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SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
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OFFICE OF PETITIONS

In re Patent No. 7,765,107
Issued: July 27, 2010
Application No. 11/097,985
Filed: April 1, 2005
Attorney Docket No. 101.031US4

ON PETITION

This is a decision on the PETITION UNDER 37 CFR 1.182 TO CORRECT THE NAME OF THE ASSIGNEE ON THE TERMINAL DISCLAIMER" filed November 20, 2010, requesting correction to the terminal disclaimer filed on February 9, 2010.

The petition is **DISMISSED** to the extent that the Terminal Disclaimer filed February 9, 2010 will not be removed from the record.

Any request for reconsideration must be filed within TWO (2) MONTHS. This 2-month period is governed by 37 CFR 1.181(f) and is not extendable under 37 CFR 1.136.

Application No. 11/097,651 was filed on April 1, 2005 and issued as U.S. Patent No. 7,765,107 on July 27, 2010.

Patentees state that a terminal disclaimer was originally filed on February 9, 2010. However, there was a clerical error in the originally filed Terminal Disclaimer with respect to the identified Assignee. Patentees request that the attached replacement Terminal Disclaimer be entered into the Official file in lieu of the Terminal Disclaimer filed on February 9, 2010, to correct the clerical error.

The Terminal Disclaimer filed February 10, 2010 (February 9, 2010 certificate of mail date) disclaimed, "the terminal part of the statutory term of any patent granted on the above-identified patent application, which would extend beyond the expiration date of the full statutory term, as presently shortened by any terminal disclaimers, of any patent issuing from U.S. Serial No. 11/097,651. The assignee hereby agrees that any patent to be granted on the captioned application shall be enforceable only for and during such period as such patent is commonly owned with any patent issuing from U.S. Serial No. 11/097,651. This agreement shall run with any patent granted on the above-identified application and shall be binding upon the assignee's successors and assigns".

The captioned application as well as U.S. Application Serial No. 10/979,665 are both divisional applications of U.S. Application Serial No. 10/322,348. The assignment for

U.S. Serial No. 10/322,348 was recorded on February 19, 2010 at Reel 023962, Frames 0725 - 0731. That assignment assigned the application underlying U.S. Serial No. 10/322,348, as well as, inter alia, all continuations and divisionals based upon that application. The Terminal Disclaimer filed February 10, 2010 (February 9, 2010 certificate of mail date) is signed by Bradley A. Forrest on behalf of assignee Jazz Pharmaceuticals, Inc.

The "replacement" Terminal Disclaimer however is signed by Monique M. Perdok Shonka, on behalf of assignee Jazz Pharmaceuticals, Inc.

The two disclaimers, list Jazz Pharmaceuticals, Inc. as the assignee and are both signed by individuals empowered to act on behalf of Jazz Pharmaceuticals, Inc. however, the difference is that in the parent application, 10/322,348, the complete chain of assignments was not properly recorded at the time the February 10, 2010 (February 9, 2010 certificate of mail date) Terminal Disclaimer was filed. Applicant has now taken the appropriate corrective action by filing assignments from Orphan Medical, Inc. to Orphan Medical, LLC; from Orphan Medical, LLC to JPI Commercial, LLC; and from JPI Commercial, LLC to Jazz Pharmaceuticals, Inc.

The difference in the two disclaimers is the reference to the assignments. A review of Office records confirms that the assignments have all now been recorded.

Nonetheless, the Terminal Disclaimer filed February 10, 2010 (February 9, 2010 certificate of mail date) was accepted and recorded by the examiner.

Moreover, assignment data printed on the patent is based solely on the information so supplied on the Issue Fee Transmittal Form (PTOL-85B). A review of the record indicates that the Issue Fee Transmittal Form (PTOL-85B) submitted June 10, 2010 identified the assignee as JPI Commercial, LLC and thus, the patent properly issued to assignee JPI Commercial, LLC , with a Notice that:

> This patent is subject to a terminal disclaimer.

Thus, there is no issue as to what was dedicated to the public. Patentees do not request that the Terminal Disclaimer be removed or nullified. There is no error in the patent requiring correction. As such, this petition does not necessitate consideration of whether issuance of a certificate of correction is warranted.

Rather, patentees request, in effect, that the Terminal Disclaimer filed February 10, 2010 (February 9, 2010 certificate of mail date) be replaced in the record with the Terminal Disclaimer filed November 20, 2010.

The Terminal Disclaimer filed February 10, 2010 (February 9, 2010 certificate of mail

date) was made of record and considered by the examiner in examination and allowance of this application. Removal of the Terminal Disclaimer filed February 10, 2010 (February 9, 2010 certificate of mail date) from the application record is inappropriate.

Placement of the Terminal Disclaimer filed November 20, 2010 (along with the petition and petition decision) in the record is sufficient to complete the record. The Terminal Disclaimer filed November 20, 2010 is accepted and recorded. No further action will be undertaken.

The petition fee of $400 has been charged to Deposit Account No. 19-0743, as authorized.

Telephone inquiries concerning this matter should be directed to the undersigned Petitions Attorney at (571) 272-3212.

Patricia Faison-Ball
Senior Petitions Attorney
Office of Petitions

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dayton T. Reardan et al.	Examiner: Lena Najarian	
Serial No.:	11/097,985	Group Art Unit: 3686	
Filed:	April 1, 2005	Docket No.: 101.031US4	
Customer No.:	21186	Confirmation No.: 5403	
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

PETITION UNDER 37 CFR 1.182 TO CORRECT THE NAME OF THE ASSIGNEE ON THE TERMINAL DISCLAIMER

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

Dear Sir:

The undersigned, on behalf of the assignee of the above-identified application, now U.S. Patent No. 7,765,107, respectfully petitions to correct the name of the assignee on the Terminal Disclaimers dated February 9, 2010, which were filed during the prosecution of the '107 patent.

Statement of Facts

On February 9, 2010 two Terminal Disclaimers were filed during the '107 patent prosecution in the name of Orphan Medical, Inc. Upon further review, Applicant notes that the proper assignee is Jazz Pharmaceuticals, Inc. Applicant has taken the appropriate corrective action by filing assignments from Orphan Medical, Inc. to Orphan Medical, LLC; from Orphan Medical, LLC to JPI Commercial, LLC; and from JPI Commercial, LLC to Jazz Pharmaceuticals, Inc., copies of the assignments are attached hereto.

Requested Relief

In view of the above, Applicant respectfully requests that the Terminal Disclaimers filed herewith naming Jazz Pharmaceuticals, Inc. as the assignee replace the Terminal Disclaimers dated February 9, 2010.

If necessary, please charge any additional fees or credit overpayment to Deposit Account 19-0743.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6905

Date November 19, 2010 By /Monique M. Perdok Shonka/
Monique M. Perdok Shonka
Reg. No. 42,989

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dayton T. Reardan et al.	Examiner: Lena Najarian	
Serial No.:	11/097,985	Group Art Unit: 3686	
Filed:	April 1, 2005	Docket No.: 101.031US4	
Customer No.: 21186		Confirmation No.: 5403	

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

TERMINAL DISCLAIMER

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

I, Monique M. Perdok Shonka, am an attorney of record for the above identified patent application as evidenced by the Power of Attorney filed in the present application on February 10, 2010. This Terminal Disclaimer is submitted on behalf of Jazz Pharmaceuticals, Inc., the assignee of the present invention. As an attorney of record, I am empowered to act on behalf of the assignee and, in accordance with 37 C.F.R. § 1.321(b)(1)(iv), to sign this Terminal Disclaimer.

Certificate Under 37 C.F.R. § 3.73(b)

The assignee, Jazz Pharmaceuticals, Inc., hereby certifies that it is the owner of the entire right, title and interest in and to: (1) the captioned application (U.S. Application Serial No. 11/097,985, now U.S. Patent No. 7,765,107) and (2) U.S. Patent No. 7,765,106, by virtue of the assignment executed November 16, 2010, attached hereto.

The undersigned representative of the assignee has reviewed the evidentiary documents of title and certifies that to the best of assignee's knowledge and belief, title is in the assignee seeking to take the action set forth in this disclaimer.

Terminal Disclaimer

The assignee of the captioned application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified patent application, which would extend beyond the expiration date of the full statutory term, as presently shortened by any terminal disclaimers, of U.S. Patent No. 7,765,106. The assignee hereby agrees that any patent to be granted on the captioned application shall be enforceable only for and during such period as such patent is commonly owned with U.S. Patent No. 7,765,106. This agreement shall run with any patent granted on the above-identified application and shall be binding upon the assignee's successors and assigns.

Limitations on the Disclaimer

The assignee does not disclaim any terminal part of any patent granted on the above-identified application prior to the expiration date of the full statutory term as presently shortened by any terminal disclaimer of U.S. Patent No. 7,765,106 in the event that it later expires before such term for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed, is the subject of a reexamination certificate cancelling all claims, or is otherwise terminated prior to the expiration date of its statutory term as presently shortened by any terminal disclaimer.

Fee Status

Please charge Deposit Account 19-0743 in the amount of $70.00 which is required under 37 C.F.R. § 1.20(d) to file a statutory disclaimer. The Commissioner of Patents and Trademarks is hereby authorized to charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402--0938
(612) 373-6905

Date November 19, 2010

By /Monique M. Perdok Shonka/
Monique M. Perdok Shonka
Reg. No. 42,989

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dayton T. Reardan et al.	Examiner: Lena Najarian	
Serial No.:	11/097,985	Group Art Unit: 3686	
Filed:	April 1, 2005	Docket No.: 101.031US4	
Customer No.: 21186		Confirmation No.: 5403	

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

TERMINAL DISCLAIMER

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

I, Monique M. Perdok Shonka, am an attorney of record for the above identified patent application as evidenced by the Power of Attorney filed in the present application on February 10, 2010. This Terminal Disclaimer is submitted on behalf of Jazz Pharmaceuticals, Inc., the assignee of the present invention. As an attorney of record, I am empowered to act on behalf of the assignee and, in accordance with 37 C.F.R. § 1.321(b)(1)(iv), to sign this Terminal Disclaimer.

Certificate Under 37 C.F.R. § 3.73(b)

The assignee, Jazz Pharmaceuticals, Inc., hereby certifies that it is the owner of the entire right, title and interest in and to: (1) the captioned application (U.S. Application Serial No. 11/097,985, now U.S. Patent No. 7,765,107) and (2) U.S. Patent No. 7,797,171, by virtue of the assignment executed on November 16, 2010, attached hereto.

The undersigned representative of the assignee has reviewed the evidentiary documents of title and certifies that to the best of assignee's knowledge and belief, title is in the assignee seeking to take the action set forth in this disclaimer.

Terminal Disclaimer

The assignee of the captioned application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified patent application, which would extend beyond the expiration date of the full statutory term, as presently shortened by any terminal disclaimers, of U.S. Patent No. 7,797,171. The assignee hereby agrees that any patent to be granted on the captioned application shall be enforceable only for and during such period as such patent is commonly owned with U.S. Patent No. 7,797,171. This agreement shall run with any patent granted on the above-identified application and shall be binding upon the assignee's successors and assigns.

Limitations on the Disclaimer

The assignee does not disclaim any terminal part of any patent granted on the above-identified application prior to the expiration date of the full statutory term as presently shortened by any terminal disclaimer of U.S. Patent No. 7,797,171 in the event that it later expires before such term for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed, is the subject of a reexamination certificate cancelling all claims, or is otherwise terminated prior to the expiration date of its statutory term as presently shortened by any terminal disclaimer.

Fee Status

Please charge Deposit Account 19-0743 in the amount of $70.00 which is required under 37 C.F.R. § 1.20(d) to file a statutory disclaimer. The Commissioner of Patents and Trademarks is hereby authorized to charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402--0938
(612) 373-6905

Date November 19, 2010 By /Monique M. Perdok Shonka/
Monique M. Perdok Shonka
Reg. No. 42,989

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner: Lena Najarian
Serial No.:	11/097,985	Group Art Unit: 3686
Filed:	April 1, 2005	Docket: 101.031US4
Customer No.	21186	
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD	

POWER OF ATTORNEY
CERTIFICATE UNDER 37 CFR § 3.73(b)

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

In accordance with 37 C.F.R. § 1.36, M.P.E.P. §§ 402.05 and 402.07, please appoint the following attorneys and/or patent agents to prosecute this application and to transact all business in the Patent and Trademark Office in connection therewith:

Customer Number: 21186

CERTIFICATE UNDER 37 CFR § 3.73(b)

Jazz Pharmaceuticals, Inc. hereby certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of the assignments attached herewith. To the best of my knowledge and belief, title is in Jazz Pharmaceuticals, Inc., the assignee.

Pursuant to 37 C.F.R. § 3.73(b) I hereby declare that I am empowered to sign this certificate on behalf of Jazz Pharmaceuticals, Inc., the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true.

Please direct all correspondence in this case to:

Schwegman, Lundberg & Woessner, P.A.
Customer No. 21186

Date 11/19/2010

By _____
Name: Carol Gamble
Title: Sr. Vice President and General Counsel

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	3098
CONNECTION TEL	
SUBADDRESS	
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PATENT PROTECTION FOR HIGH TECHNOLOGY

P.O. Box 2938
Minneapolis, MN 55402
Telephone (612) 373-6900 Facsimile (612) 339-3061

November 12, 2010

Time: 1:15 pm
(Minneapolis, Minn.)

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

FAX NUMBER 571-273-0140

FROM: Monique M. Perdok Shonka

Please deliver to Assignment Recordation Services

Document(s) Transmitted: **Agreement and Plan of Merger (7 pgs.), Appendix A (1 pg.), Recordation Form Cover Sheet (1 pg.), Authorization to charge Deposit Account 19-0743 in the amount of $400.00 to cover the recordation fee.**

Total pages of this transmission, including cover letter: 10

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.

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

By: /Monique M. Perdok Shonka/
Name: Monique M. Perdok Shonka

SCHWEGMAN ▪ LUNDBERG ▪ WOESSNER
PATENT PROTECTION FOR HIGH TECHNOLOGY

P.O. Box 2938
Minneapolis, MN 55402
Telephone (612) 373-6900 Facsimile (612) 339-3061

November 17, 2010

Time: 1:15 pm
(Minneapolis, Minn.)

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

FROM: Monique M. Perdok Shonka

FAX NUMBER 571-273-0140

Please deliver to Assignment Recordation Services

Document(s) Transmitted: **Agreement and Plan of Merger (7 pgs.), Appendix A (1 pg.), Recordation Form Cover Sheet (1 pg.), Authorization to charge Deposit Account 19-0743 in the amount of $400.00 to cover the recordation fee.**

Total pages of this transmission, including cover letter: 10

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.

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

By: /Monique M. Perdok Shonka/
Name: Monique M. Perdok Shonka
USPTO Reg. No. 42,989

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

Leshere Wolfe

11-12-10
Date of Transmission

RECORDATION FORM COVER SHEET
PATENTS ONLY

Atty Ref/Docket No.: 101.000001

Patent and Trademark Office

To the Director of the U.S. Patent and Trademark Office: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

Orphan Medical, Inc.

Additional name(s) of conveying party(ies) attached?

[ ]Yes [X]No

3. Nature of conveyance:

[ ] Assignment [X] Merger
[ ] Security Agreement [ ] Change of Name
[ ] Other

Execution Date: March 14, 2008

2. Name and address of receiving party(ies):

Name: Orphan Medical, LLC

Street Address: 3180 Porter Drive

City: Palo Alto State: CA Zip: 94304
Country: United States of America

Additional name(s) & address(es) attached? [ ]Yes [X]No

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No.(s)

B. Patent No.(s)

Additional numbers attached? [X]Yes [ ]No

See Attached Appendix

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Monique M. Perdok Shonka

Address:
Schwegman, Lundberg & Woessner, P.A.
P.O. Box 2938
Minneapolis, MN 55402--0938

6. Total number of applications and patents involved: 5

7. Total fee (37 CFR 3.41):$ 400.00

[]Enclosed
[X]Authorized to be charged to deposit account 19-0743

8. Please charge any additional fees or credit any over payments to our Deposit Account No.: 19-0743

DO NOT USE THIS SPACE

9. Statement and signature.
To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Monique M. Perdok Shonka/Reg. No. 42,989 / Monique M. Perdok Shonka / November 12, 2010
Name of Person Signing Signature Date

Total number of pages including cover sheet: 10

Mail documents to be recorded with required cover sheet information to:
Commissioner of Patents and Trademarks
Mail Stop Assignment Recordation Services
P.O. Box 1450
Alexandria, VA 22313-1450

Appendix A

Serial No.	Filing Date	U.S. Patent No.	Issue Date
09/470,570	Dec 22, 1999	6,472,431	Oct 29, 2002
10/194,021	Jul 11, 2002	6,780,889	Aug 24, 2004
10/841,709	May 7, 2004	7,262,219	Aug 28, 2007
11/777,877	Jul 13, 2007		
12/913,644	Oct 27, 2010		
10/322,348	Dec 17, 2002	7,668,730	Feb 23, 2010
10/979,665	Nov 2, 2004	7,765,106	Jul 27, 2010
11/097,651	Apr 1, 2005	7,797,171	Sep 14, 2010
11/097,985	Apr 1, 2005	7,765,107	Jul 27, 2010
12/704,097	Feb 11, 2010		

This assignment applies to any continuation, divisional or continuation-in-part of any listed application.

AGREEMENT AND PLAN OF MERGER

This Agreement and Plan of Merger (this "***Agreement***") is made and entered into as of March 14, 2008 by and between **ORPHAN MEDICAL, LLC**, a Delaware limited liability company ("***Orphan LLC***"), and **ORPHAN MEDICAL, INC.**, a Delaware corporation ("***Orphan Inc.***").

RECITALS

A. Orphan Inc. is a corporation organized under and governed by the laws of the State of Delaware and a wholly-owned subsidiary of Jazz Pharmaceuticals, Inc., a Delaware corporation ("***Jazz***"). Orphan Inc. has authorized capital stock of 100 shares of Common Stock (the "***Common Stock***"). As of the date of this Agreement, Orphan Inc. has 100 shares of Common Stock issued and outstanding.

B. The Board of Directors of Orphan Inc. has determined that it is advisable and in the best interests of Orphan Inc. and its sole stockholder that Orphan Inc. be merged with and into Orphan LLC pursuant to the terms and conditions herein provided (the "***Merger***").

C. The managers of Orphan LLC have determined that the Merger is advisable and in the best interests of Orphan LLC.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, Orphan Inc. and Orphan LLC hereby agree, subject to the terms and conditions hereafter set forth, as follows:

SECTION 1. MERGER

1.1 Merger. Upon the terms and subject to the conditions set forth in this Agreement and in accordance with the Delaware Limited Liability Company Act (the "***DLLCA***") and the Delaware General Corporation Law (the "***DGCL***"), at the Effective Time (as defined in Section 1.3), Orphan Inc. shall be merged with and into Orphan LLC, and the separate existence of Orphan Inc. shall cease. Orphan LLC will continue as the surviving company in the Merger (the "***Surviving Company***").

1.2 Effect of the Merger. The Merger shall have the effects set forth in this Agreement and in the applicable provisions of the DLLCA and the DGCL.

1.3 Effective Time. As soon as practicable after the satisfaction or waiver of the conditions set forth in Section 1.7, Orphan Inc. and Orphan LLC shall cause a properly executed certificate of merger conforming to the requirements of the DLLCA (the "***Certificate of Merger***") to be filed with the Secretary of State of the State of Delaware. The Merger shall become effective at the time the Certificate of Merger is filed with the Secretary of State of the State of Delaware, or at such later time as is agreed to by the parties hereto and specified in the Certificate of Merger (the time at which the Merger becomes effective being referred to in this

Agreement as the "*Effective Time*"). At 9:30 a.m. (Pacific daylight time) or such other practicable time on the date on which the Certificate of Merger is to be so filed, a closing shall be held at the offices of Cooley Godward Kronish LLP, 3175 Hanover Street, Palo Alto, California (or such other place or time as Orphan Inc. and Orphan LLC may jointly designate) for the purpose of confirming the satisfaction or waiver of each of the conditions set forth in Section 1.7.

1.4 Organizational Documents; Member; Manager; Interests. As of the Effective Time: (a) the Certificate of Formation of Orphan LLC as in effect immediately prior to the Effective Time shall continue to be the certificate of formation of the Surviving Company; (b) the operating agreement of Orphan LLC as in effect immediately prior to the Effective Time shall continue to be the operating agreement of the Surviving Company; (c) Jazz shall be the sole member of the Surviving Company and the managers of Orphan LLC immediately prior to the Effective Time shall continue to be the managers of the Surviving Company until as otherwise provided by law or the operating agreement of the Surviving Company; and (d) the outstanding limited liability company interests of the Surviving Company shall remain outstanding and are not affected by the Merger.

1.5 Cancellation of Common Stock. At the Effective Time, by virtue of the Merger and without any action on the part of the sole stockholder of Orphan Inc., each share of Common Stock outstanding immediately prior to the Effective Time shall be cancelled and extinguished without the payment of any additional consideration (whether in the form of cash, securities or otherwise) by Orphan LLC.

1.6 Orphan Inc. Share Transfer Books Closed. At the Effective Time, the holder of shares of Common Stock outstanding immediately prior to the Effective Time shall cease to have any rights as the stockholder of Orphan Inc., and the stock transfer books of Orphan Inc. shall be closed with respect to all such shares of Common Stock. No further transfer of any such shares of Common Stock shall be made on such stock transfer books after the Effective Time.

1.7 Conditions to Merger. The obligation of Orphan Inc. and Orphan LLC to effect the Merger is subject to satisfaction of the following conditions (any or all of which may be waived by Orphan LLC in its sole discretion to the extent permitted by law):

(a) the Merger shall have been approved by the sole stockholder of Orphan Inc. in accordance with applicable provisions of the DGCL; and

(b) any and all consents, permits, authorizations, approvals, and orders deemed in the sole discretion of Orphan LLC to be material to consummation of the Merger shall have been obtained.

SECTION 2. MISCELLANEOUS PROVISIONS

2.1 Further Assurances. Each party hereto shall execute and cause to be delivered to each other party hereto such instruments and other documents, and shall take such other actions, as such other party may reasonably request for the purpose of carrying out or evidencing any of the transactions contemplated by this Agreement.

2.2 **Governing Law.** This Agreement shall be construed and interpreted in accordance with the laws of the State of Delaware, without regard to its provisions concerning conflict of laws that would cause the laws of another jurisdiction to govern.

2.3 **Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be binding as of the date first written above, and all of which shall constitute one and the same instrument. Each such copy shall be deemed an original, and it shall not be necessary in making proof of this Agreement to produce or account for more than one such counterpart.

2.4 **Severability.** Any provision of this Agreement that is invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions hereof, and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

2.5 **Successors and Assigns.** This Agreement shall inure to the benefit of, and be binding upon, each of the parties hereto and each of their respective successors and assigns.

2.6 **Entire Agreement.** This Agreement sets forth the entire understanding of the parties hereto relating to the subject matter hereof and supersedes all prior agreements and understandings among or between any of the parties relating to the subject matter.

[Signature Page Follows]

IN WITNESS WHEREOF, the undersigned have caused this Agreement to be executed effective as of the date first written above.

Orphan Medical, Inc.

By: _____
Name: Carol A. Gamble
Title: Secretary

Orphan Medical, LLC

By: _____
Name: Carol A. Gamble
Title: Manager

699333 v2/HN

Delaware

The First State

I, HARRIET SMITH WINDSOR, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF MERGER, WHICH MERGES:

"ORPHAN MEDICAL, INC.", A DELAWARE CORPORATION,

WITH AND INTO "ORPHAN MEDICAL, LLC" UNDER THE NAME OF "ORPHAN MEDICAL, LLC", A LIMITED LIABILITY COMPANY ORGANIZED AND EXISTING UNDER THE LAWS OF THE STATE OF DELAWARE, AS RECEIVED AND FILED IN THIS OFFICE THE FOURTEENTH DAY OF MARCH, A.D. 2008, AT 3:08 O'CLOCK P.M.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.

Harriet Smith Windsor

Harriet Smith Windsor, Secretary of State

4517425 8100M

080319856

AUTHENTICATION: 6451560

DATE: 03-14-08

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 03:08 PM 03/14/2008
FILED 03:08 PM 03/14/2008
SRV 080319856 - 4517425 FILE

CERTIFICATE OF MERGER

OF

ORPHAN MEDICAL, INC.

INTO

ORPHAN MEDICAL, LLC

(Pursuant to Sections 103 and 264 of the Delaware General Corporation Law and Section 18-209 of the Delaware Limited Liability Company Act.)

