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Paper 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 IPR2016-01578
Patent 8,338,470 B1

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

Opinion for the Board filed by *Administrative Patent Judge* SNEDDEN.

Opinion Concurring filed by *Administrative Patent Judge* FITZPATRICK.

SNEDDEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Amneal Pharmaceuticals LLC ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1–7 (Paper 2; "Pet.") of US 8,338,470 B1 (Ex. 1001; "the '470 patent"). Hospira, Inc. ("Patent Owner") filed a Patent Owner Preliminary response. Paper 9 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. We thus institute an *inter partes* review of claims 1–7 of the '470 patent.

A. Related Proceedings

Patent Owner has asserted the '470 patent in *Hospira, Inc. v. Amneal Pharmaceuticals LLC*, No. 1:15-cv-00697 (D. Del.). Pet. 61; Paper 6, 2.

Petitioner has sought *inter partes* review for related patents in the following proceedings: Case IPR2016-01577 (U.S. Patent No. 8,242,158 B2), Case IPR2016-01579 (U.S. Patent No. 8,455,527 B2), and Case IPR2016-01580 (U.S. Patent No. 8,648,106 B2).

B. The '470 patent (Ex. 1001)

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. 13–14.

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

Petitioner supports its challenge with the Declarations of James Cain, MD, MBA, FAAP (Ex. 1002) and Alpaslan Yaman, Ph.D. (Ex. 1003).

II. ANALYSIS

A. Claim Interpretation

We interpret claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs. LLC v. Lee,* 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable construction standard, claim terms are generally given 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) (quoting *Phillips v. AWH Corp*, 415 F.3d 1303, 1312 (Fed. Cir. 2005)).

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

The parties address express constructions for two terms, "dexmedetomidine" and "ready to use," both of which appear in claim 1 and are incorporated by the remainder of the claims of the '470 patent. As set forth below, we determine that no terms require an express construction for purposes of this Decision.

Petitioner proposes an express construction for "dexmedetomidine," to which Patent Owner agrees. Pet. 13; Prelim. Resp. 12. We determine that an express construction for "dexmedetomidine" is unnecessary for the purposes of determining whether to institute an *inter partes* review.

Independent claim 1 recites "[a] ready to use liquid pharmaceutical composition for parenteral administration to a subject." The parties present competing constructions for "ready to use." Petitioner, relying on extrinsic evidence, argues that "ready to use" should be construed such that the composition "requir[es] no further dilution or reconstitution before administration to a patient." Pet. 11 (citing Ex. 1002, ¶¶ 31; Ex. 1003, ¶ 48; Ex. 1044). As Petitioner notes (*see* Pet. 11–12), the '470 patent defines "ready to use" compositions as "premixed compositions that are suitable for administration to a patient without dilution." Ex. 1001, 3:56–63.

The '470 patent further provides:

> The terms "premix" or "premixture" as used herein refers [sic] to a pharmaceutical formulation that does not require reconstitution or dilution prior to administration to a patient. For example, in contrast to non-premixed formulations of dexmedetomidine, the premixed compositions provided herein are suitable for administration to a patient without dilution by, for example, a clinician, hospital personnel, caretaker, patient or any other individual.

Id. at 3:51–58. Patent Owner, noting this additional disclosure, argues that "ready to use" means "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. 9 (emphasis added) (citing Ex. 1001, 3:51–53; 2:65–3:6). Both of the parties' constructions for "ready to use" find support in the specification, as set forth in specification excerpts quoted above. The distinction between the two is whether the composition must be ready-to-use upon manufacture, or if it can become ready-to-use subsequent to its manufacture, including shortly before its administration to a patient. On the record presented, we need not and do not resolve this distinction. That is because, regardless of whether the ready-for-use formulation must be suitable for administration *upon manufacture*, as Patent Owner argues, we determine Petitioner has established a reasonable likelihood that it would prevail in its obviousness challenge. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (instructing that claim terms need only be construed to the extent necessary to resolve the controversy).

