41. (Proposed) A method of distributing a sensitive drug **under exclusive control of a central pharmacy**, the method comprising:

receiving prescription requests **at the central pharmacy** from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber;

entering the information into **an exclusive computer database under exclusive control of the central pharmacy** for analysis of potential abuse situations, **wherein the use of the exclusive computer database is required for distribution of the sensitive drug**;

checking the credentials of the authorized prescriber;

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient;

checking the exclusive central computer database for potential abuse associated with the patient or the authorized prescriber;

providing the sensitive drug to the patient under control of the exclusive central pharmacy provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

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42. (Proposed) A method of distributing a sensitive drug **under an exclusive controlling entity**, the method comprising:

receiving prescription requests from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber;

entering the information into **an exclusive computer database under exclusive control of the exclusive controlling entity** for analysis of potential abuse situations, **wherein the use of the exclusive computer database is required for distribution of the sensitive drug**;

checking the credentials of the authorized prescriber;

confirming with the patient that educational material has been read prior to providing the sensitive drug;

checking the exclusive central computer database for potential abuse associated with the patient;

providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

SCHWEGMAN ■ LUNDBERG ■ WOESSNER ■ KLUTH
PATENT, TRADEMARK & COPYRIGHT ATTORNEYS
P.O. Box 2938
Minneapolis, MN 55402
Telephone (612) 373-6900 Facsimile (612) 339-3061

July 31, 2006

Time: 10:30 A.M.
(Minneapolis, Minn.)

TO: Commissioner for Patents
Attn: Lena Najarian
Patent Examining Corps
Facsimile Center
P.O. Box 1450
Alexandria, VA 22313-1450

FAX NUMBER (571) 273-8300

FROM: Bradley A. Forrest
Reg. No. 30,837
OUR REF: 101.031US1

TELEPHONE: 571-272-7072

*** Please deliver to Examiner Lena Najarian in Art Unit 3626. ***

Document(s) Transmitted: **Proposed Interview Agenda (1 page); Proposed Claims for Examiner Interview (9 pages).**

PLEASE NOTE: I neglected to send the proposed interview agenda with the proposed claims on Friday. Here is the agenda, with the proposed claims.

Total pages of this transmission, including cover letter: 11 pgs.
If you do NOT receive all of the pages described above, please telephone us at 612-373-6900 or fax us at 612-339-3061.

In re. Patent Application of: Dayton T. Reardan et al.
Serial No.: 10/322,348
Filed: December 17, 2002
Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Examiner: Lena Najarian
Group Art Unit: 3626
Docket No.: 101.031US1

Please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office on the date shown below.

John D Gustav-Wrathall
John Gustav-Wrathall

7-31-06
Date of Transmission

Application No. 10/322,348
Filed: 12/17/2002

Interview Agenda
2PM August 2, 2006.
Attendees:
For Applicant: Brad Forrest; Felissa Cagan
For USPTO: Examiner Najarian and Supervisor Thomas

1. Objective of Interview
2. Problems associated with sensitive drug distribution
3. Discussion of the current claims and art used to reject the claims.
4. Propose new claims/claim limitations to place claims in condition for allowance.

Proposed claims for 101.031US1 (serial 10/322,348) fax to 571-273-8300

1. (Previously Presented) A method of distributing a sensitive drug, the method comprising:

receiving prescription requests from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor;

entering the information into a central computer database for analysis of potential abuse situations;

checking the credentials of the doctor;

confirming with the patient that educational material has been read prior to shipping the sensitive drug;

confirming receipt of the sensitive drug; and

generating periodic reports via the central computer database to evaluate potential abuse patterns.

2. (Previously Presented) The method of claim 1 wherein receipt of the sensitive drug is confirmed by telephone call from a central pharmacy to the patient.

3. (Original) The method of claim 1 and further comprising launching an investigation of lost shipments.

4. (Previously Presented) The method of claim 1 and further comprising recording the confirmation with the patient that the educational material has been read in the central computer database.

5. (Original) The method of claim 1 and further comprising verifying the patient's home address.

6. (Original) The method of claim 1 and further comprising recording a designee identified by the patient to receive the sensitive drug.

7. (Original) The method of claim 1 and further comprising establishing a delivery date.

8. (Previously Presented) The method of claim 1 wherein prescription refills requested prior to an anticipated date are questioned by a pharmacist.

9. (Previously Presented) The method of claim 1 and further comprising shipping comprehensive printed materials to the doctor if the doctor is a first time prescriber of the sensitive drug.

10. (Original) The method of claim 1 wherein the credentials of the doctor comprise DEA (Drug Enforcement Agency) and state license numbers.

11. – 31. (Cancelled)

32. (Previously Presented) A method of distributing a sensitive drug under exclusive control of an exclusive central pharmacy, the method comprising:

receiving prescription requests from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor;

entering the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations;

checking the credentials of the doctor;

confirming with the patient that educational material has been read prior to shipping the sensitive drug;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

33. (Previously Presented) A method of distributing a sensitive drug under exclusive control of an exclusive central pharmacy, the method comprising:

receiving prescription requests from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor;

entering the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations;

checking the credentials of the doctor;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

34. (Previously Presented) The method of claim 33 wherein the exclusive central pharmacy controls the exclusive central database.

35. (Previously Presented) The method of claim 33 and further comprising selectively blocking shipment of the sensitive drug to a patient.

36. (Previously Presented) The method of claim 33 wherein an abuse pattern is associated with a patient, and shipment is blocked upon such association.

37. (Previously Presented) The method of claim 33 wherein the sensitive drug comprises gamma hydroxy butyrate (GHB).

Additional limitations:

1 – only way to distribute sensitive drug is through use of the central database.

This differs significantly from Moradi et al., which selects a pharmacy based on the patient's location and ensures delivery of a prescription. There is no discussion in Maradi et al., of requiring use of the central database to distribute a sensitive drug. In other words, many different pharmacies may or may not use the system of Moradi et al. In the current claims, the use of a single central database is required for all distribution of the sensitive drug.

Lilly describes cooperative use of a database by multiple pharmacies to keep track of a prescription history for patients. This does not describe requiring the use of a central database for tracking all shipments of a sensitive drug. Thus, neither reference, alone or combined, suggests the requirement that all shipments of a sensitive drug be controlled through the use of a central database.

None of the references, alone or combined, suggest that a sensitive drug can only be distributed under control of a single source, or required to be tracked through the use of a single central database. It provides the ability to track potential abuse patterns with much greater accuracy, and may have been the basis for allowing the life improving drug Xyrem, to make it onto the market.

A progression of claims based off claim 32 and 33.

38. (Proposed) A method of distributing a sensitive drug, the method comprising:

receiving prescription requests from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber;

entering the information into an exclusive computer database for analysis of potential abuse situations, **wherein the use of the exclusive computer database is required for distribution of the sensitive drug;**

checking the credentials of the authorized prescriber;

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

Last element optional?

39. (Proposed) A method of distributing a sensitive drug, the method comprising:

receiving prescription requests **at a central pharmacy** from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber;

entering the information into **an exclusive computer database under exclusive control of the central pharmacy** for analysis of potential abuse situations, **wherein the use of the exclusive computer database is required for distribution of the sensitive drug**;

checking the credentials of the authorized prescriber;

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

40. (Proposed) A method of distributing a sensitive drug **under control of an exclusive central pharmacy**, the method comprising:

receiving prescription requests **at the central pharmacy** from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber;

entering the information into **an exclusive computer database under exclusive control of the central pharmacy** for analysis of potential abuse situations, **wherein the use of the exclusive computer database is required for distribution of the sensitive drug**;

checking the credentials of the authorized prescriber;

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient;

checking the exclusive central computer database for potential abuse associated with the patient;

providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

41. (Proposed) A method of distributing a sensitive drug **under exclusive control of a central pharmacy**, the method comprising:

receiving prescription requests **at the central pharmacy** from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber;

entering the information into **an exclusive computer database under exclusive control of the central pharmacy** for analysis of potential abuse situations, **wherein the use of the exclusive computer database is required for distribution of the sensitive drug;**

checking the credentials of the authorized prescriber;

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient;

checking the exclusive central computer database for potential abuse associated with the patient or the authorized prescriber;

providing the sensitive drug to the patient under control of the exclusive central pharmacy provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

42. (Proposed) A method of distributing a sensitive drug **under an exclusive controlling entity**, the method comprising:

receiving prescription requests from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber;

entering the information into **an exclusive computer database under exclusive control of the exclusive controlling entity** for analysis of potential abuse situations, **wherein the use of the exclusive computer database is required for distribution of the sensitive drug**;

checking the credentials of the authorized prescriber;

confirming with the patient that educational material has been read prior to providing the sensitive drug;

checking the exclusive central computer database for potential abuse associated with the patient;

providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

Interview Summary	Application No.	Applicant(s)	
	10/322,348	REARDAN ET AL.	
	Examiner	Art Unit	
	Lena Najarian	3626	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Lena Najarian*.

(2) *Joseph Thomas*.

(3)*Brad Forrest*.

(4)*Felissa Cagan*.

Date of Interview: *02 August 2006*.

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☒ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: ~~[illegible]~~ 1, in particular + proposed new claims

Identification of prior art discussed: Moradi + Lilly

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: _____.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Discussed possible amendments to the claims. The Examiners will reconsider the applied references in light of any amendments + remarks to be made in response to the non-final rejection.