ORPHAN MEDICAL, LLC, a Delaware limited liability company (the "***Company***"), does hereby certify to the following facts relating to the merger of Orphan Medical, Inc. ("***Orphan Inc.***") with and into the Company (the "***Merger***"):

FIRST: The Company is a limited liability company organized and existing under and by virtue of the Delaware Limited Liability Company Act (the "***DLLCA***").

SECOND: Orphan Inc. is a corporation organized and existing under and by virtue of the Delaware General Corporation Law (the "***DGCL***").

THIRD: An Agreement and Plan of Merger has been approved and executed by the Company and Orphan Inc. The executed Agreement and Plan of Merger is on file with the Company at its principal place of business located at 3180 Porter Drive, Palo Alto, CA 94304. A copy of the executed Agreement and Plan of Merger will be furnished by the Company, on request and without cost, to any member of the Company or any stockholder of Orphan Inc.

FOURTH: The Company shall survive the Merger and its name shall remain "Orphan Medical, LLC."

FIFTH: Upon the filing of this Certificate of Merger with the Secretary of State of Delaware, the Merger shall become effective (the "***Effective Date***") and the separate existence of Orphan Inc. will cease.

SIXTH: This Certificate of Merger was duly adopted and approved in accordance with the applicable provisions of Section 264 of the DGCL and Section 18-209 of the DLLCA.

IN WITNESS WHEREOF, the Company has caused this Certificate of Merger to be executed and acknowledged by the authorized person set forth below on this 14th day of March, 2008.

ORPHAN MEDICAL, LLC
A Delaware limited liability company

By: /s/ Carol A. Gamble

Name: Carol A. Gamble

Title: Manager

699336 v2/HN

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	3101
CONNECTION TEL	
SUBADDRESS	
CONNECTION ID	
ST. TIME	11/12 14:29
USAGE T	01'03
PGS. SENT	8
RESULT	OK

SCHWEGMAN • LUNDBERG • WOESSNER
PATENT PROTECTION FOR HIGH TECHNOLOGY

P.O. Box 2938
Minneapolis, MN 55402
Telephone (612) 373-6900 Facsimile (612) 339-3061

November 12, 2010

Time: 1:22
(Minneapolis, Minn.)

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

FROM: Monique M. Perdok Shonka

FAX NUMBER 571-273-0140

Please deliver to Assignment Recordation Services

Document(s) Transmitted: **Assignment Document (5 pgs.), Appendix A (1 pg.), Recordation Form Cover Sheet (1 pg.), Authorization to charge Deposit Account 19-0743 in the amount of $400.00 to cover the recordation fee.**

On February 19, 2010 an assignment from Orphan Medical, LLC to JPI Commercial, LLC was filed and recorded in U.S. Serial No. 10/322,348 (now U.S. Patent No. 7,668,730). The recordation cover sheet for this assignment, however, identified Jazz Pharmaceuticals, Inc. as the assignee. Upon further review, it is noted that this recordation cover sheet was in error. Provided herewith is the proper recordation cover sheet for assigning this patent, as well as other applications/patents, to JPI Commercial, LLC (see Appendix A).

Total pages of this transmission, including cover letter: 8

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PATENT PROTECTION FOR HIGH TECHNOLOGY

P.O. Box 2938
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Total pages of this transmission, including cover letter: 8

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.

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

By: /Monique M. Perdok Shonka/
Name: Monique M. Perdok Shonka
USPTO Reg. No. 42,989

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

Leshere Wolfe

11-12-10
Date of Transmission

RECORDATION FORM COVER SHEET
PATENTS ONLY

Atty Ref/Docket No.: 101.000001 Patent and Trademark Office

To the Director of the U.S. Patent and Trademark Office: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

Orphan Medical, LLC

Additional name(s) of conveying party(ies) attached?

[ ]Yes [X]No

3. Nature of conveyance:

[X] Assignment [ ] Merger
[ ] Security Agreement [ ] Change of Name
[ ] Other

Execution Date: March 17, 2008

2. Name and address of receiving party(ies):

Name: JPI Commercial, LLC

Street Address: 3180 Porter Drive

City: Palo Alto State: CA Zip: 94304
Country: United States of America

Additional name(s) & address(es) attached? [ ]Yes [X]No

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No.(s) B. Patent No.(s)

Additional numbers attached? [X]Yes [ ]No

See attached Appendix A

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Monique M. Perdok Shonka

Address:
Schwegman, Lundberg & Woessner, P.A.
P.O. Box 2938
Minneapolis, MN 55402--0938

6. Total number of applications and patents involved: 10

7. Total fee (37 CFR 3.41):$ 400.00

[]Enclosed
[X]Authorized to be charged to deposit account 19-0743

8. Please charge any additional fees or credit any over payments to our Deposit Account No.: 19-0743

DO NOT USE THIS SPACE

9. Statement and signature.
To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Monique M. Perdok Shonka/Reg. No. 42,989 /Monique M. Perdok Shonka/ November 12, 2010
Name of Person Signing Signature Date

Total number of pages including cover sheet: 7

Mail documents to be recorded with required cover sheet information to:
Commissioner of Patents and Trademarks
Mail Stop Assignment Recordation Services
P.O. Box 1450
Alexandria, VA 22313-1450

Appendix A

Serial No.	Filing Date	U.S. Patent No.	Issue Date
09/470,570	Dec 22, 1999	6,472,431	Oct 29, 2002
10/194,021	Jul 11, 2002	6,780,889	Aug 24, 2004
10/841,709	May 7, 2004	7,262,219	Aug 28, 2007
11/777,877	Jul 13, 2007		
12/913,644	Oct 27, 2010		
10/322,348	Dec 17, 2002	7,668,730	Feb 23, 2010
10/979,665	Nov 2, 2004	7,765,106	Jul 27, 2010
11/097,651	Apr 1, 2005	7,797,171	Sep 14, 2010
11/097,985	Apr 1, 2005	7,765,107	Jul 27, 2010
12/704,097	Feb 11, 2010		

This assignment applies to any continuation, divisional or continuation-in-part of any listed application.

ORPHAN ASSET TRANSFER AGREEMENT

THIS ASSET TRANSFER AGREEMENT (the "Agreement") is dated as of March 17, 2008, by and among Orphan Medical, LLC., a Delaware limited liability company ("Orphan LLC"), Jazz Pharmaceuticals, Inc., a Delaware corporation ("Jazz Pharmaceuticals") and JPI Commercial, LLC, a Delaware limited liability company ("JPI"). All terms used but not defined herein are defined in that certain Senior Secured Note and Warrant Purchase Agreement, dated as of March 14, 2008 (the "Purchase Agreement"), by and among the Purchasers (as defined therein), Jazz Pharmaceuticals and JPI.

WHEREAS, Orphan Medical, Inc., a Delaware corporation ("Orphan Medical") merged with and into Orphan LLC as evidenced by that certain Certificate of Merger filed with the Delaware Secretary of State dated March 14, 2008 whereby Orphan LLC has assumed all of Orphan Medical's rights and obligations, in respect of the Antizol Assets, Antizol Contracts, Luvox CR Assets, Luvox CR Contracts, Xyrem Assets, Xyrem Contracts, the Orphan Note Purchase Agreement and the Orphan Notes;

WHEREAS, Orphan LLC and JPI are wholly owned subsidiaries of Jazz Pharmaceuticals and are considered affiliates of Jazz Pharmaceuticals for the purposes of this Agreement;

WHEREAS, in connection with this Agreement, JPI and Jazz Pharmaceuticals are entering into the Purchase Agreement;

WHEREAS, in connection with this Agreement, Jazz Pharmaceuticals, Orphan LLC and LB I Group Inc. in its capacity as "Collateral Agent," have entered into that certain License Termination Agreement, dated as of March 17, 2008, whereby the parties have terminated that certain Xyrem License Agreement, dated as of January 1, 2006, by and among Orphan LLC (as successor in interest to Orphan Medical), Jazz Pharmaceuticals and the Collateral Agent and that certain Antizol License Agreement, dated as of January 1, 2006, by and among Orphan LLC (as successor in interest to Orphan Medical), Jazz and the Collateral Agent; and

WHEREAS, the parties to the Purchase Agreement are entering into the Purchase Agreement in consideration and in reliance on Orphan LLC and JPI's entry into this Agreement.

NOW, THEREFORE, in consideration of the above premises and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereby agree as follows:

1. Effectiveness. This Agreement shall be effective as of the Initial Closing.

2. Assignment of Orphan Note Purchase Agreement Related Assets and Obligations. Orphan LLC hereby assigns all of its rights and interests in and its obligations under (i) the Orphan Note Purchase Agreement , (ii) each of the Orphan Notes, (iii) the Intellectual Property Security Agreement, dated as of June 24, 2005, by Twist Merger Sub, Inc. in favor of the LB I Group Inc., as collateral agent (the "IP Agreement") and (iv) the UCC-1 Financing Statement naming Orphan Medical as debtor (together with the Orphan Note Purchase Agreement, the Orphan Notes and the IP Agreement, the "Orphan Documents")

to JPI and JPI hereby assumes all of Orphan LLC's obligations under the Orphan Documents.

3. Orphan LLC Assets Assignment. Orphan LLC hereby assigns, sells, transfers and sets over to JPI all of Orphan LLC's legal, beneficial, and other rights, benefits, privileges and interests in and to the following:

    a. Antizol Intellectual Property;

    b. Antizol Regulatory Approval;

    c. Xyrem Intellectual Property; and

    d. Xyrem Regulatory Approval.

4. JPI Acceptance of Assignment; Assumption. JPI hereby expressly accepts and assumes all legal, beneficial, and other rights, benefits, privileges and interests in and to (i) the Antizol Intellectual Property, (ii) the Antizol Regulatory Approval, (iii) the Xyrem Intellectual Property and (iv) the Xyrem Approval.

5. Succession and Assignment. This Agreement shall be binding upon and inure to the benefit of Orphan LLC, Jazz Pharmaceuticals and JPI and their respective successors and permitted assigns. No party hereto may assign either this Agreement or any of its rights, interests or obligations hereunder without the prior written approval of the other parties hereto.

6. Third Party Beneficiary. The Parties agree that LB I Group Inc. shall be a third party beneficiary of this Agreement.

7. Amendments and Waivers. No amendment of any provision of this Agreement shall be valid unless the same shall be in writing and signed by Jazz Pharmaceuticals and JPI and consented to by LB I Group Inc. in its capacity as third party beneficiary hereof.

8. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be an original but all of which together shall constitute one instrument. Each counterpart may consist of a number of copies hereof, each signed by less than all, but together signed by all, of the parties hereto.

9. Governing Law. This Agreement shall be construed and enforced in accordance with, and the rights of the parties shall be governed by, the laws of the State of New York, including Section 5-1401 of the General Obligations Law of said State.

[SIGNATURE PAGE FOLLOWS]

JAZZ PHARMACEUTICALS, INC.

By: _____
Name: Carol A. Gamble
Title: Secretary

JPI COMMERCIAL, LLC

By: _____
Name: Carol A. Gamble
Title: Secretary

ORPHAN MEDICAL, LLC

By: _____
Name: Carol A. Gamble
Title: Manager

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	3109
CONNECTION TEL	
SUBADDRESS	
CONNECTION ID	
ST. TIME	11/17 15:52
USAGE T	00'48
PGS. SENT	5
RESULT	OK

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PATENT PROTECTION FOR HIGH TECHNOLOGY

P.O. Box 2938
Minneapolis, MN 55402
Telephone (612) 373-6900 Facsimile (612) 339-3061

November 17, 2010

Time: 3:42 PM
(Minneapolis, Minn.)

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

FAX NUMBER 571-273-0140

FROM: Monique M. Perdok Shonka

Please deliver to Assignment Recordation Services

Document(s) Transmitted: **Assignment Document (2 pgs.), Appendix A (1 pg), Recordation Form Cover Sheet (1 pg.), Authorization to charge Deposit Account 19-0743 in the amount of $400.00 to cover the recordation fee.**

Total pages of this transmission, including cover letter: 5

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.

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

By: Monique M. Perdok Shonka

SCHWEGMAN ▪ LUNDBERG ▪ WOESSNER
PATENT PROTECTION FOR HIGH TECHNOLOGY

P.O. Box 2938
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Please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

By: Monique M. Perdok Shonka
Name: Monique M. Perdok Shonka
USPTO Reg. No. 42,989

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

Leshere Wolfe
Leshere Wolfe

11-17-10
Date of Transmission

RECORDATION FORM COVER SHEET
PATENTS ONLY

Atty Ref/Docket No.: 101.000001

Patent and Trademark Office

To the Director of the U.S. Patent and Trademark Office: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

JPI Commercial, LLC.

Additional name(s) of conveying party(ies) attached?

[ ]Yes [X]No

3. Nature of conveyance:

[X] Assignment [ ] Merger
[ ] Security Agreement [ ] Change of Name
[ ] Other

Execution Date:

2. Name and address of receiving party(ies):

Name: Jazz Pharmaceuticals, Inc.

Street Address: 3180 Porter Drive

City: Palo Alto State: CA Zip: 94304
Country: United States of America

Additional name(s) & address(es) attached? [ ]Yes [X]No

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No.(s)

See Attached Appendix A

B. Patent No.(s)

Additional numbers attached? [X]Yes [ ]No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Monique M Perdok Shonka

Address:
Schwegman, Lundberg & Woessner, P.A.
P.O. Box 2938
Minneapolis, MN 55402--0938

6. Total number of applications and patents involved: 10

7. Total fee (37 CFR 3.41):$ 400.00

[]Enclosed
[X]Authorized to be charged to deposit account 19-0743

8. Please charge any additional fees or credit any over payments to our Deposit Account No.: 19-0743

DO NOT USE THIS SPACE

9. Statement and signature.
To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Monique M. Perdok Shonka/Reg. No. 42,989 Monique M Perdok Shonka 11/17/2010
Name of Person Signing Signature Date

Total number of pages including cover sheet: 5

Mail documents to be recorded with required cover sheet information to:
Commissioner of Patents and Trademarks
Mail Stop Assignment Recordation Services
P.O. Box 1450
Alexandria, VA 22313-1450

ASSIGNMENT

WHEREAS, JPI Commercial, LLC, a corporation organized and existing under and by virtue of the laws of the State of Delaware, and having an office and place of business at 3180 Porter Drive, Palo Alto, California 94304 (hereinafter "Assignor"), is the owner of United States of America Letters Patent and Patent Applications listed in Appendix A;

AND WHEREAS, Jazz Pharmaceuticals, Inc., a corporation organized and existing under and by virtue of the laws of the State of Delaware, and having an office and place of business at 3180 Porter Drive, Palo Alto, CA 94304 (hereinafter "Assignee"), is desirous of acquiring the entire right, title and interest in and to said inventions, improvements and application and in and to said patents and applications listed in Appendix A.

NOW, THEREFORE, to all whom it may concern, be it known that for good and valuable consideration, the receipt and sufficiency whereof is hereby acknowledged, we have sold, assigned, and transferred, and by these presents do sell, assign and transfer unto said Assignee, its successors or assigns, the entire right, title and interest for all countries in and to all inventions and improvements disclosed in the aforesaid application, and in and to the said application, all divisions, continuations, continuations-in-part, or renewals thereof, all Letters Patent which may be granted there from, and all reissues or extensions of such patents, and in and to any and all applications which have been or shall be filed in any foreign countries for Letters Patent on the said inventions and improvements, including an assignment of all rights under the provisions of the International Convention, and all Letters Patent of foreign countries which may be granted there from; and we do hereby authorize and request the Commissioner of Patents and Trademarks to issue any and all United States Letters Patent for the aforesaid inventions and improvements to the said Assignee as the assignee of the entire right, title and interest in and to the same, for the use of the said Assignee, its successors and assigns.

AND, for the consideration aforesaid, Assignor does hereby agree that it, its successors, assigns, and legal representatives will make, execute and deliver any and all other instruments in writing including any and all further application papers, affidavits, assignments and other documents, and will communicate to said Assignee, its successors and representatives all facts known to it relating to said improvements and the history thereof and will testify in all legal proceedings and generally do all things which may be necessary or desirable more effectually to secure to and vest in said Assignee, its successors or assigns the entire right, title and interest in and to the said improvements, inventions, applications, Letters Patent, rights, titles, benefits, privileges and advantages hereby sold, assigned and conveyed, or intended so to be.

IN TESTIMONY WHEREOF, I have hereunto set my hand this 16 day of November, 2010.

Assignor:
JPI Commercial, LLC

By _____
Name Carol A. Gamble
Title Manager

STATE OF California)
)ss
COUNTY OF Santa Clara)

On this 16 day of November, 2010 before me personally appeared Carol Gamble, to me known to be the person who executed the foregoing instrument on behalf of the Assignor, and ~~he~~/she duly acknowledged to me that he/she executed the same for the uses and purposes therein set forth.

[SEAL]

CAROLYN K. BROWNSON
Commission # 1705524
Notary Public - California
San Mateo County
My Comm. Expires Nov 23, 2010

Carolyn K. Brownson
Notary Public

Appendix A

Serial No.	Filing Date	U.S. Patent No.	Issue Date
09/470,570	Dec 22, 1999	6,472,431	Oct 29, 2002
10/194,021	Jul 11, 2002	6,780,889	Aug 24, 2004
10/841,709	May 7, 2004	7,262,219	Aug 28, 2007
11/777,877	Jul 13, 2007		
12/913,644	Oct 27, 2010		
10/322,348	Dec 17, 2002	7,668,730	Feb 23, 2010
10/979,665	Nov 2, 2004	7,765,106	Jul 27, 2010
11/097,651	Apr 1, 2005	7,797,171	Sep 14, 2010
11/097,985	Apr 1, 2005	7,765,107	Jul 27, 2010
12/704,097	Feb 11, 2010		

This assignment applies to any continuation, divisional or continuation-in-part of any listed application.

Electronic Patent Application Fee Transmittal

Application Number:	11097985
Filing Date:	01-Apr-2005
Title of Invention:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Dayton T. Reardan
Filer:	Gregory M. Stark/John Gustav-Wrathall
Attorney Docket Number:	101.031US4

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Petition fee- 37 CFR 1.17(f) (Group I)	1462	1	400	400
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Statutory or terminal disclaimer	2814	2	70	140

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**540**

Electronic Acknowledgement Receipt

EFS ID:	8882770
Application Number:	11097985
International Application Number:	
Confirmation Number:	5403
Title of Invention:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Gregory M. Stark/John Gustav-Wrathall
Filer Authorized By:	Gregory M. Stark
Attorney Docket Number:	101.031US4
Receipt Date:	20-NOV-2010
Filing Date:	01-APR-2005
Time Stamp:	00:05:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$540
RAM confirmation Number	6820
Deposit Account	190743
Authorized User	

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 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		101031US4_peti_111910.pdf	974206 233d95bf8645ddc21080c5f4744b97755a45de1c	yes	36

Multipart Description/PDF files in .zip description

Document Description	Start	End
Miscellaneous Incoming Letter	1	1
Petition for review by the Office of Petitions.	2	3
Terminal Disclaimer Filed	4	6
Terminal Disclaimer Filed	7	9
Power of Attorney	10	10
Miscellaneous Incoming Letter	11	21
Miscellaneous Incoming Letter	22	30
Miscellaneous Incoming Letter	31	36

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	32344 b1db16142545bfb1d14281efb03ece13e640c651	no	2

Warnings:

Information:

Total Files Size (in bytes):	1006550

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.:	101.031US4	Serial No.:	11/097,985
Filed:	April 1, 2005	Due Date:	N/A
Examiner:	Lena Najarian	Group Art Unit:	3686
Customer No.:	21186	Confirmation No.:	5403

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 Petition under 37 C.F.R. 1.182 to Correct the Name of the Assignee on the Terminal Disclaimer (2 pgs.)
X Authorization to charge Deposit Account 19-0743 in the amount of $400.00 to cover the petition fee set forth in 37 CFR 1.17(f) (Group I)
X Terminal Disclaimer of U.S. Patent No. 7,765,106 (3 pgs.)
X Terminal Disclaimer of U.S. Patent No. 7,797,171 (3 pgs.)
X Authorization to charge Deposit Account 19-0743 in the amount of $140.00 to cover the fee for the Terminal Disclaimer
X Power of Attorney (1 pg)
X Copy of Assignment from Orphan Medical, Inc. to Orphan Medical, LLC (11 pgs)
X Copy of Assignment from Orphan Medical, LLC to JPI Commercial, LLC (9 pgs)
X Copy of Assignment from JPI Commercial, LLC to Jazz Pharmaceuticals, Inc. (6 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, P.A.
Customer No.: 21186

By: /Monique M. Perdok Shonka/
Monique M. Perdok Shonka
Reg. No. 42,989

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.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/097,985	07/27/2010	7765107	101.031US4	5403

21186 7590 07/07/2010

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

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 1369 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Dayton T. Reardan, Excelsior, MN;
Patti A. Engel, Eagan, MN;
Bob Gagne, St. Paul, MN;

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.
11/097,985	04/01/2005	Dayton T. Reardan	101.031US4	5403

21186 7590 06/29/2010

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

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
06/29/2010	ELECTRONIC

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

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
request@slwip.com

Supplemental Notice of Allowability	Application No. 11/097,985	Applicant(s) REARDAN ET AL.	
	Examiner LENA NAJARIAN	Art Unit 3686	

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *5/12/10*.

2. ☒ The allowed claim(s) is/are *26-31*.

3. ☐ 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 the:
      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)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 20100512
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Jerry O'Connor/
SPE, GAU 3686

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11097985	REARDAN ET AL.
	Examiner	**Art Unit**
	LENA NAJARIAN	3686

SEARCHED

Class	Subclass	Date	Examiner
705	2, 3	8/7/09	LN
	updated all of above	6/21/10	LN

SEARCH NOTES

Search Notes	Date	Examiner
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	8/7/09	LN
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	8/14/09	LN
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	9/3/09	LN
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	9/9/09	LN
forward/backward search	2/18/10	LN
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2/18/10	LN
considered 705 template EIC search results	1/19/10	LN

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
705	3	2/18/10	LN
	PGPUB text search (see interference search printout)	2/18/10	LN
	updated all of above	6/21/10	LN

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11097985	REARDAN ET AL.
	Examiner	Art Unit
	LENA NAJARIAN	3686

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/09/2009	02/18/2010	06/21/2010						
	1	-	-	-						
	2	-	-	-						
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2	27	✓	=	=						
3	28	✓	=	=						
4	29	✓	=	=						
5	30	✓	=	=						
6	31	✓	=	=						

PTO/SB/08A(04-07)
Modified form approved for use through 09/30/2007. OMB 651-0031
US Patent & 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 contains a valid OMB control number.