B. Prior Art

Petitioner relies upon the following prior art in its challenges.

1. 2010 Precedex Label (Ex. 1007)[7]

The 2010 Precedex Label discloses Precedex™ as the trade name for a formulation of dexmedetomidine hydrochloride. Ex. 1007, 13.

[7] Petitioner asserts that 2010 Precedex Label "was published September 2010." Pet. 15. Patent Owner does not challenge, and based on the current record, we have no reason to doubt, that Precedex Label qualifies as prior art under 35 U.S.C. § 102(b).

Precedex™ is a drug product provided in glass vial at a concentration of 200 µg/2 mL (100 µg/mL). *Id.* at 4. The 2010 Precedex Label discloses that Precedex™ "must be diluted in 0.9% sodium chloride solution to achieve required concentration (4 mcg/mL) prior to administration." *Id.* at 3. The total volume of the disclosed preparation is 50 mL. *Id.*

The 2010 Precedex Label discloses that Precedex™ has a "potential for absorption" when used with some types of natural rubber. *Id.* at 4.

2. Palmgrén (Ex. 1017)

Palmgrén discloses results of experiments on adsorption of drugs, including medetomidine, to various plastic containers. Ex. 1017, Abstract. Palmgrén discloses that medetomidine was "known to interact with PVC and polystyrene plastic" and examined medetomidine performance in glass and polypropylene as compared to modified polystyrene. *Id.* at 370. Palmgrén discloses that

> the loss of basic drugs to polystyrene well plates and [modified polystyrene]-tubes in water was a rapid process. All the drug losses were achieved within the first 15 min (Fig. 2). After 4.5 h, the relative amount remaining in [modified polystyrene] tubes in aqueous solution was 64.7 ± 6.8%, 38.4 ± 9.1%, 31.9 ± 6.7%, and 23.5 ± 6.1% for metoprolol, medetomidine, propranolol, and midazolam, respectively (Table 4) . . . As seen in Table 4, the loss of basic drugs to [modified polystyrene]-plastic was much higher than to glass and PP-tubes.

Ex. 1017, 374.

3. De Giorgi (Ex. 1015)

De Giorgi discloses the results of a study designed to analyze safety risks in injectable medications for patients in the pediatric and neonatal intensive care units. *Id.* at Abstract. De Giorgi discloses the frequency and

severity of thirty different types of medication errors observed in the study. The authors determined that microbial contamination, dosage errors, and dilution errors were among the top errors observed. *Id.* at 173. De Giorgi concludes that "the involvement of a clinical pharmacist and the introduction of ready-to-use syringes for selected drugs have been shown to be the most cost-effective tool" for addressing safety risks in injectable medications. *Id.* at 177.

4. Eichhorn (Ex. 1016)

Eichhorn provides a summary of the discussions at a medication safety conference related to a "new paradigm" to address "persistent problems of medication safety in the operating room." Ex. 1016, 1. Eichhorn discloses different types of medication errors, such as wrong drug or dose or route, and adverse reactions. *Id.* at 4–5. Eichhorn discloses a preference away from "[r]outine provider-prepared medications," and toward "[s]tandardized pre-prepared medication kits by case type." *Id.* at 1. Eichhorn further discloses the concept of "ready-to-use" medications for use "in the operating room . . . that are prepared by outsource specialty companies who do that exclusively" for the purpose of decreasing medication errors in the operating room. *Id.* at 5.

