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Paper No. 9
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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, ZHENYU YANG, and TINA E. HULSE, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

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

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.").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the Petition and Preliminary Response, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1, 13–15, 17, 18, 20, and 24–28. Accordingly, we institute an *inter partes* review of those claims.

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, which 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 apparently 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.

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 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 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. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1, 13–15, 17, 18, 20, and 24–28 of the '010 patent on the following grounds:

Reference	Basis	Claim(s) 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

Petitioner also relies on the testimony of Thomas N. Feinberg, Ph.D. Ex. 1002.

II. ANALYSIS

A. Person 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

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[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).

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. Patent Owner largely agrees 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.

At this stage of the proceeding, given the claims recite compositions of propofol in a container, we adopt the level of ordinary skill set forth by Patent Owner and note that the prior art itself also demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (holding the absence of specific findings on "level of skill in the art does not give rise to reversible error 'where the prior art itself reflects an appropriate level and a need for testimony is not shown'") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

B. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 890 (mem.) (2016). Under that standard, and absent any special definitions, we give 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 re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity,

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