Joseph Thomas
JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Lena Najarian
Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner: Lena Najarian
Serial No.:	10/322,348	Group Art Unit: 3626
Filed:	December 17, 2002	Docket No.: 101.031US1
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD	

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

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

This responds to the Office Action dated June 19, 2006. Please amend the above-identified patent application as follows.

IN THE CLAIMS

Please amend the claims as follows:

1 – 31. (Cancelled)

32. (Currently Amended) A method of distributing a sensitive drug under exclusive control of an exclusive central pharmacy, the method comprising:

only receiving prescription requests at the exclusive central pharmacy from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor;

requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations;

checking the credentials of the doctor;

confirming with the patient that educational material has been read prior to shipping the sensitive drug;

checking the exclusive central database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive central database;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

33. (Currently Amended) A method of distributing a sensitive drug under exclusive control of an exclusive central pharmacy, the method comprising:

receiving prescription requests from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor;

entering the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations;

checking the credentials of the doctor;

checking the exclusive central database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive central database;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

34. (Currently Amended) The method of claim 33 wherein the exclusive central pharmacy controls the exclusive ~~central~~ database.

35. (Previously Presented) The method of claim 33 and further comprising selectively blocking shipment of the sensitive drug to a patient.

36. (Previously Presented) The method of claim 33 wherein an abuse pattern is associated with a patient, and shipment is blocked upon such association.

37. (Previously Presented) The method of claim 33 wherein the sensitive drug comprises gamma hydroxy butyrate (GHB).

38. (New) A method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests at the central pharmacy from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of the sensitive drug;

checking of the credentials of the authorized prescriber;

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient;

requiring checking of the exclusive central computer database for potential abuse associated with the patient and/or the authorized prescriber;

only providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

39. (New) A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB;

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive central computer database for potential GHB abuse associated with the patient;

only providing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns.

40. (New) A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB;

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive central computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns.

41. (New) A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

manufacturing GHB;

only providing manufactured GHB to the exclusive central pharmacy;

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB;

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive central computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns.

42. (New) A method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests at the central pharmacy from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of the sensitive drug;

checking of the credentials of the authorized prescriber;

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient;

requiring checking of the exclusive central computer database for potential abuse associated with the patient and/or the authorized prescriber;

only providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse; and

confirming receipt by the patient of the sensitive drug.

REMARKS

This responds to the Office Action dated June 19, 2006, and the references cited therewith.

Claims 32-34 are amended. Claims 1-10 are canceled. Claims 38-42 are added. As a result, claims 32-42 are now pending in this application.

Interview Summary

Applicant wishes to thank Examiner Najarian and Supervisor Thomas for the courtesies extended to Bradley Forrest and Felissa Cagan during an in-person interview on August 2, 2006. We discussed possible amendments to the claims. Some of the discussed amendments are reflected in amended claims 32 and 33, as well as in new independent claims 38-42. No exhibits were presented.

Double Patenting Rejection

Claims 1-10 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10 of copending Application No. 10/979,665. Applicant has cancelled claims 1-10 without prejudice.

§112 Rejection of the Claims

Claim 34 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 34 has been amended to resolve the rejection.

§103 Rejection of the Claims

Claims 1-2, 4-8, 10, and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) and further in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1). Claims 1-10 have been cancelled, and claim 32 has been amended consistent with amendments discussed.

Claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) as applied to claim 1 above, and further in view of Andreasson et al. (U.S. Patent Publication No. 2003/0160698 A1). Claim 3 was cancelled as described above.

Claim 9 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) as applied to claim 1 above, and further in view of Mayaud (U.S. Patent No. 5,845,255). Claim 9 was cancelled as described above.

Claims 33-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1). Claim 33 was amended consistent with amendments discussed.

Claim 37 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1), and further in view of Melker et al. (U.S. Patent Publication No. 2002/0177232).

New claims 38-42 have been added and are consistent with amendments discussed. In particular, none of the references describe a required checking of an exclusive database for potential abuse, and then not shipping or distributing the sensitive drug if the required check uncovers potential abuse. Some of the claims expressly recite mailing of the sensitive drug only if the check is ok, and a further claim recites that the sensitive drug is GHB extensively throughout the elements of the claim.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6972 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6972

Date 8-8-2006

By _____
Bradley A. Forrest
Reg. No. 30,837

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8 day of ~~July~~ Aug. 2006.

Name

Signature

Electronic Patent Application Fee Transmittal

Application Number:	10322348
Filing Date:	17-Dec-2002
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor:	Dayton T. Reardan
Filer:	Gregg Alan Peacock/John Gustav-Wrathall
Attorney Docket Number:	101.031US1
Filed as Small Entity	

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Independent claims in excess of 3	2201	1	100	100
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	100

Electronic Acknowledgement Receipt

EFS ID:	1146223
Application Number:	10322348
Confirmation Number:	5446
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor:	Dayton T. Reardan
Customer Number:	21186
Filer:	Gregg Alan Peacock/John Gustav-Wrathall
Filer Authorized By:	Gregg Alan Peacock
Attorney Docket Number:	101.031US1
Receipt Date:	08-AUG-2006
Filing Date:	17-DEC-2002
Time Stamp:	17:06:15
Application Type:	Utility
International Application Number:	

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	$100
RAM confirmation Number	358
Deposit Account	190743
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part	Pages
1		101031us1_response.pdf	529480	yes	10

	Multipart Description		
	Doc Desc	Start	End
	Transmittal letter	1	1
	Amendment - After Non-Final Rejection	2	2
	Claims	3	7
	Applicant Arguments/Remarks Made in an Amendment	8	10

Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	8153	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	537633		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.: 101.031US1
Filed: December 17, 2002
Examiner: Lena Najarian

Serial No.: 10/322,348
Due Date: September 19, 2006
Group Art Unit: 3626

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

We are transmitting herewith the following attached items (as indicated with an "X"):

X Amendment and Response (9 pgs.).
X Authorization to charge Deposit Account 19-0743 in the amount of $100.00 to cover the fee for additional claims as calculated below.

If not provided for in a separate paper filed herewith, if an additional fee is required due to changes to the claims, the fee has been calculated as follows:

CLAIMS AS AMENDED						
	(1) Claims Remaining After Amendment		(2) Highest Number Previously Paid For	(3) Present Extra	Rate	Fee
TOTAL CLAIMS	11	-	31	0	x 25 =	$0.00
INDEPENDENT CLAIMS	7	-	6	1	x 100 =	$100.00
[]MULTIPLE DEPENDENT CLAIMS PRESENTED						$0.00
TOTAL						$100.00

Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
Customer Number 21186

By: _____
Atty: Bradley A. Forrest
Reg. No. 30,837

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8 day of August, 2006.

John D. Gustav-Wrathall
Name

Signature

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
(GENERAL)

PTO/SB/06 (08-03)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 10/322,348

CLAIMS AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE	SMALL ENTITY FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY FEE
BASIC FEE (37 CFR 1.16(a))				$____	OR		$____
TOTAL CLAIMS (37 CFR 1.16(c))	minus 20 =	*	X $____ =		OR	X $____ =	
INDEPENDENT CLAIMS (37 CFR 1.16(b))	minus 3 =	*	X $____ =		OR	X $____ =	
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(d))			+ $____ =		OR	+ $____ =	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL		OR	TOTAL	

CLAIMS AS AMENDED – PART II

8/8/06

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
AMENDMENT A	Total (37 CFR 1.16(c))	* 11	Minus	** 30	=	X $25 =		OR	X $____ =	
	Independent (37 CFR 1.16(b))	* 7	Minus	*** 6	= 1	X $100 =	100	OR	X $____ =	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =	PD	OR	+ $____ =	
						TOTAL ADD'L FEE	100.00	OR	TOTAL ADD'L FEE	
AMENDMENT B	Total (37 CFR 1.16(c))	*	Minus	**	=	X $____ =		OR	X $____ =	
	Independent (37 CFR 1.16(b))	*	Minus	***	=	X $____ =		OR	X $____ =	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =		OR	+ $____ =	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
AMENDMENT C	Total (37 CFR 1.16(c))	*	Minus	**	=	X $____ =		OR	X $____ =	
	Independent (37 CFR 1.16(b))	*	Minus	***	=	X $____ =		OR	X $____ =	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =		OR	+ $____ =	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/322,348	12/17/2002	Dayton T. Reardan	101.031US1	5446

21186 7590 10/18/2006

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	10/322,348	REARDAN ET AL.	
	Examiner	Art Unit	
	Lena Najarian	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 32-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 32-42 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 8/8/06. Claims 32-42 are pending. Claims 1-31 are cancelled. Claims 32, 33, and 34 have been amended. Claims 38-42 are newly added.

Double Patenting

2. The rejection of claims 1-10 under 35 U.S.C. 101 is hereby withdrawn due to the amendment filed 8/8/06.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 32-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claim 32 recites "only" receiving prescription requests "at the exclusive central pharmacy." It is unclear to the Examiner whether the exclusive central pharmacy *only* receives prescription requests (i.e., limiting what the central pharmacy can receive to prescription requests) or whether receiving prescription requests *only* happens at the exclusive central pharmacy (i.e, excluding other pharmacies from receiving the prescription requests). Clarification is required.

