Petitioner filed a response to Patent Owner's observations. Paper 40.

An oral hearing was held on March 13, 2016, a transcript of which has been entered in the record. Paper 46 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1, 13–15, 17, 18, 20, and 24–28 of the '010 patent are unpatentable.

A. Related Proceedings

The parties identify several district court proceedings as relating to the '010 patent. Pet. 3; Paper 5, 1–2. None of the proceedings is currently pending, and Petitioner is not a party to any of the proceedings. Pet. 5.

Patent Owner also identifies Case No. IPR2015-00715, where a different Petitioner also challenged the '010 patent. Paper 5, 2. That proceeding was terminated before institution. *Dr. Reddy's Labs., Inc. v. Fresenius Kabi USA, LLC*, Case IPR2015-00715, Paper 12 (PTAB Apr. 2, 2015).

B. The '010 Patent

Propofol (2,6-diisopropylphenol) is a well-known intravenous anesthetic agent. Ex. 1001, 1:14–15. The '010 patent relates to pharmaceutical formulations of propofol that are stored in containers having nonreactive, inert closures. *Id.* at 1:8–10. Propofol is a hydrophobic, water-insoluble oil that must be incorporated with solubilizing agents, surfactants, or an oil-in-water emulsion. *Id.* at 1:20–23.

Propofol compositions have been the subject of several patents. *Id.* at 1:26–27. The formulation described in U.S. Patent No. 5,714,520 is sold as Diprivan, which comprises "a sterile, pyrogen-free emulsion containing 1% (W/v) propofol in 10% (w/v) soybean oil." *Id.* at 2:33–36. According to the Specification, the inventors recognized that the relatively high volume of soybean oil used in prior art formulations protects propofol from degradation in a container. *Id.* at 3:63–66. Thus, the Specification states that "at oil contents (and/or propofol solvent contents) lower than about 10% (w/v), degradation of propofol has been found to occur if the container closure is not inert or non-reactive to propofol." *Id.* at 3:66–4:2. Preferred closures include those "coated or treated with inert materials such as siliconized polymer." *Id.* at 9:43–45.

C. Illustrative Claim

Petitioner challenges claims 1, 13–15, 17, 18, 20, and 24–28 of the ’010 patent, of which claim 1 is the only independent claim. Claim 1 is illustrative and is reproduced below:

> 1. A sterile pharmaceutical composition of propofol in a container, comprising:
>
> a container which includes a closure and a composition in the container, and
>
> the composition in the container comprising from 0.5% to 10% by weight propofol and from about 0 to about 10% by weight solvent for propofol,
>
> where when the composition in the container sealed with the closure is agitated at a frequency of 300–400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 93% of the starting concentration (w/v) of the propofol;
>
> where the closure is selected from the group consisting of siliconized bromobutyl rubber, metal, and siliconized chlorobutyl rubber.

D. Grounds of Unpatentability Instituted for Trial

We instituted trial on the following grounds:

Reference	Basis	Claims challenged
Diprivan PDR[1] in view of Farinotti[2] and van den Heuvel[3]	§ 103	1, 13–15, 17, 18, 20, and 24–28
Diprivan PDR in view of Farinotti and Lundgren[4]	§ 103	1, 13–15, 17, 18, 20, and 24–28

II. ANALYSIS

A. The Level of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would have been someone with substantial research or industry experience in pharmaceutical drug product development, including experience with sterile drugs and their packaging, and having at least a master's degree or doctorate in a related technical field, such as analytical, physical or organic chemistry, chemical engineering, pharmaceutics or related subject matter or having equivalent experience in such fields. Pet. 8. In its Preliminary Response, Patent Owner largely agreed with Petitioner's definition, with the exception that Patent Owner's definition requires experience with propofol and drug product emulsions, emulsion systems and their packaging. Prelim. Resp. 19.

In our Decision to Institute, we adopted Patent Owner's definition, given the claims recite compositions of propofol in a container. Dec. Inst. 5.

---

[1] Physicians' Desk Reference, Product Identification Guide and Product Information for Diprivan, 341, 2939–45 (1997) ("Diprivan PDR," Ex. 1005).
[2] R. Farinotti, *Interactions physicochimiques et mode de conservation du Diprivan* ® [Physio-Chemical Interactions and Storage of Diprivan®], 13 Ann. Fr. Anesth. Reanim. 453–56 (1994) (Ex. 1006). Citations to Farinotti in this Decision are to the certified translation provided as Ex. 1007.
[3] J.G. van den Heuvel, US 5,383,864, issued Jan. 24, 1995 (Ex. 1010).
[4] Lundren et al., WO 00/12043, published Mar. 9, 2000 (Ex. 1031).

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.