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In re Patent Application of: Roychowdhury *et al.*		Examiner	To Be Assigned
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For: METHODS OF TREATMENT USING A DEXMEDETOMIDINE PREMIX FORMULATION

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Sir:

This accelerated examination support document is provided in support of the petition for accelerated examination filed herewith and the application filed herewith under 35 U.S.C. § 111(a).

Identification of the Limitations of the Claims Disclosed by the Cited References begins on page 2 of this paper.

Detailed Explanation of Patentability begins on Page 44 of this paper.

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Identification of the Limitations of the Claims Disclosed by the Cited References:

1. "Dexmedetomidine HCL Draft Labeling: Precedex™ Dexmedetomidine Hydrochloride Injection," FDA approved label, dated December 17, 1999, and available online July 26, 2001, pages 1-13. ("the Precedex™ label").

a. Independent Claim 1

A method of providing sedation to a patient in need thereof, the method comprising

The Precedex™ label discloses a method of providing sedation to a patient in need thereof (p. 1, ¶3; p. 6, ¶4).

Independent claim 1 is not anticipated by the Precedex™ label because the Precedex™ label fails to disclose or suggest a ready to use liquid pharmaceutical composition. The Precedex™ label discloses dexmedetomidine hydrochloride at a concentration of 100 µg/mL disposed within 2 mL clear glass vials and 2 mL ampoules. In contrast to claim 1, which is directed to a 0.005 to about 50 µg/mL dexmedetomidine composition disposed within a sealed glass container that is formulated as a ready to use liquid pharmaceutical composition for administration to a subject upon removal from the sealed glass container, the dexmedetomidine composition of the Precedex™ label must be removed from the 2 mL vial or ampoule and diluted to a concentration of 4 µg/mL prior to administration to a subject (p. 12, ¶6-¶8; p. 13, ¶5-¶6).

administering to the patient an effective amount of a composition, wherein the compostion ccomprises dexmedetomidine or a pharmaceutically acceptable salt thereof

The Precedex™ label discloses administering to a patient an effective amount of a composition, wherein the compostion comprises dexmedetomidine or a pharmaceutically acceptable salt thereof (p. 1, ¶1-¶2; p. 6, ¶4; p. 12, ¶2-¶3; p. 13, ¶5).

Independent claim 1 is not anticipated by the Precedex™ label because the Precedex™ label fails to disclose or suggest a ready to use liquid pharmaceutical composition. The Precedex™ label discloses dexmedetomidine hydrochloride at a concentration of 100 µg/mL disposed within 2 mL clear glass vials and 2 mL ampoules. In contrast to claim 1, which is directed to a 0.005 to about 50 µg/mL dexmedetomidine composition disposed within a sealed glass container that is formulated as a ready to use liquid pharmaceutical composition for administration to a subject upon removal from the sealed glass container, the dexmedetomidine

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composition of the Precedex™ label must be removed from the 2 mL vial or ampoule and diluted to a concentration of 4 µg/mL prior to administration to a subject (p. 12, ¶6-¶8; p. 13, ¶5-¶6).

at a concentration of about 0.005 to about 50 µg/mL,

The Precedex™ label discloses a pharmaceutical composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof, wherein the dexmedetomidine is present at a concentration of about 4 µg/mL (p. 12, ¶6-¶8; p. 13, ¶5-¶6).

Independent claim 1 is not anticipated by the Precedex™ label because the Precedex™ label fails to disclose or suggest 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. The Precedex™ label discloses dexmedetomidine hydrochloride at a concentration of 100 µg/mL disposed within 2 mL clear glass vials and 2 mL ampoules. In contrast to claim 1, which is directed to a 0.005 to about 50 µg/mL dexmedetomidine composition disposed within a sealed glass container that is formulated as a ready to use liquid pharmaceutical composition for administration to a subject upon removal from the sealed glass container, the dexmedetomidine composition of the Precedex™ label must be removed from the 2 mL vial or ampoule and diluted to a concentration of 4 µg/mL prior to administration to a subject (p. 12, ¶6-¶8; p. 13, ¶5-¶6).

wherein the composition is a ready to use liquid pharmaceutical composition for parenteral administration to the patient

The Precedex™ label discloses a liquid pharmaceutical composition for parenteral administration to a patient (p. 1, ¶1-¶2; p. 6, ¶4; p. 12, ¶2-¶3).