5. Claims 32-42 recite the limitations for which there is no antecedent basis in the claims. In particular, the following passages lack or have vague antecedent basis:

(i) "the exclusive central database": claim 32, lines 11 and 13

claim 33, lines 8 and 10

(ii) "the exclusive database": claim 34, line 2

(iii) "the exclusive central computer database": claim 38, line 12

claim 39, line 12

claim 40, line 12

claim 41, line 14

claim 42, line 12.

(iv) Claims 35-37 incorporate the deficiencies of claim 33, through dependency, and are also rejected.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 32, 38, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US

2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1), and further in view of Ukens ("Specialty Pharmacy").

(A) Claim 32 has been amended to now recite only receiving prescription requests at the exclusive central pharmacy and requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy.

As per these features, Ukens discloses restricting distribution of a specialty medication to only one pharmacy (see page 3, paragraphs 3-5 of Ukens).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Ukens within Moradi, Lilly, and Califano. The motivation for doing so would have been to limit access to dangerous drugs (page 3, paragraph 5 of Ukens).

Claim 32 has also been amended to now recite "checking the exclusive central database for potential abuse of the sensitive drug; only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive central database."

Moradi discloses checking the exclusive central database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive central database (para. 43, para. 45, para. 6, and Fig. 3, items 318 & 322 of Moradi).

The remainder of claim 32 is rejected for the same reasons given in the previous Office Action, and incorporated herein.

(B) Referring to claim 38, Moradi discloses a method of distributing a drug under control of an exclusive central pharmacy, the method comprising (para. 3 and para. 24 of Moradi):

receiving prescription requests at the central pharmacy from an authorized prescriber containing information identifying a patient, the drug, and various credentials of the authorized prescriber (para. 35, para. 116, and para. 117 of Moradi);

checking of the credentials of the authorized prescriber (para. 118 of Moradi);

requiring checking of the exclusive central computer database for potential abuse associated with the patient and/or the authorized prescriber (para. 43, para. 45, and Fig. 3, items 318 & 322 of Moradi);

only providing the drug to the patient provided information in the exclusive computer database is not indicative of potential abuse (para. 43, para. 45, and Fig. 3, items 318 & 322 of Moradi);

and

confirming receipt by the patient of the drug (see abstract of Moradi).

Moradi does not expressly disclose that the drug is a sensitive drug, entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of the sensitive drug, confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient, and generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

Lilly et al. disclose that the drug is a sensitive drug, entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, and generating periodic reports via the exclusive computer database to evaluate potential diversion patterns. (para. 33, para. 69, para. 54, para. 58, para. 61, para. 11, and para. 57 of Lilly; the Examiner interprets "controlled substance" to be a form of "sensitive drug").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Lilly within Moradi. The motivation for doing so would have been to immediately detect problems related to abuse, fraud, and misuse of medications (para. 57 of Lilly).

Moradi and Lilly do not disclose confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient.

Califano et al. disclose confirming with the patient that educational material has been read prior to providing the drug to the patient (para. 84 of Califano).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Califano within Moradi and Lilly. The motivation for doing so would have been to ensure that the patient knows about the risks and dangers associated with the drug (para. 43 of Califano).

Moradi, Lilly, and Califano do not expressly disclose wherein the use of the exclusive computer database is required for distribution of the sensitive drug.

However, Ukens discloses restricting distribution of a specialty medication to only one pharmacy (see page 3, paragraphs 3-5 of Ukens).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Ukens within Moradi, Lilly, and Califano. The motivation for doing so would have been to limit access to dangerous drugs (page 3, paragraph 5 of Ukens).

(C) Claim 42 repeats the same limitations as claim 38 and is rejected for the same reasons given for that claim.

8. Claims 33-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1).

(A) Claim 33 has been amended to now recite "checking the exclusive central database for potential abuse of the sensitive drug; only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive central database."

Moradi discloses checking the exclusive central database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive central database (para. 43, para. 45, para. 6, and Fig. 3, items 318 & 322 of Moradi).

The remainder of claim 33 is rejected for the same reasons given in the previous Office Action, and incorporated herein.

(B) Referring to claim 34, Moradi discloses wherein the exclusive central pharmacy controls the exclusive database (para. 7 and para. 43 of Moradi).

(C) Claims 35 and 36 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

9. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1), and further in view of Melker et al. (US 2002/0177232 A1).

(A) Claim 37 has not been amended and is rejected for the same reasons given in the previous Office Action, and incorporated herein.

10. Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1), and further in view of Talk About Sleep ("An Interview with Orphan Medical about Xyrem").

(A) Referring to claim 39, Moradi discloses a method of distributing a drug under control of an exclusive central pharmacy, the method comprising (para. 3 and para. 24 of Moradi):

receiving prescription requests for the drug at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber (para. 35, para. 116, and para. 117 of Moradi);

checking of the credentials of the authorized prescriber (para. 118 of Moradi);

requiring checking of the exclusive central computer database for potential abuse associated with the patient (para. 43, para. 45, and Fig. 3, items 318 & 322 of Moradi);

only providing the drug to the patient provided information in the exclusive computer database is not indicative of potential abuse (para. 43, para. 45, and Fig. 3, items 318 & 322 of Moradi);

and

confirming receipt by the patient of the drug (see abstract of Moradi).

Moradi does not expressly disclose that the drug is gamma hydroxy butyrate (GHB), entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB, confirming with the patient that GHB educational material has been read prior to providing GHB to the patient for a first time, and generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns.

Lilly et al. disclose that the drug is a sensitive drug, entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, and generating periodic reports via the exclusive computer database to evaluate potential diversion patterns. (para. 33, para. 69, para. 54, para. 58, para. 61, para. 11, and para. 57 of Lilly; the Examiner interprets "controlled substance" to be a form of "sensitive drug").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Lilly within Moradi. The motivation for doing so would have been to immediately detect problems related to abuse, fraud, and misuse of medications (para. 57 of Lilly).

Moradi and Lilly do not disclose confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient.

Califano et al. disclose confirming with the patient that educational material has been read prior to providing the drug to the patient (para. 84 of Califano).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Califano within Moradi and Lilly. The motivation for doing so would have been to ensure that the patient knows about the risks and dangers associated with the drug (para. 43 of Califano).

Moradi, Lilly, and Califano do not expressly disclose that the drug is GHB and wherein the use of the exclusive computer database is required for distribution of GHB.

However, Talk About Sleep discloses providing GHB through a specialty distribution system that utilizes a central pharmacy (see "An Interview with Orphan Medical about Xyrem," talkaboutsleep.com).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Talk About Sleep within Moradi, Lilly, and Califano. The motivation for doing so would have been to provide this medicine to patients that need it in a responsible manner (see "An Interview with Orphan Medical about Xyrem," talkaboutsleep.com).

(B) Claim 40 differs from claim 39 by reciting "mailing" GHB as opposed to "providing." As per this feature, the Examiner respectfully submits that Moradi discloses mailing the drugs (see para. 6 of Moradi).

The remainder of claim 40 is rejected for the same reasons given for claim 39 above.

(C) Claim 41 differs from claim 40 by reciting "manufacturing GHB and only providing manufactured GHB to the exclusive central pharmacy."

As per these features, the Examiner respectfully submits that Talk About Sleep discloses manufacturing GHB and only providing manufactured GHB to the exclusive central pharmacy (see "An Interview with Orphan Medical about Xyrem," talkaboutsleep.com).

The remainder of clam 41 is rejected for the same reasons given for claim 40 above.

Response to Arguments

11. Applicant's arguments filed 8/8/06 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 8/8/06.

(1) Applicant argues at page 8 that none of the references describe a required checking of an exclusive database for potential abuse, and then not shipping or distributing the sensitive drug if the required check uncovers potential abuse.

(A) As per the first argument, the Examiner respectfully submits that Moradi discloses at para. 43 a database that keeps track of medicine orders that are delivered to the patients. The Moradi system ensures that patients do not receive medication in excess of their prescription and prevents prescription abuse (see para. 45 of Moradi). As such, it is respectfully submitted that Moradi checks the database for potential abuse and does not ship or distribute the drug if abuse is uncovered (i.e., the medicine has already been delivered).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches tracking the distribution of prescription drugs and other controlled articles (US 6,952,681 B2) and an apparatus and method for processing prescription requests using a remotely located prescription processing system (US 7,058,584 B2).

