IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Ashley, Robert	Examiner:	Susan Tran
Serial No.:	13/277,789	Group Art Unit:	1615
Confirmation No:	4179	Docket:	512-53 DIV/CON II
Filed:	October 20, 2011	Dated:	September 19, 2012
For:	**Methods of Treating Acne**		

Commissioner for Patents
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Response to May 14, 2012 Office Action

Sir:

In Response to May 14, 2012 Office Action, 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.

Listing of the Claims:

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

Claims 1-20 (Cancelled).

21. (Previously Presented) 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. (Previously Presented) The method according to Claim 21, wherein said doxycycline is doxycycline monohydrate.

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

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

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

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

27. (Previously Presented) 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. (Previously Presented) 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. (Previously Presented) The method according to Claim 28, wherein said doxycycline is doxycycline monohydrate.

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

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

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

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

34. (Previously Presented) 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. (Previously Presented) 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. (Previously Presented) The method according to Claim 35, wherein said doxycycline is doxycycline monohydrate.

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

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

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

40. (Previously Presented) 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 1-20 were previously cancelled. Claims 21-40 were previously added. Thus, Claims 21-40 are pending.

The Claimed Invention

Pending Claims 21, 28 and 35 are independent. These claims recite a method for treating papules and pustules of rosacea by oral administration of doxycycline (or a salt thereof). Papules and pustules occur on skin in facial rosacea. 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. The claims recite that all these doses result in no reduction of skin microflora during a six-month treatment

Applicant takes this opportunity to elaborate on the disease of rosacea. There are four sub-types of rosacea. Rosacea patients can have any one, or occasionally more than one, of these sub-types. One sub-type affects the eyes and is called ocular rosacea. Another sub-type is characterized by papules and pustules, and is called herein facial rosacea.[1] Ocular rosacea and facial rosacea are distinct medical conditions.[2]

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[1] The National Rosacea Society assembled a committee to develop a standard classification system of rosacea. Their report, authored by Wilkin et al., appeared in J. Am. Acad. Dermatol. 46, 584-587 (2002), and is attached as Exhibit A. This authoritative report identified four specific sub-types of rosacea. Subtype 2 is called "papulopustular rosacea," and is characterized by transient papules and/or pustules. Subtype 4 is called "ocular rosacea," and is characterized by ocular manifestations.

[2] (a) In addition to evidence provided in footnote 1, facial rosacea and ocular rosacea are treated by physicians in different specialties with different Board certifications, *i.e.*, dermatologists and ophthalmologists, respectively.

(b) Moreover, the agency that approves drugs in the United States, namely the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration, evaluates drugs for facial rosacea and ocular rosacea in different divisions. Facial rosacea is evaluated in the Division of Dermatologic and Dental Products. Ocular rosacea is evaluated in the Division of Anti-Infection and Ophthalmologic Products. For the examiner's convenience, a 2006 chart of the organization of the CDER showing the separate divisions of Dermatologic and Dental Products and of Anti-Infection and Ophthalmologic Products is attached as Exhibit B.

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