Independent claim 1 is not anticipated by the Precedex™ label because the Precedex™ label fails to disclose or suggest a ready to use liquid pharmaceutical composition. The Precedex™ label discloses dexmedetomidine hydrochloride at a concentration of 100 µg/mL disposed within 2 mL clear glass vials and 2 mL ampoules. In contrast to claim 1, which is directed to a 0.005 to about 50 µg/mL dexmedetomidine composition disposed within a sealed glass container that is formulated as a ready to use liquid pharmaceutical composition for administration to a subject upon removal from the sealed glass container, the dexmedetomidine composition of the Precedex™ label must be removed from the 2 mL vial or ampoule and

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diluted to a concentration of 4 µg/mL prior to administration to a subject (p. 12, ¶6-¶8; p. 13, ¶5-¶6).

disposed within a sealed glass container.

The Precedex™ label discloses a pharmaceutical composition wherein the composition is disposed within a sealed glass container (p. 13, ¶5-¶6).

Independent claim 1 is not anticipated by the Precedex™ label because the Precedex™ label fails to disclose or suggest 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. The Precedex™ label discloses dexmedetomidine hydrochloride at a concentration of 100 µg/mL disposed within 2 mL clear glass vials and 2 mL ampoules. In contrast to claim 1, which is directed to a 0.005 to about 50 µg/mL dexmedetomidine composition disposed within a sealed glass container that is formulated as a ready to use liquid pharmaceutical composition for administration to a subject upon removal from the sealed glass container, the dexmedetomidine composition of the Precedex™ label must be removed from the 2 mL vial or ampoule and diluted to a concentration of 4 µg/mL prior to administration to a subject (p. 12, ¶6-¶8; p. 13, ¶5-¶6).

b. Dependent Claim 2

The method of claim 1, wherein the dexmedetomidine or pharmaceutically acceptable salt thereof is at a concentration of about 0.05 to about 15 ug/mL.

The Precedex™ label discloses a pharmaceutical composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof, wherein the dexmedetomidine is present at a concentration of about 4 µg/mL (p. 12, ¶6-¶8; p. 13, ¶5-¶6).

Claim 2 is not anticipated by the Precedex™ label for at least the reason discussed with respect to claim 1. For example, the Precedex™ label fails to disclose or suggest 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 0.05 to about 15 µg/mL disposed within a sealed glass container. The Precedex™ label discloses dexmedetomidine hydrochloride at a concentration of 100 µg/mL disposed within 2 mL clear glass vials and 2 mL ampoules. In contrast to claim 2, which is directed to a 0.05 to about 15 µg/mL dexmedetomidine composition disposed within a sealed glass container that is formulated

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as a ready to use liquid pharmaceutical composition for administration to a subject upon removal from the sealed glass container, the dexmedetomidine composition of the Precedex™ label must be removed from the 2 mL vial or ampoule and diluted to a concentration of 4 µg/mL prior to administration to a subject (p. 12, ¶6-¶8; p. 13, ¶5-¶6).

c. Dependent Claim 3

The method of claim 1, wherein the dexmedetomidine or pharmaceutically acceptable salt thereof is at a concentration of about 0.5 to about 10 ug/mL.

The Precedex™ label discloses a pharmaceutical composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof, wherein the dexmedetomidine is present at a concentration of about 4 µg/mL (p. 12, ¶6-¶8; p. 13, ¶5-¶6).

Claim 3 is not anticipated by the Precedex™ label for at least the reason discussed with respect to claim 1. For example, the Precedex™ label fails to disclose or suggest 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 0.5 to about 10 µg/mL disposed within a sealed glass container. The Precedex™ label discloses dexmedetomidine hydrochloride at a concentration of 100 µg/mL disposed within 2 mL clear glass vials and 2 mL ampoules. In contrast to claim 3, which is directed to a 0.5 to about 10 µg/mL dexmedetomidine composition disposed within a sealed glass container that is formulated as a ready to use liquid pharmaceutical composition for administration to a subject upon removal from the sealed glass container, the dexmedetomidine composition of the Precedex™ label must be removed from the 2 mL vial or ampoule and diluted to a concentration of 4 µg/mL prior to administration to a subject (p. 12, ¶6-¶8; p. 13, ¶5-¶6).

d. Dependent Claim 4

The method of claim 1, wherein the dexmedetomidine or pharmaceutically acceptable salt thereof is at a concentration of about 1 to about 7 ug/mL.

The Precedex™ label discloses a pharmaceutical composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof, wherein the dexmedetomidine is present at a concentration of about 4 µg/mL (p. 12, ¶6-¶8; p. 13, ¶5-¶6).

Claim 4 is not anticipated by the Precedex™ label for at least the reason discussed with respect to claim 1. For example, the Precedex™ label fails to disclose or suggest a ready to use liquid pharmaceutical composition for parenteral administration to a subject, comprising

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