IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Roychowdhury *et al.*	)	Examiner	To Be Assigned
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For: DEXMEDETOMIDINE PREMIX FORMULATION

ACCELERATED EXAMINATION SUPPORT DOCUMENT

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Sir:

This Accelerated Examination Support Document is provided in support of the Petition for Accelerated Examination and application filed herewith under 35 U.S.C. § 111(a).

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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 ready to use liquid pharmaceutical composition

The Precedex™ label discloses a liquid pharmaceutical composition (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 diluted to a concentration of 4 µg/mL prior to administration to a subject (p. 12, ¶6-¶8; p. 13, ¶5-¶6).

for parenteral administration to a subject, comprising

The Precedex™ label discloses a pharmaceutical composition wherein the composition is formulated as a liquid for parenteral administration to a subject (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 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).

dexmedetomidine or a pharmaceutically acceptable salt thereof

The Precedex™ label discloses a pharmaceutical composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof (p. 1, ¶1-¶2; 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 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).

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).

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 ready to use liquid pharmaceutical composition 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 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 ready to use liquid pharmaceutical composition 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 ready to use liquid pharmaceutical composition 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

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