IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Horst OLSCHEWSKI et al.
Title:	TREPROSTINIL ADMINISTRATION BY INHALATION
Appl. No.:	13/469,854
Filing Date:	5/11/2012
Examiner:	Sarah Elizabeth Townsley
Art Unit:	1629
Confirmation Number:	9171

REPLY UNDER 37 CFR § 1.116

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Commissioner:

This paper responds to the outstanding Final Office Action dated March 13, 2014 and a telephonic interview that Applicants' representative, Alexey Saprigin (Reg. # 56,439) and Examiner Townsley conducted on May 21, 2014.

Amendments to the Specification begin on page 2 of this document.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this document.

Remarks begin on page 5 of this document.

Amendments to the Specification:

Please amend the specification as follows:

Please replace paragraph 0078 with the following rewritten paragraph:

Study iii) was a randomized, open-label, single blind study. The primary objective was to explore the shortest possible inhalation time for a 15µg dose of inhaled treprostinil. A total of 48 patients inhaled one dose of TRE during right heart catheter investigation. The drug was applied in 18, 9, 3, 2 or 1 breaths. The aerosol was generated by a pulsed ultrasonic nebulizer (Optineb® ~~VENTA-NEB®,~~ Nebutec, Elsenfeld, Germany) in cycles consisting of 2 seconds aerosol production (pulse) and 4 seconds pause. The device included an opto-acoustical trigger for the patient to synchronize the inspiration to the end of the aerosol pulse, thereby providing exact dosage. The TRE dose of 15µg was either generated during 18 cycles (Optineb filled with 100µg/ml TRE, n=6), 9 cycles (200µg/ml TRE, n=6), 3 cycles (600µg/ml TRE, n=21), 2 cycles (1000µg/ml TRE, n=7) or 1 cycle (2000µg/ml TRE, n=8). Hemodynamics and gas exchange were recorded for 120 - 180 minutes.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-8. (Canceled)

9. (currently amended) A kit for treating a patient, comprising

(i) an ultrasonic nebulizer (a) adapted to receive a pharmaceutical formulation for inhalation comprising an aerosolable solution of treprostinil or a pharmaceutically acceptable salt thereof at a concentration from 500 µg/ml to 2500 µg/ml, wherein the formulation is free of metacresol and (b) adapted to administer a therapeutically effective single event dose of the formulation comprising from 15 µg to 90 µg of treprostinil or a pharmaceutically acceptable salt thereof by inhalation in ~~10~~ 20 or less breaths;

(ii) a pharmaceutical formulation for inhalation comprising an aerosolable solution of treprostinil or a pharmaceutically acceptable salt thereof at a concentration from 500 µg/ml to 2500 µg/ml, wherein the formulation is free of metacresol; and

(iii) instructions for a patient to use the kit to by administering a therapeutically effective single event dose of the formulation comprising from 15 µg to 90 µg of treprostinil or a pharmaceutically acceptable salt thereof by inhalation in ~~10~~ 20 or less breaths.

10. (original) The kit of claim 9, wherein the concentration of treprostinil or its pharmaceutically acceptable salt in the aerosolable solution is 600 µg/ml.

11. (original) The kit of claim 9, wherein the ultrasonic nebulizer is adapted to administer a therapeutically effective single event dose of the formulation comprising from 15 µg to 90 µg of treprostinil or a pharmaceutically acceptable salt thereof by inhalation in 3 or less breaths.

12. (original) The kit of claim 9, wherein the ultrasonic nebulizer is adapted to administer a therapeutically effective single event dose of the formulation comprising from 15 µg to 90 µg of treprostinil or a pharmaceutically acceptable salt thereof by inhalation in one breath.

13. (original) The kit of claim 9, wherein the ultrasonic nebulizer is adapted to administer the therapeutically effective single event dose of the formulation as droplets with a diameter less than about 5 microns.

14. (original) The kit of claim 9, wherein the ultrasonic nebulizer is a pulsed ultrasonic nebulizer comprising an opto-acoustical trigger for the patient to synchronize inspiration with an aerosol pulse.

REMARKS

Applicants respectfully request reconsideration and allowance of the present application.

CLAIMS STATUS

Applicants have canceled claims 1-8, to present the claimed invention in a clearer manner. Applicants reserve the right to file one or more continuing applications directed to the subject matter of the canceled claims. Claim 9 is amended to recite that each event is administered in 20 or less breaths, support for which can be found in paragraph 45. No new matter has been added.

After the amendment, claims 9-14 are pending.

The PTO should enter the present amendment because it merely cancels claims and raises no new issues.

SPECIFICATION AMENDMENT

Applicants have amended paragraph 0078 to correct an inadvertent typographical error. Support for the amendment may be found in paragraph 0072 and in the remaining text of paragraph 0078. In particular, paragraph 0072 teaches that in Example 2, to which paragraph 0078 belongs, "**All** inhalations were performed with the **Optineb®** ultrasonic nebulizer (Nebutec, Elsenfeld, Germany)." Furthermore, paragraph 0078 states as follows: "The TRE dose of 15µg was either generated during 18 cycles (**Optineb** filled with 100µg/ml TRE, n=6), 9 cycles (200µg/ml TRE, n=6), 3 cycles (600µg/ml TRE, n=21), 2 cycles (1000µg/ml TRE, n=7) or 1 cycle (2000µg/ml TRE, n=8)."

MAY 21ST INTERVIEW

Applicants thank the Examiner for the interview. During the interview, among other things, Applicants' representative explained the Examiner that Nebu-Tec nebulizer is not compatible with treprostinil. This argument in a greater detail may be found below.

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