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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/541,524	07/03/2012	Priyanka Roychowdhury	077350.0355	8238

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EXAMINER	
POLANSKY, GREGG	

ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
08/17/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary for Applications Under Accelerated Examination	Application No.	Applicant(s)	
	13/541,524	ROYCHOWDHURY ET AL.	
	Examiner	Art Unit	
	Gregg Polansky	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Since this application has been granted special status under the accelerated examination program, NO extensions of time under 37 CFR 1.136(a) will be permitted and a SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE:

ONE MONTH OR THIRTY (30) DAYS, WHICHEVER IS LONGER,
FROM THE MAILING DATE OF THIS COMMUNICATION – if this is a non-final action or a *Quayle* action.
(Examiner: For **FINAL** actions, please use PTOL-326.)

The objective of the accelerated examination program is to complete the examination of an application within twelve months from the filing date of the application. Any reply must be filed electronically via EFS-Web so that the papers will be expeditiously processed and considered. If the reply is not filed electronically via EFS-Web, the final disposition of the application may occur later than twelve months from the filing of the application.

Status

1)☒ Responsive to communication(s) filed on *03 July 2012*.

2)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

- See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *7/03/2012 (two)*.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicants' two Information Disclosure Statements filed on 7/03/2012 are acknowledged and have been reviewed.

2. Claims 1-7 are pending and presently under consideration.

3. In view of the rejection of the instant claims over the prior art as set forth in the rejection below, a pre-first action interview with Applicants would likely not have resulted in the application being placed in condition for allowance and therefore, the interview was not conducted. However, Applicants' representative, Dennis Bissonnette, was called on 8/02/2012 to inform him of the status of the application and that a first action on the merits was forthcoming.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyawaki et al. (US 2011/0230534 A1), evidenced by Precedex® Package Insert (Document EN-2680, Hospira, Inc., 9/2010, downloaded on 8/10/2012 from "www.precedex.com/wp-content/uploads/2010/11/Precedex_PI.pdf", pages 1-24), Sunkel et al. (US 6806291 B1), Ibrahim et al. (US 5716988), and Xylocaine® Package Insert (AstraZeneca LP, 2001 and 2007, downloaded on 8/10/2012 from "www.pdr3d.com/print.php?c=4818", pages 1-30).

Miyawaki et al. teach a kit for parenterally administered local anesthesia, including a local anesthetic agent and dexmedetomidine or a salt thereof. The dexmedetomidine concentration disclosed by Miyawaki et al. is between $1x10^{-15}$ M to $1x10^{-6}$ M (i.e., $2x10^{-10}$ µg/ml to 0.2 µg/ml), or more preferably, $1x10^{-10}$ M to $1x10^{-6}$ M (i.e., $2x10^{-5}$ µg/ml to 0.2 µg/ml). See paragraphs [0023] to [0031]. The reference teaches formulating dexmedetomidine hydrochloride with physiological saline (i.e., aqueous 0.9% sodium chloride solution) to prepare solutions having concentrations of $4x10^{-6}$ M, $4x10^{-7}$ M, $4x10^{-8}$ M and $4x10^{-9}$ M (i.e., 0.8 µg/ml, 0.08 µg/ml, 0.008 µg/ml and 0.0008 µg/ml, respectively). See paragraph [0056]. It is noted that the concentrations taught by Miyawaki et al. (e.g., 0.8 µg/ml) is encompassed by the concentration ranges of instant Claims 1-3. Further, 0.8 µg/ml also reads on instant Claim 4 (a concentration of **about 1** to about 7 µg/ml) because 0.8 µg/ml is about 1 µg/ml (see the definition of

"about" at page 7, paragraph [0035] of the instant Specification). The stock dexmedetomidine hydrochloride solution used by Miyawaki et al. to prepare the above solutions was Precedex®, which is provided by the manufacturer in a glass vial. See for evidentiary purposes the Precedex® Package Insert, page 1, bottom of left column.

Although Miyawaki et al. do not teach the use of sealed glass containers (e.g. sealed glass vials or ampules), the use of such containers for parenteral pharmaceuticals is common and well known.

For example, the Xylocaine® Package Insert teaches Xylocaine® (lidocaine HCl) in isotonic solution is provided in glass ampules and single or multiple dose vials, at various concentrations. Further, the ampules and vials are provided comprising various volumes of the parenteral solutions (e.g., 2, 5, 10, 20 and 50 ml). See page 1, the "Description" section, and page 8, the "How Supplied" section. Sunkel et al. disclose pharmaceutical compositions for parenteral administration contained in ampules and multiple dose vials made of glass or plastic. See column 4, lines 14-16 and 29-31. In fact, the compositions of Sunkel et al. may include dexmedetomidine. See column 5, line 5. Ibrahim et al. provide another example of the use of sealed glass vials for parenteral aqueous pharmaceutical solutions. See column 3, lines 45-62, which discloses aqueous solutions of oxaliplatinum contained in 50 ml sealed glass vials.

It would have been obvious to one of ordinary skill in the art to provide the dexmedetomidine in sealed glass containers in the kit taught by Miyawaki et al. because to do so was a common and predictable method of providing parenteral pharmaceutical compositions at the time of the invention. Additionally, further motivation to use sealed

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