Eichhorn further references a 2008 national consensus conference on the safety of intravenous drug delivery systems and notes that "there was a clear preference for manufacturer prepared completely ready-to-use [intravenous] medication in all settings." *Id.*

5. Lavoisier (Ex. 1018)[8]

Lavoisier is a product sheet for a 0.9% sodium chloride solution as an injectable solution. Ex. 1018, 1. The product sheet discloses various forms of packaging for the product, including glass ampoules at a volume of 2 ml, 5 ml, 10 ml, or 20 ml. *Id.*

C. Ground 3: Obviousness of Claims 1–7 over the Combination of 2010 Precedex Label, De Giorgi, Eichhorn, Palmgrén, and Lavoisier

Petitioner contends that claims 1–7 are rendered obvious by the combined teachings of 2010 Precedex Label, De Giorgi, Eichhorn, Palmgrén, and Lavoisier. Pet. 39–51. Petitioner sets forth the foregoing teachings of 2010 Precedex Label, De Giorgi, Eichhorn, Palmgrén, and Lavoisier and provides a detailed discussion and claim charts explaining how each claim limitation of the challenged claims is disclosed by the combination of references. *Id*. In particular, Petitioner contends that the 2010 Precedex Label discloses "a liquid formulation of dexmedetomidine hydrochloride stored in a glass vial at a concentration of 200 µg/2 mL (100 µg/mL), which is intended for parenteral administration via intravenous infusion." *Id.* at 40 (citing Ex. 1007, Sec. 2.4, Sec. 3, Sec. 11). Petitioner further contends that the 2010 Precedex Label discloses "preparation of a 4

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[8] Lavoisier bears a mark of "DATE OF REVISION June 2009." Ex. 1018, 2. Petitioner appears to rely on that information to support its assertion that Lavoisier qualifies as prior art under 35 U.S.C. § 102(b). Pet. 17. Patent Owner does not challenge, and based on the current record, we have no reason to doubt, the prior-art status of Lavoisier.

μg/mL solution of Precedex for parenteral administration by diluting 2 mL of Precedex in 48 mL of 0.9% sodium chloride injection to a total of 50 mL." *Id.* at 40–41 (citing Ex. 1007, Sec. 2.4).

Petitioner relies on De Giorgi, Eichhorn, and Lavoisier to support their argument that one of skill in the art would have been motivated to prepare ready-to-use (or premixed), diluted solutions of Precedex at the 4 μg/mL concentration as instructed in the 2010 Precedex Label, because "[De Giorgi, Eichhorn, and Lavoisier] establish that, at the time of filing, those of skill in the art recognized the need for and indeed had been advocating for additional standardization of drug preparation methods." *Id.* at 44. For example, with reference to Eichhorn, Petitioner contends as follows:

> Eichhorn reported that a January 26, 2010 consensus conference by the Anesthesia Patient Safety Foundation "to develop new strategies for 'predictable prompt improvement' of medication safety in the operating room," recommended that "[r]outine provider-prepared medications should be discontinued whenever possible. … [and s]tandardized pre-prepared medication kits by case type should be used whenever possible." Ex. 1016, p. 1. Eichhorn also referred to "a 2008 national consensus conference on the safety of intravenous drug delivery systems, [where] there was a clear preference for manufacturer-prepared completely ready-to-use IV medication in all settings." *Id*., p. 5.

Id. at 45 (bracketed material and ellipses added by Petitioner).[9]

With reference to Lavoisier, Petitioner contends that 0.9% sodium chloride solutions were routinely available in sealed glass containers for use as an injectable solution. *Id.* at 45 (citing Ex. 1018; Ex. 1003 ¶ 90).

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[9] A manufacturer-prepared composition would fall within the scope of a "ready to use" composition under the claim construction proposed by either Petitioner or Patent Owner. Pet. 11–13; Prelim. Resp. 9–12.

Petitioner further contends that "[De Giorgi] disclosed the benefits of avoiding microbial contamination by using pre-prepared medications packaged in sterile, sealed glass containers." *Id.* at 46 (citing Ex. 1015, Abstract).

