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Paper 11
Date: 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 IPR2016-01579
Patent 8,455,527 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
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner, Amneal Pharmaceuticals LLC, filed a Petition to institute an *inter partes* review of claims 1–11 and 13 of U.S. Patent No. 8,455,527 B1 (Ex. 1001, "the '527 patent") pursuant to 35 U.S.C. § 311(a). Paper 2 ("Pet."). Patent Owner, Hospira Inc., filed a Preliminary Response under 35 U.S.C. § 313. Paper 9 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). Upon consideration of the Petition and Preliminary Response, and for the reasons explained below, we determine that the information presented shows a reasonable likelihood that Petitioner would prevail with respect to at least one claim challenged in the Petition. *See* 35 U.S.C. § 314(a); 37 C.F.R § 42.108. We institute an *inter partes* review of all challenged claims.

A. Related Matters

Patent Owner has asserted the '527 patent in *Hospira, Inc. v. Amneal Pharmaceuticals LLC*, No. l:15-cv-00697 (D. Del.). Pet. 67; Paper 6, 2.

Petitioner has filed petitions for *inter partes* reviews of U.S. Patent Nos. 8,338,470 B1, 8,242,158 B1, and 8,648,106 B2, which are related to the '527 patent. Pet. 67; Paper 6, 2; *see also* Cases IPR2016-01578, IPR2016-01577, IPR2016-01580.

B. The '527 Patent

4-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole is known shorthand as medetomidine. Ex. 1001, 1:24–25. It is a racemic mixture of two

enantiomers: levomedetomidine and dexmedetomidine. *Id*.; Ex. 2005 ¶25.[1] The '527 patent focuses on the latter enantiomer, dexmedetomidine, and "relates to 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 1:17–20.

The '527 patent acknowledges that, before the claimed invention, both medetomidine and dexmedetomidine were known to be α_2-adrenoceptor agonists and used as antihypertensive, sedative, and analgesic agents. *Id*. at 1:26–47. The '527 patent also acknowledges prior patents disclosing medical administration of dexmedetomidine, including via epidural, parenteral, intravenous, oral, hypodermic, and transmucosal routes. *Id*. at 1:32–57 (citing various U.S. patents).

C. The Challenged Claims

Of the challenged claims, claim 1 is independent. It is illustrative and reproduced below.

> 1. A method of providing sedation to a patient in need thereof, the method comprising administering to the patient an effective amount of a composition, wherein the composition comprises dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 0.005 to about 50 μg/mL, wherein the composition is a ready to use liquid pharmaceutical composition for parenteral administration to the patient disposed within a sealed glass container.

D. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

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[1] Exhibit 2005 is a declaration by Robert Linhardt, Ph.D.

References	Basis	Claims
2010 Precedex Label (Ex. 1007)[2] and Palmgren (Ex. 1017)[3]	§ 103(a)[4]	1–11 and 13
Aantaa (Ex. 1006),[5] 2010 Precedex Label, and Palmgren	§ 103(a)	1–11 and 13
2010 Precedex Label, De Giorgi (Ex. 1015),[6] Eichhorn (Ex. 1016),[7] Palmgren, and Lavoisier (Ex. 1018)[8]	§ 103(a)	1–11 and 13

Pet. 11.

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[2] The 2010 Precedex Label is the FDA label for approved use of precedex, the commercial or brand name for dexmedetomidine-HCl. Ex. 1007, [7].
[3] Palmgren, 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).
[4] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, which was enacted September 16, 2011, made amendments to 35 U.S.C. §§ 102 and 103. AIA § 3(b)–(c). Those amendments became effective eighteen months later on March 16, 2013. *Id*. at § 3(n). Because the application from which the '527 patent issued was filed before March 16, 2013, our citations to 35 U.S.C. §§ 102 and 103 are to their pre-AIA versions.
[5] U.S. Patent No. 6,716,867 B1, issued April 6, 2004.
[6] 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).
[7] 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 FOUNDATION 1, 3–8 (Spring 2010).
[8] Lavoisier product sheet for NaCl 0.9% injectable solution (June 2009).

II. ANALYSIS

A. Claim Construction

"A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). Pursuant to that standard, the claim language should be read in light of the specification, as it would be interpreted by one of ordinary skill in the art. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Thus, we generally give claim terms their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning 'is the meaning that the term would have to a person of ordinary skill in the art in question.'" (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc))). A patentee, however, may rebut this presumption by acting as his own lexicographer, providing a definition of the term in the specification with "reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

The parties address express constructions for two limitations, "dexmedetomidine" and "ready to use," both of which appear in claim 1 and are incorporated by the remainder of the claims of the '527 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. 10; Prelim. Resp. 12. The construction, however, is unnecessary as the plain and ordinary meaning of the term is

readily apparent.