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

In
10-13-06

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER

Notice of References Cited	Application/Control No. 10/322,348	Applicant(s)/Patent Under Reexamination REARDAN ET AL.	
	Examiner Lena Najarian	Art Unit 3626	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,952,681 B2	10-2005	McQuade et al.	705/28
*	B	US-7,058,584 B2	06-2006	Kosinski et al.	705/2
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
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	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
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	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Ukens, C. "Specialty Pharmacy," 6/5/00, Drug Topics, v. 144, p. 40.
	V	"An Interview with Orphan Medical about Xyrem," http://www.talkaboutsleep.com/sleep-disorders/archives/Narcolepsy_xyrem_interview.htm, 2/12/01.
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims

Application/Control No.	Applicant(s)/Patent under Reexamination
10/322,348	REARDAN ET AL.
Examiner	**Art Unit**
Lena Najarian	3626

√	Rejected	–	(Through numeral) Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

Claim		Date
Final	Original	10/13/06
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Claim		Date
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Search Notes	Application/Control No.	Applicant(s)/Patent under Reexamination
	10/322,348	REARDAN ET AL.
	Examiner	Art Unit
	Lena Najarian	3626

SEARCHED			
Class	Subclass	Date	Examiner
	updated previous searches	10/4/2006	LN

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
EIC search	10/6/2006	LN

EXPEDITED PROCEDURE – EXAMINING GROUP 3626

S/N 10/322,348 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner: Lena Najarian
Serial No.:	10/322,348	Group Art Unit: 3626
Filed:	December 17, 2002	Docket No.: 101.031US1
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD	

AMENDMENT & RESPONSE UNDER 37 C.F.R. 1.116

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

In response to the Final Office Action dated October 18, 2006, please amend the application as follows:

IN THE CLAIMS

Please amend the claims as follows:

1 – 31. (Cancelled)

32. (Currently Amended) A method of distributing a sensitive drug under exclusive control of an exclusive central pharmacy, the method comprising:

~~only~~ receiving all prescription requests at the exclusive central pharmacy from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor;

requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations;

checking the credentials of the doctor;

confirming with the patient that educational material has been read prior to shipping the sensitive drug;

checking the exclusive computer~~central~~ database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer~~central~~ database;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

33. (Currently Amended) A method of distributing a sensitive drug under exclusive control of an exclusive central pharmacy, the method comprising:

receiving prescription requests from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor;

entering the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations;

checking the credentials of the doctor;

checking the exclusive computer~~central~~ database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer~~central~~ database;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

34. (Currently Amended) The method of claim 33 wherein the exclusive central pharmacy controls the exclusive computer database.

35. (Previously Presented) The method of claim 33 and further comprising selectively blocking shipment of the sensitive drug to a patient.

36. (Previously Presented) The method of claim 33 wherein an abuse pattern is associated with a patient, and shipment is blocked upon such association.

37. (Previously Presented) The method of claim 33 wherein the sensitive drug comprises gamma hydroxy butyrate (GHB).

38. (Currently Amended) A method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests at the central pharmacy from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of the sensitive drug;

checking of the credentials of the authorized prescriber;

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient;

requiring checking of the exclusive ~~central~~ computer database for potential abuse associated with the patient and/or the authorized prescriber;

only providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

39. (Currently Amended) A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB;

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive ~~central~~ computer database for potential GHB abuse associated with the patient;

only providing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns.

40. (Currently Amended) A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB;

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive ~~central~~ computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns.

41. (Currently Amended) A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

manufacturing GHB;

only providing manufactured GHB to the exclusive central pharmacy;

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB;

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive ~~central~~ computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns.

42. (Currently Amended) A method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests at the central pharmacy from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of the sensitive drug;

checking of the credentials of the authorized prescriber;

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient;

requiring checking of the exclusive ~~central~~ computer database for potential abuse associated with the patient and/or the authorized prescriber;

only providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse; and

confirming receipt by the patient of the sensitive drug.

REMARKS

This responds to the Office Action dated October 18, 2006.

Claims 32-34 and 38-42 are amended. Claims 32-42 are pending in this application.

§112 Rejection of the Claims

Claims 32-42 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims have been amended to clarify the § 112 rejections, and not in response to art. They are not believed to introduce any new issues, and are believed to place the application in better condition for appeal.

§103 Rejection of the Claims

Claims 32, 38 and 42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) and further in view of Ukens ("Specialty Pharmacy"). This rejection is respectfully traversed, as the references do not disclose all the claimed elements. None of the references describe a required checking of an exclusive database for potential abuse, and then not shipping or distributing the sensitive drug if the required check uncovers potential abuse. In addition, the references are not properly combinable at least due to significant teaching away from such combining.

Moradi does not teach an exclusive computer database.

Claims 32, 38 and 42 all refer to an exclusive computer database. The Office Action indicates that "Moradi discloses checking the exclusive central database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive central database (para. 43, para. 45, para. 6 and FIG. 3, items 318 and 322 of Moradi)."

The cited portions of Moradi are repeated below, and it is clear that there is no teaching of an exclusive computer database as claimed.

Paragraph 43:

"If the prescription is verified as OK, the processing continues in the exemplary embodiment by having the pharmacist fill the prescription and enter the prescription data into the pharmacist's existing Pharmacy Management System (PMS). The PMS system assigns the prescription a prescription number, and the pharmacist enters that prescription number and the number of refills into the PODP 216, which then communicates that data back to the CSS 102 with an identification of the prescription. The pharmacist then gives, at step 322, the ordered medicine and a copy of the prescription image to a prescription deliverer, which is a delivery person in the exemplary embodiments, for delivery to the patient. The CSS 102 is notified that the delivery person is in the process of delivering the medication and the status of the prescription is changed to "delivery" within the CSS database 204. The exemplary embodiment further includes providing the delivery person with a "Route Slip" that has printed directions to the patient's address along with the scanned prescription image. The delivery person hand-delivers the medicine to the recipient if and only if the recipient is holding the original copy of the prescription that is identical to the image provided to the delivery person. This ensures that the proper patient gets the medicine and that the medicine is delivered only once. After the medicine is delivered, the delivery person receives, at step 324, the patient's signature to certify a correct delivery. The delivery person can also stamp the original prescription to signify that the medicine specified in that prescription has been delivered and that the prescription has already been filled. The delivery person then returns, also at step 324, to the POD system 106 and the POD operator updates the order status to "Done" in the PODP 212 so that this information is communicated as a confirmation to the CSS 102 and the CSS Database 204. The exemplary embodiment supports status designations of: delivered, no one at the address, prescription mismatch or one of a number of other potential reasons for non-delivery. Embodiments of the present invention provide the delivery person with a wireless communication device that initiates communication of the delivery status immediately upon delivery of the medication to the patient without

requiring the delivery person to first return to the POD 106. These devices also include a written signature digitizer that is able to capture and digitize the patient's signature and transmit that image to along with the delivery status."

Paragraph 43 may mention various electronic systems, such as the pharmacy management system, but makes no mention of an exclusive computer database.

Paragraph 45:

"All checks to make sure that a patient is not allowed to have a prescription filled twice are performed by the exemplary embodiment of the present invention by human operators (e.g., the driver or the POD operator). This further ensures that patients do not receive medication in excess of there prescription and to prevent prescription abuse."

Paragraph 45 also makes no reference to an exclusive computer database.

Paragraph 5:

"Delivery of prescription medication has changed little in recent times. Conventional prescription medication delivery begins by a prescription being first issued by a physician and then the patient is required to present that prescription to a pharmacist. The pharmacist then prepares the prescribed medication and delivers it to the patient. This process requires the patient to visit the pharmacist and to either wait at the pharmacist's facility or to return to the pharmacist's facility when the prescription is ready. This is often inconvenient for the patient."

Paragraph 5 also makes no reference to an exclusive computer database.

Fig. 3, items 318 and 322: These elements appear to be described in paragraph 43 as discussed above, and do not mention the use of an exclusive computer database. Further, no reference to item 318 was found in the application.

Ukens teaches away from using a central pharmacy

The Office Action indicates that "Ukens discloses restricting distribution of a specialty medication to only one pharmacy (see page 3, paragraphs 3-5 of Ukens)." It goes on to state that

"At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Ukens within Moradi, Lilly, and Califano. The motivation for doing so would have been to limit access to dangerous drugs (page 3, paragraph 5 of Ukens)."

These statements are respectfully traversed. Paragraphs 3-5 of Ukens describes that "…restricted distribution of such products raises issues of patient access and safety." It then goes on to state that "by restricting distribution of a specialty medication to only one pharmacy, a manufacturer exposes patients to the risk of not receiving the medications in a timely manner if there's a disruption in the delivery system. In addition, shunting one part of therapy away from a patient's regular pharmacist can create the potential for undiscovered drug interactions. In paragraph 5, Ukens states: "A better way to handle specialty pharmaceuticals would be for manufacturers to set the criteria for their specialty products and then open distribution to any pharmacy that measures up,…" Thus, while Ukens acknowledges the potential for restricting distribution to a single pharmacy, it describes a better way that does not expose patients to some identified risks. In essence, it advocates away from the use of a single pharmacy. Thus, one of skill in the art would not combine the teachings of Ukens with Moradi, Lilly and Califano to arrive at the current claims.

Ukens does not describe the use of an exclusive computer database. This combination of four references does not provide or suggest a solution to one of skill in the art allowing distribution of a sensitive drug as claimed.

Previous rejections of claim 32 were incorporated.

The Office Action incorporates the same reasons to reject claim 32 as in the previous Office Action. The suggestion to combine the reference in the previous Office Action is not directed to solving the same or similar problem which the claimed invention addresses. Further, there is no teaching in the prior art of application of the combination to solve the same or similar problems which the claimed invention addresses. The Office Action indicates that the motivation for combining the features of Lilly within Moradi would be "to ensure that prescribers have an accurate view of their patients' use of prescription drugs and to help protect professionals from lawsuits and other potential liabilities (para. 58 of Lilly)." As stated in the

response to arguments section A of the Final Office Action, Lilly also describes reducing misused and abused prescriptions and the need for better tracking and management of prescription in Paragraph 12. However, the purpose for such reductions is related to abuse by the patient, and not abuse of a sensitive drug as claimed. The purpose of the presently claimed invention is to track sensitive drugs and reduce the potential for abuse, such as diversion of the sensitive drug.