With regard to the limitation of claim 1 requiring the recited composition to be "disposed within a sealed glass container," Petitioner argues as follows:

> First, the 2010 Precedex Label disclosed that Precedex has a "potential for absorption" when used with some types of natural rubber. Ex. 1007, Sec. 206, ll. 203-206. Second, Palmgren (Ex. 1017), disclosed that it was well known in the art that medetomidine, a racemic mixture containing dexmedetomidine, interacts with plastics found in infusion bags (e.g., PVC) and intravenous tubing, which can lead to drug loss and treatment failure. Ex. 1017, p. 370. Accordingly, a POSA would have a reasoned basis for using a sealed glass container when formulating dexmedetomidine solutions because both Palmgren and the Precedex 2010 Label disclosed the use and suitability of glass containers to do so, and also because doing so would avoid potentially adverse interactions with other materials. Ex. 1003, ¶¶ 52–63.

Pet. 41–42; *see also id.* at 46 ("Palmgren disclosed the advantages of resistance to drug loss by using sealed glass containers (Ex. 1017, pp. 374-376).").

Patent Owner argues that 2010 Precedex Label does not disclose a ready to use dexmedetomidine composition and that "[t]he addition of [De] Giorgi, Eichhorn, and Lavoisier to this combination cannot remedy this deficiency." Prelim. Resp. 52. Patent Owner supports this position arguing 1) that "[De] Giorgi does not disclose the use of sealed glass containers" and "failed to provide any motivation to formulate a ready to use

dexmedetomidine composition at the claimed concentrations disposed within a sealed glass container" (*id.* at 52–54), and 2) that Eichhorn does not disclose the use of sealed glass containers, does not mention dexmedetomidine specifically, and does not provide a clear motivation to prepare a ready to use dexmedetomidine composition in a sealed glass containers (*id.* at 55–56).

We do not find these arguments persuasive. "Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Thus, it follows that Petitioner's obviousness challenge cannot be rebutted by individually attacking the relied-upon combined teachings. A reference "must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole." *Id.* With regard to the "sealed glass container" limitation, Petitioner persuasively argues that "a POSA would have a reasoned basis for using a sealed glass container when formulating dexmedetomidine solutions because both Palmgren and the Precedex 2010 Label disclosed the use and suitability of glass containers to do so, and also because doing so would avoid potentially adverse interactions with other materials." Pet. 41–42 (citing Ex. 1003 ¶¶ 52–63; Ex. 1007, Sec. 206; Ex. 1017, 370).

Petitioner relies on De Giorgi to establish that it was known that microbial contamination and dilution errors were both common and that "using ready-to-use injectable drugs, such as vancomycin syringes, offers a safe alternative to reduce both microbiological contamination and dilution errors." Pet. 16 (citing Ex. 1015, 176). Eichhorn is relied on for its disclosure of strategies to improve medication safety and its

recommendation that "[r]outine provider-prepared medications should be discontinued whenever possible. … [and s]tandardized pre-prepared medication kits by case type should be used whenever possible." Pet. 45 (quoting Ex. 1016, 1 (bracketed material and ellipses added by Petitioner)). On the current record, we find these disclosures relevant to the issue of whether a person of ordinary skill in the art would have been motivated to modify the disclosures of 2010 Precedex Label and Palmgrén to arrive at the invention of the challenged claims.

Patent Owner argues a person of ordinary skill in the art would have faced difficulties in modifying 2010 Precedex Label and Palmgrén to arrive at the composition of the challenged claims. For example, Patent Owner argues that "[De] Giorgi analyzed about 60 different injectable drugs in total . . . , but importantly, estimated that only '15 drugs could be provided in ready to use syringes (CIVAS).'" Prelim. Resp. 54 (citing Ex. 1015, 171–72). Patent Owner further argues that "Eichhorn offers an array of strategies to address medication safety concerns," and that, while

> Eichhorn acknowledges "a clear preference for manufacturer-prepared completely ready-to-use IV medication in all settings," [Eichhorn] cited "increased cost and potential inapplicability" as drawbacks of this preference. Ex. 1016, p. 5. Thus, Eichhorn acknowledges that this approach is not feasible for all drugs.

Id. at 56.

