Expedited Procedure under 37 C.F.R. 1.116
Examining Group 1627

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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 of Use

AMENDMENT AFTER FINAL

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

Sir:

This Amendment is in response to the Final Office action mailed from the U.S. Patent and Trademark Office on July 20, 2010, in the above-identified application.

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 cancel Claims 21 and 22.

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 and wherein the biocompatible polymer is a polylactide-co-glycolide polymer.

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 (Withdrawn/Original) A method of treating an individual in need of naltrexone comprising administering naltrexone, in the absence of co-administering alcohol, to an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 (Withdrawn/Original) The method of Claim 3 wherein the naltrexone is administered in a long acting formulation comprising naltrexone.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 (Withdrawn/Original) A method of increasing the days prior to occurrence of alcohol consumption in an individual in need of naltrexone comprising administering a long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 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.

21-22. (Cancelled)

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. (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 two times greater than that achieved by 50 mg/day oral administration and wherein the biocompatible polymer is a polylactide-co-glycolide polymer.

REMARKS

Claims 21 and 22 are cancelled. Claims 1 and 26 are amended to incorporate the subject matter of allowable claim 22. Claims 1, 2, 6-20, 23 and 26 are under consideration. Claims 3-5 have been withdrawn. Claims 1-20, 23, and 26 are pending in the application. Reconsideration is respectfully requested.

Allowable Subject Matter

Applicants thank the Examiner for the indication of allowable subject matter with regard to claim 22. Applicants have amended claims 1 and 26 to incorporate the subject matter of claim 22. In view of the amendments to the claims, allowance of claims 1, 2, 6-20, 23 and 26 is respectfully requested.

Claim Rejections -35 U.S.C. §112

The Examiner has maintained the rejection of the claims 1, 2, 6-23 and 26 under 35 U.S.C. §112, first paragraph. In view of the amendments to claims 1 and 26 and all claims dependent thereon, it is believed that the rejection under this section is moot. Applicants respectfully request the withdrawal of the rejection.

A general authorization is hereby granted to charge Deposit Account No. 502807 for any fees required under § 37 C.F.R. 1.16 and 1.17 in order to maintain pendency of this application.

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