IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Elliot Ehrich		
Application No.	11/083,167	Group No.	1617
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 May 5, 2009, in the above-identified application.

A Petition for Extension of Time for two months 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:

Please add new Claim 26.

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 to the individual wherein the serum AUC of naltrexone is ~~at least about two times, preferably~~ at least about three times~~, more preferably about 3.3 times~~ greater than that achieved by 50 mg/day oral administration.

2. (Currently Amended) The [[A]] method of claim 1 ~~treating an individual in need of naltrexone~~ comprising administering [[a]] 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 (Withdrawn/Original) A method of treating an individual in need of naltrexone comprising administering naltrexone, in the absence of co-administering alcohol, to an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 (Withdrawn/Original) The method of Claim 3 wherein the naltrexone is administered in a long acting formulation comprising naltrexone.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 (Withdrawn/Original) A method of increasing the days prior to occurrence of alcohol consumption in an individual in need of naltrexone comprising administering a long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. (Currently Amended) The [[A]] method of claim 1 ~~treating an individual in need of naltrexone~~ 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~~, such as within ten 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. (Currently Amended) The method of claim 1 further comprising a second administration of a long acting formulation comprising naltrexone at least about 7 days~~, preferably at least about 14 days, more preferably at least about 21 days, such as about 28 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. (Currently Amended) The method of claim 1 wherein the individual is an individual afflicted by alcohol dependency~~, such as a heavy drinker~~.

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

20. (Currently Amended) The method of claim 1 wherein naltrexone is administered by injection~~, such as intramuscularly or subcutaneously~~.

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

22. (Currently Amended) The method of claim 1 wherein the long acting formulation comprises a polylactide-co-glycolide polymer~~, such as a polymer which possesses a molecular weight of at least 100,000 daltons~~.

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. (New) 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

Claims 3-5 have been withdrawn. Claims 1, 2, 6, 15, 18, 20, and 22 have been amended. New claim 26 has been added. Support for claim 26 is found in claim 1 as originally filed and in the specification at page 3, line 12. Claims 1-23 and 26 are pending in the application. Reconsideration is respectfully requested.

Claim Rejections – 35 USC §112

The Examiner has rejected claims 6, 18, 20, and 22 on the grounds that the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. Applicants have amended claims 6, 18, 20, and 22 to remove the language objected to by the Examiner. Withdrawal of the rejection under this section is respectfully requested.

Claim Rejections – 35 USC §102

Claims 1, 2, 6-21 and 23 are rejected under 35 U.S.C. §102(b) as being anticipated by Tice et al. (6,306,425 B1). The Examiner states that Tice teaches muscular injectable naltrexone microsphere compositions and their use in reducing consumption of alcohol. The Examiner also states that Tice discloses a composition comprising a matrix consisting of polymer poly-(D,L-lactide). The Examiner further states that Tice discloses naltrexone being released in a controlled manner for greater than 28 or about 32 days. The Examiner states that Tice discloses that smaller doses may be administered after the first dose, because one continues to obtain release from the prior injected microspheres to which is added the release from the lately administered microspheres, or one can enjoy enhanced levels of the naltrexone without increasing the amount of the microspheres which are administered. The Examiner further states that Tice discloses microspheres that are formulated from about 150-350 mg of naltrexone such that the plasma concentration is in a therapeutic range of at least about 2 ng/ml. The Examiner *asserts* that the Tice microsphere formulation gave an AUC of more than 3.3 times greater than that achieved by 50 mg/day oral administration based on the Examiner's interpretation of Tice at column 14, lines 40-55. With regard to claims 6 and

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