Substitute for form 1449A/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** (Use as many sheets as necessary)	*Complete if Known*	
	Application Number	11/097,985
	Filing Date	April 1, 2005
	First Named Inventor	Dayton T. Reardan
	Group Art Unit	3686
	Examiner Name	Lena Najarian
Sheet 1 of 1	Attorney Docket No: 101.031US4	

US PATENT DOCUMENTS				
Examiner Initial *	**USP Document Number**	**Publication Date**	**Name of Patentee or Applicant of cited Document**	**Filing Date If Appropriate**

FOREIGN PATENT DOCUMENTS				
Examiner Initials*	**Foreign Document No**	**Publication Date**	**Name of Patentee or Applicant of cited Document**	**T [1]**

OTHER DOCUMENTS – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T [1]**
	"Application Serial No. 11/097,651 , Non-Final Office Action mailed 3-03-10", 19 Pgs	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /L.N./

EXAMINER	/Lena Najarian/	**DATE CONSIDERED**	06/21/2010

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant is to place a check mark here if English language Translation is attached

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BIB DATA SHEET

CONFIRMATION NO. 5403

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/097,985	04/01/2005	705	3686	101.031US4

APPLICANTS

Dayton T. Reardan, Excelsior, MN;
Patti A. Engel, Eagan, MN;
Bob Gagne, St. Paul, MN;

**** CONTINUING DATA ***************************

This application is a DIV of 10/322,348 12/17/2002 PAT 7,668,730

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
05/31/2005

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /LENA NAJARIAN/ Examiner's Signature	☐ Met after Allowance LN Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		MN	16	6	2

ADDRESS

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

TITLE

SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

FILING FEE RECEIVED		
865	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
11097985	REARDAN ET AL.
Examiner	**Art Unit**
LENA NAJARIAN	3686

ORIGINAL		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
705	2	G	0	6	Q	10 / 00 (2006.0)						

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
705	3				

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		17												
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	13	4	29												
	14	5	30												
	15	6	31												
	16														

/LENA NAJARIAN/ Examiner.Art Unit 3686 (Assistant Examiner)	6/21/10 (Date)	**Total Claims Allowed:** 6
/Gerald J. O'Connor/ SPE, GAU 3686 (Primary Examiner)	6/23/2010 (Date)	O.G. Print Claim(s) 1 O.G. Print Figure 4B

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

21186 7590 03/10/2010

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

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

LeShere Wolfe	(Depositor's name)
/LeShere Wolfe/	(Signature)
June 10, 2010	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/097,985	04/01/2005	Dayton T. Reardan	101.031US4	5403

TITLE OF INVENTION: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	06/10/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
NAJARIAN, LENA	3686	705-002000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☒ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Schwegman, Lundberg
2 & Woessner, P.A.
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: JPI Commercial, LLC.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Palo Alto, California

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ☒ Issue Fee
- ☒ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 19-0743 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature: /David D'Zurilla/ Date: June 10, 2010

Typed or printed name: David D'Zurilla Registration No.: 36,776

This collection of information is required by 37 CFR 1.311. 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner: Lena Najarian	
Serial No.:	11/097,985	Group Art Unit: 3686	
Filed:	April 1, 2005	Docket No.: 101.031US4	
Customer No.:	21186	Confirmation No.: 5403	
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

COMMUNICATION RE: FEE ADDRESS

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

In response to the Notice of Allowance and Issue Fee Due, please record the Fee Address under the provisions of 37 CFR 1.363 as the following:

Customer Number 21186

Please direct any inquiries to the undersigned attorney at (612) 371-2140.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 371-2140

Date June 10, 2010 By /David D'Zurilla/

David D'Zurilla
Reg. No. 36,776

DDZ:CMG:lrw

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 10th day of June, 2010.

LeShere Wolfe
Name

/LeShere Wolfe/
Signature

Electronic Patent Application Fee Transmittal

Application Number:	11097985
Filing Date:	01-Apr-2005
Title of Invention:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Dayton T. Reardan
Filer:	Karen L. Himmel/LeShere Wolfe
Attorney Docket Number:	101.031US4

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Publ. Fee- early, voluntary, or normal	1504	1	300	300
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	2501	1	755	755

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1055**

Electronic Acknowledgement Receipt

EFS ID:	7786351
Application Number:	11097985
International Application Number:	
Confirmation Number:	5403
Title of Invention:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Karen L. Himmel/LeShere Wolfe
Filer Authorized By:	Karen L. Himmel
Attorney Docket Number:	101.031US4
Receipt Date:	10-JUN-2010
Filing Date:	01-APR-2005
Time Stamp:	13:27:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1055
RAM confirmation Number	11272
Deposit Account	190743
Authorized User	

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 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		101031US4FEESXMIT.pdf	388069 f6ecb9cbd2a8368debc8489b0504ed0d95b47421	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Issue Fee Payment (PTO-85B)	2	2
	Change of Address	3	3

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	31867 4d8d88bf382c753427d92c2a863fe1959a42e258	no	2

Warnings:

Information:

Total Files Size (in bytes):	419936

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.:	101.031US4	Serial No.:	11/097,985
Filed:	April 1, 2005	Due Date:	June 10, 2010
Examiner:	Lena Najarian	Group Art Unit:	3686
Customer No.:	21186	Confirmation No.:	5403

Notice of Allowance Date: March 10, 2010

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

We are transmitting herewith the following:

X Authorization to charge Deposit 19-0743 in the amount of $755.00 to cover the Small Entity Issue Fee Payment.
X Authorization to charge Deposit 19-0743 in the amount of $300.00 to cover the Publication Fee Payment.
X Issue Fee Transmittal (Form PTOL-85).
X Communication Re: Fee Address (1 page).

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

SCHWEGMAN, LUNDBERG & WOESSNER, P.A. By /David D'Zurilla/
Customer No.: 21186 David D'Zurilla
DDZ:CMG:lrw Reg. No. 36,776

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LeShere Wolfe /LeShere Wolfe/
Name Signature

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
U.S. Patent & 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 contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	Unknown
Filing Date	Even Date Herewith
First Named Inventor	Reardan, Dayton
Group Art Unit	Unknown
Examiner Name	Unknown

Sheet 2 of 2

Attorney Docket No: 101.031US4

	US-2004/ 0,107,117	06/03/2004	Denny, Lawrence A.	11/25/2003
	US-2004/ 0,117,126	06/17/2004	Fetterman, Jeffrey E., et al.	11/25/2003
	US-2004/ 0,122,712	06/24/2004	Hill, Sr., Kenneth A., et al.	12/20/2002
	US-2004/ 0,122,713	06/24/2004	Hill, Sr., Kenneth A., et al.	12/20/2002
	US-2004/ 0,162,740	08/19/2004	Ericsson, Arthur D., et al.	02/14/2003
	US-2004/ 0,176,985	09/09/2004	Lilly, Ralph B., et al.	03/18/2004
	US-5,845,255	12/01/1998	Mayaud, C.	10/02/1997
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CP

5M

FOREIGN PATENT DOCUMENTS				
Examiner Initials*	**Foreign Document No**	**Publication Date**	**Name of Patentee or Applicant of cited Document**	**T²**

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	**Cite No [1]**	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T²**
		NASCSA National Conference, (November 2000),8 pages	
		"Diversion Prevention Through Responsible Distribution", NADDI Regional Training, (May 2001),12 pages	
		"Diversion Prevention Through Responsible Distribution", NADDI Regional Training Tennessee, (June 2001),14 Pages	
		"Diversion Prevention Through Responsible Distribution", NADDI National Conference, (November 2001),15 pages	
		"Peripheral and Central Nervous System Drugs Advisory Committee", Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research, Holiday Inn, Bethesda, Maryland,(06/06/2001),7 pages	

EXAMINER /Lena Najarian/ **DATE CONSIDERED** 08/06/2009

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /L.N./

PTO/SB/08A(04-07)
Modified form approved for use through 09/30/2007. OMB 651-0031
US Patent & 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 contains a valid OMB control number.

Substitute for form 1449A/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** (Use as many sheets as necessary)	*Complete if Known*	
	Application Number	11/097,985
	Filing Date	April 1, 2005
	First Named Inventor	Dayton T. Reardan
	Group Art Unit	3686
	Examiner Name	Lena Najarian
Sheet 1 of 1	Attorney Docket No: 101.031US4	

US PATENT DOCUMENTS				
Examiner Initial *	**USP Document Number**	**Publication Date**	**Name of Patentee or Applicant of cited Document**	**Filing Date If Appropriate**

FOREIGN PATENT DOCUMENTS				
Examiner Initials*	**Foreign Document No**	**Publication Date**	**Name of Patentee or Applicant of cited Document**	**T [1]**

OTHER DOCUMENTS – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T [1]**
	"Application Serial No. 11/097,651 , Non-Final Office Action mailed 3-03-10", 19 Pgs	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant is to place a check mark here if English language Translation is attached

Electronic Patent Application Fee Transmittal

Application Number:	11097985
Filing Date:	01-Apr-2005
Title of Invention:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Dayton T. Reardan
Filer:	Gregory M. Stark/John Gustav-Wrathall
Attorney Docket Number:	101.031US4

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	7596278
Application Number:	11097985
International Application Number:	
Confirmation Number:	5403
Title of Invention:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Gregory M. Stark/John Gustav-Wrathall
Filer Authorized By:	Gregory M. Stark
Attorney Docket Number:	101.031US4
Receipt Date:	12-MAY-2010
Filing Date:	01-APR-2005
Time Stamp:	13:14:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	9436
Deposit Account	190743
Authorized User	

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 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		101031us4_idsf_051210.pdf	155406 b38459cb0be0efa11312ded10b72d8fd8027cd7a	yes	6

Multipart Description/PDF files in .zip description

Document Description	Start	End
Miscellaneous Incoming Letter	1	1
Miscellaneous Incoming Letter	2	3
Transmittal Letter	4	5
Information Disclosure Statement (IDS) Filed (SB/08)	6	6

Warnings:

Information:

2	NPL Documents	P101-031US3.pdf	708609 e973603195edd5048f46371d1599d67d6b85a347	no	19

Warnings:

Information:

3	Fee Worksheet (PTO-875)	fee-info.pdf	30717 adc5e6c5fafb217855003c77e44d753917307bdf	no	2

Warnings:

Information:

Total Files Size (in bytes):	894732

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.:	101.031US4	Serial No.:	11/097,985
Filed:	April 1, 2005	Due Date:	N/A
Examiner:	Lena Najarian	Group Art Unit:	3686
Customer No.:	21186	Confirmation No.:	5403

Mail Stop Issue Fee
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 Communication Concerning Prior and Copending Applications (2 pgs.)
X Supplemental Information Disclosure Statement under 37 C.F.R. 1.97(d) (2 pgs.), Form 1449 (1 pg.) Copies of Cited References (1).
X Authorization to charge Deposit Account No. 19-0743 in the amount of $180 to cover the fee under 37 C.F.R. 1.17(p).

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, P.A.
Customer No.: 21186

By: _____
David D'Zurilla
Reg. No. 36,776

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 Issue Fee Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 12 day of May, 2010.

John D. Gustav-Wrathall
Name

/John D. Gustav-Wrathall/
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dayton T. Reardan et al.	Examiner:	Lena Najarian
Serial No.:	11/097,985	Group Art Unit:	3686
Filed:	April 1, 2005	Docket:	101.031US4
Customer No.:	21186	Confirmation No.:	5403
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

COMMUNICATION CONCERNING PRIOR OR COPENDING APPLICATION(S)

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

Pursuant to the guidance of MPEP §§ 2001.06(b) and 2004(9), Applicants would like to bring the following additional application(s) to the Examiner's attention. The identification of these applications is not intended to suggest that the subject matter claimed in any listed application is, or has been, substantially similar to any claim or claims in the present application.

Serial No./ Patent No.	Filing Date	Attorney Docket	Title
10/979,665	November 2, 2004	101.031US2	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
11/097,651	April 1, 2005	101.031US3	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
12/704,097	February 11, 2010	101.031US5	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 371-2140

Date May 12, 2010 By / /

David D'Zurilla
Reg. No. 36,776

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 12 day of May, 2010.

John D. Gustav-Wrathall — Name

/John D. Gustav-Wrathall/ — Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dayton T. Reardan et al.	Examiner:	Lena Najarian
Serial No.:	11/097,985	Group Art Unit:	3686
Filed:	April 1, 2005	Docket:	101.031US4
Customer No.:	21186	Confirmation No.:	5403
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97(d)

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

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Supplemental Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

The attached documents were discovered as a result of an office action in a related U.S. patent application. Enclosed for the Examiner's information is a copy of the cited document and the Office Action.

Pursuant to 37 C.F.R. §1.97(d)(1) and 37 C.F.R. §1.97(e)(2), Applicants state that no item of information contained in the Supplemental Information Disclosure Statement was cited in any communication from a foreign patent office in a counterpart foreign application and that no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

Examiner is authorized to charge Deposit Account No. 19-0743 in the amount of $180 to cover the fee under 37 C.F.R. 1.17(p).

Pursuant to 37 C.F.R. § 1.98(a)(2), copies of cited U.S. Patents and Published Applications, and Non-Published Applications identifiable by USPTO Serial Number, are no longer required to be provided to the Office. Applicants acknowledge the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R § 1.98(a)(2).

The Examiner is invited to contact the undersigned at the telephone number indicated if there are any questions regarding this communication.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 371-2140

Date May 12, 2010 By / /
David D'Zurilla
Reg. No. 36,776

DDZ:jdgw

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: MS Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 12 day of May, 2010.

John D. Gustav-Wrathall /John D. Gustav-Wrathall/
Name Signature

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

21186 7590 03/10/2010

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

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	

DATE MAILED: 03/10/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/097,985	04/01/2005	Dayton T. Reardan	101.031US4	5403

TITLE OF INVENTION: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	06/10/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

21186 7590 03/10/2010

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

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/097,985	04/01/2005	Dayton T. Reardan	101.031US4	5403

TITLE OF INVENTION: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	06/10/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
NAJARIAN, LENA	3686	705-002000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1_____

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2_____ 3_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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.

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.
11/097,985	04/01/2005	Dayton T. Reardan	101.031US4	5403

21186 7590 03/10/2010

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

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	

DATE MAILED: 03/10/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 1109 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 1109 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	11/097,985	REARDAN ET AL.	
	Examiner	Art Unit	
	LENA NAJARIAN	3686	

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *11/3/09*.

2. ☒ The allowed claim(s) is/are *26-31*.

3. ☐ 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 the:
      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)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 20091103
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Examiner's Amendment

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David D'Zurilla (Reg. No. 36,776) on 1/20/10.

The application has been amended as follows:

26. (Currently Amended) A computerized method to control abuse of a prescription ~~sensitive~~ drug comprising:

controlling with a computer processor the distribution of said prescription ~~sensitive~~ drug via an exclusive central pharmacy that maintains a central database that tracks all prescriptions of said prescription ~~sensitive~~ drug and analyzes for potential abuse situations;

receiving in the computer processor all prescription requests, for any and all patients being prescribed the prescription ~~sensitive~~ drug, only at the exclusive central pharmacy, from any and all medical doctors allowed to prescribe the prescription ~~sensitive~~ drug;

processing with the computer processor all prescriptions for the prescription ~~sensitive~~ drug only by the exclusive central pharmacy using only the central database;

determining with the computer processor current and anticipated patterns of potential prescription abuse of said prescription ~~sensitive~~ drug from periodic reports

generated only by the central database based on prescription request data from a particular medical doctor and further based on filling of prescriptions by a particular patient, wherein said request data contain information identifying the patient, the drug prescribed, and credentials of the medical doctor; and

selecting with the computer processor multiple controls for distribution by said exclusive central pharmacy, the controls comprising communicating prescriptions from a physician to the central pharmacy; identifying the physician's name, license, and DEA (Drug Enforcement Agency) registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the prescription ~~sensitive~~ drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive printed materials to the physician; contacting the patient's insurance company if any; verifying patient registry information; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address of the patient; shipping via US postal service or a commercial shipping service; receiving the name of an at least 18 year old designee to receive the drug; confirming receipt of an initial shipment of the drug to the patient returning the drug to the pharmacy after two attempts to deliver; launching an investigation when a shipment is lost; shipping to another pharmacy for delivery; requiring manufacture at a single location; releasing inventory in a controlled manner to the central pharmacy; questioning early refills; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; limiting the prescription to a one month supply; requiring rewriting of the prescription periodically; and making the database available to the DEA for checking for abuse patterns in the data, for cash payments, and for inappropriate questions.

27. (Currently Amended) The method of claim 26 wherein initially selected controls comprise communicating prescriptions from a physician to the central pharmacy;

identifying the physician's name, license, and DEA registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the prescription ~~sensitive~~ drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; verifying patient registry information; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address of the patient; shipping via US postal service; confirming receipt of an initial shipment of the drug to the patient; releasing inventory in a controlled manner to the central pharmacy; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; and making the database available to the DEA for checking for abuse patterns in the data.

Allowable Subject Matter

2. Claims 26-31 are allowed.

3. The following is an examiner's statement of reasons for allowance:

Claim 26, now renumbered as claim 1, is directed to a computerized method to control abuse of a prescription drug.

The closest prior art of record, Moradi (US 2004/0019794 A1), Lilly et al. (US 2004/0176985 A1), and Ukens ("Specialty Pharmacy") teach receiving prescription request data from a medical doctor, selecting multiple controls for distribution by a central pharmacy, determining current and anticipated patterns of potential abuse, and restricting distribution of a medication to only one pharmacy.

However, the closest prior art of record does not teach or fairly suggest receiving in the computer processor all prescription requests, for any and all patients being prescribed the prescription drug, only at the exclusive central pharmacy, from any and all medical doctors allowed to prescribe the prescription drug and processing with the computer processor all prescriptions for the prescription drug only by the exclusive central pharmacy using only the central database.

Dependent claims 27 and 28 (now renumbered as claims 2 and 3) incorporate the allowable subject matter of claim 26, through dependency, and are also allowable for the same reasons.

Claim 29, now renumbered as claim 4, is directed to a computerized method to control abuse of gamma hydroxy butyrate (GHB).

The closest prior art of record, Moradi (US 2004/0019794 A1), Lilly et al. (US 2004/0176985 A1), Ukens ("Specialty Pharmacy"), and Melker et al. (US 2002/0177232 A1) teach receiving prescription request data from a medical doctor, selecting multiple controls for distribution by a central pharmacy, determining current and anticipated patterns of potential abuse, restricting distribution of a medication to only one pharmacy, and that GHB is an illicit substance.

However, the closest prior art of record does not teach or fairly suggest receiving in the computer processor all prescription requests, for any and all patients being prescribed GHB, only at the exclusive central pharmacy, from any and all medical doctors allowed to prescribe GHB and processing in the computer processor all prescriptions for GHB only by the exclusive central pharmacy using only the central database.

Dependent claims 30 and 31 (now renumbered as claims 5 and 6) incorporate the allowable subject matter of claim 29, through dependency, and are also allowable for the same reasons.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

4. 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, 9:30 - 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. 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.

/L. N./
Examiner, Art Unit 3686
ln
2/18/10

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686

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

BIB DATA SHEET

CONFIRMATION NO. 5403

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/097,985	04/01/2005	705	3686	101.031US4

APPLICANTS

Dayton T. Reardan, Excelsior, MN;
Patti A. Engel, Eagan, MN;
Bob Gagne, St. Paul, MN;

**** CONTINUING DATA ***************************

This application is a DIV of 10/322,348 12/17/2002 PAT 7,668,730

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
05/31/2005

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /LENA NAJARIAN/ Examiner's Signature	☐ Met after Allowance LN Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		MN	16	6	2

ADDRESS

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

TITLE

Sensitive drug distribution system and method

FILING FEE RECEIVED		
565	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11097985	REARDAN ET AL.
	Examiner	Art Unit
	LENA NAJARIAN	3686

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/09/2009	02/18/2010							
	1	-	-							
	2	-	-							
	3	-	-							
	4	-	-							
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	21	-	-							
	22	-	-							
	23	-	-							
	24	-	-							
	25	-	-							
1	26	✓	=							
2	27	✓	=							
3	28	✓	=							
4	29	✓	=							
5	30	✓	=							
6	31	✓	=							

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L6	57	("4847764" | "5014875" | "5502944" | "5797515" | "5842976" | "5850344" | "5860563" | "5867821" | "5873488" | "5884806" | "5897024" | "5905653" | "5907493" | "5924074" | "5945651" | "5950632" | "5963452" | "5971594" | "5991731" | "6003006" | "6004020" | "6021392" | "6032155" | "6039467" | "6112502" | "6115649" | "6330491").PN. OR ("6564121").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/02/18 16:07
L7	1166	705/3	US-PGPUB	OR	OFF	2010/02/18 16:42
L8	5	((drug or prescription or medication or medicine or pharmaceutical) AND (pharmacy) AND (central or exclusive or sole or one or only) AND (abus$ or fraud$ or misus$) AND (doctor or physician) AND (pattern)).CLM.	US-PGPUB	OR	ON	2010/02/18 16:44
L9	20	(single or one or exclusive or sole) adj2 pharmacy same (sensitive or controlled) same (substance or drug or prescription or medication or pharmaceutical)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/02/18 16:46

L10	29	(single or one or exclusive or sole or only or central) adj2 pharmacy same (sensitive or controlled) same (substance or drug or prescription or medication or pharmaceutical)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/02/18 16:51
L11	30	(single or one or exclusive or sole or only or central) adj2 pharmacy same (sensitive or controlled) same (substance or drug or prescription or medication or pharmaceutical or medicine)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/02/18 16:52
L12	10	(single or one or exclusive or sole or only or central) adj2 pharmacy same (sensitive or controlled) same (substance or drug or prescription or medication or pharmaceutical or medicine) same (database or data adj1 base or databank or data adj1 bank)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/02/18 16:52
L16	84	("4847764" | "5014875" | "5502944" | "5797515" | "5842976" | "5850344" | "5860563" | "5867821" | "5873488" | "5884806" | "5897024" | "5905653" | "5907493" | "5924074" | "5945651" | "5950632" | "5963452" | "5971594" | "5991731" | "6003006" | "6004020" | "6021392" | "6032155" | "6039467" | "6112502" | "6115649" | "6330491").PN. OR ("6564121").URPN.	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/02/18 17:15

EAST Search History (Interference)

< This search history is empty>

2/18/2010 5:16:06 PM
C:\Documents and Settings\lnajarian2\My Documents\EAST\Workspaces\11097985.wsp

Modified form approved for use through 09/30/2007. OMB 651-0031
US Patent & 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 contains a valid OMB control number.

Substitute for form 1449A/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** (Use as many sheets as necessary)	*Complete if Known*	
	Application Number	11/097,985
	Filing Date	April 1, 2005
	First Named Inventor	Dayton T. Reardan
	Group Art Unit	3686
	Examiner Name	Lena Najarian
Sheet 1 of 1	Attorney Docket No: 101.031US4	

US PATENT DOCUMENTS				
Examiner Initial *	**USP Document Number**	**Publication Date**	**Name of Patentee or Applicant of cited Document**	**Filing Date If Appropriate**

FOREIGN PATENT DOCUMENTS				
Examiner Initials*	**Foreign Document No**	**Publication Date**	**Name of Patentee or Applicant of cited Document**	**T [1]**

OTHER DOCUMENTS – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T [1]**
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Advisory Action mailed 02-05-07", 3 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Amendment and Response to Final Office Action mailed 01-17-07", 17 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Amendment and Response to Final Office Action mailed 03-29-06", 11 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Final Office Action mailed 10-18-06", 14 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Final Office Action mailed 12-29-05", 11 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Non Final Office Action mailed 06-17-05", 26 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Non Final Office Action mailed 06-29-05", 12 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Non Final Office Action Response mailed 08-08-06", 10 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Preliminary Amendment mailed 09-30-04", 11 pgs	
	"Application Serial No. 10/731,915 (Atty Ref 101.031US1) Non Final Office Action mailed 10-05-04", 21 pgs	
	"Application Serial No. 10/731,915 (Atty Ref 101.031US1), Non Final Office Action mailed 08-12-05", 22 pgs	
	"Application Serial No. 10/731,915 (Atty Ref 101.031US1), Non Final Office Action Response mailed 02-02-05", 17 pgs	
	"Application Serial No. 101.031US1 (Atty Ref 101.031US1), Non Final Office Action mailed 06-19-06", 18 pgs	

EXAMINER	/Lena Najarian/	**DATE CONSIDERED**	02/18/2010

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /L.N./

STIC Scientific and Technical Information Center

Search Report
EIC 3600

STIC Database Tracking Number:

To: Najarian, Lena **Location: KNX o5, A59** **Art Unit: 3686** **Date: 01/09/10** **Case Serial Number: 11/097,985**	**From: Paul Obiniyi** **Location: EIC3600** **KNX 04 B68/ Rm04 B71** **Phone: (571) 272-27734** **paul.obiniyi@uspto.gov**

Search Notes

Dear Examiner Najarian :

Please find attached the results of your search for the above-referenced case. The search was conducted in template files.

I have listed *potential* references of interest in the first part of the search results. However, please be sure to scan through the entire report. There may be additional references that you might find useful.

If you have any questions about the search, or need a refocus, please do not hesitate to contact me.

Thank you for using the EIC, and we look forward to your next search!

Paul

I. Potential References of Interest

A. Dialog

3/3,K/3 (Item 2 from file: 148)
DIALOG(R)File 148: Gale Group Trade & Industry DB

05549369 SUPPLIER NUMBER: 11731339 (USE FORMAT 7 OR 9 FOR FULL TEXT)
SIMS implementation takes center stage. (use of Strategic Inventory
Management System at Walgreens)
Chain Drug Review, v14, n5, p52(1)
Dec 9, 1991
ISSN: 0164-9914 LANGUAGE: ENGLISH RECORD TYPE: FULLTEXT
WORD COUNT: 686 LINE COUNT: 00054

... things will enable us to cut the cost of the inventory we carry at
any **one** time by as much as $200 million."
In terms of retail technology, Walgreens has been unmatched in the
chain **drug** store industry since the early 1980s, when it
launched Intercom. **That system linked the pharmacy files
in all of its stores with a central
data base, thus facilitating the
processing of third-party claims, providing for automatic reordering of
prescription drugs**, and allowing
prescriptions on file at any Walgreens outlet to be filled at any of...

