IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Ashley, Robert	Examiner:	Susan Tran
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For:	**Methods of Treating Acne**		

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Carla Bryan (Printed Name) /carla bryan/ (Signature)

Fifth Preliminary Amendment

Sir:

Applicant thanks Examiner Tran for her courteous consideration during a personal interview with the applicant's undersigned representative on April 23, 2012. Applicant respectfully requests the instant Amendment be entered.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 5 of this paper.

Dr. Reddy's Laboratories, Ltd., et al.
v.
Galderma Laboratories, Inc.
IPR2015-

Amendment to the Claims:

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

Claims 1-20 (Cancelled).

21. (New) A method for treating papules and pustules of rosacea in a human in need thereof, the method comprising

administering orally to said human doxycycline, or a pharmaceutically acceptable salt thereof,

in an amount that

(i) is effective to treat the papules and pustules of rosacea;

(ii) is 10-80% of a 50 mg dose of doxycycline; and

(iii) results in no reduction of skin microflora during a six-month treatment, without administering a bisphosphonate compound.

22. (New) The method according to Claim 21, wherein said doxycycline is doxycycline monohydrate.

23. (New) The method according to Claim 22, wherein said doxycycline monohydrate is administered in an amount of 40 milligrams.

24. (New) The method according to Claim 23, wherein said doxycycline monohydrate is administered by sustained release.

25. (New) A method according to Claim 24, wherein said doxycycline monohydrate is administered once a day.

26. (New) The method according to Claim 22, wherein said doxycycline monohydrate is administered in a dose of 20 mg twice a day.

27. (New) The method according to Claim 21, wherein said doxycycline, or a pharmaceutically acceptable salt thereof, is administered in an amount which provides a serum concentration in the range of about 0.1 to about 0.8 μg/ml.

28. (New) A method for treating papules and pustules of rosacea in a human in need thereof, the method comprising

administering orally to said human doxycycline, or a pharmaceutically acceptable salt thereof,

in an amount that

(i) is effective to treat the papules and pustules of rosacea;

(ii) is 40-80% of a 50 mg dose of doxycycline; and

(iii) results in no reduction of skin microflora during a six-month treatment, without administering a bisphosphonate compound.

29. (New) The method according to Claim 28, wherein said doxycycline is doxycycline monohydrate.

30. (New) The method according to Claim 29, wherein said doxycycline monohydrate is administered in an amount of 40 milligrams.

31. (New) The method according to Claim 30, wherein said doxycycline monohydrate is administered by sustained release.

32. (New) A method according to Claim 31, wherein said doxycycline monohydrate is administered once a day.

33. (New) The method according to Claim 29, wherein said doxycycline monohydrate is administered in a dose of 20 mg twice a day.

34. (New) The method according to Claim 28, wherein said doxycycline, or a pharmaceutically acceptable salt thereof, is administered in an amount which provides a serum concentration in the range of about 0.1 to about 0.8 µg/ml.

35. (New) A method for treating papules and pustules of rosacea in a human in need thereof, the method comprising

administering orally to said human doxycycline, or a pharmaceutically acceptable salt thereof, in an amount of 40mg per day, wherein the amount results in no reduction of skin microflora during a six-month treatment, without administering a bisphosphonate compound.

36. (New) The method according to Claim 35, wherein said doxycycline is doxycycline monohydrate.

37. (New) The method according to Claim 36, wherein said doxycycline monohydrate is administered by sustained release.

38. (New) A method according to Claim 37, wherein said doxycycline monohydrate is administered once a day.

39. (New) The method according to Claim 36, wherein said doxycycline monohydrate is administered in a dose of 20 mg twice a day.

40. (New) The method according to Claim 35, wherein said doxycycline, or a pharmaceutically acceptable salt thereof, is administered in an amount which provides a serum concentration in the range of about 0.1 to about 0.8 µg/ml.

REMARKS

Claims 2-20 were previously cancelled. Claim 1 is presently cancelled. New Claims 21-40 are presently added. Thus, Claims 21-40 are pending.

Applicant thanks Examiner Tran for discussing the instant application during a personal interview with the applicant's undersigned representative on April 23, 2012.

During the interview, the applicant's undersigned representative presented draft claims to the examiner. Such claims are independent Claims 21, 28 and 35 presented in the instant Amendment. These claims are more defined than those allowed in the parent application, now US 7,232,572 (hereinafter "US'572").

Claim 1 of US'572 recites a method for treating papules and pustules of rosacea by the oral administration of a tetracycline compound, or its pharmaceutically acceptable salt, in an amount that is effective to treat the papules and pustules, but has substantially no antibiotic activity, the amount being 10-80% of the antibiotic amount. The amount is recited to result in no reduction of skin microflora during a six-month treatment.

Similarly, the pending claims recite a method for treating papules and pustules of rosacea. However, in the pending claims, the tetracycline compound is defined as being doxycycline, or its pharmaceutically acceptable salt. The dose is expressed differently in each independent claim. The dose recited in Claim 21 is 10-80% of a 50 mg dose of doxycycline. The dose recited in Claim 28 is 40-80% of a 50 mg dose of doxycycline. The dose recited in Claim 35 is 40 mg. Support for these claims can be found throughout the specification, including for example, from page 9, line 27, to page 10, line 10, and page 15, lines 23-29. As in Claim 1 of the '572 patent, the amount of doxycycline administered results in no reduction of skin microflora during a six-month treatment.

Since the pending claims are more defined than Claim 1 of the '572 patent, the instant claims are also allowable.

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