IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant: | Elliot Ehrich | | |
| Application No. | 11/083,167 | Group No. | 1627 |
| Filed: | March 17, 2005 | Examiner: | Kendra D. Carter |
| Confirmation No. | 8002 | | |

For: Naltrexone Long Acting Formulations and Methods for Use

AMENDMENT

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

Sir:

This Amendment is in response to the Office action mailed from the U.S. Patent and Trademark Office on January 6, 2010, in the above-identified application.

A Petition for Extension of Time for one month and the appropriate fees are being filed concurrently.

Please amend the above-identified application as follows:

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

**Remarks/Arguments** begin on page **5** of this paper.

**Amendments to the Claims:**

The Claim Listing below will replace all prior versions of the claims in the application:

**Claim Listing:**

1. (Currently Amended) A method for treating an individual in need of naltrexone comprising the step of parenterally administering a long acting formulation comprising naltrexone and a biocompatible polymer to the individual wherein the serum AUC of naltrexone is at least about three times greater than that achieved by 50 mg/day oral administration.

2. (Previously Presented) The method of claim 1 comprising administering the long acting formulation in a dose comprising between about 160 and 240 mg of naltrexone or about 310 to about 480 mg of naltrexone.

3. (Withdrawn/Original) A method of treating an individual in need of naltrexone comprising administering naltrexone, in the absence of co-administering alcohol, to an individual who has not undergone alcohol abstinence within three days, such as five days, prior to the naltrexone administration.

4. (Withdrawn/Original) The method of Claim 3 wherein the naltrexone is administered in a long acting formulation comprising naltrexone.

5. (Withdrawn/Original) A method of increasing the days prior to occurrence of alcohol consumption in an individual in need of naltrexone comprising administering a long acting formulation comprising naltrexone, in the absence of co-administering alcohol, to an individual who has not abstained from alcohol within three days, such as five days, prior to the naltrexone administration.

6. (Previously Presented) The method of claim 1 comprising administering [[a]] the long acting formulation comprising naltrexone in a dosage between about 160 mg to about 480 mg naltrexone every four weeks for a period of about 24 weeks or more wherein the individual has not used oral naltrexone within five or more days before said administration.

7. (Original) The method of claim 1 wherein the long acting formulation releases naltrexone for a period of at least two weeks.

8. (Original) The method of claim 1 wherein the long acting formulation releases naltrexone for a period of about four weeks.

9. (Original) The method of claim 1 wherein the long acting formulation is administered in a dose of at least about 160 mg of naltrexone.

10. (Original) The method of claim 1 wherein the long acting formulation is administered in a dose between about 160 and 240 mg of naltrexone.

11. (Original) The method of claim 10 wherein the long acting formulation is administered in a dose of about 190 mg of naltrexone.

12. (Original) The method of claim 1 wherein the long acting formulation is administered in a dose between about 310 and 480 mg of naltrexone.

13. (Original) The method of Claim 1 wherein the long acting formulation is administered in a dose of about 380 mg of naltrexone.

14. (Original) The method of claim 1 wherein the long acting formulation is administered over a period of about 24 week period or longer.

15. (Previously Presented) The method of claim 1 further comprising a second administration of a long acting formulation comprising naltrexone at least about 7 days after the first administration.

16. (Original) The method of Claim 15 wherein the second long acting formulation is substantially similar to the first long acting formulation.

17. (Original) The method of Claim 15 wherein the second long acting formulation is the same as the first long acting formulation.

18. (Previously Presented) The method of claim 1 wherein the individual is an individual afflicted by alcohol dependency.

19. (Original) The method of claim 1 wherein the individual does not receive an initial oral dose of naltrexone.

20. (Previously Presented) The method of claim 1 wherein naltrexone is administered by injection.

21. (Original) The method of claim 1 wherein the long acting formulation comprises a polylactide polymer or a poly lactic acid polymer.

22. (Previously Presented) The method of claim 1 wherein the long acting formulation comprises a polylactide-co-glycolide polymer.

23. (Original) The method of claim 1 wherein the naltrexone is present in the long acting formulation at a concentration of about 35 % by weight.

24-25. (Canceled)

26. (Previously Presented) A method for treating an individual in need of naltrexone comprising the step of parenterally administering a long acting formulation comprising naltrexone to the individual wherein the serum AUC of naltrexone is at least about two times greater than that achieved by 50 mg/day oral administration.

REMARKS

Claim 1 has been amended. Support for the amendment to claim 1 is found on page 4, lines 19-21 and page 7, line 4. The term "biocompatible polymer" is also defined in column 6, line 65 to column 7, line 58, of U.S. Pat. No. 6,358,443, incorporated by reference on page 5, line 6 of the present application. Claims 3-5 have been withdrawn. Claims 1-23 and 26 are pending in the application. Reconsideration is respectfully requested.

Claim Rejections 35 U.S.C. §112, first paragraph

The Examiner has rejected claims 1, 2, 6-23 and 26 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner states that the instant claims are drawn to a method for treating an individual in need of naltrexone comprising the step of parenterally administering a long acting formulation wherein the serum AUC of naltrexone is at least about three times greater than that achieved by 50 mg/day oral administration. The Examiner asserts that the specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation citing the *Wands* factors (*In re Wands*, 8 USPQ2d 1400, 1404 (CAFC 1988). Applicants respectfully disagree.

The Examiner argues that the predictability of every long acting formulation providing an AUC of naltrexone at least about two or three times greater than that achieved by 50 mg/day oral administration is relatively low. The Examiner makes reference to Tice (U.S. Pat. No. 6,306,425) as the state of the art and the Examiner asserts that Tice teaches that every long acting formulation of naltrexone does not give an AUC of naltrexone of at least about two or three times greater than that achieved by 50 mg/day oral administration. The Examiner concludes that because there is a "potential" of reaching the claimed AUC serum values, the actual long acting formulation that gives these results is unpredictable.

The Examiner further argues that the specification provides no working examples. The Examiner also asserts that Applicants have failed to provide any

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