With reference to Lavoisier, Patent Owner further argues as follows:

> Lavoisier taught that "[w]hen a drug is added to this solution, **admixture should be dispensed instantly**." Ex. 1018, p. 1 (emphasis added). As such, this reference explicitly teaches away from adding a drug to the sodium chloride solution and

> storing the resulting admixture in the containers provided by Lavoisier . . . .
>
> Petitioner argues that 0.9% sodium chloride solution is routinely used in the industry because 0.9% sodium chloride is an isotonic solution suitable for formulation of parenteral drugs. Pet., p. 47. However, at the time of the invention, it was not predictable or expected that dexmedetomidine could be formulated with 0.9% sodium chloride solution at the claimed concentrations in a ready to use composition. In particular, it was not expected that dexmedetomidine could be formulated in a stable form that was ready to use upon manufacture at concentrations lower than 100 μg/mL. Rather, the McCormick FDA Memorandum taught that the concentrated form of dexmedetomidine "is prepared for use by diluting it with sterile 0.9% sodium chloride solution for injection after which it is stable for 24 hours" (Ex. 1013, p. 8), and the Rappaport FDA Memorandum further cautioned that administration of dexmedetomidine for greater than 24 hours cannot be recommended without "appropriate studies to assure persistent effectiveness." Ex. 1019, p. 29.

Id. at 58–59.

Upon consideration of the arguments presented and evidence of record, we find that Petitioner has offered sufficient evidence to institute trial, and Patent Owner's arguments do not persuade us that we should decline to go forward with a trial. We determine that Petitioner has demonstrated a reasonable likelihood that claims 1–7 would have been obvious over the teachings of 2010 Precedex Label, De Giorgi, Eichhorn, Palmgrén, and Lavoisier.

D. Petitioner's Remaining Grounds

Petitioner asserts that the subject matter of claims 1–7 would have been obvious in view of the combination of references set forth in Grounds 1 and 2. Pet. 18–38. In view of our instituting an *inter partes* review of all of

these claims on another ground, as set forth above, we deny institution on these additional grounds. *See* 37 C.F.R. § 42.108(a)-(b).

III. CONCLUSION

We conclude that Petitioner has established a reasonable likelihood of prevailing on its assertions that claims 1–7 of the '470 patent are unpatentable as obvious.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term. Thus, our view with regard to any conclusion reached in the foregoing could change upon consideration of Patent Owner's merits response and upon completion of the record.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is granted with regard to the following asserted ground: obviousness of claims 1–7 of the '470 patent over the combination of 2010 Precedex Label, De Giorgi, Eichhorn, Palmgrén, and Lavoisier.

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '470 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

FURTHER ORDERED that the trial is limited to the ground listed in the Order. No other grounds are authorized.

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Case IPR2016-01579
Patent 8,455,527 B1

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

FITZPATRICK, *Administrative Patent Judge*, concurring.

In light of Petitioner's evidence in support of a legal conclusion that the subject matter of the challenged claims would have been obvious even under Patent Owner's construction of the claims and, in particular, of the term "ready to use," the Board's Opinion does not construe fully the term "ready to use."

Nonetheless, I would construe the term in Petitioner's favor, as referring to "premixed compositions that are suitable for administration to a patient without dilution, such that they do not require reconstitution or

dilution prior to administration to a patient." *See* Ex. 1001, 3:51–53, 3:60–62.

Patent Owner's proposed construction—"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" (*see* Prelim. Resp. 9)—oversteps in reading additional features into the claim that the specification describes as exemplary only. *See* Ex. 1001, 3:53–58 ("*For example*, in contrast to non-premixed formulations of dexmedetomidine, the premixed compositions provided herein are suitable for administration to a patient without dilution by, *for example*, a clinician, hospital personnel, caretaker, patient or any other individual." (emphasis added)).

If, during the *inter partes* review, Patent Owner reargues its construction of "ready to use," it should additionally argue how that construction would affect patentability. Under Patent Owner's construction, I would interpret claim 1 as a product-by-process claim. In which case, for patentability purposes, it likely would not matter how, when, or by whom the composition was made. *See In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) ("The patentability of a product does not depend on its method of production.").

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