3/3,K/4 (Item 1 from file: 261)
DIALOG(R)File 261: UPI News

00269530 20020718199W2270 (USE FORMAT 7 FOR FULLTEXT)
'Date-rape' drug approval raises concerns
UPI News
Thursday, July 18, 2002 18:03 EDT
JOURNAL CODE: UP LANGUAGE: ENGLISH RECORD TYPE: FULLTEXT
DOCUMENT TYPE: NEWSWIRE
WORD COUNT: 1,020

...concerns about the potential for abuse, the FDA has imposed tight
restrictions to prevent the **drug** from falling into the
wrong hands. These
include allowing only **one central
pharmacy to distribute the drug and
requiring doctors prescribing it and patients using it
to register with a
database.**

Deborah Zvosec, a research investigator at the Minneapolis Medical Research
Foundation who warned of the...

3/3,K/6 (Item 1 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT

00878844 **Image available**
INFORMATION TRANSMISSION AND COLLECTION APPARATUS AND METHOD
APPAREIL ET PROCEDE DE TRANSMISSION ET DE RECUEIL D'INFORMATIONS
Patent Applicant/Inventor:
HOLBROOK Keith Richard, 235 Timberwind Lane, Vandalia, OH 45377, US, US (Residence), US (Nationality)
KUMBROCH Kent Forrest, 8161 Julian Place, Centerville, OH 45458, US, US (Residence), US (Nationality)
Legal Representative:
KAUFMAN Marc S (et al) (agent), Suite 800, 8180 Greensboro Drive, McLean, VA 22102, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200213040 A1 20020214 (WO 0213040)
Application: WO 2001US19588 20010620 (PCT/WO US0119588)
Priority Application: US 2000635237 20000809
Designated States:
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)
CA JP
(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR
Publication Language: English
Filing Language: English
Fulltext Word Count: 9101
Fulltext Availability:
Detailed Description

Detailed Description
... distribution system I 1 0, and are thus provided with appropriate channels for communicating with **one** another and individual 50 to transact business or other matters. **Data collection and distribution system I 1 0 includes central database 60 for storing various information relating to individual 50. While for purposes of illustrating this embodiment, central database 60 is segmented into four distinct sectors (medical, pharmaceutical,** financial and personal), it may be segmented into additional sectors involving other business services.

In this embodiment, individual 50 visits first **pharmacy 70 to obtain medicine prescribed by a medical doctor. Upon reviewing the prescription data, first pharmacy 70 requests from individual 50 access to information stored in central database** 60 for purposes of modifying information relating to individual 50 by recording the **prescription** information. The information may be modified using a computer, such as a personal computer, a...

3/3,K/8 (Item 1 from file: 429)
DIALOG(R)File 429: Adis News(Arc)

00083356 11735503-800523195
UK pilot project to identify hospital prescribing patterns.
JOURNAL NAME: PharmacoEconomics & Outcomes News
PUBLICATION DATE: 22 APRIL 1997 (19970422)

REFERENCES:
Pharmacists' help sought in pilot project to analyse hospital prescribing. Pharmaceutical Journal 258 : 431, 29 MAR 1997 (English, News Item (England))

SUMMARY TEXT:
...database to help assess and compare prescribing patterns between hospitals in that country, reports the **Pharmaceutical** Journal. This project parallels the collection and analysis of general practice **Prescription** Analysis and CosT (PACT) data by the **Prescription** Pricing Authority.
As part of the project, **which is to be undertaken by the National Prescribing Centre, a representative sample of hospitals will collect relevant aggregated data in electronic format from their pharmacy computer systems. These data will be compiled into a single, centralised database from which targeted information can be generated.** This information will:
- enable participating hospitals to compare their **prescribing** patterns and costs to national trends and averages
- assist health authorities and hospitals in monitoring hospital prescribing, which may have an important influence on **drug** prescribing in general practice
- enable the National Health Service Executive and health authorities to more...

II. Inventor Search Results from Dialog

t/ 3,k/ all

20/3,K/1 (Item 1 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0015351683 - Drawing available
WPI ACC NO: 2005-701943/200572
Related WPI Acc No: 2004-516067; 2005-354186; 2005-701214
XRPX Acc No: N2005-576014
Food and drug administration approval acquisition method of e.g. narcotics, involves selecting controls from group containing identifying physician name and license, and verifying whether physician is eligible to **prescribe drug**
Patent Assignee: ORPHAN MEDICAL INC (ORPH-N)
Inventor: **ENGEL P A**; **GAGNE B**; REARDAN D T
Patent Family (1 patents, 1 countries)

Patent Number	Kind	Date	Application Number	Kind	Date	Update
US 20050222874	A1	20051006	US 2002322348	A	20021217	200572 B
			US 200597651	A	20050401	

Priority Applications (no., kind, date): US 2002322348 A 20021217; US 200597651 A 20050401

Patent Details
Number Kind Lan Pg Dwg Filing Notes
US 20050222874 A1 EN 22 13 Division of application US 2002322348

...from group containing identifying physician name and license, and verifying whether physician is eligible to **prescribe drug**
Inventor: **ENGEL P A**...

...**GAGNE B**

Alerting Abstract ...name, license and drug enforcement agency registration information and verifying whether physician is eligible to **prescribe drug**. The food and drug administration is negotiated by adding controls from group until approval is...

Original Publication Data by Authority

Argentina

Assignee name & address:
Inventor name & address:
...**Engel, Patti A**...

...**Gagne, Bob**
Examiner:
Original Abstracts:
...for a sensitive drug. Information is kept in the database regarding all physicians allowed to **prescribe** the sensitive **drug**, **and** all patients **receiving** the drug. Abuses are identified by monitoring data in the database for prescription patterns by...

...and prescriptions obtained by patients. Further verification is made that the physician is eligible to **prescribe** the **drug** by **consulting** a **separate** database, and optionally whether any actions are taken against the physician. Multiple controls beyond those...
Claims:

20/3,K/2 (Item 2 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0015350954 - Drawing available
WPI ACC NO: 2005-701214/200572
Related WPI Acc No: 2004-516067; 2005-354186; 2005-701943
XRPX Acc No: N2005-575389

Abuse control method of sensitive drug e.g. cocaine, involves providing database for drug enforcement agency for checking abuse patterns of drug, with respect to each cash payment and inappropriate questions
Patent Assignee: ORPHAN MEDICAL INC (ORPH-N)
Inventor: **ENGEL P A**; **GAGNE B**; REARDAN D T
Patent Family (1 patents, 1 countries)

Patent Number	Kind	Date	Application Number	Kind	Date	Update
US 20050216309	A1	20050929	US 2002322348	A	20021217	200572 B
			US 200597985	A	20050401	

Priority Applications (no., kind, date): US 2002322348 A 20021217; US 200597985 A 20050401

Patent Details

Number	Kind	Lan	Pg	Dwg	Filing Notes
US 20050216309	A1	EN	23	13	Division of application US 2002322348

Inventor: **ENGEL P A**...

...**GAGNE B**

Alerting Abstract ...NOVELTY - The current and anticipated patterns of potential **prescription** abuse of sensitive **drug** are determined from periodic reports generated by database, based on **prescription** **request** data with information identifying patient, prescribed drug, credential of doctor. The database is made available...

Original Publication Data by Authority

Argentina

Assignee name & address:
Inventor name & address:
...**Engel, Patti A**...

...**Gagne, Bob**
Examiner:
Original Abstracts:
...for a sensitive drug. Information is kept in the database regarding all physicians allowed to **prescribe** the sensitive **drug**, **and** all patients **receiving** the drug. Abuses are identified by monitoring data in the database for prescription patterns by...

...and prescriptions obtained by patients. Further verification is made that the physician is eligible to **prescribe** the **drug** by **consulting** a **separate** database, and optionally whether any actions are taken against the physician. Multiple controls beyond those...
Claims:

20/3,K/3 (Item 3 from file: 350)

DIALOG(R)File 350: Derwent WPIX

0015006281 - Drawing available
WPI ACC NO: 2005-354186/200536
Related WPI Acc No: 2004-516067; 2005-701214; 2005-701943
XRPX Acc No: N2005-289217
Sensitive drug e.g. Xyrem, distributing method for treating cataplexy, involves making periodic reports via database to evaluate potential abuse patterns, where database has information identifying patient, drug and credentials
Patent Assignee: ORPHAN MEDICAL INC (ORPH-N)
Inventor: ENEEL P A; **GAGNE B**; REARDAN D T
Patent Family (1 patents, 1 countries)

Patent Number	Kind	Date	Application Number	Kind	Date	Update
US 20050090425	A1	20050428	US 2002322348	A	20021217	200536 B
			US 2004979665	A	20041102	

Priority Applications (no., kind, date): US 2002322348 A 20021217; US 2004979665 A 20041102

Patent Details

Number	Kind	Lan	Pg	Dwg	Filing Notes
US 20050090425	A1	EN	23	13	Division of application US 2002322348

...Inventor: **GAGNE B**

Alerting Abstract ...and monitors the patient and prescribing physician registries to ensure proper distribution of the sensitive **drug**.

Original Publication Data by Authority

Argentina

Assignee name & address:
Inventor name & address:
...**Gagne, Bob**
Examiner:
Original Abstracts:
...for a sensitive drug. Information is kept in the database regarding all physicians allowed to **prescribe** the sensitive **drug**, **and** all patients **receiving** the drug. Abuses are identified by monitoring data in the database for prescription patterns by...

...and prescriptions obtained by patients. Further verification is made that the physician is eligible to **prescribe** the **drug** by **consulting** a **separate** database, and optionally whether any actions are taken against the physician. Multiple controls beyond those...
Claims:
1. A method of distributing a sensitive drug, the method comprising: **receiving prescription** requests from a medical doctor containing information identifying the patient, the sensitive drug, and various...

20/3,K/4 (Item 4 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0014328324 - Drawing available
WPI ACC NO: 2004-516067/200449
Related WPI Acc No: 2005-354186; 2005-701214; 2005-701943
XRPX Acc No: N2004-408813
Sensitive drug e.g. cocaine, distributing method, involves confirming with patient that educational material has been read prior to shipping, confirming receipt of drug, and generating periodic reports via central database
Patent Assignee: ENEEL P A (ENEE-I); GAGNE B (GAGN-I); REARDAN D T (REAR-I)
Inventor: ENEEL P A; **GAGNE B**; REARDAN D T
Patent Family (1 patents, 1 countries)

Patent			Application			
Number	Kind	Date	Number	Kind	Date	Update
US 20040117205	A1	20040617	US 2002322348	A	20021217	200449 B

Priority Applications (no., kind, date): US 2002322348 A 20021217

Patent Details

Number	Kind	Lan	Pg	Dwg	Filing Notes
US 20040117205	A1	EN	23	13	

...Inventor: **GAGNE B**

Original Publication Data by Authority

Argentina

Assignee name & address:
Inventor name & address:
...**Gagne, Bob**
Examiner:
Original Abstracts:
...for a sensitive drug. Information is kept in the database regarding all physicians allowed to **prescribe** the sensitive **drug**, **and** all patients **receiving** the drug. Abuses are identified by monitoring data in the database for prescription patterns by...

...and prescriptions obtained by patients. Further verification is made that the physician is eligible to **prescribe** the **drug** by **consulting** a **separate** database, and optionally whether any actions are taken against the physician. Multiple controls beyond those...
Claims:
1. A method of distributing a sensitive drug, the method comprising: **receiving prescription** requests from a medical doctor containing information identifying the patient, the sensitive drug, and various...

III. Text Search Results from Dialog

A. Full-Text Databases I

show files

```
File 348:EUROPEAN PATENTS 1978-201002
       (c) 2010 European Patent Office
File 349:PCT FULLTEXT 1979-2010/UB=20100107|UT=20091231
       (c) 2010 WIPO/Thomson
File  15:ABI/Inform(R) 1971-2010/Jan 14
       (c) 2010 ProQuest Info&Learning
File   9:Business & Industry(R) Jul/1994-2010/Jan 14
       (c) 2010 Gale/Cengage
File 610:Business Wire 1999-2010/Jan 15
       (c) 2010 Business Wire.
File 810:Business Wire 1986-1999/Feb 28
       (c) 1999 Business Wire
File 275:Gale Group Computer DB(TM) 1983-2010/Dec 10
       (c) 2010 Gale/Cengage
File 624:McGraw-Hill Publications 1985-2010/Jan 14
       (c) 2010 McGraw-Hill Co. Inc
File 621:Gale Group New Prod.Annou.(R) 1985-2010/Dec 02
       (c) 2010 Gale/Cengage
File 636:Gale Group Newsletter DB(TM) 1987-2010/Dec 16
       (c) 2010 Gale/Cengage
File 613:PR Newswire 1999-2010/Jan 15
       (c) 2010 PR Newswire Association Inc
File 813:PR Newswire 1987-1999/Apr 30
       (c) 1999 PR Newswire Association Inc
File  16:Gale Group PROMT(R) 1990-2010/Jan 15
       (c) 2010 Gale/Cengage
File 160:Gale Group PROMT(R) 1972-1989
       (c) 1999 The Gale Group
File 634:San Jose Mercury  Jun 1985-2009/Dec 31
       (c) 2010 San Jose Mercury News
File 148:Gale Group Trade & Industry DB 1976-2010/Jan 15
       (c) 2010 Gale/Cengage
File  20:Dialog Global Reporter 1997-2010/Jan 14
       (c) 2010 Dialog
File 256:TecTrends 1982-2010/Jan W2
       (c) 2010 Info.Sources Inc. All rights res.
File 625:American Banker Publications 1981-2008/Jun 26
       (c) 2008 American Banker
File 637:Journal of Commerce 1986-2010/Jan 15
       (c) 2010 UBM Global Trade
File 635:Business Dateline(R) 1985-2010/Jan 15
       (c) 2010 ProQuest Info&Learning
File 570:Gale Group MARS(R) 1984-2010/Dec 16
       (c) 2010 Gale/Cengage
File  47:Gale Group Magazine DB(TM) 1959-2010/Dec 28
```

(c) 2010 Gale/Cengage
File 268:Banking Info Source 1981-2010/Jan W2
(c) 2010 ProQuest Info&Learning
File 626:Bond Buyer Full Text 1981-2008/Jul 07
(c) 2008 Bond Buyer
File 267:Finance & Banking Newsletters 2008/Sep 29
(c) 2008 Dialog
File 608:MCT Information Svc. 1992-2010/Jan 15
(c) 2010 MCT Information Svc.

? **ds**

Set Items Description
S1 181039 (PRESCRIBE OR PRESCRIBING OR PRESCRIPTION OR DRUG? ? OR MEDICINE? ? OR FORMULA OR PHARMACEUTICAL OR DIAGNOSIS)(3N)(REQUEST OR WANT OR NEEDS OR DEMAND??? OR ASK??? OR QUERY??? OR QUERIES OR INQUIR??? OR QUESTION? ?)
S2 444736 (PRESCRIBE OR PRESCRIBING OR PRESCRIPTION)(3N)(DRUG? ? OR MEDICINE? ? OR FORMULA OR PHARMACEUTICAL OR DIAGNOSIS)
S3 20687 (ONE OR SINGLE OR SINGULAR OR LONE)(3N)(DRUGSTORE?? O R DRUG()STORE OR PHARMACY?) OR EXCLUSIVE()CENTRA()PHARMACY
S4 15102 (CENTRAL OR CENTRE OR CENTER)(3N)((REPOSITORY OR DATABASE OR DATA()BASE OR REGIST? OR DATABANK? ? OR DATATABLE? ? OR DATA OR INFORMATION OR KNOWLEDGE)()(BASE? ? OR BANK? ? OR SET? ? OR FILE? ? OR TABLE? ?) OR DB OR (ORGANI?ED()COLLECTION? ? OR RELATED OR INTERRELATED)(2W)(FILES OR INFORMATION OR DATA) OR DBMS)
S5 6313500 (MANAGEMENT OR MANAG??? OR SUPERVIS??? OR REGULAT??? OR CONTROL? OR PROCESS?)(3N)(DISTRIBUTION OR SUPPL??? OR DELIVER??? OR PROVID??? OR ALLOCAT??? OR ASSIGN?)
S6 0 S6(7N)(PRESCRIBE OR PRESCRIBING OR PRESCRIPTION)(3N)(DRUG? ? OR MEDICINE? ? OR FORMULA OR PHARMACEUTICAL OR DIAGNOSIS)
S7 520 AU=(REARDAN, D?OR REARDAN D? OR REARDAN(2N)D? OR ENGEL, P? OR ENGEL P? OR ENGEL(2N)P? OR GAGNE, B? OR GAGNE B? OR GAGNE(2N)B?)
S8 1 S7 AND S1
S9 200 (S1:S2)(7N)S3
S10 0 S9(7N)S4
S11 0 (S1:S2)(7N)S4
S12 8 (S1:S2)(50N)S4
S13 2162 (S1:S2)(3N)S5
S14 1 S13(7N)S3
S15 70 S2(3N)S3
S16 0 S15(50N)S4
S17 9 S12 OR S14
S18 14 S15 NOT PY>2002

?

? **t/3,k/all**

18/3,K/1 (Item 1 from file: 15)
DIALOG(R)File 15: ABI/Inform(R)

01917747 05-68739
The new trade marketplace and what it means to healthcare marketers
Barbera, Patrick

Medical Marketing & Media v34n10 PP: 88-100 Oct 1999
ISSN: 0025-7354 JRNL CODE: MMM
WORD COUNT: 3279

...TEXT: states, filling over 225 million prescriptions each year, and accounting for over $6 billion in **prescription drug** sales. Meanwhile PCS, **one** of the leading **pharmacy** management operations in the United States, manages nearly 300 million prescriptions each year, serves more...

18/3,K/2 (Item 1 from file: 9)
DIALOG(R)File 9: Business & Industry(R)

02787026 Supplier Number: 25245512 (USE FORMAT 7 OR 9 FOR FULLTEXT)
CONSUMERS RATE PHARMACISTS : Consumers weigh in on how they choose a pharmacy and how they think their R.Ph. can better serve them

Drug Topics, v 146, n 10, p 53
May 20, 2002
DOCUMENT TYPE: Journal; Survey ISSN: 0012-6616 (United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 2092

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...West.

Choosing a pharmacy

Approximately nine out of 10 (88%) consumers said they had obtained **prescription drugs** at a **pharmacy**. Most persons patronized **one pharmacy**. Almost half (46%) of the survey respondents reported filling the majority of their prescriptions at...

18/3,K/3 (Item 2 from file: 9)
DIALOG(R)File 9: Business & Industry(R)

01980142 Supplier Number: 25447247 (USE FORMAT 7 OR 9 FOR FULLTEXT)
The New Trade Marketplace and What it Means to Healthcare Marketers
(The top-five pharmaceutical wholesalers made up almost 78.8% of industry sales in 1997 as industry consolidates)
Medical Marketing & Media, v 34, n 10, p 89

October 1999
DOCUMENT TYPE: Journal; Ranking; Industry Overview ISSN: 0025-7354 (
United States)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 3284

(USE FORMAT 7 OR 9 FOR FULLTEXT)

TEXT:
...states, filling over 225 million prescriptions each year, and accounting
for over $6 billion in **prescription**
drug sales. Meanwhile PCS, **one** of the
leading **pharmacy** management operations in the United
States, manages nearly 300 million prescriptions each year, serves more...

18/3,K/4 (Item 3 from file: 9)
DIALOG(R)File 9: Business & Industry(R)

01201823 Supplier Number: 23814056 (USE FORMAT 7 OR 9 FOR FULLTEXT)
FELDENE FOLLOWS DIFLUCAN ONE
(Pfizer Consumer Healthcare will support the launch of its Rx-strength
Feldene P Gel OTC for arthritic pain & rheumatism with UKPd3mil
marketing spend)
Beauty Counter, n 3, p 25
March 1997
DOCUMENT TYPE: Journal ISSN: 0906-3751 (United Kingdom)
LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 124

TEXT:
...size in order to encourage consumer trial.

Feldene P Gel is the company's second **Prescription**-only
medicine to switch to **Pharmacy**-only,
following Diflucan **One**'s move at the end of 1995. Its
promotion will incorporate a national television advertising...

18/3,K/5 (Item 1 from file: 16)
DIALOG(R)File 16: Gale Group PROMT(R)

09936703 Supplier Number: 89274163 (USE FORMAT 7 FOR FULLTEXT)
CONSUMERS RATE PHARMACISTS : Consumers weigh in on how they choose a
pharmacy and how they think their R.Ph. can better serve them.
LoBuono, Charlotte

Drug Topics, v146, n10, p53
May 20, 2002
Language: English Record Type: Fulltext
Document Type: Magazine/Journal; Trade
Word Count: 2146

... West.
Choosing a pharmacy
Approximately nine out of 10 (88%) consumers said they had obtained **prescription drugs** at a **pharmacy**. Most persons patronized **one pharmacy**. Almost half (46%) of the survey respondents reported filling the majority of their prescriptions at...

18/3,K/6 (Item 2 from file: 16)
DIALOG(R)File 16: Gale Group PROMT(R)

06953352 Supplier Number: 58513409 (USE FORMAT 7 FOR FULLTEXT)
Home comforts.
Chemist & Druggist, pV
Dec 4, 1999
Language: English Record Type: Fulltext
Document Type: Magazine/Journal; Professional Trade
Word Count: 2463

... they joined the housebound list, and all patients receiving this support would be registered with **one pharmacy** for all their **pharmaceutical** needs - **prescription** or OTC purchases.
The role of community pharmacists would change from one of counting out...

18/3,K/7 (Item 3 from file: 16)
DIALOG(R)File 16: Gale Group PROMT(R)

02072092 Supplier Number: 42678965 (USE FORMAT 7 FOR FULLTEXT)
Georgia
Drug Store News, pS11
Jan 20, 1992
Language: English Record Type: Fulltext
Document Type: Magazine/Journal; Trade
Word Count: 65

(USE FORMAT 7 FOR FULLTEXT)

ABSTRACT:
TEXT:
...and individual pharmacies that engage in wholesale distribution. The
regulations would specifically exempt transfers of
prescription drugs from
one retail **pharmacy** to another for
"emergency medical reasons," provided that such transactions do not exceed
5 percent...

18/3,K/8 (Item 1 from file: 148)
DIALOG(R)File 148: Gale Group Trade & Industry DB

14787861 SUPPLIER NUMBER: 89274163 (USE FORMAT 7 OR 9 FOR FULL TEXT)
CONSUMERS RATE PHARMACISTS : Consumers weigh in on how they choose a
pharmacy and how they think their R.Ph. can better serve them.
LoBuono, Charlotte
Drug Topics, 146, 10, 53
May 20, 2002
ISSN: 0012-6616 LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 2146 LINE COUNT: 00202

... West.
Choosing a pharmacy
Approximately nine out of 10 (88%) consumers said they had obtained
prescription drugs at a
pharmacy. Most persons patronized **one**
pharmacy. Almost half (46%) of the survey respondents
reported filling the majority of their prescriptions at...

18/3,K/9 (Item 2 from file: 148)
DIALOG(R)File 148: Gale Group Trade & Industry DB

07481976 SUPPLIER NUMBER: 15637633 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Going native. (UK retailers to expand domestic operations)(includes related
articles) (Cover Story)
Braithwaite, Paul
Super Marketing, n1130, p14(3)
July 8, 1994
DOCUMENT TYPE: Cover Story ISSN: 0261-4251 LANGUAGE: ENGLISH
RECORD TYPE: FULLTEXT
WORD COUNT: 2638 LINE COUNT: 00200

... in all markets. We recognise that we have the expertise in moving a
lot of **medicines** from **prescription**
-only to **pharmacy** status." Nurofen is
one such product.
This would be done by taking over suppliers, or doing deals with them
...

18/3,K/10 (Item 3 from file: 148)
DIALOG(R)File 148: Gale Group Trade & Industry DB

06404171 SUPPLIER NUMBER: 13596837 (USE FORMAT 7 OR 9 FOR FULL TEXT)
CDR names Grass Retailer of the Year. (Chain Drug Review's 1992 Chain Drug Retailer of the Year; Alex Grass)
Chain Drug Review, v15, n6, p1(2)
Jan 4, 1993
ISSN: 0164-9914 LANGUAGE: ENGLISH RECORD TYPE: FULLTEXT
WORD COUNT: 1711 LINE COUNT: 00131

... The numbers bear out that contention. Fifty percent of Rite Aid's sales come from **prescription drugs**, and **one**-half of the **pharmacy** total comes from third-party prescriptions, a percentage Grass believes will increase dramatically in the...

