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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/591,200	11/12/2009	Horst Olschewski	080618-0716	4093

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EXAMINER	
TOWNSLEY, SARA ELIZABETH	
ART UNIT	PAPER NUMBER
1629	

MAIL DATE	DELIVERY MODE
10/10/2014	PAPER

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.

Office Action Summary	Application No. 12/591,200	Applicant(s) OLSCHEWSKI ET AL.	
	Examiner SARA E. TOWNSLEY	Art Unit 1629	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/28/2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

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.

4)☐ 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.

Disposition of Claims*

5)☒ Claim(s) *18,25,27-30 and 32-40* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *18, 25, 27-30, and 32-40* is/are rejected.

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

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

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

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

11)☐ 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).

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).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)

3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

FINAL REJECTION

Receipt is acknowledged of Applicants' Amendments and Remarks, filed Apr. 28, 2014.

Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The rejections and/or objections set forth below are either maintained or newly applied, and constitute the complete set presently applied to the instant claims.

STATUS OF THE CLAIMS

Claims 1-17, 19-24, 26, and 31 have been canceled.

No claims have been amended, and no new claims have been added.

Thus, claims 18, 25, 27-30, and 32-40 now represent all claims currently pending and under consideration.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement (IDS) submitted on Jun. 13, 2014 was filed after the mailing date of the non-final action on Mar. 19, 2014. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated Mar. 19, 2014, on the ground that the references cited therein continue to read on the limitations of the amended claims.

Claim Rejections - 35 USC § 103

Claims 18, 25, 27-30, and 32-40 stand rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Chaudry (US Pub. 2004/0265238) in view of Cewers (USPN 6,357,671).

Chaudry discloses methods for treating pulmonary hypertension in humans by administering an inhalable formulation comprising at least one hypertension reducing agent, e.g., a vasodilator, in the form of a solution or suspension (abstract). In particular, Chaudry exemplifies an inhalable formulation comprising a pharmaceutically acceptable salt of treprostinil, treprostinil sodium, in a concentration of 0.1-10.0 mg/ml (Example 4; claim 44), which is preferably administered via nebulization (paras. [0040], para. [0057]; claims 27-29).

Chaudry teaches that a nebulized solution is a particular form of an aerosol (para. [0055]), and that administration of a nebulized aerosol is preferred (para. [0053]); thus, it is implicit that the disclosed inhalable formulations are aerosolizable solutions.

Further, Chaudry discloses that prophetic examples 1-4 (including treprostinil, Example 4) are believed to “be suitable for administration via nebulization to an individual suffering from pulmonary hypertension . . . The objective of these formulations

is to provide localized delivery of a pulmonary hypertension reducing agent to a mammal (e.g. humans) in need thereof." Thus, the disclosed compounds, and in particular the exemplified compounds, are administrable by inhalation via a nebulizer.

Thus, Chaudry discloses a method of treating pulmonary hypertension comprising administering by inhalation to a human in need thereof a therapeutically effective dose of an inhalable formulation with an ultrasonic nebulizer, as recited by claim 18.

The inhalable formulation of Chaudry Example 4 comprises treprostinil sodium in a concentration of 0.1-10.0 mg/ml (Example 4; claim 44), which encompasses the range of 500-2500 mcg/ml (= 0.5-2.5 mg/ml) as recited by claim 27.

Chaudry further discloses that a therapeutically effective amount of the hypertension-reducing agent (e.g., treprostinil) may include from about, e.g.,

- 0.51 mg/ml to about 1.00 mg/ml (510 – 1000 mcg/ml);
- 1.01 mg/ml to about 1.50 mg/ml (1010 – 1500 mcg/ml); and
- 1.51 mg/ml to about 2.00 mg/ml (1510 – 2000 mcg/ml)

(para. [0037]). These concentration ranges fall squarely within the claimed range of 500 – 2500 mcg/ml, as recited by claim 27.

Chaudry also teaches that "[t]he solution of Example 4 may be made by methods known to those of ordinary skill in the art" (para. [0098]). In other words, the reference itself teaches that any concentration within the exemplified range can be arrived at by routine experimentation.

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