IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

REPLY UNDER 37 CFR § 1.116

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Commissioner:

This paper responds to the Final Office Action dated October 17, 2012.

The listing of claims begins on page 2 of this document.

Remarks begin on page 4 of this document.

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 an ultrasonic nebulizer, wherein said therapeutically effective single event dose comprises from 15 μg to 90 μg of treprostinil or a pharmaceutically acceptable salt thereof and said therapeutically effective single event dose is inhaled in 10 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. (Canceled)

27. (Previously Presented) The method of claim 18, wherein the ultrasonic nebulizer comprises an aerosolable solution having a concentration of said treprostinil or a pharmaceutically acceptable salt thereof from 500 μg/ml to 2500 μg/ml.

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.

REMARKS

Applicants respectfully request reconsideration and allowance of the present application.

CLAIMS STATUS

Claims 18, 25, 27-30 and 32-34 are pending.

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

Claims 1-8, 10-23 and 25-31 stand rejected as obvious over Chaudry (US 2004/0265238) in view of Sandifier et al. (J. Appl. Physiol. 99:2363-68 (2005)) and Cloutier (US patent no. 6,521,212). Applicants respectfully traverse.

Before addressing the rejection in greater detail, Applicants note that Sandifier may be disqualified as prior art under 37 C.F.R. 1.131. Applicants reserve the right to submit a Declaration under Rule 131 to disqualify Sandifier.

Even if Sandifier is applied to the instant claims, the PTO has not established a *prima facie* case of obviousness for the reasons discussed below. In addition, the evidence of secondary considerations provided in prior responses and submitted herewith would rebut any possible case of *prima facie* obviousness by establishing that the presently claimed method constitutes an improvement over the results reported in Sandifier.

Chaudry relates to inhalable formulations for treating pulmonary hypertension and methods of using same, see e.g. title. Chaudry teaches that "his formulation comprises at least one hypertension reducing agent, including but not limited to an angiotensin converting enzyme inhibitor, angiotensin receptor blocker, beta-blocker, calcium-channel blocker or vasodilator, or any combination thereof," see abstract. Chaudry further discloses his hypertension reducing agents in an extensive list in paragraphs 0022-0027. Applicants acknowledge that in paragraph 0026, Chaudry mentions treprostinil among a multitude of examples of vasodilators that can be used in his formulations. Applicants further acknowledge that Chaudry's prophetic example 4 discloses a formulation comprising

treprostinil sodium. However, each active agent is unique, with different potency and side effect profiles, so that they exhibit different treatment results in humans depending on (a) the type of inhalation device and (b) the dosing regimen applied to that type of inhalation device.

Chaudry discloses a large number inhalation devices, which may be used for administering his formulations in paragraphs 0052-0057. Applicants acknowledge that Chaudry mentions ultrasonic nebulizers in paragraph 0057 as a part of this disclosure. As noted above, however, each active agent is unique, with different potency and side effect profiles, so that they exhibit different treatment results in humans depending on (a) the type of inhalation device and (b) the dosing regimen applied to that type of inhalation device.

Chaudry does not teach at least the following elements of claim 18:

1) Chaudry does not disclose **a combination of treprostinil and an ultrasonic nebulizer**, i.e., does not disclose treprostinil and a ultrasonic nebulizer in a single embodiment, despite mentioning a) treprostinil in paragraph 0026 and in example 4 and b) an ultrasonic nebulizer in paragraph 0057.

2) Chaudry does not teach administering by inhalation to a human in need thereof a therapeutically effective single event dose of an inhalable formulation with **an ultrasonic nebulizer**, wherein the **therapeutically effective single event dose that comprises from 15 µg to 90 µg of treprostinil** or a pharmaceutically acceptable salt thereof being **inhaled in 10 or less breaths by the human**,

Applicants respectfully submit that one of ordinary skill in the art would not have arrived at any of these missing elements based on the cited references.

ELEMENT 1 – Ultrasonic Nebulizer

With respect to element 1, not only does Chaudry fail to disclose the combination of treprostinil and an ultrasonic nebulizer, but Chaudry also fails to provide any reason for one of ordinary skill to arrive at the combination of treprostinil and an ultrasonic nebulizer by selecting treprostinil from the list of his hypertension reducing agents in paragraphs 0022-0027, while selecting an ultrasonic nebulizer from Chaudry's inhalation devices mentioned in

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