18/3,K/11 (Item 1 from file: 20)
DIALOG(R)File 20: Dialog Global Reporter

13715000 (USE FORMAT 7 OR 9 FOR FULLTEXT)
THE OUTDOORSMAN
Guy Archer
MOSCOW TIMES
November 10, 2000
JOURNAL CODE: WTMT LANGUAGE: English RECORD TYPE: FULLTEXT
WORD COUNT: 399

(USE FORMAT 7 OR 9 FOR FULLTEXT)

... mother-in-law, I went on a spree, robbing pharmacies of all of their expensive **prescription drugs**. In **one pharmacy**, I ran into to my friends from the Junior League who had come in to...

18/3,K/12 (Item 2 from file: 20)
DIALOG(R)File 20: Dialog Global Reporter

08805617 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Two Huge California Pension Funds Discuss Health-Care Alliance
Andrew LePage
KRTBN KNIGHT-RIDDER TRIBUNE BUSINESS NEWS (SACRAMENTO BEE - CALIFORNIA)
December 20, 1999
JOURNAL CODE: KSAB LANGUAGE: English RECORD TYPE: FULLTEXT
WORD COUNT: 1046

(USE FORMAT 7 OR 9 FOR FULLTEXT)

... to help retirees cover gaps in their Medicare coverage and to create a stand-alone **pharmacy prescription drug plan.**
One major complication: CalSTRS would likely have to fund its pilot direct-contracting program out of...

18/3,K/13 (Item 1 from file: 635)

DIALOG(R)File 635: Business Dateline(R)

2203341 80589777
State to delay drug price plan Relief for uninsured in April
Moore, Michael O D
Bangor Daily News p1
Dec 16, 2000
WORD COUNT: 807
DATELINE: Augusta Maine

TEXT:

...Medicare spends on drugs in Maine annually.

Of the 100 drugs, many are simply different **prescription** strengths of **one drug**. A typical **pharmacy** startup operation stocks about 3,500 individual drugs, Concannon said.

The delay probably makes sense...

18/3,K/14 (Item 1 from file: 608)
DIALOG(R)File 608: MCT Information Svc.

06732446 (USE FORMAT 7 OR 9 FOR FULLTEXT)
Two Huge California Pension Funds Discuss Health-Care Alliance
Andrew LePage
Sacramento Bee, Calif
December 20, 1999
DOCUMENT TYPE: NEWSPAPER RECORD TYPE: FULLTEXT LANGUAGE: ENGLISH
WORD COUNT: 1125

...TEXT: to help retirees cover gaps in their Medicare coverage and to create a stand-alone **pharmacy prescription drug** plan.
One major complication: CalSTRS would likely have to fund its pilot direct-contracting program out of...

?

17/3,K/1 (Item 1 from file: 348)
DIALOG(R)File 348: EUROPEAN PATENTS

01038741
Automated database-oriented prescription drug ordering system
Automatisiertes Datenbank-orientiertes Arzneimittelbestellsystem
Systeme de commande de medicament prescrit automatise et oriente base de donnees
PATENT ASSIGNEE:
Cohen, Kopel H., (2124940), 2362 Harbour Oaks Drive, Longboat Key, FL 34228, (US), (applicant designated states: AT;BE;CH;CY;DE;DK;ES;FI;FR;GB;GR;IE;IT;LI;LU;MC;NL;PT;SE)
INVENTOR:
Cohen, Kopel H., 2362 Harbour Oaks Drive, Longboat Key, FL 34228, (US)

LEGAL REPRESENTATIVE:
  Cross, Rupert Edward Blount et al (42891), BOULT WADE TENNANT, 27
    Furnival Street, London EC4A 1PQ, (GB)
PATENT (CC, No, Kind, Date): EP 921488 A1 990609 (Basic)
APPLICATION (CC, No, Date): EP 98310032 981208;
PRIORITY (CC, No, Date): US 986805 971208
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI;
  LU; MC; NL; PT; SE
INTERNATIONAL PATENT CLASS (V7): G06F-019/00;
ABSTRACT WORD COUNT: 134

LANGUAGE (Publication,Procedural,Application): English; English; English
FULLTEXT AVAILABILITY:
Available Text Language Update Word Count
    CLAIMS A (English) 9923 1636
    SPEC A (English) 9923 6124
Total word count - document A 7760
Total word count - document B 0
Total word count - documents A + B 7760

...SPECIFICATION of health care providers. This querying is performed using
  the computer processor 21 and the **DBMS**. The
  central database subsystem 11 can, for example, query
  the database 24, retrieving the information stored in...

...each patient record sequentially determining, for each record, the date
  on which the patient's **prescription**
  needs to be refilled. This date can be calculated
  using the quantity, daily dosage frequency, and...

17/3,K/2 (Item 1 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT

01639734
PROCESS FOR THE PRODUCTION OF A FINE CHEMICAL
PROCEDE DE PRODUCTION D'UN PRODUIT CHIMIQUE FIN
Patent Applicant/Assignee:
  METANOMICS GMBH, Tegeler Weg 33, 10589 Berlin, DE, DE (Residence), DE
    (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
  EBNETH Marcus, Anklamer Str. 52, 10115 Berlin, DE, DE (Residence), DE
    (Nationality), (Designated only for: US)
Legal Representative:
  FITZNER Uwe (agent), Hauser Ring 10, 40878 Ratingen, DE
Patent and Priority Information (Country, Number, Date):
  Patent: WO 200834648 A1 20080327 (WO 0834648)
  Application: WO 2007EP53344 20070404 (PCT/WO EP2007053344)
  Priority Application: EP 20061124855 20060405; EP 20061124954 20060407;
    EP 20061127379 20060412; EP 20061142105 20060515; EP 20061142733
    20060518; EP 20061142527 20060518; EP 20061142584 20060518; EP
    20061146775 20060519; EP 20061173944 20060524; EP 20061155248 20060613;
   Designated States:
(All protection types applied unless otherwise stated - for applications
2004+)
  AE AG AL AM AT AU AZ BA BB BG BH BR BW BY BZ CA CH CN CO CR CU CZ DE DK
  (EA) AM AZ BY KG KZ MD RU TJ TM

Publication Language: English
Filing Language: English
Fulltext Word Count: 3258831

17/3,K/3 (Item 2 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT

00541148 **Image available**
INTERACTIVE PRESCRIPTION COMPLIANCE AND LIFE SAFETY SYSTEM
SYSTEME INTERACTIF DE SUIVI DE LA CONFORMITE DE PRESCRIPTIONS, ET DE SECURITE DES PERSONNES
Patent Applicant/Assignee:
O'BRIEN Charles T,
Inventor(s):
O'BRIEN Charles T,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200004521 A1 20000127 (WO 0004521)
Application: WO 99US15612 19990709 (PCT/WO US9915612)
Priority Application: US 98115650 19980715
Designated States:
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)
AU BR CA CN IL IN JP KP KR MX NO NZ SG VN AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE
Publication Language: English
Fulltext Word Count: 7832

Fulltext Availability:
Detailed Description
Detailed Description
... be over 100 million. Currently no system exists to assure compliance in the taking of **prescription drugs**. Pager systems such as United States Patent 5,623,242 to Dawson/Byron April 22, 1997, provides that a signal is sent from a **central data base** containing all the pertinent information of the prescription to an individual pager reminding them to...

17/3,K/4 (Item 3 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT

00472691
TELEMEDICINE
TELEMEDECINE
Patent Applicant/Assignee:
ABBOTT LABORATORIES,
Inventor(s):
CAPLE Kimberlee S,
CUNNINGHAM David S,
EASON Reginald L,

GORDON Julian,
HENNING Timothy P,
STROUPE Stephen D,
Patent and Priority Information (Country, Number, Date):
Patent: WO 9904043 A1 19990128
Application: WO 98US13681 19980630 (PCT/WO US9813681)
Priority Application: US 97892002 19970714
Designated States:
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)
CA JP AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE
Publication Language: English
Fulltext Word Count: 14264
Fulltext Availability:
Detailed Description
Claims

Claim
... test results;
inputting said test results into said central processing unit;
accessing at least one **data base**
with said **central** processing unit, said
data base comprising electronic and
information selected from the group consisting of chronic diseases,
infectious diseases, environmental diseases, general health infon-nation,
fertility, nutrition, medical treatment, **prescription**
drugs, over-the-counter drugs, medicine, care maps,
treatment guidelines, medical texts, medical journals, product
information, DNA
data, sequence listings, and fingerprint information;
electronically comparing said test results with said
data base via said
central
processing unit;
generating a recommended course of action with said central processing
unit; and transmitting...system, internet network, world
wide web network, and data processing center;
accessing at least one **data base**
with said **central** processing unit, said
data base comprising electronic
information selected from the group consisting of chronic diseases,
infectious diseases, environmental diseases, general health information,
fertility, nutrition, medical treatment, **prescription**
drugs, over-the-counter drugs medicine, care maps,
treatment guidelines, medical tests, product information, DNA data...
blindness, reading, cognitive function, Alzheimer disease, optical
medical information, eye diseases, ear diseases, medical treatment,
prescription drugs,
over-the-counter drugs, medicine, care maps, treatment guidelines,
medical tests, medical journals, optical lenses...

...eyewear, and hearing aids; a modem connected to said central process
unit for accessing said **data base**;
and said **central** processing unit comparing said
responses to said data base and generating said recommendation, and said
recommendation being selected from the group consisting of medical
treatment, **prescription drugs**,
over-the-counter drugs, medicine, and prescriptions for eyeglasses,

contact lenses, or hearing aids.
52...

17/3,K/5 (Item 1 from file: 636)
DIALOG(R)File 636: Gale Group Newsletter DB(TM)

05955581 Supplier Number: 127541312 (USE FORMAT 7 FOR FULLTEXT)
People are living longer and better, but some problems persist.(Aging Gracefully)
Research Alert, v22, n23, p3
Dec 3, 2004
Language: English Record Type: Fulltext
Document Type: Newsletter; Trade
Word Count: 831

... private insurers cover the other 15%.
The average Medicare enrollee age 65 or older had **prescription drug** costs of more than $1,340 in 2000 for 30 filled prescriptions, up from 18...

...MARKET)
SOURCE
"Older Americans 2004: Key Indicators of Well-Being," Federal Interagency Forum on Aging-**Related** Statistics, **Data** Dissemination Branch, National **Center** for Health Statistics, 3311 Toledo Rd., Room 5412, Hyattsville, MD 20782; phone: 301-441-6247...

17/3,K/6 (Item 1 from file: 813)
DIALOG(R)File 813: PR Newswire

0761862 NE030
STATE OF ARIZONA TURNS TO COMMUNITY CARE NETWORK & VALUERX TO CONTROL PRESCRIPTION DRUG COSTS IN WORKERS' COMPENSATION

DATE: November 14, 1994 14:40 EST WORD COUNT: 395

...and more than 13 million employees are covered under its worker's compensation programs. ValueRx **Pharmacy** Program, Inc., is **one** of the nation's leading pharmacy benefit **managers providing prescription drug** programs to employers and intermediaries.

Both CCN and ValueRx are wholly-owned subsidiaries of Value...

17/3,K/7 (Item 1 from file: 148)
DIALOG(R)File 148: Gale Group Trade & Industry DB

05549369 SUPPLIER NUMBER: 11731339 (USE FORMAT 7 OR 9 FOR FULL TEXT)
SIMS implementation takes center stage. (use of Strategic Inventory

Management System at Walgreens)
Chain Drug Review, v14, n5, p52(1)
Dec 9, 1991
ISSN: 0164-9914 LANGUAGE: ENGLISH RECORD TYPE: FULLTEXT
WORD COUNT: 686 LINE COUNT: 00054

... launched Intercom. That system linked the pharmacy files in all of its stores with a **central data base**, thus facilitating the processing of third-party claims, providing for automatic reordering of **prescription drugs**, and allowing prescriptions on file at any Walgreens outlet to be filled at any of...

17/3,K/8 (Item 2 from file: 148)
DIALOG(R)File 148: Gale Group Trade & Industry DB

04146267 SUPPLIER NUMBER: 08096845 (USE FORMAT 7 OR 9 FOR FULL TEXT)
National data base eyed as tool to assess outcomes.
Robinson, Michele L.
Hospitals, v63, n20, p18(1)
Oct 20, 1989
ISSN: 0018-5973 LANGUAGE: ENGLISH RECORD TYPE: FULLTEXT
WORD COUNT: 772 LINE COUNT: 00061

... trends and assess the effectiveness of specific interventions.
HCFA is also developing a data resource **center**.
Medicare **data files** will be made available to groups for appropriate research. In the future, it plans to release data tapes that link Part A and B ambulatory data and **prescription drug** use under the new Medicare **prescription drug** benefit.
HCFA would also like to link its data files with the Blues and private...

17/3,K/9 (Item 1 from file: 20)
DIALOG(R)File 20: Dialog Global Reporter

69431939 (USE FORMAT 7 OR 9 FOR FULLTEXT)
The curse of the baby boomers
GUARDIAN UNLIMITED
February 02, 2009
JOURNAL CODE: WGUU LANGUAGE: English RECORD TYPE: FULLTEXT
WORD COUNT: 1066

(USE FORMAT 7 OR 9 FOR FULLTEXT)

... can be raised dramatically.
Last month, Peter Mandelson called for more investment in manufacturing. He **asked pharmaceutical< / B> href="http:/ / www.computing.co.uk/ computing/ news/ 2233767/ knowledge-i ndustries-central-uk">kno wledge-based** " industries to lead us out of the recession and into a brighter future.

While his...

3/3,K/1 (Item 1 from file: 15)
DIALOG(R)File 15: ABI/Inform(R)

02304794 103766776
Study aims to reduce DUR noise for pharmacists
Ukens, Carol
Drug Topics v146n2 PP: 26-29 Jan 21, 2002
ISSN: 0012-6616 JRNL CODE: RXT

...ABSTRACT: the most clinically significant and how often they occur is the first phase of a **one**-year study funded by the Centers for Disease Control & Prevention. AdvancePCS and its **Center** for Healthier Aging will examine the giant **pharmacy** benefit manager's **prescription database** to find out whether serious **drug-drug** interactions are happening.

3/3,K/2 (Item 1 from file: 148)
DIALOG(R)File 148: Gale Group Trade & Industry DB

09965873 SUPPLIER NUMBER: 20076611 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Efforts to restrict records draws warning from CVS's Ortiz.(patient prescription records, Carlos Ortiz)
Frederick, James
Drug Store News, v19, n20, pCP1(2)
Dec 8, 1997
ISSN: 0191-7587 LANGUAGE: English RECORD TYPE: Fulltext
WORD COUNT: 882 LINE COUNT: 00076

... exists in the United States today, patients need and want their pharmacist to be their **one** monitor for medication conflicts," Ortiz concluded. "This is only possible if the pharmacist has access to all their **prescription** records.

"The chain **drug** store industry has spent millions, possibly billions, of dollars in developing centralized **pharmacy prescription** records ... because our customers demanded them," he added. "If we were to require a patient release for every person who must touch this **central database**, it would cease to be a viable proposition."

The Alliance for Health Reform was set...

3/3,K/3 (Item 2 from file: 148)
DIALOG(R)File 148: Gale Group Trade & Industry DB

05549369 SUPPLIER NUMBER: 11731339 (USE FORMAT 7 OR 9 FOR FULL TEXT)

SIMS implementation takes center stage. (use of Strategic Inventory
Management System at Walgreens)
Chain Drug Review, v14, n5, p52(1)
Dec 9, 1991
ISSN: 0164-9914 LANGUAGE: ENGLISH RECORD TYPE: FULLTEXT
WORD COUNT: 686 LINE COUNT: 00054

... things will enable us to cut the cost of the inventory we carry at
any **one** time by as much as $200 million."
In terms of retail technology, Walgreens has been unmatched in the
chain **drug** store industry since the early 1980s, when it
launched Intercom. **That system linked the pharmacy files
in all of its stores with a central
data base, thus facilitating the
processing of third-party claims, providing for automatic reordering of
prescription drugs**, and allowing
prescriptions on file at any Walgreens outlet to be filled at any of...

3/3,K/4 (Item 1 from file: 261)
DIALOG(R)File 261: UPI News
(c) 2005 United Press International. All rights reserved.

00269530 20020718199W2270 (USE FORMAT 7 FOR FULLTEXT)
'Date-rape' drug approval raises concerns
UPI News
Thursday, July 18, 2002 18:03 EDT
JOURNAL CODE: UP LANGUAGE: ENGLISH RECORD TYPE: FULLTEXT
DOCUMENT TYPE: NEWSWIRE
WORD COUNT: 1,020

...concerns about the potential for abuse, the FDA has imposed tight
restrictions to prevent the **drug** from falling into the
wrong hands. These
include allowing only **one central
pharmacy to distribute the drug and
requiring doctors prescribing it and patients using it
to register with a
database.**

Deborah Zvosec, a research investigator at the Minneapolis Medical Research
Foundation who warned of the...

3/3,K/6 (Item 1 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT
(c) 2010 WIPO/Thomson. All rights reserved.

00878844 **Image available**
INFORMATION TRANSMISSION AND COLLECTION APPARATUS AND METHOD
APPAREIL ET PROCEDE DE TRANSMISSION ET DE RECUEIL D'INFORMATIONS
Patent Applicant/Inventor:
HOLBROOK Keith Richard, 235 Timberwind Lane, Vandalia, OH 45377, US, US
(Residence), US (Nationality)
KUMBROCH Kent Forrest, 8161 Julian Place, Centerville, OH 45458, US, US
(Residence), US (Nationality)
Legal Representative:

KAUFMAN Marc S (et al) (agent), Suite 800, 8180 Greensboro Drive, McLean, VA 22102, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200213040 A1 20020214 (WO 0213040)
Application: WO 2001US19588 20010620 (PCT/WO US0119588)
Priority Application: US 2000635237 20000809
Designated States:
(Protection type is "patent" unless otherwise stated - for applications prior to 2004)
CA JP
(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR
Publication Language: English
Filing Language: English
Fulltext Word Count: 9101
Fulltext Availability:
Detailed Description

Detailed Description
... distribution system I 1 0, and are thus provided with appropriate channels for communicating with **one** another and individual 50 to transact business or other matters. **Data collection and distribution system I 1 0 includes central database 60 for storing various information relating to individual 50. While for purposes of illustrating this embodiment, central database 60 is segmented into four distinct sectors (medical, pharmaceutical,** financial and personal), it may be segmented into additional sectors involving other business services.

In this embodiment, individual 50 visits first **pharmacy 70 to obtain medicine prescribed by a medical doctor. Upon reviewing the prescription data, first pharmacy 70 requests from individual 50 access to information stored in central database** 60 for purposes of modifying information relating to individual 50 by recording the **prescription** information. The information may be modified using a computer, such as a personal computer, a...

3/3,K/7 (Item 2 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT

00831859 **Image available**
A MEDICAL DIAGNOSIS AND PRESCRIPTION COMMUNICATIONS DELIVERY SYSTEM, METHOD AND APPARATUS
SYSTEME METHODE ET APPAREIL DE FOURNITURE DE COMMUNICATIONS RELATIVES AUX DIAGNOSTICS ET AUX PRESCRIPTIONS MEDICALES
Patent Applicant/Assignee:
MEDEVIEW COM INC, 1400 Main Street, Waltham, MA 02451, US, US (Residence), US (Nationality), (For all designated states except: US)
Patent Applicant/Inventor:
SCHAEFFER Derace L, 3489 Elmwood Avenue, Rochester, NY 14610, US, -- (Residence), -- (Nationality), (Designated only for: US)
KAUFMAN Robert M, One Glen Oak Drive, Wayland, MA 01778, US, -- (Residence), -- (Nationality), (Designated only for: US)
GATES Ronald W, 1934 E. 45th Pl., Tulsa, OK 74429, US, -- (Residence), --

(Nationality), (Designated only for: US)
CLARK Robert D, 15471 So. 297th E. Avenue, Coweta, OK 74429, US, --
(Residence), -- (Nationality), (Designated only for: US)
TATE Terry N, 14915 E. 34th, Tulsa, OK 74134, US, -- (Residence), --
(Nationality), (Designated only for: US)
Legal Representative:
CHANDRA Arun (agent), Morgan & Finnegan, L.L.P., 345 Park Avenue, New
York, NY 10154, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200165449 A1 20010907 (WO 0165449)
Application: WO 2001US6529 20010228 (PCT/WO US0106529)
Priority Application: US 2000516702 20000301
Designated States:
(Protection type is "patent" unless otherwise stated - for applications
prior to 2004)
AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CR CU CZ DE DK DM DZ EE
Publication Language: English
Filing Language: English
Fulltext Word Count: 9133

Fulltext Availability:
Detailed Description

Detailed Description
... referring physician prescribes medication to treat a patient. In Step
3400, the coded encounter and **diagnosis** data is
delivered to the Media Distribution Center.

The Media Distribution Center conducts a knowledge...

...the referring physician (Step 3700).

The referring physician reviews the suggested pharmaceuticals from
the knowledge **database** (Step 3800) and decides whether
to prescribe a suggested **pharmaceutical** (Step 3900).
If the referring physician prescribes one or more of the suggested
pharmaceuticals, an electronic **prescription** is printed
and/or electronically transferred to the participating
pharmacy (Step 4000). The
prescription can alternatively be printed for patient
education (Step 41 00) or can be given (if not electronic) to the patient
for delivery to a **pharmacy** (Step 4200).

If the referring physician does not prescribe a suggested
pharmaceutical, the referring physician completes an
electronic **prescription** form (Step 4300) and the
prescription is printed and/or electronically
transferred to a participating **pharmacy** (Step 4400).
The **prescription** can be given (if not electronic) to
the patient (Step 4200). The **prescription** is delivered
to the Media Distribution **Center** (Step 4500) and added
to the encounter record.

E. Operating The Medical **Diagnosis** And
Prescription
Communications Delive[y System, Method And Apparatus
FIG. 6 is an overview flow diagram of the medical
diagnosis and
prescription communications delivery system. As shown in FIG. 5, there

are five basic components...

3/3,K/8 (Item 1 from file: 429)
DIALOG(R)File 429: Adis News(Arc)

00083356 11735503-800523195
UK pilot project to identify hospital prescribing patterns.
JOURNAL NAME: PharmacoEconomics & Outcomes News
PUBLICATION DATE: 22 APRIL 1997 (19970422)

REFERENCES:
Pharmacists' help sought in pilot project to analyse hospital prescribing. Pharmaceutical Journal 258 : 431, 29 MAR 1997 (English, News Item (England))

SUMMARY TEXT:
...database to help assess and compare prescribing patterns between hospitals in that country, reports the **Pharmaceutical** Journal. This project parallels the collection and analysis of general practice **Prescription** Analysis and CosT (PACT) data by the **Prescription** Pricing Authority.
As part of the project, **which is to be undertaken by the National Prescribing Centre, a representative sample of hospitals will collect relevant aggregated data in electronic format from their pharmacy computer systems. These data will be compiled into a single, centralised database from which targeted information can be generated.** This information will:
- enable participating hospitals to compare their **prescribing** patterns and costs to national trends and averages
- assist health authorities and hospitals in monitoring hospital prescribing, which may have an important influence on **drug** prescribing in general practice
- enable the National Health Service Executive and health authorities to more...