Independent claim 1 recites "wherein the composition is a ready to use liquid pharmaceutical composition for parenteral administration to the patient disposed within a sealed glass container." The parties present competing constructions for "ready to use." Petitioner 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. 10. As Petitioner notes (*see* Pet. 9–10), the '527 patent defines "ready to use" compositions as "premixed compositions that are suitable for administration to a patient without dilution." Ex. 1001, 3:60–62.

The '527 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 (citing Ex. 1001, 3:51–58 (emphasis added)). 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. Obviousness over 2010 Precedex Label, De Giorgi, Eichhorn, Palmgren, and Lavoisier

In assessing obviousness, "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).[9]

[9] Additionally, secondary considerations such as "commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy." *Graham*, 383 U.S. at 17–18. In its Preliminary Response, however, Patent Owner does not argue that any secondary considerations evidence supports non-obviousness of the challenged claims.

1. 2010 Precedex Label (Ex. 1007)[10]

The 2010 Precedex Label is a drug label for Food and Drug Administration-approved "Precedex (dexmedetomidine hydrochloride) injection." Ex. 1007, l. 7. It discloses Precedex "[f]or intravenous infusion following dilution." *Id*. at l. 8.

Precedex is supplied in 2mL glass vials at a concentration of 100 mcg/mL, which are "[s]tore[d] at controlled room temperature, 25°C (77°F) with excursions allowed from 15 to 30°C (59 to 86°F)." *Id*. at ll. 698–701. The drug "must be diluted in 0.9% sodium chloride solution to achieve required concentration (4 mcg/mL) prior to administration." *Id*. at ll. 175–76.

2. Palmgren (Ex. 1017)

Palmgren discloses results of experiments on adsorption of certain acidic and basic drugs to various containers. Ex. 1017, Abstract. Palmgren reported that loss in basic drugs, including medetomidine, to polystyrene and polycarbonate was much higher than to glass and polypropylene tubes. *Id.* at 374.

3. De Giorgi (Ex. 1015)

De Giorgi discloses the results of a study designed to analyze safety

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[10] The 2010 Precedex Label bears a mark showing "Revised: 09/2010." Ex. 1007, l. 81. Petitioner appears to rely on that information to support its assertion that the 2010 Precedex Label was "published in September 2010." Pet. 12. Patent Owner does not challenge the assertion, and based on the current record, we have no reason to doubt, that the 2010 Precedex Label qualifies as prior art under 35 U.S.C. § 102(b).

risks in injectable medications for patients in the pediatric and neonatal intensive care units. Ex. 1015, 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, 3. 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 also 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.* at 5.

5. Lavoisier (Ex. 1018)[11]

Lavoisier is a product sheet for a 0.9% sodium chloride (NaCl) injectable solution. Ex. 1018, 1. Lavoisier 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.*

6. Application of the Prior Art to the Challenged Claims

Petitioner contends that claims 1–11 and 13 would have been obvious in view of 2010 Precedex Label, De Giorgi, Eichhorn, Palmgren, and Lavoisier. Pet. 11. Petitioner sets forth the foregoing teachings of these references and provides a detailed discussion and claim charts explaining how each claim limitation of the challenged claims is disclosed by the combination of references. Pet. 45–59. 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 46 (citing Ex. 1007, ll. 175–84, 207–08, 457). Petitioner further contends that the 2010 Precedex Label discloses "preparation of a 4 μg/mL solution of Precedex for parenteral administration by diluting 2 mL of Precedex in 48 mL of 0.9% sodium chloride injection to

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[11] The document 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. 14–15 (citing Ex. 1018, 2). Patent Owner does not challenge the assertion, and based on the current record, we have no reason to doubt, the prior-art status of Lavoisier.

a total of 50 mL." *Id.* at 47 (citing Ex. 1007, ll. 175–84).

Petitioner relies on De Giorgi, Eichhorn, and Lavoisier to support its 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, and indeed had been advocating for, additional standardization of drug preparation methods." *Id.* at 49. For example, with reference to Eichhorn, Petitioner states the following:

> 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 49–50 (bracketed material and ellipses added by Petitioner).

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 50 (citing Ex. 1018; Ex. 1003 ¶79). 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 51 (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 relies in part on Palmgren, arguing the following:

> 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, ¶¶53–57.

