IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Horst OLSCHEWSKI et al.
Title:	TREPROSTINIL ADMINISTRATION BY INHALATION
Appl. No.:	12/591,200
Filing Date:	11/12/2009
Examiner:	Sarah Elizabeth Townsley
Art Unit:	1629
Confirmation Number:	4093

SUBSTANTIVE SUBMISSION UNDER 37 C.F.R. § 1.114

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

Commissioner:

This paper responds to the outstanding Final Office Action dated October 10, 2014, the Advisory Action dated February 27, 2015 and the Notice of Panel Decision from Pre-Appeal Brief Review mailed May 8, 2015, while following the response filed January 12, 2015 and the Notice of Appeal filed March 9, 2015. A Request for Continued Examination including petition for a five month extension of time accompanies this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this document. **Remarks** begin on page 5 of this document.

Amendments to the Claims:

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. (New) 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/ml 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. (New) 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. (New) 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. (New) 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. (New) 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. (New) The method of claim 18, wherein said administering results in pulmonary vasodilation in the human for longer than 3 hours.

REMARKS

Applicants respectfully request reconsideration and allowance of the present application.

CLAIMS STATUS

Applicants have added new claims 41-46. Support for the new claims may be found in throughput the specification as filed including, in examined claims 18 and 27 as well as in paragraph [0094] for claim 41; in examined claim 18 as well as in paragraphs [0070], [0075] and [0078] for claim 42; in paragraph [0078] for claims 43-45; in paragraphs [0093]-[0094] for claim 46. No new matter has been added.

Applicants have canceled claim 27, without prejudice or disclaimer.

After the amendment, pending claims include a) examined claims 18, 25, 28-30 and 32-40 and b) new claims 41-46.

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

Claims 18, 25, 27-30 and 32-40 stand rejected as obvious over Chaudry (US 2004/0265238) in view of Cewers (USPN 6,357,671). Applicants respectfully traverse.

The PTO failed to establish a *prima facie* case of obviousness at least because of the reasons discussed below.

1) The cited references do not teach or suggest the dosage recited in claim 18

Chaudry generically encompasses a number of drugs and inhalation devices, creating an enormous number of drug-device dosing possibilities. The only specific guidance provided by Chaudry in relation to treprostinil dosing is found in prophetic example 4, reproduced here in its entirety:

"Example 4
[0097]
5 Treprostinil sodium 0.1-10.0 mg/ml Sodium Chloride 2.0-10.0 mg/ml Sodium

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.