IV.
Text Search Results from Dialog

A. Full-Text Databases I I

show files

File 5:Biosis Previews(R) 1926-2010/Jan W2
(c) 2010 The Thomson Corporation
File 10:AGRICOLA 70-2009/Dec
(c) format only 2009 Dialog
File 11:PsycINFO(R) 1887-2010/Jan W1
(c) 2010 Amer. Psychological Assn.
File 24:CSA Life Sciences Abstracts 1966-2010/Feb
(c) 2010 CSA.
File 34:SciSearch(R) Cited Ref Sci 1990-2010/Jan W2
(c) 2010 The Thomson Corp
File 35:Dissertation Abs Online 1861-2009/Nov

(c) 2009 ProQuest Info&Learning
File 45:EMCare 2010/Jan W2
(c) 2010 Elsevier B.V.
File 50:CAB Abstracts 1972-2010/Jan W2
(c) 2010 CAB International
File 51:Food Sci.&Tech.Abs 1969-2010/Jan W2
(c) 2010 FSTA IFIS Publishing
File 53:FOODLINE(R): Science 1972-2010/Jan 12
(c) 2010 LFRA
File 65:Inside Conferences 1993-2010/Jan 15
(c) 2010 BLDSC all rts. reserv.
File 71:ELSEVIER BIOBASE 1994-2010/Jan W2
(c) 2010 Elsevier B.V.
File 72:EMBASE 1993-2010/Jan 15
(c) 2010 Elsevier B.V.
File 73:EMBASE 1974-2010/Jan 15
(c) 2010 Elsevier B.V.
File 79:Foods Adlibra(TM) 1974-2002/Apr
(c) 2002 General Mills
File 91:MANTIS(TM) 1880-2009/Nov
2001 (c) Action Potential
File 98:General Sci Abs 1984-2009/Dec
(c) 2009 The HW Wilson Co.
File 135:NewsRx Weekly Reports 1995-2010/Dec W4
(c) 2010 NewsRx
File 138:Physical Education Index 1990-2010/Feb
(c) 2010 CSA.
File 143:Biol. & Agric. Index 1983-2009/Nov
(c) 2009 The HW Wilson Co
File 144:Pascal 1973-2009/Dec W3
(c) 2009 INIST/CNRS
File 149:TGG Health&Wellness DB(SM) 1976-2010/Nov W4
(c) 2010 Gale/Cengage
File 154:MEDLINE(R) 1990-2009/Dec 09
(c) format only 2009 Dialog
File 155:MEDLINE(R) 1950-2009/Dec 09
(c) format only 2009 Dialog
File 156:ToxFile 1965-2009/Nov W3
(c) format only 2009 Dialog
File 162:Global Health 1983-2010/Jan W2
(c) 2010 CAB International
File 164:Allied & Complementary Medicine 1984-2010/Jan
(c) 2010 BLHCIS
File 172:EMBASE Alert 2010/Jan 15
(c) 2010 Elsevier B.V.
File 203:AGRIS 1974-2009/Sep
Dist by NAL, Intl Copr. All rights reserved
File 266:FEDRIP 2009/Nov
Comp & dist by NTIS, Intl Copyright All Rights Res
File 357:Derwent Biotech Res. _1982-2010/Dec W1
(c) 2010 Thomson Reuters
File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec
(c) 2006 The Thomson Corp
File 444:New England Journal of Med. 1985-2010/Jan W2
(c) 2010 Mass. Med. Soc.
File 457:The Lancet 1992-2010/Jan W2
(c) 2010 Elsevier Limited.All rights res
File 467:ExtraMED(tm) 2000/Dec
(c) 2001 Informania Ltd.

File 482:Newsweek 2000-2010/Jan 13
(c) 2010 Newsweek, Inc.
File 74:Int.Pharm.Abs 1970-2009/Sep B2
(c) 2009 The Thomson Corporation
File 107:Adis R&D Insight 1986-2010/Jan W3
(c) 2010 Wolters Kluwer Pharma Sol
File 128:PHARMAPROJECTS 1980-2010/Jan W1
(c) 2010 Informa UK Ltd
File 173:Adis Clinical Tri.Ins 1990-2010/Jan W3
(c) Wolters Kluwer Pharma Sol
File 174:Pharm-line(R) 1978-2002/Dec W3
(c) CROWN COPYRIGHT 2003
File 229:Drug Info. Fulltext 2002
(c) 2002 Ameri.Soc.of Health-Systems Pharm.
File 305:Analytical Abstracts 1980-2010/Nov W2
(c) 2010 Royal Soc Chemistry
File 355:Derwent Chemistry Resource UD=200983
(c) 2010 Thomson Reuters
File 373:Adis Clinical Trials Insight 1982-1989
(c) Wolters Kluwer Pharma Sol
File 376:Derwent Drug File 1964-1982
(c) 2008 Thomson Reuters
File 377:Derwent Drug File 1983-2010/Dec W2
(c) 2010 Thomson Reuters.
File 393:Beilstein Database - Abstracts 2008/Q2
(c) 2008 Beilstein GmbH
File 399:CA SEARCH(R) 1967-2010/UD=15203
(c) 2010 American Chemical Society
File 441:ESPICOM Pharm&Med DEVICE NEWS 2010/Jan W2
(c) 2010 ESPICOM Bus.Intell.
File 445:IMS R&D Focus 1991-2010/Jan W2
(c) 2010 IMS Health & Affiliates
File 452:Drug Data Report 1992-2008_1992-2009/Dec
(c) 2010 Prous Science
File 453:Drugs of the Future 1990-2010/Jan
(c) 2010 Prous Science
File 458:Daily Essentials 2010/Jan 15
(c) 2010 Prous Science
File 459:Daily Essentials (Archival) 1996-2010/Jan W2
(c) 2010 Prous Science

? **ds**

Set Items Description
S1 54773 (PRESCRIBE OR PRESCRIBING OR PRESCRIPTION OR DRUG? ? OR MEDICINE? ? OR FORMULA OR PHARMACEUTICAL OR DIAGNOSIS)(3N)(REQUEST OR WANT OR NEEDS OR DEMAND??? OR ASK??? OR QUERY??? OR QUERIES OR INQUIR??? OR QUESTION? ?)
S2 162491 (PRESCRIBE OR PRESCRIBING OR PRESCRIPTION)(3N)(DRUG? ? OR MEDICINE? ? OR FORMULA OR PHARMACEUTICAL OR DIAGNOSIS)
S3 3668 (ONE OR SINGLE OR SINGULAR OR LONE)(3N)(DRUGSTORE?? OR DRUG()STORE OR PHARMACY?) OR EXCLUSIVE()CENTRA()PHARMACY
S4 4751 (CENTRAL OR CENTRE OR CENTER)(3N)((REPOSITORY OR DATABASE OR DATA()BASE OR REGIST? OR DATABANK? ? OR DATATABLE? ? OR DATA OR INFORMATION OR KNOWLEDGE)()(BASE? ? OR BANK? ? OR SET? ? OR FILE? ? OR TABLE? ?) OR DB OR (ORGANI?ED()COLLECTION? ? OR RELATED OR INTERRELATED)(2W)(FILES OR INFORMATION OR DATA) OR DBMS)
S5 42 S4(7N)((MEDICAL OR HEALTHCARE OR HEALTH()CARE)()PROVIDER? ?

OR PHYSICIAN? ? OR DOCTOR? ? OR NURSE? ? OR PHARMACIST OR THERAPIST)
S6 991828 (MANAGEMENT OR MANAG??? OR SUPERVIS??? OR REGULAT??? OR CONTROL? OR PROCESS?)(3N)(DISTRIBUTION OR SUPPL??? OR DELIVER??? OR PROVID??? OR ALLOCAT??? OR ASSIGN?)
S7 626 S6(7N)(PRESCRIBE OR PRESCRIBING OR PRESCRIPTION)(3N)(DRUG? ? OR MEDICINE? ? OR FORMULA OR PHARMACEUTICAL OR DIAGNOSIS)
S8 5426 AU=(REARDAN, D?OR REARDAN D? OR REARDAN(2N)D? OR ENGEL, P? OR ENGEL P? OR ENGEL(2N)P? OR GAGNE, B? OR GAGNE B? OR GAGNE(-2N)B?)
S9 0 S8 AND S1
S10 0 S8 AND S2
S11 13 (S1:S2)(3N)S3
S12 0 (S1:S2)(3N)S4
S13 0 (S1:S2)(3N)S5
S14 440 (S1:S2)(7N)S6
S15 339 S14(7N)S7
S16 0 S15(3N)S5
S17 55 S5 OR S11
S18 32 S17 NOT PY>2002

18/3,K/1 (Item 1 from file: 45)
DIALOG(R)File 45: EMCare

0003990477 EMCARE No: 33426773
Not for **nurses** only. A NIDSEC (Nursing Information and **Data Set** Evaluation **Center**) primer.
Curtin L.; Simpson R.L.
Cerner Corp., Kansas City, MO, USA.
CORRESP. AUTHOR/AFFIL: Curtin L.: Cerner Corp., Kansas City, MO, USA.

Health management technology (Health Manag Technol) (United States)
November 1, 2000, 21/11 (60, 62)
ISSN: 1074-4770
DOCUMENT TYPE: Journal; Article RECORD TYPE: Citation
LANGUAGE: English

Not for **nurses** only. A NIDSEC (Nursing Information and **Data Set** Evaluation **Center**) primer.

18/3,K/2 (Item 2 from file: 45)
DIALOG(R)File 45: EMCare

0003685209 EMCARE No: 129605260
Perspectives on Teaching among Community-Based Family Physicians
Peters A.S.; Clark-Chiarelli N.; Block S.D.
Department of Ambulatory Care, Harvard Med. Sch. Harvard Pilgrim H., Boston, MA, United States; Department of Ambulatory Care, Harvard Medical School, Harvard Pilgrim Health Care, 126 Brookline Avenue, Boston, MA 02215, United States

AUTHOR EMAIL: Toni Peters@hms.harvard.edu
CORRESP. AUTHOR/AFFIL: Peters A.S.: Department of Ambulatory Care, Harvard Medical School, Harvard Pilgrim Health Care, 126 Brookline Avenue, Boston, MA 02215, United States
CORRESP. AUTHOR EMAIL: Toni Peters@hms.harvard.edu

Teaching and Learning in Medicine (Teach. Learn. Med.) (United States) December 1, 1999, 11/4 (244-248)
PUBLISHER: Lawrence Erlbaum Associates Inc.
ISSN: 1040-1334
DOCUMENT TYPE: Journal; Review RECORD TYPE: Abstract
LANGUAGE: English SUMMARY LANGUAGE: English
NUMBER OF REFERENCES: 10

DESCRIPTORS:
clinical education; **data base**; health **center**; income; medical practice; perception; **physician**; primary medical care; productivity; telephone

---

18/3,K/3 (Item 3 from file: 45)
DIALOG(R)File 45: EMCare

0003533818 EMCARE No: 128521021
Management and Delivery of Radiation Dose Distribution Images Using the Internet
Onogi Y.; Nakagawa K.; Aoki Y.; Kozuka T.; Toyoda T.; Sasaki Y.
Department of Radiology, University of Tokyo Hospital:
CORRESP. AUTHOR/AFFIL: Department of Radiology, University of Tokyo Hospital

Nippon Acta Radiologica (Nippon Acta Radiol.) (Japan) December 1, 1998 , 58/1 (34-37)
PUBLISHER: Japan Radiological Society
CODEN: NHGZA ISSN: 0048-0428
DOCUMENT TYPE: Journal; Article RECORD TYPE: Abstract
LANGUAGE: Japanese SUMMARY LANGUAGE: English
NUMBER OF REFERENCES: 11

DESCRIPTORS:
cancer patient; **data base**; histogram; hospital; information **center**; machine; medical personnel ; medical staff; oncology; **physician**; radiation; radiation injury; register; X ray film

---

18/3,K/4 (Item 4 from file: 45)
DIALOG(R)File 45: EMCare

0003512341 EMCARE No: 128235245
A NIDSEC primer: Part 2--Setting the standards.
Simpson R.L.
NIDSEC, Washington, DC 20024, USA.
CORRESP. AUTHOR/AFFIL: Simpson R.L.: NIDSEC, Washington, DC 20024, USA.

Nursing management (Nurs Manage) (United States) February 1, 1998, 29/2 (26-29)
ISSN: 0744-6314
DOCUMENT TYPE: Journal; Article RECORD TYPE: Abstract
LANGUAGE: English

The Nursing Information and **Data** **Set** Evaluation **Center** (NIDSEC), established by the American **Nurses** Association (ANA), recently published the criteria by which it evaluates information systems that support nursing...

18/3,K/5 (Item 5 from file: 45)
DIALOG(R)File 45: EMCare

0003510785 EMCARE No: 128222434
A NIDSEC primer: Part 1--Setting the standards.
Simpson R.L.
CORRESP. AUTHOR/AFFIL: Simpson R.L.

Nursing management (Nurs Manage) (United States) January 1, 1998, 29/1 (49-50)
ISSN: 0744-6314
DOCUMENT TYPE: Journal; Article RECORD TYPE: Abstract
LANGUAGE: English

The Nursing Information and **Data** **Set** Evalution **Center**, established by the American **Nurses** Association, recently published the criteria by which it evaluates information systems that support nursing practice...

18/3,K/6 (Item 6 from file: 45)
DIALOG(R)File 45: EMCare

0003195459 EMCARE No: 26365772
Promotion of health information access via grateful med and loansome doc: Why isn't it working?

Burnham J.F.; Perry M.
Biomedical Library, University of South Alabama, Mobile, AL 36688, United States
CORRESP. AUTHOR/AFFIL: Burnham J.F.: Biomedical Library, University of South Alabama, Mobile, AL 36688, United States

Bulletin of the Medical Library Association (BULL. MED. LIBR. ASSOC.) (United States) October 1, 1996, 84/4 (498-506)
CODEN: BMLAA ISSN: 0025-7338
DOCUMENT TYPE: Journal; Article RECORD TYPE: Abstract
LANGUAGE: English SUMMARY LANGUAGE: English
NUMBER OF REFERENCES: 13

DESCRIPTORS:
data base; health care; health **center**; information system; medical care; medical literature; **physician**; rural area; United States

---

18/3,K/7 (Item 1 from file: 73)
DIALOG(R)File 73: EMBASE

0074871063 EMBASE/Medline No: 1992022735
Monitoring selected drugs by office-based physicians
Hanpft R.; Hannig M.; Becker E.; Sauer A.; Wohlers J.; Beske F.
Institute for Health Systems Research, Kiel, Germany
CORRESP. AUTHOR/AFFIL: Beske F.: Weimarer Strasse 8, 2300 Kiel-Wik, Germany

Post Marketing Surveillance (POST MARK. SURVEILL.) (Netherlands) December 1, 1991, 5/2 (145-158)
CODEN: PMSUE ISSN: 0269-2333
DOCUMENT TYPE: Journal; Article RECORD TYPE: Abstract
LANGUAGE: English SUMMARY LANGUAGE: English

...collection has been developed by which it has become possible to transfer treatment data from **physicians**' computers into the monitoring **centre**'s **data bank**.

18/3,K/8 (Item 2 from file: 73)
DIALOG(R)File 73: EMBASE

0073348546 EMBASE/Medline No: 1987112580
Ambulatory care administrators: Who are they?
Howard D.M.; Pajor M.
Division of Ambulatory Care, American Hospital Association, Chicago, IL,

United States:
CORRESP. AUTHOR/AFFIL: Division of Ambulatory Care, American Hospital Association, Chicago, IL, United States

Journal of Ambulatory Care Management (J. AMBUL. CARE MANAGE.) (United Kingdom) July 14, 1987, 10/1 (70-77)
CODEN: JACMD ISSN: 0148-9917
DOCUMENT TYPE: Journal; Article RECORD TYPE: Abstract
LANGUAGE: English

...an average number of beds of 422 (average nursing home has 85-90 beds); the **pharmacy** dispenses about **one prescription** (or **drug** order) a day for every two occupied beds, i.e. 250 prescriptions per day in...

18/3,K/9 (Item 3 from file: 73)
DIALOG(R)File 73: EMBASE

0072518044 EMBASE/Medline No: 1983003512
Occupational medicine at sea: The seafarer as a patient
Urner C.J.
Lykes Cent., Lykes Bros. Steamship Co. Inc., New Orleans, LA 70130, United States:
CORRESP. AUTHOR/AFFIL: Lykes Cent., Lykes Bros. Steamship Co. Inc., New Orleans, LA 70130, United States

Journal of Occupational Medicine (J. OCCUP. MED.) (United States) December 1, 1982, 24/11 (917-922)
CODEN: JOCMA ISSN: 0096-1736
DOCUMENT TYPE: Journal; Article RECORD TYPE: Abstract
LANGUAGE: English

...the loss of Radio Advice to Ships at Sea, and the loss of an extensive **central** medical **data** **base** readily accessible to treating **physicians** present serious administrative and financial problems now being faced by the maritime industry. One of...

18/3,K/10 (Item 1 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)

02347916 SUPPLIER NUMBER: 114168385 (USE FORMAT 7 OR 9 FOR FULL TEXT)
The intervention of surveillance across classification systems.

Schoneman, Doris
International Journal of Nursing Terminologies and Classifications, 13, 4, 137(11)
Oct-Dec,
2002
PUBLICATION FORMAT: Magazine/Journal; Refereed ISSN: 1541-5147
LANGUAGE: English RECORD TYPE: Fulltext TARGET AUDIENCE: Professional
WORD COUNT: 4727 LINE COUNT: 00530

... p. 243), have been recognized. A list of recognized languages is published by the American **Nurses** Association Nursing Information and **Data Set** Evaluation **Center** (NIDSEC) (ANA, 2002). The ANA committee further delineated among data sets, classification systems, and nomenclatures... American Nurses Association. (1987). The nursing center: Concept and design. Kansas City, MO: Author.

American **Nurses** Association. (2002). Nursing Information and **Data Set** Evaluation **Center** (NIDSEC) recognized languages for nursing. Retrieved January 31, 2002, from http://www.ana.org/nidsec...

18/3,K/11 (Item 2 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)

01860218 SUPPLIER NUMBER: 56082720 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Innovation reflects consumers' wellness focus.
GROSSMAN, ANDREA M.
Drug Store News, 21, 15, 90
Sept 27,
1999
PUBLICATION FORMAT: Magazine/Journal ISSN: 0191-7587 LANGUAGE: English
RECORD TYPE: Fulltext TARGET AUDIENCE: Trade
WORD COUNT: 670 LINE COUNT: 00056

... old stand-by products that brought them to their current level of success.

According to **one drug store** buyer, "the **demand** for space (due to innovation) caused some companies to replace older products with newer ones...

18/3,K/12 (Item 3 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)

01832404 SUPPLIER NUMBER: 54526502 (USE FORMAT 7 OR 9 FOR FULL TEXT)

Integration: Problems and Solutions.
Roman, Carol; Zavodnick, Leslie
Behavioral Health Management, 19, 2, 18(1)
March,
1999
PUBLICATION FORMAT: Magazine/Journal ISSN: 1075-6701 LANGUAGE: English
RECORD TYPE: Fulltext TARGET AUDIENCE: Professional
WORD COUNT: 2267 LINE COUNT: 00195

... utilizing substance abuse population. By locking in patients who were using multiple pharmacies into a **single pharmacy**, illegal use of **prescription drugs** was decreased. A similar proposal was made to treat patients with frequent emergency room visits...

18/3,K/13 (Item 4 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)

01799209 SUPPLIER NUMBER: 21208459 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Setting the informatics standards: an overview of NIDSEC's information systems evaluation criteria. (Nursing Information and Data Set Evaluation Center)
Simpson, Roy L.
Nursing Economics, v16, n5, p279(4)
Sept-Oct,
1998
PUBLICATION FORMAT: Magazine/Journal; Refereed ISSN: 0746-1739
LANGUAGE: English RECORD TYPE: Fulltext; Abstract TARGET AUDIENCE: Professional
WORD COUNT: 2585 LINE COUNT: 00231

In this issue, Roy Simpson, RN, C, FNAP, FAAN, introduces the Nursing Information and **Data Set** Evaluation **Center** (NIDSEC), which the American **Nurses** Association developed to evaluate information systems that support nursing practice documentation. Deployment of information system...

...is speaking the same language.
Fortunately, somebody is addressing the problem. The Nursing Information and **Data Set** Evaluation **Center** (NIDSEC) was established by the American **Nurses** Association (ANA) to create and disseminate standards for information systems. These standards are designed to...

18/3,K/14 (Item 5 from file: 149)

DIALOG(R)File 149: TGG Health&Wellness DB(SM)
(c) 2010 Gale/Cengage. All rights reserved.

01758607 SUPPLIER NUMBER: 20125518 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Building the information infrastructure required for managed care.
Jones, Lynette D.
Image: Journal of Nursing Scholarship, v29, n4, p377(6)
Winter,
1997
PUBLICATION FORMAT: Magazine/Journal; Refereed ISSN: 0743-5150
LANGUAGE: English RECORD TYPE: Fulltext; Abstract TARGET AUDIENCE:
Academic; Professional
WORD COUNT: 5644 LINE COUNT: 00498

... UNLS). In American Nurses Association, (Eds.), Nursing data
systems: The emerging framework. Washington, DC: American
Nurses Publishing.
Milholland, K. (1997). Nursing information and **data**
set evaluation **center** overview
(NIDSEC). Washington, DC: American **Nurses** Association.
Mortensen, R. (1996, April). Nursing diagnoses developments in Europe.
Symposium; North American Nursing Diagnosis...

18/3,K/15 (Item 6 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)
(c) 2010 Gale/Cengage. All rights reserved.

01747280 SUPPLIER NUMBER: 20232657 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Synthesis of methods, rules, and issues of standardizing nursing
intervention language mapping.
Delaney, Connie; Moorhead, Sue
Nursing Diagnosis, v8, n4, p152(5)
Oct-Dec,
1997
PUBLICATION FORMAT: Magazine/Journal; Refereed ISSN: 1046-7459
LANGUAGE: English RECORD TYPE: Fulltext; Abstract TARGET AUDIENCE:
Professional
WORD COUNT: 2418 LINE COUNT: 00238

... order set retrieved by Moorhead and Delaney (1997) used an
organizing framework developed by the **nurses** within the
specific medical **center**. Both **data**
sets were structured similarly. Each nursing diagnosis
could be linked to one or more related factors...References
American Nurses Association. (1997). The standards and scoring
criteria for the nursing information and **data**
set evaluation **center**. Washington,
DC: Author.
American **Nurses** Association. (1995). Nursing data
systems: The emerging framework Washington, DC: Author.
Coenen, A., Ryan, P...

18/3,K/16 (Item 7 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)

01549721 SUPPLIER NUMBER: 17496695
Immunization status of hospitalized preschool children: risk factors
associated with inadequate immunization.
Kum-Nji, Philip; James, David; Herrod, Henry G.
Pediatrics, v96, n3, p434(5)
Sept,
1995
PUBLICATION FORMAT: Magazine/Journal ISSN: 0031-4005 LANGUAGE: English
RECORD TYPE: Abstract TARGET AUDIENCE: Professional

...ABSTRACT: prenatal care. Parents said that transportation to
immunization sites or reminders would be helpful. A
central data bank
accessible to schools and **doctors** could also help by
allowing accurate ascertainment of immunization status.

18/3,K/17 (Item 8 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)

01532462 SUPPLIER NUMBER: 16151086 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Fever in children: when your child has a fever. (Pamphlet)
Pamphlet by: American Academy of Family Physicians, p1(6)
Annual,
1992
DOCUMENT TYPE: Pamphlet PUBLICATION FORMAT: Pamphlet LANGUAGE: English
RECORD TYPE: Fulltext TARGET AUDIENCE: Consumer
WORD COUNT: 1289 LINE COUNT: 00111

... elixir, use a liquid measuring device to make sure you give the
right dose. Get **one** at your **drug**
store or **ask** your pharmacist.
Call your doctor if your child has any of these warning signs
Changes...

18/3,K/18 (Item 9 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)

01433752 SUPPLIER NUMBER: 14733847 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Pertussis immunisation and serious acute neurological illnesses in children.
Miller, David; Madge, Nicola; Diamond, Judith; Wadsworth, Jane; Ross, Euan
British Medical Journal, v307, n6913, p1171(6)
Nov 6,
1993
PUBLICATION FORMAT: Magazine/Journal ISSN: 0959-8146 LANGUAGE: English
RECORD TYPE: Fulltext; Abstract TARGET AUDIENCE: Professional
WORD COUNT: 3490 LINE COUNT: 00361

... described.[13] In brief, children were traced by various methods including letters to patients, family **doctors**, or hospital **doctors** or through the NHS **central register**.
Table I shows the numbers of cases and controls traced and available for follow up study...

18/3,K/19 (Item 10 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)

01244217 SUPPLIER NUMBER: 09403639 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Design considerations for integrated hospital information systems.
Zviran, Moshe
Hospital & Health Services Administration, v35, n3, p377(17)
Fall,
1990
PUBLICATION FORMAT: Magazine/Journal ISSN: 8750-3735 LANGUAGE: English
RECORD TYPE: Fulltext TARGET AUDIENCE: Professional
WORD COUNT: 4158 LINE COUNT: 00430

... departmental) data bases were formatted and presented. These included basic patient history (replicated from the **central data base**), **doctor**'s orders, and all diagnostic results.
2. The local application "asks" Smith's physician if...

...central host. The requested data are forwarded to the requesting node and presented to the **doctor**.
In conclusion, the organizational **data base** consists of a **central** portion and distributed data. The central data base contains basic patient data that are of...

