IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	: Roychowdhury *et al.*	Customer No.	: 62965
Serial No.	: 13/343,672	Confirmation No.	: 3876
Filed	: January 4, 2012	Group Art Unit	: 1629
Examiner	: Polansky, Gregg		
For	: DEXMEDETOMIDINE PREMIX FORMULATION		

RESPONSE TO OFFICE ACTION AND

STATEMENT OF THE SUBSTANCE OF THE INTERVIEW

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated February 13, 2012, Applicants request consideration of the following amendments and remarks. Applicants believe no fee is due. However, if any fee is required in connection with this communication, or if any overpayment has been made, please charge any deficiency or credit any overpayment made, to Deposit Account No. 02-4377.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 3 of this paper.

AMENDMENTS TO THE CLAIMS

The listing of claims provided below will replace all prior versions, and listings, of claims in the application.

1. (Currently amended) A pharmaceutical composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 4 μg/mL, wherein the composition is formulated as a liquid for parenteral administration to a subject, and wherein the composition is disposed within a sealed glass container as a ready to use premixture.

2. (Original) The pharmaceutical composition of claim 1, further comprising sodium chloride at a concentration of between about 0.01 and about 2.0 weight percent.

3. (Original) The pharmaceutical composition of claim 2, wherein the sodium chloride is present at a concentration of about 0.9 weight percent.

4. (Original) The pharmaceutical composition of claim 1, wherein the composition is formulated as a total volume selected from the group consisting of 20 mL, 50 mL and 100 mL.

REMARKS

Reconsideration is respectfully requested. Claim 1 is amended to recite sealed glass container and a ready to use premixture. The amendments to claim 1 are fully supported by the claims as originally filed and by the specification, including for example, at page 5, paragraph [0025]; and page 13, paragraph [0060] of the application. Accordingly, Claims 1-4 remain currently pending. The amendments to claim 1 do not constitute new matter.

I. Statement of the Substance of the Interview

In accordance with 37 C.F.R. § 1.2 and M.P.E.P. § 713.04, Applicants respectfully submit this Statement of the Substance of the Interview in reply to the Interview Summary mailed on March 6, 2012, for the above referenced patent application.

Applicants acknowledge with appreciation the courtesy extended by Examiner Gregg Polansky and Primary Examiner James Anderson during the telephone interview on February 28, 2012 with Dennis Bissonnette, Sandra Lee and Jennifer Flory, and for their careful consideration of this application and claims. Applicants have received and reviewed the Interview Summary, and provide the following statements to supplement and clarify the summary provided by the Examiners.

As evident from the Interview Summary, the pending claims were discussed in view of the rejections of record under 35 U.S.C. §§ 102(b) and 103(a). Specifically, the reference "Dexmedetomidine HCL Draft Labeling: Precedex™ Dexmedetomidine Hydrochloride Injection," FDA approved label (dated December 17, 1999, and available online July 26, 2001, pages 1-13) cited in the rejections of record was discussed.

Although no consensus was reached, Applicants noted that the claims are directed to a composition comprising 4 µg/mL dexmedetomidine that is a premixture, which does not require dilution prior to administration to a subject. The claimed composition differs from the formulation described by the cited reference, which requires dilution to a concentration of 4 µg/mL dexmedetomidine prior to administration to a patient. As such, Applicants maintained that unlike the claimed composition, the formulation disclosed by the cited reference is not a ready to use premixture.

II. Rejection Under 35 U.S.C. § 102(b)

Claims 1-4 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by "Dexmedetomidine HCL Draft Labeling: Precedex™ Dexmedetomidine Hydrochloride Injection," FDA approved label (dated December 17, 1999, and available online July 26, 2001, pages 1-13) (hereafter, "the Draft Labeling"). According to the Examiner, the Draft Labeling discloses a composition comprising a hydrochloride (HCl) salt of dexmedetomidine (Precedex) that is formulated as a sterile aqueous liquid (in 0.9% NaCl solution) for intravenous infusion (*i.e.*, parenteral administration) to a patient, wherein the dexmedetomidine HCl is present at a concentration of 118 µg/mL (which corresponds to 100 µg/mL dexmedetomidine). According to the Examiner, the Draft Labeling discloses that prior to administration to a patient, the formulation is diluted with 0.9% NaCl solution to achieve a 4 µg/mL dexmedetomidine formulation in a total volume of 50 mL. The Examiner further alleges that the dilution step would be performed in either a sealed or unsealed container. The Examiner states that in order to maintain the sterility of the composition for parenteral administration, an artisan of ordinary skill would have diluted the composition in a sealed container. Accordingly, the Examiner contends that the diluted composition describes all the elements of the claims.

Applicants respectfully traverse the rejection. Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. See M.P.E.P. § 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Every element of the claimed invention must literally be present and arranged as in the claim. *Perkin Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed. Cir. 1984).

Independent claim 1 is hereby amended to recite a pharmaceutical composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 4 µg/mL, wherein the composition is disposed within a sealed glass container as a ready to use premixture. The claims are not anticipated by the Draft Labeling because the reference does not disclose all the elements of the claims. For example, the Draft Labeling does not disclose a composition comprising about 4 µg/mL dexmedetomidine, or a pharmaceutically acceptable salt thereof, wherein the composition is disposed within a sealed glass container as a ready to use premixture.

With regard to the claims' recitation that the composition is disposed within a sealed container, the Examiner states that the 100 µg/mL composition of the Draft Labeling could only be diluted in either a sealed or an unsealed container. Applicants note that the Draft Labeling is silent regarding any dilution container. The Examiner relies on *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978), as supporting the contention that the claim element of a "sealed container" is anticipated by the cited reference because the reference allegedly discloses a genus of container with only a limited number of options (*i.e.*, dilution in a sealed or an unsealed container), wherein the limited number of options are closely related to each other in structure, and possess the same properties of the claim element. However, as noted above, the Draft Labeling does not recite any genus of container into which the concentrated composition is diluted. Accordingly, Applicants note the Examiner's position must be based on a theory of inherent anticipation.

In order for a reference to inherently anticipate a limitation, however, that limitation must necessarily be present in the disclosure. *See, e.g., Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Inherency may not be established by probabilities or possibilities. *See, e.g., In re Robertson,* 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). For example, a feature is not inherent if it is a mere probability that the limitation would appear in the prior art. *See, e.g., In re Robertson,* 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). That a limitation may result in a prior art reference from a given set of circumstances is insufficient to prove anticipation. *See, e.g., In re Rijckaert,* 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); and M.P.E.P. § 2112.

Applicants respectfully submit that the Office Action fails to make a showing based on the Draft Labeling that meets this standard. As noted above, the claims as amended are directed to a pharmaceutical composition comprising dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 4 µg/mL, wherein the composition is disposed within a sealed glass container as a ready to use premixture. As discussed above, the Draft Labeling does not disclose a 4 µg/mL ready to use premixture that is disposed within a sealed glass container. Furthermore, a 4 µg/mL ready to use premixture that is disposed within a sealed glass container is not inherent to the Draft Labeling because the reference does not disclose a 4 µg/mL ready to use premixture that is *necessarily* disposed within a sealed glass container. Assuming *arguendo*, with reference to the Examiner's own logic and interpretation of the Draft Labeling, the Examiner

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