Moradi is directed to "securely providing prescription medication to patients." Abstract. In other words, it is directed to making sure that the patient receives the medication, not preventing abuse, such as further distribution by the patient. Prescriptions are validated, a pharmacy is selected, and the prescribed medicine is delivered to the patient, as described in the Abstract. As the Office Action indicates, Moradi does not disclose that the drug is a sensitive drug, does not disclose the use of a central database for analysis of potential abuse situations, does not confirm that the patient has read educational material and does not generate periodic reports via a central database to evaluate potential abuse patterns. As is evident from these statements, Moradi lacks quite a few elements of the claimed invention, and the suggestion provided to combine Moradi with Lilly is improper, since the purpose stated is not related to the same or similar problem addressed by the claimed invention. It would seem that a suggestion to combine the references, drawing several different elements from each of the references, should be a very strong suggestion.

Even if one were to combine multiple selected elements from each of Moradi and Lilly, an element of the claimed invention is still lacking. The Office Action indicates that the combination does not disclose "confirming with the patient that educational material has been read prior to shipping the drug." Califano is cited as providing this missing element, and that the motivation for doing so "would have been to ensure that the patient knows about the risks and dangers associated with the drug (para. 43 of Califano)." Califano is directed to obtaining consent for a clinical trial. Abstract. It is not directed toward preventing abuse. The cited motivation is very different from the purpose of the presently claimed invention of distributing a sensitive drug in a manner that helps prevent abuse, making it very unlikely that one of skill in the art would be motivated to combine the references. As a proper prima facie case of obviousness has not been established, the rejection should be withdrawn.

The Response to Arguments section B of the Final Office Action, the Examiner states that the test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. This, however, does not address the fact that there is no proper suggestion to combine the references in the first place, since they are not directed towards the same or similar problems. Thus, one does not even arrive at the question of what the combination suggests if the combination is not proper.

Further in section B of the response to arguments in the Final Office Action, the Examiner states: "In response to applicant's argument that the cited motivation is very different from the purpose of the presently claimed invention, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." No such recognition is being stated by Applicant. Applicant is merely trying to say that the art addresses a different problem than that of the invention as claimed, and thus, the references are not properly combinable. The language quoted from the Final Office Action appears to state that Applicant simply recognized new advantages flowing from the combination of the references. This statement is respectfully traversed, as Applicant is merely stating that the combination is improper, since the references are directed to problems that are not similar to those addressed by the claimed invention.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 2143. The Examiner must avoid hindsight. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). As indicated above, multiple elements from each of Moradi and Lilly were combined to make the rejection. Because multiple elements from each were used, there is no reasonable expectation of success in making the combination. Further, it points toward the improper use of hindsight, using the claims as a roadmap to make the combination.

The Final Office Action in section C, purports to address the above argument by reciting that reconstruction based on hindsight is proper so long as it takes into account only knowledge that was within the level of ordinary skill and does not include knowledge gleaned only from the applicant's disclosure. Section C does not state how only knowledge within the level of ordinary

skill was used, and further does not address the argument that a reasonable expectation of success in making the combination has not been shown.

A factor cutting against a finding of motivation to combine or modify the prior art is when the prior art teaches away from the claimed combination. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path the applicant took. *In re Gurley*, 27 F.3d 551, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994); *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (C.C.P.A. 1969); *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 243, 245 (C.C.P.A. 1963). Lilly describes the cooperative use of a database by multiple different pharmacies, prescribers and patients, to keep track of the prescription history for a patient. It would be an extremely daunting task to get the cooperation of all these parties. The presently claimed invention uses a central database for analysis of potential abuse situations for distribution of a sensitive drug, not to track all prescriptions for a patient. The ambitious path set forth in Lilly would discourage one of skill in the art from considering using it to solve the problems addressed in the presently claimed invention.

Rejection of claim 38

The Office Action indicates that Moradi discloses a method of distributing a drug under control of an exclusive central pharmacy in paragraphs 3 and 24. Such paragraphs have been reviewed in detail, and no reference or suggestion of an exclusive central pharmacy for a sensitive drug was found.

Since Moradi does not describe an exclusive central pharmacy, prescription requests are not received at an exclusive central pharmacy as claimed.

As described above, Moradi does not teach or suggest an exclusive computer database for distributing a sensitive drug as claimed.

The Office Action admits that Moradi lacks several further elements, and indicates that "Lilly et al. disclose that the drug is a sensitive drug, entering the information into an exclusive computer database under exclusive control of the central pharmacy..." Applicant respectfully traverses the statement of the teaching of Lilly et al. There is no exclusive computer database for

distribution of a drug. Rather, Lilly et al., as previously pointed out, has a goal of tracking drug use for a patient. This is very different from tracking all the use of a single drug by every patient.

The references are not properly combinable for reasons already discussed above.

Claims 33-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1). Claims 33-36 also include an exclusive computer database used in distributing a sensitive drug. As indicated with respect to claim 32, none of the references, alone or combined teach or suggest the use of an exclusive computer database. Still further, the references are not properly combinable as discussed above.

Claim 37 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) and further in view of Melker et al. (U.S. Patent Publication No. 2002/0177232 A1). This rejection is respectfully traversed. Claim 37 depends from claim 33, which is already believed allowable. The addition of Melker et al., does not provide any of the teaching or suggestion lacking in the other references that are combined.

Claims 39-41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) and further in view of "Talk About Sleep: An Interview with Orphan Medical about Xyrem".

This rejection is respectfully traversed. Claims 39-41 all refer to the use of an exclusive computer database for distribution of a sensitive drug. None of the references alone or combined teach or suggest such an exclusive computer database. "Talk About Sleep: An Interview with Orphan Medical about Xyrem" also does not describe the use of an exclusive computer database for distribution of a sensitive drug such as Xyrem. Further, one or more of the references are not

believed properly combinable as previously described. Thus, these claims are believed in condition for allowance, which is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6972 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

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Date 1-17-2007

By _____
Bradley A. Forrest
Reg. No. 30,837

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 17 day of January 2007.

John D. Gustav Waldron
Name

_____
Signature

Electronic Acknowledgement Receipt

EFS ID:	1444001
Application Number:	10322348
International Application Number:	
Confirmation Number:	5446
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Gregg Alan Peacock/John Gustav-Wrathall
Filer Authorized By:	Gregg Alan Peacock
Attorney Docket Number:	101.031US1
Receipt Date:	17-JAN-2007
Filing Date:	17-DEC-2002
Time Stamp:	13:31:54
Application Type:	Utility

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
1		101031us1_response.pdf	1010505	yes	17

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Amendment After Final	2	2
	Claims	3	7
	Applicant Arguments/Remarks Made in an Amendment	8	17
Warnings:			
Information:			
	Total Files Size (in bytes):	1010505	

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.: 101.031US1
Filed: December 17, 2002
Examiner: Lena Najarian

Serial No.: 10/322,348
Due Date: January 18, 2007
Group Art Unit: 3626

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

We are transmitting herewith the following attached items (as indicated with an "X"):

X Amendment and Response (16 pgs.).

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
Customer Number 21186

By: _____
Atty: Bradley A. Forrest
Reg. No. 30,837

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of January, 2007.

J. Lynn D. Gustafson-Wrobleski
Name

_____
Signature

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
(GENERAL)

PTO/SB/06 (08-03)
Approved for use through 7/31/2006. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

Application or Docket Number: 10/322,348

CLAIMS AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE	SMALL ENTITY FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY FEE
BASIC FEE (37 CFR 1.16(a))				$____	OR		$____
TOTAL CLAIMS (37 CFR 1.16(c))	minus 20 =	*	X $____ =		OR	X $____ =	
INDEPENDENT CLAIMS (37 CFR 1.16(b))	minus 3 =	*	X $____ =		OR	X $____ =	
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(d))			+ $____ =		OR	+ $____ =	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL		OR	TOTAL	

CLAIMS AS AMENDED – PART II

8/8/06

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
Total (37 CFR 1.16(c))	* 11	Minus	** 31	=	X $25 =		OR	X $____ =	
Independent (37 CFR 1.16(b))	* 7	Minus	*** 6	= 1	X $100 =	100	OR	X $____ =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =	PD	OR	+ $____ =	
					TOTAL ADD'L FEE	100.00	OR	TOTAL ADD'L FEE	

1-17-07

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE	ADDITIONAL FEE	OR	RATE	ADDITIONAL FEE
Total (37 CFR 1.16(c))	* 11	Minus	** 31	=	X $____ =		OR	X $____ =	
Independent (37 CFR 1.16(b))	* 7	Minus	*** 7	=	X $____ =		OR	X $____ =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =		OR	+ $____ =	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE	ADDITIONAL FEE	OR	RATE	ADDITIONAL FEE
Total (37 CFR 1.16(c))	*	Minus	**	=	X $____ =		OR	X $____ =	
Independent (37 CFR 1.16(b))	*	Minus	***	=	X $____ =		OR	X $____ =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =		OR	+ $____ =	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/322,348	12/17/2002	Dayton T. Reardan	101.031US1	5446

21186 7590 02/05/2007
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
NAJARIAN, LENA	

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
02/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/322,348	REARDAN ET AL.	
	Examiner	Art Unit	
	Lena Najarian	3626	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *32-42*.
   Claim(s) withdrawn from consideration: *NONE*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER

Continuation of 11.
Applicant's arguments at pages 7-9 (Moradi does not teach an exclusive computer database) and the arguments at pages 10-14 (the suggestion to combine is not directed to the same or similar problem, hindsight, Lilly teaches away, etc.) have already been addressed in the Final Rejection mailed 10/18/06 (see page 11 of Final Rejection) and the Non-Final Rejection (see pages 14-17 of Non-Final Rejection) mailed 6/19/06, respectively, and are incorporated herein.