Pet. 47–48; *see also id.* at 51 ("Palmgren disclosed the advantages of resistance to drug loss by using sealed glass containers." (citing Ex. 1017, 374–76)).

Patent Owner argues that "the 2010 [Precedex] Label and Palmgren, whether taken alone or in combination, do not disclose or suggest a ready to use composition at the claimed concentrations disposed in a sealed glass container" and that "[t]he addition of [De] Giorgi, Eichhorn, and Lavoisier to this combination cannot remedy this deficiency." Prelim. Resp. 53. We disagree.

The 2010 Precedex Label alone teaches almost the entire subject matter of claim 1, by virtue of its disclosing (1) a composition of dexmedetomidine disposed within a sealed glass container, albeit not one that is ready-to-use (Ex. 1007, ll. 698–99); and (2) diluting it into a ready-to-use composition of dexmedetomidine, albeit not one that is disposed within

a sealed glass container (*id*. at ll. 175–84). Petitioner relies on the additional references to show why a person of ordinary skill in the art would have manufactured ready-to-use compositions of dexmedetomidine and contained them in sealed glass containers such that no further dilution or reconstitution would be necessary at a healthcare facility. Pet. 48–51.

Patent Owner also argues patentability by attacking Petitioner's relied-upon references individually. For example, Patent Owner argues that De Giorgi and Eichhorn "do not relate specifically to dexmedetomidine" and do "not disclose the use of sealed glass containers." Prelim. Resp. 51, 56. Patent Owner also argues that "Lavoisier teaches only that an isotonic solution of 0.9% sodium chloride can be disposed within a sealed glass container." Prelim. Resp. 51. These and similar Patent Owner arguments do not rebut Petitioner's ground of unpatentability, which is based on the combined teachings of multiple references. *Cf. In re Merck & Co*., 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references."). A reference "must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole." *Id.*

Patent Owner also argues a person of ordinary skill in the art would have faced difficulties in, or be taught away from, modifying the prior art teachings to arrive at a composition within the scope 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'." Prelim.

Resp. 55 (citing Ex. 1015, 171–72). With respect to Eichhorn, Patent Owner further argues the following:

> Eichhorn acknowledges "a clear preference for manufacturer-prepared completely ready-to-use IV medication in all settings," but 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 57. With reference to Lavoisier, Patent Owner argues the following:

> 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 . . . .

Id. at 59. None of these arguments, or the cited evidence, sufficiently demonstrates a teaching away from the claimed invention to avoid trial. Rather, upon consideration of the arguments and evidence presented by both sides,[12] we find that Petitioner has demonstrated a reasonable likelihood of prevailing in showing that claims 1–11 and 13 would have been obvious over the teachings of the 2010 Precedex Label, De Giorgi, Eichhorn, Palmgren, and Lavoisier.

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[12] *See, e.g., Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) ("As with other subsidiary obviousness inquiries, what a reference teaches and whether it teaches toward or away from the claimed invention are questions of fact. However, obviousness must be determined in light of all the facts[.]" (brackets, quotation marks, and internal citation omitted)).

C. Petitioner's Other Grounds

Petitioner asserts that the subject matter of claims 1–11 and 13 also would have been obvious in view of: (1) the 2010 Precedex Label and Palmgren; and (2) Aantaa, the 2010 Precedex Label, and Palmgren. Pet. 11. In view of our instituting an *inter partes* review of all of these claims on the ground discussed above, we deny institution on these additional grounds. *See* 37 C.F.R. § 42.108(a)–(b).

III. CONCLUSION

We have considered the information presented in the Petition and Preliminary Response and determine that there is a reasonable likelihood that Petitioner would prevail with respect to all claims challenged in the Petition.

IV. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review of U.S. Patent No. 8,455,527 B1 is hereby instituted on the ground that claims 1–11 and 13 are asserted to be unpatentable under 35 U.S.C. § 103(a) as obvious over 2010 Precedex Label, De Giorgi, Eichhorn, Palmgren, and Lavoisier;

FURTHER ORDERED that no other ground of unpatentability alleged in the Petition for any claim is authorized for this *inter partes* review; and

FURTHER ORDERED that 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; the trial

commences on the entry date of this Decision.

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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 limitation "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 limitation 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 the recited "ready to use liquid pharmaceutical composition" of claim 1 as a product-by-process limitation. 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.").

The methods of the challenged claims require only one step: "administering to the patient an effective amount of a composition." Patent Owner could have included additional steps in its claimed methods specifying a process for making the composition. It did not.

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