18/3,K/20 (Item 11 from file: 149)

DIALOG(R)File 149: TGG Health&Wellness DB(SM)

00800223 SUPPLIER NUMBER: 16151086 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Fever in children: when your child has a fever. (Pamphlet)
Pamphlet by: American Academy of Family Physicians, p1(6)
Annual,
1992
DOCUMENT TYPE: Pamphlet PUBLICATION FORMAT: Pamphlet LANGUAGE: English
RECORD TYPE: Fulltext TARGET AUDIENCE: Consumer
WORD COUNT: 1289 LINE COUNT: 00111

... elixir, use a liquid measuring device to make sure you give the
right dose. Get **one** at your **drug**
store or **ask** your pharmacist.
Call your doctor if your child has any of these warning signs
Changes...

18/3,K/21 (Item 1 from file: 154)
DIALOG(R)File 154: MEDLINE(R)

14029226 PMID: 11155636
Not for **nurses** only. A NIDSEC (Nursing Information and
Data Set Evaluation **Center&l**
t;/ B>) primer.
Curtin L; Simpson R L
Cerner Corp., Kansas City, MO, USA.
Health management technology (United States) Nov 2000, 21 (11) p60,
62, ISSN 1074-4770--Print Journal Code: 9423239
Publishing Model Print
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed

Not for nurses only. A NIDSEC (Nursing Information and
Data Set Evaluation Center&l
t;/ B>) primer.

18/3,K/22 (Item 2 from file: 154)
DIALOG(R)File 154: MEDLINE(R)

12850417 PMID: 9611867
ANA standards for nursing data sets in information systems.
Averill C B; Marek K D; Zielstorff R; Kneedler J; Delaney C; Milholland D
K

St. Luke's Regional Medical Center, Boise, Idaho 83712, USA.
Computers in nursing (UNITED STATES) May-Jun 1998, 16 (3) p157-61, ISSN 0736-8593--Print Journal Code: 8507717
Publishing Model Print
Document type: Journal Article; Review
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed

The American **Nurses** Association has established the Nursing Information and **Data Set** Evaluation **Center**. The purpose of this Center is to develop and disseminate standards pertaining to information systems...

18/3,K/23 (Item 3 from file: 154)
DIALOG(R)File 154: MEDLINE(R)

12756097 PMID: 9496094
A NIDSEC primer: Part 2--Setting the standards.
Simpson R L
NIDSEC, Washington, DC 20024, USA.
Nursing management (UNITED STATES) Feb 1998, 29 (2) p26-9, ISSN 0744-6314--Print Journal Code: 8219243
Publishing Model Print
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed

The Nursing Information and **Data Set</B> ; Center (NIDSEC), established by the American Nurses Association (ANA), recently published the criteria by which it evaluates information systems that support nursing ...**

18/3,K/24 (Item 4 from file: 154)
DIALOG(R)File 154: MEDLINE(R)

12744901 PMID: 9479160
A NIDSEC primer: Part 1--Setting the standards.
Simpson R L
Nursing management (UNITED STATES) Jan 1998, 29 (1) p49-50, ISSN 0744-6314--Print Journal Code: 8219243
Publishing Model Print
Document type: Journal Article
Languages: ENGLISH

Main Citation Owner: NLM
Record type: MEDLINE; Completed

The Nursing Information and Data Set</B> ; Center, established by the American Nurses Association, recently published the criteria by
which it evaluates information systems that support nursing practice...

18/3,K/25 (Item 1 from file: 155)
DIALOG(R)File 155: MEDLINE(R)

14029226 PMID: 11155636
Not for nurses only. A NIDSEC (Nursing Information and
Data Set Evaluation Center&l
t;/B>) primer.
Curtin L; Simpson R L
Cerner Corp., Kansas City, MO, USA.
Health management technology (United States) Nov 2000, 21 (11) p60,
62, ISSN 1074-4770--Print Journal Code: 9423239
Publishing Model Print
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed

Not for nurses only. A NIDSEC (Nursing Information and
Data Set Evaluation Center&l
t;/B>) primer.

18/3,K/26 (Item 2 from file: 155)
DIALOG(R)File 155: MEDLINE(R)

12850417 PMID: 9611867
ANA standards for nursing data sets in information systems.
Averill C B; Marek K D; Zielstorff R; Kneedler J; Delaney C; Milholland D
K
St. Luke's Regional Medical Center, Boise, Idaho 83712, USA.
Computers in nursing (UNITED STATES) May-Jun 1998, 16 (3) p157-61,
ISSN 0736-8593--Print Journal Code: 8507717
Publishing Model Print
Document type: Journal Article; Review
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed

The American Nurses Association has established the
Nursing Information and Data Set

Evaluation Center . The purpose of this Center is to
develop and disseminate standards pertaining to information systems...

18/3,K/27 (Item 3 from file: 155)
DIALOG(R)File 155: MEDLINE(R)

12756097 PMID: 9496094
A NIDSEC primer: Part 2--Setting the standards.
Simpson R L
NIDSEC, Washington, DC 20024, USA.
Nursing management (UNITED STATES) Feb 1998, 29 (2) p26-9, ISSN
0744-6314--Print Journal Code: 8219243
Publishing Model Print
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed

The Nursing Information and Data Set</B> ; Center (NIDSEC), established by the
American Nurses Association (ANA), recently published
the criteria by which it evaluates information systems that support nursing
...

18/3,K/28 (Item 4 from file: 155)
DIALOG(R)File 155: MEDLINE(R)

12744901 PMID: 9479160
A NIDSEC primer: Part 1--Setting the standards.
Simpson R L
Nursing management (UNITED STATES) Jan 1998, 29 (1) p49-50, ISSN
0744-6314--Print Journal Code: 8219243
Publishing Model Print
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: MEDLINE; Completed

The Nursing Information and Data Set</B> ; Center, established by the American
Nurses Association, recently published the criteria by
which it evaluates information systems that support nursing practice...

18/3,K/29 (Item 1 from file: 444)
DIALOG(R)File 444: New England Journal of Med.

00106307

A Study Of Medical Injury And Medical Malpractice: An Overview (Special Report)

Hiatt, Howard H.; Barnes, Benjamin A.; Brennan, Troyen A.; Laird, Nan M.; Lawthers, Ann G.; Leape, Lucian L.; Localio, A. Russell; Newhouse, Joseph P.; Peterson, Lynn M.; Thorpe, Kenneth E.; Weiler, Paul C.; Johnson, William G.
The New England Journal of Medicine
Aug 17, 1989; 321 (7),pp 480-484
LINE COUNT: 00429 WORD COUNT: 05928

TEXT
...in hospitalization and because access to records is more readily available in hospitals than in physicians' offices. The existence of a central data base, the Statewide Planning and Research Cooperative System, permitted us to select from the records of...

18/3,K/30 (Item 1 from file: 74)
DIALOG(R)File 74: Int.Pharm.Abs

00313857 37-08956
INAPPROPRIATE PRESCRIBING IN THE ELDERLY: PBM'S IMPROVEMENT PLAN PROVIDES FOUNDATION FOR OTHERS
[Anonymous]
Formulary (USA), V35, (Mar), p283, 2000
Notes
CODEN: FORMF9 ISSN: 1082-801X LANGUAGE: English RECORD TYPE: Abstract

To examine inappropriate drug prescribing in geriatric patients, one pharmacy benefit management (PBM) company's paid claim database was used to examine drugs that have...

18/3,K/31 (Item 2 from file: 74)
DIALOG(R)File 74: Int.Pharm.Abs

00159916 26-10031
UTILIZATION OF A NATIONAL DATA BASE FOR OUTPATIENT DRUG PRESCRIBING REVIEW: NATIONAL AMBULATORY MEDICAL CARE SURVEY, 1985
Knapp, D. A.; Koch, H.; Michocki, R. J.
Sch. of Pharm., Univ. of Maryland, 20 N. Pine St., Baltimore, MD 21201, USA
Journal of Pharmaceutical Marketing Management (USA), V3, (1), p99-109, 1988
CODEN: JPMMEY ISSN: 0883-7597 LANGUAGE: English RECORD TYPE: Abstract

A study was conducted to demonstrate how an affordable national physician drug use data base, the National Center for Health Statistics' National Ambulatory Medical Care Survey, can be utilized to clinically profile and...

18/3,K/32 (Item 3 from file: 74)
DIALOG(R)File 74: Int.Pharm.Abs

00137679 25-02014
LOOK AT IN-HOUSE NURSING HOME RPHS
Kushner, D.; Feierman, R.
American Druggist (USA), V195, (Apr), p65-66, 68, 1987
CODEN: AMDRAG ISSN: 0190-5279 LANGUAGE: English RECORD TYPE: Abstract

...full time pharmacists is presented.
This study indicates that the average in-house nursing home pharmacy dispenses about one prescription (or drug order) a day for every 2 occupied beds. For the average in-house pharmacy, serving...

V. Text Search Results from Dialog

A. Abstract Databases

show files

File 350:Derwent WPIX 1963-2009/UD=201004
(c) 2010 Thomson Reuters
File 347:JAPIO Dec 1976-2009/Sep(Updated 091230)
(c) 2010 JPO & JAPIO
File 35:Dissertation Abs Online 1861-2009/Nov
(c) 2009 ProQuest Info&Learning
File 583:Gale Group Globalbase(TM) 1986-2002/Dec 13
(c) 2002 Gale/Cengage
File 65:Inside Conferences 1993-2010/Jan 18
(c) 2010 BLDSC all rts. reserv.

File 2:INSPEC 1898-2010/Jan W2
(c) 2010 The IET
File 474:New York Times Abs 1969-2010/Jan 11
(c) 2010 The New York Times
File 99:Wilson Appl. Sci & Tech Abs 1983-2009/Nov
(c) 2009 The HW Wilson Co.
File 34:SciSearch(R) Cited Ref Sci 1990-2010/Jan W2
(c) 2010 The Thomson Corp
File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec
(c) 2006 The Thomson Corp
File 169:Insurance Periodicals 1984-1999/Nov 15
(c) 1999 NILS Publishing Co.
File 6:NTIS 1964-2010/Jan W3
(c) 2010 NTIS, Intl Cpyrght All Rights Res
File 63:Transport Res(TRIS) 1970-2010/Dec
(c) fmt only 2010 Dialog
File 8:Ei Compendex(R) 1884-2010/Jan W2
(c) 2010 Elsevier Eng. Info. Inc.
File 14:Mechanical and Transport Engineer Abstract 1966-2009/Nov
(c) 2009 CSA.
File 7:Social SciSearch(R) 1972-2010/Jan W2
(c) 2010 The Thomson Corp
File 139:EconLit 1969-2009/Dec
(c) 2009 American Economic Association

? **ds**

Set	Items	Description
S1	11118	(PRESCRIBE OR PRESCRIBING OR PRESCRIPTION OR DRUG? ? OR MEDICINE? ? OR FORMULA OR PHARMACEUTICAL OR DIAGNOSIS)(3N)(REQUEST OR WANT OR NEEDS OR DEMAND??? OR ASK??? OR QUERY??? OR QUERIES OR INQUIR??? OR QUESTION? ?)
S2	22749	(PRESCRIBE OR PRESCRIBING OR PRESCRIPTION)(3N)(DRUG? ? OR MEDICINE? ? OR FORMULA OR PHARMACEUTICAL OR DIAGNOSIS)
S3	587	(ONE OR SINGLE OR SINGULAR OR LONE)(3N)(DRUGSTORE?? OR DRUG()STORE OR PHARMACY?) OR EXCLUSIVE()CENTRA()PHARMACY
S4	6849	(CENTRAL OR CENTRE OR CENTER)(3N)((REPOSITORY OR DATABASE OR DATA()BASE OR REGIST? OR DATABANK? ? OR DATATABLE? ? OR DATA OR INFORMATION OR KNOWLEDGE)()(BASE? ? OR BANK? ? OR SET? ? OR FILE? ? OR TABLE? ?) OR DB OR (ORGANI?ED()COLLECTION? ? OR RELATED OR INTERRELATED)(2W)(FILES OR INFORMATION OR DATA) OR DBMS)
S5	14	S4(7N)((MEDICAL OR HEALTHCARE OR HEALTH()CARE)()PROVIDER? ? OR PHYSICIAN? ? OR DOCTOR? ? OR NURSE? ? OR PHARMACIST OR THERAPIST)
S6	2081499	(MANAGEMENT OR MANAG??? OR SUPERVIS??? OR REGULAT??? OR CONTROL? OR PROCESS?)(3N)(DISTRIBUTION OR SUPPL??? OR DELIVER??? OR PROVID??? OR ALLOCAT??? OR ASSIGN?)
S7	145	S6(7N)(PRESCRIBE OR PRESCRIBING OR PRESCRIPTION)(3N)(DRUG? ? OR MEDICINE? ? OR FORMULA OR PHARMACEUTICAL OR DIAGNOSIS)
S8	1912	AU=(REARDAN, D?OR REARDAN D? OR REARDAN(2N)D? OR ENGEL, P? OR ENGEL P? OR ENGEL(2N)P? OR GAGNE, B? OR GAGNE B? OR GAGNE(-2N)B?)
S9	1	S8 AND S1
S10	4	S8 AND S2
S11	75	(S1:S2) AND S3
S12	18	(S1:S2) AND S4
S13	2	(S1:S2) AND S5
S14	1020	(S1:S2) AND S6

S15 8 S11 AND S6
S16 122 S14 AND S7
S17 0 S16 AND S4
S18 30 S5 OR S12 OR S13
S19 16 S18 NOT PY>2002

19/3,K/1 (Item 1 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0012474803 - Drawing available
WPI ACC NO: 2002-421553/200245
XRPX Acc No: N2002-331669
Earthquake resistance diagnosis system for building, has diagnosis center with reinforcement construction consignment unit that requests for contractor if existing building needs reinforcement
Patent Assignee: INTERPORT INT KK (INTE-N)
Inventor: GOTO A
Patent Family (1 patents, 1 countries)

Patent	Kind	Date	Application	Kind	Date	Update
JP 2002089052	A	20020327	JP 2000279650	A	20000914	200245 B

Priority Applications (no., kind, date): JP 2000279650 A 20000914

Patent Details

Number	Kind	Lan	Pg	Dwg	Filing Notes
JP 2002089052	A	JA	6	6	

Alerting Abstract ...contractor if seismic capacity evaluation performed on an existing building indicates that the existing building **needs** reinforcement. The **diagnosis center** produces diagnosis **data based** on the seismic capacity evaluation and monitoring data sent from a monitoring unit (1).

Original Publication Data by Authority

Argentina

19/3,K/2 (Item 2 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0011074980 - Drawing available
WPI ACC NO: 2002-010154/200201
XRPX Acc No: N2002-008495
Multi-user distribution system for assisting physicians, correlates input patient's request with preselected materials such as medical assessment tests and medical products for delivery to patients as medical module
Patent Assignee: SPARKS E (SPAR-I)
Inventor: SPARKS E
Patent Family (2 patents, 2 countries)

Patent	Kind	Date	Application	Kind	Date	Update
US 20010037215	A1	20011101	US 2000195202	P	20000407	200201 B
			US 2001808144	A	20010315	

CA 2342549 A1 20011007 CA 2342549 A 20010403 200204 E

Priority Applications (no., kind, date): US 2000195202 P 20000407; US 2001808144 A 20010315

Patent Details
Number Kind Lan Pg Dwg Filing Notes
US 20010037215 A1 EN 15 3 Related to Provisional US 2000195202
CA 2342549 A1 EN
Original Titles:
Multi-user distribution system and **center** for diagnosis-**related** educational **information** and home medical tests and devices

Alerting Abstract ...ADVANTAGE - The medical module is produced by correlating the received **request** with the **diagnosis** test devices, and the reliability of the medical module is improved, since it is prepared...

19/3,K/3 (Item 3 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0010442956 - Drawing available
WPI ACC NO: 2001-042053/200106
XRPX Acc No: N2001-031489
Diagnostic surveillance and classification system especially for skin melanomas, digitizes three-dimensional color image data, undertaking extensive comparisons, with further applications in medical and cosmetic fields
Patent Assignee: ALBRECHT P (ALBR-I); INB VISION AG (INBV-N); INST NEUROSIMULATION & BILDTECHNOLOGIEN (NEUR-N); MICHAELIS B (MICH-I); UNIV MAGDEBURG VON GUERICKE OTTO (UYMA-N)
Inventor: ALBRECHT P; MICHAELIS B
Patent Family (5 patents, 27 countries)
Patent Application
Number Kind Date Number Kind Date Update
DE 20010292 U1 20001012 DE 10021431 U 20000503 200106 B
DE 20010292 U 20000503
EP 1151721 A2 20011107 EP 2001109573 A 20010418 200168 E
DE 10021431 A1 20011122 DE 10021431 A 20000503 200201 E
US 20020016539 A1 20020207 US 2001849386 A 20010503 200213 E
DE 10021431 C2 20020822 DE 10021431 A 20000503 200257 E

Priority Applications (no., kind, date): DE 10021431 A 20000503; DE 20010292 U 20000503

Patent Details
Number Kind Lan Pg Dwg Filing Notes
DE 20010292 U1 DE 13 1 Based on application DE 10021431
EP 1151721 A2 DE
Regional Designated States,Original: AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI TR

Alerting Abstract ...DESCRIPTION OF DRAWINGS - The block diagram, dominated by the **doctor** (Arzt), reads: measurement head,

local computer, patient **data bank**,
central computer, external **data**
bank, data visualization station and selected
comparative data.

Original Publication Data by Authority

Argentina

19/3,K/4 (Item 4 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0009750797 - Drawing available
WPI ACC NO: 2000-036914/200003
Related WPI Acc No: 2001-181235
XRPX Acc No: N2000-027681
Interactive prescription compliance and personal safety system
Patent Assignee: O'BRIEN C T (OBRI-I); OBRIEN C T (OBRI-I)
Inventor: O'BRIEN C T; OBRIEN C T
Patent Family (6 patents, 35 countries)

Patent Number	Kind	Date	Application Number	Kind	Date	Update
US 5963136	A	19991005	US 1998115650	A	19980715	200003 B
WO 2000004521	A1	20000127	WO 1999US15612	A	19990709	200013 E
AU 199949821	A	20000207	AU 199949821	A	19990709	200029 E
EP 1023711	A1	20000802	EP 1999933859	A	19990709	200038 E
			WO 1999US15612	A	19990709	
TW 439048	A	20010607	TW 1999111763	A	19990712	200175 E
CA 2306998	C	20020618	CA 2306998	A	19990709	200250 E
			WO 1999US15612	A	19990709	

Priority Applications (no., kind, date): US 1998115650 A 19980715

Patent Details

Number	Kind	Lan	Pg	Dwg	Filing Notes
US 5963136	A	EN	15	7	
WO 2000004521	A1	EN			
National Designated States,Original: AU BR CA CN IL IN JP KP KR MX NO NZ SG VN					
Regional Designated States,Original: AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE					
AU 199949821	A	EN			Based on OPI patent WO 2000004521
EP 1023711	A1	EN			PCT Application WO 1999US15612
					Based on OPI patent WO 2000004521
Regional Designated States,Original: AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE					
TW 439048	A	ZH			
CA 2306998	C	EN			PCT Application WO 1999US15612
					Based on OPI patent WO 2000004521

Alerting Abstract ...USE - For correct intake of
prescription drugs. As a life safety
system by sending a primary care giver to the user nonuse...

Original Publication Data by Authority

Argentina

Assignee name & address:
Original Abstracts:
...related to the health status of a person, including taking of medicines
(8, 9), responsiveness <B>to **queries**
(11, 12), and attendance of health care and service providers (18) in the
home by...

...site verification of procedures related to the health status of a
person, including taking of **medicines**, responsiveness to
queries, and attendance of health care
and service providers **in** the home by
providing for signals to and from a person's location, with alarm...
Claims:
...the user in order to create a permanent patient data base;D. the
customer service **center** providing
electronic data storage and
prescription information for the user and communicating with a data
processing center, in...

19/3,K/5 (Item 5 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0009393427 - Drawing available
WPI ACC NO: 1999-329173/199928
XRPX Acc No: N1999-247059
Health product ordering system for ordering **prescription**
drugs
Patent Assignee: COHEN K H (COHE-I)
Inventor: COHEN K H
Patent Family (2 patents, 26 countries)

Patent Number	Kind	Date	Application Number	Kind	Date	Update
EP 921488	A1	19990609	EP 1998310032	A	19981208	199928 B
CA 2255291	A1	19990608	CA 2255291	A	19981208	199948 E

Priority Applications (no., kind, date): US 1997986805 A 19971208

Patent Details

Number	Kind	Lan	Pg	Dwg	Filing Notes
EP 921488	A1	EN	20	7	
Regional Designated States,Original: AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI					
CA 2255291	A1	EN			

Health product ordering system for ordering **prescription**
drugs

Original Titles:
...Automated database-oriented **prescription**
drug ordering system...

Alerting Abstract ...NOVELTY - The health-related product automation
system automatically takes action with respect to ordering
prescription drugs, based upon the
health status and prescription activity of outpatients....USE - Automated

database-oriented **prescription drug**
ordering system, for ordering health related products including
prescription drugs.

Original Publication Data by Authority

Argentina

Assignee name & address:
Original Abstracts:
...for automating activity relating to ordering health-related products
using: a central database subsystem which <B> stores
patient-**related information** and
information related to ordering health care products, a
provider subsystem which is
accessible to health care provider, and a product order subsystem which is
accessible...
Claims:

19/3,K/6 (Item 1 from file: 347)
DIALOG(R)File 347: JAPIO

06834300 **Image available**
HEALTH MANAGEMENT DATA GATHERING SYSTEM IN HOME NURSING

PUB. NO.: 2001-061794 [JP 2001061794 A]
PUBLISHED: March 13, 2001 (20010313)
INVENTOR(s): ADACHI MAYUKO
APPLICANT(s): NEC CORP
APPL. NO.: 11-237453 [JP 99237453]
FILED: August 24, 1999 (19990824)

ABSTRACT
...in the case that a nurse wants to take out the vital data, the network
data base center
400 is accessed from a **nurse** terminal 100 through the
communication channel network 200. By the access, a data base management...

19/3,K/7 (Item 2 from file: 347)
DIALOG(R)File 347: JAPIO

06647145 **Image available**
BIOLOGICAL INFORMATION MANAGEMENT SYSTEM

PUB. NO.: 2000-232963 [JP 2000232963 A]
PUBLISHED: August 29, 2000 (20000829)
INVENTOR(s): OKANO HIROSHI
ARIFUKU KIYOSHI
TODOROKI KENTARO
KANZAKI KEISUKE
APPLICANT(s): TOTO LTD
APPL. NO.: 11-311274 [JP 99311274]

FILED: November 01, 1999 (19991101)
PRIORITY: 10-357993 [JP 98357993], JP (Japan), December 16, 1998 (19981216)

ABSTRACT

... 41, the biological information 43 for the user and the biological information 45 for the **doctor** respectively in a **data base** 33. Then, the **center** system 31 transmits the raw biological information 41, the biological information 45 for the doctor...

19/3,K/8 (Item 1 from file: 2)
DIALOG(R)File 2: INSPEC

08502127
Title: Virtual center for renal support: definition of a novel knowledge-based telemedicine system
Author(s): Prado, M.; Roa, L.; Reina-Tosina, J.; Palma, A.; Milan, J.A.
Author Affiliation: Grupo de Ingenieria Biomedica, Seville Univ., Spain
Book Title: 2001 Conference Proceedings of the 23rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society (Cat. No.01CH37272)
Inclusive Page Numbers: 3878-81 vol.4
Publisher: IEEE, Piscataway, NJ
Country of Publication: USA
Publication Date: 2001
Conference Title: 2001 Conference Proceedings of the 23rd Annual International Conference of the IEEE Engineering n Medicine and Biology Society
Conference Date: 25-28 Oct. 2001
Conference Location: Istanbul, Turkey
ISBN: 0 7803 7211 5
U.S. Copyright Clearance Center Code: 0-7803-7211-5/01/$17.00
Item Identifier (DOI): http://dx.doi.org/10.1109/IEMBS.2001.1019687
Part: vol.4
Number of Pages: 4 vol. 4132
Language: English
Subfile(s): B (Electrical & Electronic Engineering); C (Computing & Control Engineering)
INSPEC Update Issue: 2003-002

Abstract: ...technical and physiological problems, compute not previously measured variables and is also an aid for **diagnosis**, **prescription** and supervision of therapies
Identifiers: **knowledge-based** telemedicine system; virtual **center**; renal support; home health care paradigm; end stage renal disease patients; model-based system analysis...