Applicant's additional arguments filed 1/17/07 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 1/17/07.

(1) Applicant argues that Ukens teaches away from using a central pharmacy.

In response to applicant's argument that Ukens teaches away from a central pharmacy, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The Examiner is relying on the portion of Ukens that discloses that there was at the time of the invention, restricted distribution of pharmaceuticals via one pharmacy. The Examiner acknowledges that the prior art teaches disadvantages concerning the use of a central pharmacy. However, the Examiner also recognizes an advantage, such as limiting distribution of dangerous drugs.

OK to enter
LN 1-31-07

EXPEDITED PROCEDURE – EXAMINING GROUP 3626

S/N 10/322,348 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Lena Najarian
Serial No.:	10/322,348	Group Art Unit:	3626
Filed:	December 17, 2002	Docket No.:	101.031US1
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

AMENDMENT & RESPONSE UNDER 37 C.F.R. 1.116

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

In response to the Final Office Action dated October 18, 2006, please amend the application as follows:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.: 101.031US1
Filed: December 17, 2002
Examiner: Lena Najarian

Serial No.: 10/322,348
Due Date: January 18, 2007
Group Art Unit: 3626

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

We are transmitting herewith the following attached items (as indicated with an "X"):

X Notice of Appeal (1 pg.).
X Petition for Extension of Time (1 pg.)
X Authorization to charge Deposit Account 19-0743 in the amount of $225.00 to cover the Extension of Time Fee.

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
Customer Number 21186

By: _____
Atty: Bradley A. Forrest
Reg. No. 30,837

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 19 day of March, 2007.

John D. Gustav-Wrathall
Name

_____
Signature

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
(GENERAL)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner: Lena Najarian
Serial No.:	10/322,348	Group Art Unit: 3626
Filed:	December 17, 2002	Docket No: 101.031US1
Title	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD	

PETITION FOR A TWO-MONTH EXTENSION OF TIME

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

In accordance with the provision of 37 CFR § 1.136(a), it is respectfully requested that a two-month extension of time be granted in which to respond to the Final Office Action mailed October 18, 2006, said period of response being extended from January 18, 2007 to March 19, 2007.

Please charge Deposit Account No. 19-0743 in the amount of $225.00 to cover the required extension fee. Please charge any additional fees or credit overpayment to deposit Account No. 19-0743.

Respectfully Submitted

DAYTON T. REARDAN ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6972

Date: 3-19-2007 By: _____
Bradley A. Forrest
Reg. No: 30,837

CERTIFICATE UNDER 37 CFR § 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 19 day of March 2007.

Name: _____ Signature: _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner: Lena Najarian
Serial No.:	10/322,348	Group Art Unit: 3626
Filed:	December 17, 2002	Docket: 101.031US1
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD	

NOTICE OF APPEAL FROM THE DECISION OF THE EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In compliance with 37 C.F.R. § 41.31(a)(1), Applicants hereby appeal to the Board of Patent Appeals and Interferences from the decision dated October 18, 2006, of the Examiner rejecting claims 32-42 of the above-identified patent application.

A request for an extension of time to respond to the Examiner's rejection is submitted herewith along with payment of the required extension fee.

Please charge the amount of $250.00 in payment of the Notice of Appeal fee under 37 C.F.R. § 41.20(b)(1), as well as any additional required fees, to Deposit Account No. 19-0743.

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By Applicants' Attorneys,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6972

Date 3-19-2007 By _____
Bradley A. Forrest
Reg. No. 30,837

I hereby certify that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 19 day of March 2007.

John O. Grosfur-Wrathall
Name

_____
Signature

Electronic Patent Application Fee Transmittal

Application Number:	10322348
Filing Date:	17-Dec-2002
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Filer:	Gregg Alan Peacock/John Gustav-Wrathall
Attorney Docket Number:	101.031US1
Filed as Small Entity	

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Notice of appeal	2401	1	250	250
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 2 months with $0 paid	2252	1	225	225
Miscellaneous:				
		Total in USD ($)		**475**

Electronic Acknowledgement Receipt	
EFS ID:	1604738
Application Number:	10322348
International Application Number:	
Confirmation Number:	5446
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Gregg Alan Peacock/John Gustav-Wrathall
Filer Authorized By:	Gregg Alan Peacock
Attorney Docket Number:	101.031US1
Receipt Date:	19-MAR-2007
Filing Date:	17-DEC-2002
Time Stamp:	17:49:07
Application Type:	Utility

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	$475
RAM confirmation Number	986
Deposit Account	190743
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
1		101031us1_noa.pdf	148852	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Extension of Time	2	2
	Notice of Appeal Filed	3	3

Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	8315	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	157167		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

TABLE OF CONTENTS

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Dayton T. Reardan et al.	Examiner: Lena Najarian
Serial No.: 10/322,348	Group Art Unit: 3626
Filed: December 17, 2002	Docket: 101.031US1

For: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

APPEAL BRIEF UNDER 37 CFR § 41.37

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

Sir:

The Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on March 19, 2007, from the Final Rejection of claims 32-42 of the above-identified application, as set forth in the Final Office Action mailed on October 26, 2006.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of $250.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of pending claims.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, Jazz Pharmaceuticals.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

The present application was filed on December 17, 2002, with claims 1-25. A Preliminary Amendment was filed on September 30, 2004, adding claims 26-31. A non-final Office Action was mailed June 29, 2005. A response was filed September 29, 2005. A Final Office Action was mailed December 29, 2005. A Request for Continued Examination was filed with an Amendment and Response to Final Office Action on March 29, 2006, in which claims 11-31 were cancelled and new claims 32-37 were added. A non-final Office Action was mailed June 19, 2006. A response was filed August 8, 2006, in which claims 1-10 were cancelled and new claims 38-42 were added. A second Final Office Action was mailed October 18, 2006. A response to Final Office Action was filed January 17, 2007. An Advisory Action was mailed February 5, 2007. Claims 32-42 stand finally rejected, remain pending, and are the subject of the present appeal.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Advisory Action dated February 5, 2007.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 32

32. A method of distributing a sensitive drug under exclusive control of an exclusive central pharmacy, the method comprising:

receiving all prescription requests at the exclusive central pharmacy from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor; [*page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking the credentials of the doctor; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that educational material has been read prior to shipping the sensitive drug; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

checking the exclusive computer database for potential abuse of the sensitive drug; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer database; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the sensitive drug; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 33

33. A method of distributing a sensitive drug under exclusive control of an exclusive central pharmacy, the method comprising:

receiving prescription requests from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor; [*page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking the credentials of the doctor; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

checking the exclusive computer database for potential abuse of the sensitive drug; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer database; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the sensitive drug; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 38

38. A method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests at the central pharmacy from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber; [*page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of the sensitive drug; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential abuse associated with the patient and/or the authorized prescriber; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the sensitive drug; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 39

39. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber; [page 4, lines 11-18; *page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only providing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the GHB; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 40

40. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber; [page 4, lines 11-18; *page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the GHB; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 41

41. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

manufacturing GHB; [*page 4, line 25-page 5, line 2*]

only providing manufactured GHB to the exclusive central pharmacy; [*page 4, line 25-page 5, line 2*]

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber; [page 4, lines 11-18; *page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the GHB; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 42

42. A method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests at the central pharmacy from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber; [page 4, lines 11-18; *page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of the sensitive drug; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential abuse associated with the patient and/or the authorized prescriber; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse; and [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the sensitive drug. [*page 2, line 14*]

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 32-42 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32, 38 and 42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) and further in view of Ukens ("Specialty Pharmacy").

Claims 33-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1).

Claim 37 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) and further in view of Melker et al. (U.S. Patent Publication No. 2002/0177232 A1).

Claims 39-41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) and further in view of "Talk About Sleep: An Interview with Orphan Medical about Xyrem".

7. ARGUMENT

A) The Applicable Law

1) 35 U.S.C. § 112, second paragraph

With regard to 35 U.S.C. § 112, second paragraph, the Board of Patent Appeals and Interferences has stated:

> In rejecting a claim under the second paragraph of 35 U.S.C.§112, it is incumbent on the examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims. *Ex parte* Wu, 10 USPQ 2d 2031, 2033 (B.P.A.I. 1989)(citing *In re* Moore, 439 F.2d 1232, 169 USPQ 236 (C.C.P.A. 1971); *In re* Hammack, 427 F.2d 1378, 166 USPQ 204 (C.C.P.A. 1970)).

The M.P.E.P. adopts this line of reasoning, stating that:

> The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:
>
> (1) The content of the particular application disclosure;
> (2) The teachings of the prior art; and
> (3) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. *M.P.E.P.* § 2173.02.

2) 35 U.S.C. §103(a)

The determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on factual evidence. *See Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1336-37 (Fed.Cir. 2005). The legal conclusion, that a claim is obvious within § 103(a), depends on at least four underlying factual issues set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966): (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) evaluation of any relevant secondary considerations.

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested, by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) ; MPEP § 2143.03. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) ; MPEP § 2143.03. As part of establishing a *prima facie* case of obviousness, the Examiner's analysis must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *Id.* To facilitate review, this analysis should be made explicit. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ____ (2007)(slip opinion at 14)(citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)).

