IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name:	Horst OLSCHEWSKI
Title:	TREPROSTINIL ADMINISTRATION BY INHALATION (as amended)
Appl. No.:	12/591,200
Filing Date:	11/12/2009
Examiner:	Sara Elizabeth TOWNSLEY
Art Unit:	1629
Confirmation Number:	4093

SUPPLEMENT AMENDMENT AND REPLY UNDER 37 CFR 1.111

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

Commissioner:

This communication is supplemental to the response filed on November 9, 2015, in response to the Advisory Action dated February 27, 2015, and final Office Action dated October 10, 2014, concerning the above-referenced patent application.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this document.

Remarks/Arguments begin on page 5 of this document.

Please amend the application as follows:

AMENDMENTS

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

Listing of Claims:

1-17. (Canceled)

18. (Previously Presented) A method of treating pulmonary hypertension comprising:

administering by inhalation to a human in need thereof a therapeutically effective single event dose of an inhalable formulation with a pulsed ultrasonic nebulizer, wherein said therapeutically effective single event dose comprises from 15 µg to 90 µg of treprostinil or a pharmaceutically acceptable salt thereof, said therapeutically effective single event dose is inhaled in 18 or less breaths by the human.

19.-24. (Canceled)

25. (Previously Presented) The method of claim 18, wherein the single event dose contains from 15 µg to 60 µg of treprostinil or a pharmaceutically acceptable salt thereof.

26-27. (Canceled)

28. (Previously Presented) The method of claim 18, wherein said administering does not significantly disrupt gas exchange in said human.

29. (Previously Presented) The method of claim 18, wherein said administering does not significantly affect heart rate of said human.

30. (Previously Presented) The method of claim 18, wherein said administering does not significantly affect systemic arterial pressure and systemic arterial resistance of said human.

31. (Canceled)

32. (Previously Presented) The method of claim 18, wherein said administering of said therapeutically effective single event dose is performed in 5 or less breaths.

33. (Previously Presented) The method of claim 18, wherein said human receives several therapeutically effective single event doses per day.

34. (Previously Presented) The method of claim 27, wherein the concentration of said treprostinil or a pharmaceutically acceptable salt thereof in the aerosolable solution is 600 µg/ml.

35. (Previously Presented) The method of claim 18, wherein the single event dose is administered in 5 minutes or less.

36. (Previously Presented) The method of claim 27, wherein the single event dose is administered in 5 minutes or less.

37. (Previously Presented) The method of claim 34, wherein the single event dose is administered in 5 minutes or less.

38. (Previously Presented) The method of claim 18, wherein said therapeutically effective single event dose is inhaled in 12 or less breaths by the human.

39. (Previously Presented) The method of claim 27, wherein said therapeutically effective single event dose is inhaled in 12 or less breaths by the human.

40. (Previously Presented) The method of claim 34, wherein said therapeutically effective single event dose is inhaled in 12 or less breaths by the human.

41. (Previously Presented) A method of treating pulmonary hypertension comprising: administering by inhalation to a human in need thereof a therapeutically effective single event dose of an inhalable formulation with a pulsed ultrasonic nebulizer having a concentration of said treprostinil or a pharmaceutically acceptable salt thereof from 500 µg/m1 to 2000 µg/ml, wherein said therapeutically effective single event dose comprises from 15 µg to 90 µg of treprostinil, or its acid derivative, or a pharmaceutically acceptable salt thereof, said therapeutically effective single event dose being inhaled in 18 or less breaths by the human.

42. (Previously Presented) A method of treating pulmonary hypertension comprising: administering by inhalation to a human in need thereof a therapeutically effective single event

dose of an inhalable formulation with a pulsed ultrasonic nebulizer having a concentration of said treprostinil or a pharmaceutically acceptable salt thereof of 600 µg/ml, wherein said therapeutically effective single event dose comprises from 15 µg to 90 µg of treprostinil, or its acid derivative, or a pharmaceutically acceptable salt thereof, said therapeutically effective single event dose being inhaled in 18 or less breaths by the human.

43. (Previously Presented) The method of claim 18, wherein the pulsed ultrasonic nebulizer comprises an opto-acoustical trigger for timing inspiration by the human to coincide with generation of an aerosol pulse produced by the pulsed ultrasonic nebulizer.

44. (Previously Presented) The method of claim 41, wherein the pulsed ultrasonic nebulizer comprises an opto-acoustical trigger for timing inspiration by the human to coincide with generation of an aerosol pulse produced by the pulsed ultrasonic nebulizer.

45. (Previously Presented) The method of claim 42, wherein the pulsed ultrasonic nebulizer comprises an opto-acoustical trigger for timing inspiration by the human to coincide with generation of an aerosol pulse produced by the pulsed ultrasonic nebulizer.

46. (Previously Presented) The method of claim 18, wherein said administering results in pulmonary vasodilation in the human for longer than 3 hours.

REMARKS

This supplemental response and attached Declarations are filed to supplement the response filed with the RCE on November 9, 2015. To assist the Examiner in considering the original response and this supplemental response, this supplemental response includes the same substantive comments included in the original response and also additional comments based on two newly submitted Declarations. Applicants respectfully request reconsideration and allowance of the present application.

CLAIMS STATUS

Applicants added new claims 41-46 in the previous response filed on November 9, 2015. No further amendments are made in this supplemental response.

Upon entry of the amendments submitted November 9, 2015, claims 18, 25, 28-30, and 32-46 will be pending and subject to examination.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 18, 25, 27-30, and 32-40 stand rejected as obvious over U.S. Published Patent Application No. 2004/0265238 to Chaudry in view of U.S. Patent No. 6,357,671 to Cewers. Applicants respectfully traverse.

To support an obviousness rejection, MPEP § 2143.03 requires "all words of a claim to be considered," and MPEP § 2141.02 requires consideration of the "[claimed] invention and prior art as a whole." Further, the Board of Patent Appeals and Interferences recently confirmed that a proper, post-*KSR* obviousness determination still requires the Office make "a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art." *In re Wada and Murphy*, Appeal 2007-3733 (BPAI Jan. 14, 2008) (citing *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995)). In sum, it remains well-settled law that an obviousness rejection requires at least a suggestion of all of the claim elements.

The obviousness rejection is improper because the cited references do not teach or suggest all features of the pending claims, including the "single event dose," "18 or less breaths," or a "pulsed ultrasonic nebulizer," as discussed in greater detail below.

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