The court in *Fine* stated that:

> Obviousness is tested by "what the combined teaching of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 878 (CCPA 1981)). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined *only* if there is some suggestion or incentive to do so." *Id.* (emphasis in original).

The M.P.E.P. adopts this line of reasoning, stating that:

> "In order for the Examiner to establish a *prima facie* case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991))." MPEP § 2142.

The test for obviousness under §103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ

543, 551 (Fed. Cir.1985). The Examiner must, as one of the inquiries pertinent to any obviousness inquiry under 35 U.S.C. §103, recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990), *reh'g denied*, 1990 U.S. App. LEXIS 19971 (Fed. Cir.1990). The fact that a reference teaches away from a claimed invention is highly probative that the reference would not have rendered the claimed invention obvious to one of ordinary skill in the art. *Stranco Inc. v. Atlantes Chemical Systems, Inc.*, 15 USPQ2d 1704, 1713 (Tex. 1990). When the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *KSR Int'l Co.*, 550 U.S. ____ (2007)(slip opinion at 12)(citing *United States v. Adams*, 383 U.S. 39, 51-51 (1966)).

Further, the Office Action must provide specific, objective evidence of record for a finding of a suggestion or motivation to combine reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding. *See KSR Int'l Co.*, 550 U.S. ____ (2007)(slip opinion at 14)(citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)); *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). Finally, the Examiner must avoid hindsight. *In re Bond* at 834.

Additionally, there must be a rational underpinning grounded in evidence to support the legal conclusion of obviousness. See *In re Kahn*, 78 USPQ2d 1329 (Fed. Cir. 2006), which states that, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn* citing *In re Lee*, 61 USPQ2d 1430 (Fed. Cir.2002). Additionally, "mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole." *In re Kahn.*

B) Discussion of the rejection of claims 32-42 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-42 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the response to the Final Office Action, claims 32-42 were amended to clarify the claims in view of the § 112 rejections, and not in response to art. These amendments, as indicated in the Advisory Action mailed February 5, 2007, were entered.

The Advisory Action did not include any direct mention of the status of these Section 112 rejections. Thus, Applicant respectfully submits that the Section 112 rejections have been over come by these amendments. If the Examiner believes otherwise, Applicant reserves the right to submit further argument against the 35 U.S.C. § 112, Second paragraph rejections in a reply to the Examiner's Answer.

C) Discussion of the 35 U.S.C. § 103(a) rejections.

1) Discussion of the rejection of claims 32, 38 and 42 under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1; hereinafter "Moradi") in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1; hereinafter "Lilly") in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1; hereinafter "Califano") and further in view of Ukens ("Specialty Pharmacy;" hereinafter "Ukens").

Applicant respectfully traverses the rejection of claims 32, 38, and 42 because the proposed combination of Moradi, Lilly, Califano, and Ukens fails to teach or suggest each of the claim elements and because Ukens teaches away from the combination.

a. Failure to teach or suggest an exclusive computer database

Each of the claims 32, 38 and 42 all refer to an exclusive computer database. The Final Office Action indicates that "Moradi discloses checking the exclusive central database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive central database (para. 43, para. 45, para. 6, and FIG. 3, items 318 and 322 of Moradi)."

The method of claims 32, 38, and 42 utilize the exclusive computer database to implement strict control over distribution of sensitive drugs. These controls allow for tracking of who is prescribing these drugs and who is receiving them. These controls further ensure proper education about the sensitive drugs is provided to patients and understood. Without this exclusive computer database, such controls are much more difficult to implement.

The cited portions of Moradi are repeated below, and it is clear that there is no teaching of an exclusive computer database as claimed.

Paragraph 43:

> "If the prescription is verified as OK, the processing continues in the exemplary embodiment by having the pharmacist fill the prescription and enter the prescription data into the pharmacist's existing Pharmacy Management System (PMS). The PMS system assigns the prescription a prescription number, and the pharmacist enters that prescription number and the number of refills into the PODP 216, which then communicates that data back to the CSS 102 with an identification of the prescription. The pharmacist then gives, at step 322, the ordered medicine and a copy of the prescription image to a prescription deliverer, which is a delivery person in the exemplary embodiments, for delivery to the patient. The CSS 102 is notified that the delivery person is in the process of delivering the medication and the status of the prescription is changed to "delivery" within the CSS database 204. The exemplary embodiment further includes providing the delivery person with a "Route Slip" that has printed directions to the patient's address along with the scanned prescription image. The delivery person hand-delivers the medicine to the recipient if and only if the recipient is holding the original copy of the prescription that is identical to the image provided to the delivery person. This ensures that the proper patient gets the medicine and that the medicine is delivered only once. After the medicine is delivered, the delivery person receives, at step 324, the patient's signature to certify a correct delivery. The delivery person can also stamp the original prescription to signify that the medicine specified in that prescription has been delivered and that the prescription has already been filled. The delivery person then returns, also at step 324, to the POD system 106 and the POD operator updates the order status to "Done" in the PODP 212 so that this information is communicated as a confirmation to the CSS 102 and the CSS Database 204. The exemplary embodiment supports status designations of: delivered, no one at the address, prescription mismatch or one of a number of other potential reasons for non-delivery. Embodiments of the present invention provide the delivery person with a wireless communication device that initiates communication of the delivery status immediately upon delivery of the medication to the patient without requiring the delivery person to first return to the POD 106. These devices also

include a written signature digitizer that is able to capture and digitize the patient's signature and transmit that image to along with the delivery status."

Paragraph 43 may mention various electronic systems, such as the pharmacy management system, but makes no mention of an exclusive computer database.

Paragraph 45:

"All checks to make sure that a patient is not allowed to have a prescription filled twice are performed by the exemplary embodiment of the present invention by human operators (e.g., the driver or the POD operator). This further ensures that patients do not receive medication in excess of their prescription and to prevent prescription abuse."

Paragraph 45 also makes no reference to an exclusive computer database.

Paragraph 6:

"Delivery of prescription medication by mail is also possible. Current systems require the prescription to be provided to a pharmacy and the pharmacy then mails the medication. This technique has a delay in the initial fulfillment of a new prescription because the prescription is often mailed to the pharmacy, and there is also a delay in mailing the prescription. This technique is better used for prescription refills, including maintenance prescriptions that have routinely refilled prescriptions for medication for which the patient has a recurring therapeutic need. In the case of a refill prescription, there is usually time available to accommodate the delays of this technique. This technique is also open to fraud since the individual patient typically does not personally present his or her prescription to the pharmacy. This technique can also lead to an improper person receiving the prescription, such as when a child that is living with the recipient retrieves mail that contains the mailed prescription."

Paragraph 6 also makes no reference to an exclusive computer database.

Fig. 3, items 318 and 322: These elements appear to be described in paragraph 43 as discussed above, and do not mention the use of an exclusive computer database. Further, no reference to item 318 was found in the application. Applicant therefore submits that Moradi fails to provide any teaching of an exclusive computer database as claimed. Applicant further submits that Lilly, Califano, and Ukens fail to cure this deficiency.

Absent any teaching or suggestion of a central database as claimed, Applicant respectfully submits that Claims 32, 38, and 42 are patentable over the proposed combination of Moradi, Lilly, Califano, and Ukens.

b. Ukens teaches away from the proposed combination of references

Applicant respectfully submits that Ukens teaches away from the proposed combination with Moradi, Lilly, and Califano to produce the presently claimed invention. A factor cutting against a finding of motivation to combine or modify the prior art is when the prior art teaches away from the claimed combination. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path the applicant took. *In re Gurley*, 27 F.3d 551, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994); *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (C.C.P.A. 1969); *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 243, 245 (C.C.P.A. 1963).

The Final Office Action indicates that "Ukens discloses restricting distribution of a specialty medication to only one pharmacy (see page 3, paragraphs 3-5 of Ukens)." The Final Office Action goes on to state that "At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Ukens within Moradi, Lilly, and Califano. The motivation for doing so would have been to limit access to dangerous drugs (page 3, paragraph 5 of Ukens)."

These statements are respectfully traversed. Paragraphs 3-5 of Ukens describes that "...restricted distribution of such products raises issues of patient access and safety." It then goes on to state that "by restricting distribution of a specialty medication to only one pharmacy, a manufacturer exposes patients to the risk of not receiving the medications in a timely manner if there's a disruption in the delivery system. In addition, shunting one part of therapy away from a patient's regular pharmacist can create the potential for undiscovered drug interactions. In paragraph 5, Ukens states: "A better way to handle specialty pharmaceuticals would be for manufacturers to set the criteria for their specialty products and then open distribution to any pharmacy that measures up,..." Thus, while Ukens acknowledges the potential for restricting distribution to a single pharmacy, it describes a "better way" that does not expose patients to

some identified risks. Applicant respectfully submits that one of skill in the art, upon reading Ukens, would be discourage from utilizing an architecture including an exclusive database of a single pharmacy as claimed. As a result, one of skill in the art would be guided in a direction to create a decentralized pharmacy with multiple databases which is a divergent path from that of the present application and claims.

Applicant respectfully submits that when considering the scope and content of the cited references and the differences between these references and claims 32, 38, and 42, one can plainly see the deficiencies of the prior art in failing to teach an exclusive computer database associated with an exclusive central pharmacy as claimed. Further, the differences between the cited references, namely Ukens, and the present claim would lead a person of skill in the art in a divergent direction from the path of the present claims. Applicant therefore requests reversal of the 35 U.S.C. § 103(a) rejection of claims 32, 38, and 42 because the cited references fail to teach or suggest all of the claim elements and because Ukens teaches away from the claims.

2) Discussion of the rejection of claims 33-36 under 35 U.S.C. § 103(a) as being unpatentable over Moradi in view of Lilly.

Applicant respectfully traverses the rejection of claims 33-36 because the combination of Moradi and Lilly fails to teach or suggest all of the claimed elements. For example, the method of independent claim 33 utilizes an exclusive computer database as discussed above.

a. Failure to teach or suggest an exclusive computer database

Claim 33 includes an exclusive computer database. The Final Office Action indicates that "Moradi discloses checking the exclusive central database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive central database (para. 43, para. 45, para. 6, and FIG. 3, items 318 and 322 of Moradi)."

As discussed above, the exclusive computer database is utilized to implement strict control over distribution of sensitive drugs. These controls allow for tracking of who is prescribing these drugs and who is receiving them. These controls further ensure proper

education about the sensitive drugs is provided to patients and understood. Without this exclusive computer database, such controls are much more difficult to implement.

The cited portions of Moradi are repeated below, and it is clear that there is no teaching of an exclusive computer database as claimed.

Paragraph 43:

> "If the prescription is verified as OK, the processing continues in the exemplary embodiment by having the pharmacist fill the prescription and enter the prescription data into the pharmacist's existing Pharmacy Management System (PMS). The PMS system assigns the prescription a prescription number, and the pharmacist enters that prescription number and the number of refills into the PODP 216, which then communicates that data back to the CSS 102 with an identification of the prescription. The pharmacist then gives, at step 322, the ordered medicine and a copy of the prescription image to a prescription deliverer, which is a delivery person in the exemplary embodiments, for delivery to the patient. The CSS 102 is notified that the delivery person is in the process of delivering the medication and the status of the prescription is changed to "delivery" within the CSS database 204. The exemplary embodiment further includes providing the delivery person with a "Route Slip" that has printed directions to the patient's address along with the scanned prescription image. The delivery person hand-delivers the medicine to the recipient if and only if the recipient is holding the original copy of the prescription that is identical to the image provided to the delivery person. This ensures that the proper patient gets the medicine and that the medicine is delivered only once. After the medicine is delivered, the delivery person receives, at step 324, the patient's signature to certify a correct delivery. The delivery person can also stamp the original prescription to signify that the medicine specified in that prescription has been delivered and that the prescription has already been filled. The delivery person then returns, also at step 324, to the POD system 106 and the POD operator updates the order status to "Done" in the PODP 212 so that this information is communicated as a confirmation to the CSS 102 and the CSS Database 204. The exemplary embodiment supports status designations of: delivered, no one at the address, prescription mismatch or one of a number of other potential reasons for non-delivery. Embodiments of the present invention provide the delivery person with a wireless communication device that initiates communication of the delivery status immediately upon delivery of the medication to the patient without requiring the delivery person to first return to the POD 106. These devices also include a written signature digitizer that is able to capture and digitize the patient's signature and transmit that image to along with the delivery status."

Paragraph 43 may mention various electronic systems, such as the pharmacy management system, but makes no mention of an exclusive computer database.

Paragraph 45:

> "All checks to make sure that a patient is not allowed to have a prescription filled twice are performed by the exemplary embodiment of the present invention by human operators (e.g., the driver or the POD operator). This further ensures that patients do not receive medication in excess of there prescription and to prevent prescription abuse."

Paragraph 45 also makes no reference to an exclusive computer database.

Paragraph 6:

> "Delivery of prescription medication by mail is also possible. Current systems require the prescription to be provided to a pharmacy and the pharmacy then mails the medication. This technique has a delay in the initial fulfillment of a new prescription because the prescription is often mailed to the pharmacy, and there is also a delay in mailing the prescription. This technique is better used for prescription refills, including maintenance prescriptions that have routinely refilled prescriptions for medication for which the patient has a recurring therapeutic need. In the case of a refill prescription, there is usually time available to accommodate the delays of this technique. This technique is also open to fraud since the individual patient typically does not personally present his or her prescription to the pharmacy. This technique can also lead to an improper person receiving the prescription, such as when a child that is living with the recipient retrieves mail that contains the mailed prescription."

Paragraph 6 also makes no reference to an exclusive computer database.

Fig. 3, items 318 and 322: These elements appear to be described in paragraph 43 as discussed above, and do not mention the use of an exclusive computer database. Further, no reference to item 318 was found in the application.

Applicant further submits that independent claim 33 must be read as including a sensitive drug under exclusive control of a central pharmacy. This control is through the exclusive computer database of the central pharmacy. This is not to say that all drugs are under exclusive control of the central pharmacy, rather the sensitive drug is under exclusive control of the central pharmacy. This is different from the cited paragraphs [0007] and [00043] of Moradi which merely provides a pharmacy including a central server without any limitation as to the prescriptions which may be filled.

Applicant therefore submits that Moradi fails to provide any teaching of an exclusive computer database as claimed. Applicant further submits that Lilly fails to cure this deficiency. Absent any teaching or suggestion of a central database as claimed, Applicant respectfully submits that claims 33 is patentable over the proposed combination of Moradi and Lilly.

Claims 34-36 depend from patentable independent claim 33 and are patentable for the same reasons, plus the elements of the claims.

Thus, Applicant respectfully requests reversal of the 35 U.S.C. § 103(a) rejections of claims 33-36 because the combination of Moradi and Lilly fails to teach or suggest all of the claim elements.

3) Discussion of the rejection of claim 37 under 35 U.S.C. § 103(a) as being unpatentable over Moradi in view of Lilly and further in view of Melker et al. (U.S. Patent Publication No. 2002/0177232 A1; hereinafter "Melker").

Applicant respectfully submits that claim 37 depends from patentable independent claim 33 and is patentable for the same reasons. Further, Melker fails to cure the deficiencies of Moradi and Lilly as set forth above with regard to claims 33-36. Thus, Applicant respectfully requests reversal of the 35 U.S.C. § 103(a) rejection of claim 37.

4) Discussion of the rejection of claims 39-41 under 35 U.S.C. § 103(a) as being unpatentable over Moradi in view of Lilly in view of Califano and further in view of "Talk About Sleep: An Interview with Orphan Medical about Xyrem."

This rejection is respectfully traversed. Claims 39-41 all refer to the use of an exclusive computer database for distribution of a sensitive drug as discussed above with regard to claims 32-38. None of the references alone or combined teach or suggest such an exclusive computer database. "Talk About Sleep: An Interview with Orphan Medical about Xyrem" also does not describe the use of an exclusive computer database for distribution of a sensitive drug such as Xyrem. Thus, these claims are believed in condition for allowance. Applicant respectfully requests reversal of the 35 U.S.C. § 103(a) rejection of claims 39-41.

8. SUMMARY

For the reasons argued above, claims 32-42 were not properly rejected under 35 U.S.C. §§ 103(a) and 112, second paragraph. Reversal of the rejections and allowance of the pending claim are respectfully requested.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 21 day of May 2007.

John D. Gustav-Wrathall
Name

Signature

CLAIMS APPENDIX

32. A method of distributing a sensitive drug under exclusive control of an exclusive central pharmacy, the method comprising:

receiving all prescription requests at the exclusive central pharmacy from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor;

requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations;

checking the credentials of the doctor;

confirming with the patient that educational material has been read prior to shipping the sensitive drug;

checking the exclusive computer database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer database;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

33. A method of distributing a sensitive drug under exclusive control of an exclusive central pharmacy, the method comprising:

receiving prescription requests from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor;

entering the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations;

checking the credentials of the doctor;

checking the exclusive computer database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer database;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

34. The method of claim 33 wherein the exclusive central pharmacy controls the exclusive computer database.

35. The method of claim 33 and further comprising selectively blocking shipment of the sensitive drug to a patient.

36. The method of claim 33 wherein an abuse pattern is associated with a patient, and shipment is blocked upon such association.

37. The method of claim 33 wherein the sensitive drug comprises gamma hydroxy butyrate (GHB).

38. A method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests at the central pharmacy from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of the sensitive drug;

checking of the credentials of the authorized prescriber;

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient;

requiring checking of the exclusive computer database for potential abuse associated with the patient and/or the authorized prescriber;

only providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the sensitive drug; and

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

39. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB;

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

only providing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns.

40. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB;

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns.

41. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

manufacturing GHB;

only providing manufactured GHB to the exclusive central pharmacy;

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB;

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns.

42. A method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests at the central pharmacy from an authorized prescriber containing information identifying a patient, the sensitive drug, and various credentials of the authorized prescriber;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of the sensitive drug;

checking of the credentials of the authorized prescriber;

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient;

requiring checking of the exclusive computer database for potential abuse associated with the patient and/or the authorized prescriber;

only providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse; and

confirming receipt by the patient of the sensitive drug.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.

Electronic Patent Application Fee Transmittal

Application Number:	10322348
Filing Date:	17-Dec-2002
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Filer:	Gregg Alan Peacock/John Gustav-Wrathall
Attorney Docket Number:	101.031US1
Filed as Small Entity	

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Filing a brief in support of an appeal	2402	1	250	250
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	250