19/3,K/9 (Item 2 from file: 2)
DIALOG(R)File 2: INSPEC

06829491
Title: Nursing Information and Data Set Evaluation Center
Author(s): Marek, K.; Kneedler, J.; Zielstorff, R.; Delaney, C.; Marr, P.; Averill, C.; Millholland, D.K.
Author Affiliation: NIDSEC Advisory Comm., ANA, Washington, DC , USA
Inclusive Page Numbers: 257-62
Publisher: IOS Press, Amsterdam
Country of Publication: Netherlands
Publication Date: 1997
Conference Title: Nursing Informatics. The Impact of Nursing Knowledge on Health Care Informatics
Conference Date: 1997
Conference Location: Sweden
Editor(s): Gerdin, U.; Tallberg, M.; Wainwright, P.
Number of Pages: xxv+630
Language: English
Subfile(s): C (Computing & Control Engineering)
INSPEC Update Issue: 1998-006

Identifiers: American **Nurses** Association; Nursing Information and **Data Set** Evaluation **Center**; NIDSEC; ANA; standards dissemination; documentation; nursing practice; clinical information systems; Secretary of Health and Human...

19/3,K/10 (Item 3 from file: 2)
DIALOG(R)File 2: INSPEC

02998539
Title: WAMIS: a medical information system. Conception and clinical usage
Author(s): Grabner, H.; Marksteiner, A.; Dorda, W.; Wolf, W.; Grabner, G.
Author Affiliation: Dept. of Medical Computing, Univ. Wien, Vienna, Austria
Journal: Journal of Clinical Computing, vol.10, no.5-6, pp.154-69
Country of Publication: USA
Publication Date: 1982
ISSN: 0090-1091
CODEN: JCLCB7
Language: English
Subfile(s): C (Computing & Control Engineering)
INSPEC Update Issue: 1983-003

Abstract: ...fulfil three major goals: to collect all the data available on each patient in a **central data base**; to facilitate the daily work of **physicians** and nurses; and to provide a source for systematic medical research. This information system has...

19/3,K/11 (Item 4 from file: 2)
DIALOG(R)File 2: INSPEC

02474781
Title: Online information for physicians: a perspective from the Lister Hill National Center for Biomedical Communications
Author(s): Merritt, A.D.; Siegel, E.R.; Goldstein, C.M.; Bernstein, L.M.
Author Affiliation: Lister Hill Nat. Center for Biomedical Communications, Nat. Library of Medicine, Bethesda, MD, USA
Inclusive Page Numbers: 752-6
Publisher: IEEE, New York, NY
Country of Publication: USA
Publication Date: 1979
Conference Title: Proceedings of the Third Annual Symposium on Computer Application in Medical Care
Conference Date: 14-17 Oct. 1979
Conference Location: Washington, DC, USA
Conference Sponsor: IEEE George Washington Univ. Medical Center Biomedical Engng. Soc. et al
Editor(s): Dunn, R.A.
Number of Pages: 896
Language: English
Subfile(s): C (Computing & Control Engineering)
INSPEC Update Issue: 1980-003

Identifiers: information; **physicians**; Lister Hill National **Center** for Biomedical Communications; **data bases**; library

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19/3,K/12 (Item 1 from file: 474)
DIALOG(R)File 474: New York Times Abs

05808691 NYT Sequence Number: 065340900830
U.S. FORMING A **CENTRAL DATA BANK** TO IDENTIFY INCOMPETENT **DOCTORS**
HILTS, PHILIP J
New York Times, Col. 1, Pg. 8, Sec. B
Thursday August 30 1990

U.S. FORMING A **CENTRAL DATA BANK** TO IDENTIFY INCOMPETENT **DOCTORS**

19/3,K/13 (Item 1 from file: 34)
DIALOG(R)File 34: SciSearch(R) Cited Ref Sci

07538656 Genuine Article#: 178NP No. References: 14
Title: Chlorpyrifos: A ten-year US poison center exposure experience
Author: Kingston RL (REPRINT) ; Chen WL; Borron SW; Sioris LJ; Harris CR; Engebretsen KM
Corporate Source: INT POISON CTR,1295 BANADANA BLVD, SUITE 335/ST PAUL//MN/55108 (REPRINT); UNIV MINNESOTA,COLL PHARM, DEPT EXPT & CLIN PHARMACOL/MINNEAPOLIS//MN/55455; DOW AGRO SCI,GLOBAL REGULATORY TOXICOL & ENVIRONM CHEM/INDIANAPOLIS//IN/46268; INT TOXICOL CONSULTANTS LLC,/WASHINGTON//DC/20036; REGIONS HOSP,DEPT EMERGENCY MED/ST PAUL//MN/55101
Journal: VETERINARY AND HUMAN TOXICOLOGY, 1999, V41, N2 (APR), P87-92

ISSN: 0145-6296 Publication Date: 19990400
Publisher: COMPARATIVE TOXICOLOGY LAB, KANSAS STATE UNIV, MANHATTAN, KS 66506-5606
Language: English Document Type: ARTICLE (ABSTRACT AVAILABLE)

Abstract: We performed a retrospective review of **data based** on poison **center** exposure inquiries related to chlorpyrifos (CP) and the corresponding poison center-determined medical outcomes reported...

...inquiries were tabulated. Published TESS data was also tabulated to allow comparison of CP exposure **inquiries** to all non-**pharmaceutical** and insecticides/pesticides exposure inquiries for like time periods. Frequency of antidote use, product sales...

19/3,K/14 (Item 2 from file: 34)
DIALOG(R)File 34: SciSearch(R) Cited Ref Sci

06246771 Genuine Article#: YE257 No. References: 21
Title: Learning disability and epilepsy .1. Towards common outcome measures
Author: Kerr MP; Espie CA
Corporate Source: UNIV WALES COLL MED,DEPT PSYCHOL MED, WELSH CTR LEARNING DISABIL/CARDIFF CF4 4XN/S GLAM/WALES/; UNIV GLASGOW,DEPT PSYCHOL MED/GLASGOW/LANARK/SCOTLAND/
Journal: SEIZURE, 1997, V6, N5 (OCT), P331-336
ISSN: 1059-1311 Publication Date: 19971000
Publisher: W B SAUNDERS CO LTD, 24-28 OVAL RD, LONDON, ENGLAND NW1 7DX
Language: English Document Type: ARTICLE (ABSTRACT AVAILABLE)

...Abstract: standard data set is necessary as the basis of the assessment of any therapeutic intervention. **Central** components of this **data set** would encompass a definition of important characteristics of an individual, a description of their epilepsy...
...Identifiers: MENTAL-RETARDATION; CLINICAL ASPECTS; **PRESCRIPTION;** COMMUNITY; **DRUGS**

19/3,K/15 (Item 1 from file: 7)
DIALOG(R)File 7: Social SciSearch(R)

03467780 Genuine Article#: 311RJ No. References: 171
Title: Midwifery care research: What questions are being asked? What lessons have been learned?
Author: Raisler J (REPRINT)
Corporate Source: UNIV MICHIGAN,SCH NURSING, NURSE MIDWIFERY PROGRAM, 400 N INGALLS, ROOM 3320/ANN ARBOR//MI/48109 (REPRINT); COLUMBIA UNIV,NURSE MIDWIFERY EDUC PROGRAM/NEW YORK//NY/10027
Journal: JOURNAL OF MIDWIFERY & WOMENS HEALTH, 2000, V45, N1 (JAN-FEB), P20-36
Publisher: ELSEVIER SCIENCE INC, 655 AVENUE OF THE AMERICAS, NEW YORK, NY

10010
ISSN: 1526-9523
Language: English Document Type: Review
(ABSTRACT AVAILABLE)

...Identifiers--CERTIFIED **NURSE**-MIDWIVES;
NATIONAL-BIRTH-**CENTER**; CLINICAL-
DATA SET; LOW-RISK WOMEN;
UNITED-STATES; PRENATAL-CARE; HOME BIRTHS; VULNERABLE POPULATIONS;
COLLABORATIVE PRACTICE; PREMATURE RUPTURE

19/3,K/16 (Item 2 from file: 7)
DIALOG(R)File 7: Social SciSearch(R)

03110671 Genuine Article#: YE257 No. References: 21
Title: Learning disability and epilepsy .1. Towards common outcome measures
Author: Kerr MP; Espie CA
Corporate Source: UNIV WALES COLL MED,DEPT PSYCHOL MED, WELSH CTR LEARNING
DISABIL/CARDIFF CF4 4XN/S GLAM/WALES/; UNIV GLASGOW,DEPT PSYCHOL
MED/GLASGOW/LANARK/SCOTLAND/
Journal: SEIZURE, 1997, V6, N5 (OCT), P331-336
Publisher: W B SAUNDERS CO LTD, 24-28 OVAL RD, LONDON, ENGLAND NW1 7DX
ISSN: 1059-1311
Language: English Document Type: Article
(ABSTRACT AVAILABLE)

...Abstract: standard data set is necessary as the basis of the assessment
of any therapeutic intervention. **Central** components
of this **data set** would encompass
a definition of important characteristics of an individual, a
description of their epilepsy...
...Identifiers--MENTAL-RETARDATION; CLINICAL ASPECTS;
PRESCRIPTION; COMMUNITY; **DRUGS**

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11097985	REARDAN ET AL.
	Examiner	Art Unit
	LENA NAJARIAN	3686

SEARCHED

Class	Subclass	Date	Examiner
705	2, 3	8/7/09	LN

SEARCH NOTES

Search Notes	Date	Examiner
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	8/7/09	LN
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	8/14/09	LN
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	9/3/09	LN
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	9/9/09	LN
forward/backward search	2/18/10	LN
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2/18/10	LN
considered 705 template EIC search results	1/19/10	LN

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
705	3	2/18/10	LN
	PGPUB text search (see interference search printout)	2/18/10	LN

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
11097985	REARDAN ET AL.
Examiner	**Art Unit**
LENA NAJARIAN	3686

ORIGINAL		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
705	2	G	0	6	Q	10 / 00 (2006.0)						

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
705	3				

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		17												
	2		18												
	3		19												
	4		20												
	5		21												
	6		22												
	7		23												
	8		24												
	9		25												
	10	1	26												
	11	2	27												
	12	3	28												
	13	4	29												
	14	5	30												
	15	6	31												
	16														

/LENA NAJARIAN/ Examiner.Art Unit 3686	2/19/10	**Total Claims Allowed:**
(Assistant Examiner)	(Date)	6
/Gerald J. O'Connor/ SPE, GAU 3686	2/26/2010	O.G. Print Claim(s): 1 / O.G. Print Figure: 4B
(Primary Examiner)	(Date)	

Application Number	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11097985	REARDAN ET AL.

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed: 02/10/2010	**This patent is subject to a Terminal Disclaimer**	

Approved/Disapproved by:	
karen c. approved 2 td's 2/13/10	

U.S. Patent and Trademark Office

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dayton T. Reardan et al.	Examiner: Lena Najarian	
Serial No.:	11/097,985	Group Art Unit: 3686	
Filed:	April 1, 2005	Docket No.: 101.031US4	
Customer No.: 21186		Confirmation No.: 5403	

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

TERMINAL DISCLAIMER

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

I, Bradley A. Forrest, am an attorney of record for the above identified patent application as evidenced by the Power of Attorney filed herewith. This Terminal Disclaimer is submitted on behalf of Orphan Medical, Inc., the assignee of the present invention. As an attorney of record, I am empowered to act on behalf of the assignee and, in accordance with 37 C.F.R. § 1.321(b)(iv), to sign this Terminal Disclaimer.

Certificate Under 37 C.F.R. § 3.73(b)

The assignee, Orphan Medical, Inc., hereby certifies that it is the owner of the entire right, title and interest in and to both the captioned application (U.S. Application Serial No. 11/097,985) and to U.S. Serial No. 10/979,665, by virtue of the executed and filed assignment transferring title of both of these applications. The assignment for U.S. Serial No. 10/322,348 was recorded on at Reel 014869, Frames 0244-0250. That assignment assigned the application underlying U.S. Serial No. 10/322,348, as well as, *inter alia*, all continuations and divisionals based upon that application. The captioned application is a divisional of U.S. Serial No. 10/322,348, and U.S. Serial No. 10/979,665 is a divisional of U.S. Serial No. 10/322,348. Both applications were thus assigned to the assignee by the identified assignment.

The undersigned representative of the assignee has reviewed the evidentiary documents of title and certifies that to the best of assignee's knowledge and belief, title is in the assignee seeking to take the action set forth in this disclaimer.

Terminal Disclaimer

The assignee of the captioned application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified patent application, which would extend beyond the expiration date of the full statutory term, as presently shortened by any terminal disclaimers, of any patent issuing from U.S. Serial No. 10/979,665. The assignee hereby agrees that any patent to be granted on the captioned application shall be enforceable only for and during such period as such patent is commonly owned with any patent issuing from U.S. Serial No. 10/979,665. This agreement shall run with any patent granted on the above-identified application and shall be binding upon the assignee's successors and assigns.

Limitations on the Disclaimer

The assignee does not disclaim any terminal part of any patent granted on the above-identified application prior to the expiration date of the full statutory term as presently shortened by any terminal disclaimer of any patent issuing from U.S. Serial No. 10/979,665 in the event that it later expires before such term for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed, is the subject of a reexamination certificate cancelling all claims, or is otherwise terminated prior to the expiration date of its statutory term as presently shortened by any terminal disclaimer.

Fee Status

Please charge Deposit Account 19-0743 in the amount of $70.00 which is required under 37 C.F.R. § 1.20(d) to file a statutory disclaimer. The Commissioner of Patents and Trademarks is hereby authorized to charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402--0938
(612) 373-6972

Date 9 February 2010 By /Bradley A. Forrest/

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: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 10, 2010.

John D. Gustav-Wrathall
Name

/John D. Gustav-Wrathall/
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dayton T. Reardan et al.	Examiner: Lena Najarian	
Serial No.:	11/097,985	Group Art Unit: 3686	
Filed:	April 1, 2005	Docket No.: 101.031US4	
Customer No.: 21186		Confirmation No.: 5403	

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

TERMINAL DISCLAIMER

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

I, Bradley A. Forrest, am an attorney of record for the above identified patent application as evidenced by the Power of Attorney filed herewith. This Terminal Disclaimer is submitted on behalf of Orphan Medical, Inc., the assignee of the present invention. As an attorney of record, I am empowered to act on behalf of the assignee and, in accordance with 37 C.F.R. § 1.321(b)(iv), to sign this Terminal Disclaimer.

Certificate Under 37 C.F.R. § 3.73(b)

The assignee, Orphan Medical, Inc., hereby certifies that it is the owner of the entire right, title and interest in and to both the captioned application (U.S. Application Serial No. 11/097,985) and to U.S. Serial No. 11/097,651, by virtue of the executed and filed assignment transferring title of both of these applications. The assignment for U.S. Serial No. 10/322,348 was recorded on at Reel 014869, Frames 0244-0250. That assignment assigned the application underlying U.S. Serial No. 10/322,348, as well as, *inter alia*, all continuations and divisionals based upon that application. The captioned application is a divisional of U.S. Serial No. 10/322,348, and U.S. Serial No. 11/097,651 is a continuation of U.S. Serial No. 10/322,348. Both applications were thus assigned to the assignee by the identified assignment.

The undersigned representative of the assignee has reviewed the evidentiary documents of title and certifies that to the best of assignee's knowledge and belief, title is in the assignee seeking to take the action set forth in this disclaimer.

Terminal Disclaimer

The assignee of the captioned application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified patent application, which would extend beyond the expiration date of the full statutory term, as presently shortened by any terminal disclaimers, of any patent issuing from U.S. Serial No. 11/097,651. The assignee hereby agrees that any patent to be granted on the captioned application shall be enforceable only for and during such period as such patent is commonly owned with any patent issuing from U.S. Serial No. 11/097,651. This agreement shall run with any patent granted on the above-identified application and shall be binding upon the assignee's successors and assigns.

Limitations on the Disclaimer

The assignee does not disclaim any terminal part of any patent granted on the above-identified application prior to the expiration date of the full statutory term as presently shortened by any terminal disclaimer of any patent issuing from U.S. Serial No. 11/097,651 in the event that it later expires before such term for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed, is the subject of a reexamination certificate cancelling all claims, or is otherwise terminated prior to the expiration date of its statutory term as presently shortened by any terminal disclaimer.

Fee Status

Please charge Deposit Account 19-0743 in the amount of $70.00 which is required under 37 C.F.R. § 1.20(d) to file a statutory disclaimer. The Commissioner of Patents and Trademarks is hereby authorized to charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402--0938
(612) 373-6972

Date 9 February 2010 By /Bradley A. Forrest/

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: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 10, 2010.

John D. Gustav-Wrathall
Name

/John D. Gustav-Wrathall/
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dayton T. Reardan et al.	Examiner: Lena Najarian
Serial No.:	11/097,985	Group Art Unit: 3686
Filed:	April 1, 2005	Docket No.: 101.031US4
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD	

POWER OF ATTORNEY BY ASSIGNEE AND CERTIFICATE BY ASSIGNEE UNDER 37 CFR § 3.73(b)

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

Orphan Medical, Inc., assignee of the entire right, title and interest in the above-identified application by assignment from the inventor(s), hereby appoints the attorneys and agents of the firm of SCHWEGMAN, LUNDBERG & WOESSNER, P.A., listed under:

Customer Number: 21186

as its attorneys with full power of substitution to prosecute this application and to transact all business in the Patent and Trademark Office in connection therewith.

The assignee certifies that the above-identified assignment has been reviewed and to the best of the assignee's knowledge and belief, title is in the assignee.

Please direct all correspondence regarding this application to:

Schwegman, Lundberg & Woessner, P.A.
Customer No. 21186
Attn: David D'Zurilla
Telephone: (612) 371-2140
Facsimile: (612) 339-3061

Orphan Medical, Inc.

Dated: February 9, 2010

By: [signature]
Name: Carol Gamble
Title: Vice President

Electronic Patent Application Fee Transmittal

Application Number:	11097985
Filing Date:	01-Apr-2005
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Filer:	Gregory M. Stark/John Gustav-Wrathall
Attorney Docket Number:	101.031US4

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Statutory disclaimer	2814	2	70	140
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**140**

Electronic Acknowledgement Receipt

EFS ID:	6983032
Application Number:	11097985
International Application Number:	
Confirmation Number:	5403
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Gregory M. Stark/John Gustav-Wrathall
Filer Authorized By:	Gregory M. Stark
Attorney Docket Number:	101.031US4
Receipt Date:	10-FEB-2010
Filing Date:	01-APR-2005
Time Stamp:	10:28:19
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$140
RAM confirmation Number	6057
Deposit Account	190743
Authorized User	

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 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		101031us4_tds_021010.pdf	287980 d76d4eda6179d4e932704591851cc43315636f7f	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Terminal Disclaimer Filed	2	4
	Terminal Disclaimer Filed	5	7
	Power of Attorney	8	8

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	30001 22e0032b6a94fb9c36a02c721dc8209bc86e2675	no	2

Warnings:

Information:

Total Files Size (in bytes):	317981

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.:	101.031US4	Serial No.:	11/097,985
Filed:	April 1, 2005	Due Date:	N/A
Examiner:	Lena Najarian	Group Art Unit:	3686
Customer No.:	21186	Confirmation No.:	5403

Mail Stop 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 Terminal Disclaimer for U.S. Application Serial No. 10/979,665 (3 pgs.)
X Terminal Disclaimer for U.S. Application Serial No. 11/097,651 (3 pgs.)
X Power of Attorney (1 pg.)
X Authorization to charge Deposit Account 19-0743 in the amount of $140.00 to cover the fee for two Terminal Disclaimers

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, P.A.
Customer No.: 21186

By: /Bradley A. Forrest/
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 for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 10 day of February, 2010.

John D. Gustav-Wrathall
Name

/John D. Gustav-Wrathall/
Signature

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	11/097,985	REARDAN ET AL.	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☐ APPROVED	☒ DISAPPROVED
Date Filed : 1/22/10	**This patent is subject to a Terminal Disclaimer**	

Approved/Disapproved by:

Janice Ford

two terminals disapproved

note terminal disclaimer checklist

U.S. Patent and Trademark Office

Rev. 05/19/09	Doc. Code: DISQ.CKLIST

TERMINAL DISCLAIMER INFORMAL CHECKLIST

APPL. S.N.:	11/097,985	**DATE:**	1/28/2010
EXAMINER:	NAJARIAN, LENA	**ART UNIT:**	3686
PARALEGAL:	/JANICE M. FORD/	**MAIL ROOM DATE:**	1/22/2010
NUMBER OF TD(s) FILED:	2		

INSTRUCTIONS: The paralegal has reviewed the submitted TD with the results as set forth below.
If you agree, please use the appropriate form paragraphs identified by this informal memo in your next Office action to notify applicant about the TD. If you disagree, please contact a QAS.

THIS CHECKLIST IS AN INFORMAL, INTERNAL CHECKLIST ONLY. IT MUST NOT BE MAILED TO APPLICANT. IT WILL BE SOFT SCANNED AND NOT VIEWABLE TO THE PUBLIC.

☐ The TD is PROPER and has been accepted and recorded. (See FP 14.23.)

☒ The TD is NOT PROPER and has not been accepted for the reason(s) checked below. (See FP 14.24.)

☐ The disclaimer fee under 37 CFR 1.20(d) in the amount of $ has not been submitted, nor is there any pre authorization in the application to charge to a deposit account. (See FP 14.24 and 14.26.07.)

☐ The LIE has not processed fee for TD (the Paralegal should ask LIE to process the fee).

☐ The TD does not satisfy 37 CFR 1.32(b) (3) in that the person who signed the TD has not stated either: (a) the extent of his/her ownership interest, or (b) the extent of the business/organization entity's ownership interest on whose behalf the person signed. (See FPs 14.26 and 14.26.01.)

☐ The TD lacks the – enforceable only during the period of common ownership – clause needed to overcome a double patenting 37 CFR 1.321(c). (See FP 14.27.01).

☐ The TD lacks 37 CFR 1.321(d) statement for joint research agreement under 35 U.S.C. 103(c) (2) & (3). It doesn't include the waiver and enforceability provisions of 37 CFR 1.321(d). (See FP 14.27.011.)

☐ TD is directed to a particular claim(s); this is not acceptable, since the disclaimer must be of a terminal portion of the entire patent to be granted, MPEP 1490. (See FPs 14.26 and 14.26.02).

☐ The person who signed the terminal disclaimer:

- ☐ failed to state his/her capacity to sign for the business/organization entity. (See FP 14.28.)
- ☐ is not recognized as an officer of the assignee. (See FP 14.29.)
- ☐ does not have power of attorney, and thus, is not of record. (See FP 14.29.01.)

(Note: PoA can be given to a customer number, wherein all practitioners listed under the customer number have PoA. If PoA is established by a list of practitioners, the list may not comprise more than 10 practitioners. A representative of the assignee, who is not of record, cannot sign the TD unless it is established that the representative is a party authorized to act on behalf of the assignee.)

☐ The TD is not supported by evidence of chain of title to the assignee signing the TD due to a failure to submit either: (a) documentary evidence of a chain of title from the original inventor(s) to the assignee and a statement affirming that the documentary evidence was, or concurrently is being, submitted for recordation; or (b) the reel and frame number(s) where such documentary evidence is recorded in the Office. 37 CFR 3.73(b). (See FPs 14.30 and 14.34)

NOTE: This documentary evidence or the specifying of the reel and frame number may be found in the TD or in a separate paper submitted by applicant.)

☐ The TD is not supported by adequate evidence of chain of title to the assignee signing the TD, because the person who signed the submission under 37 CFR 3.73(b):

☐ has failed to state his/her capacity to sign for the business entity. (See FPs 14.30.02 and 14.16.02

☐ is not recognized as an officer of the assignee. (See FP 14.30.02 and 14.16.03)

(Note: On the submission under 37 CFR 3.73(b), the signature of an attorney or agent registered to practice before the Office is not sufficient, unless the attorney or agent is authorized to act on behalf of the assignee.)

☐ The TD is not signed (See FPs 14.26 and 14.26.03)

☐ The serial number of the application (or the number of the patent) which forms the basis for the double patenting is not identified (i.e., missing or incorrect) in the TD. (See FP 14.32)

☐ The serial number of the application being examined (or the number of the patent under reexam or reissue) is not identified or incorrect. (See FPs 14.26 and 14.26.04 or 14.26.05)

☐ The TD is not signed by all owners. See FPs 14.26 and 14.26.06.

☐ The period disclaimed is incorrect or not specified. (See FPs 14.24, 14.27.02 or 14.27.03)

☒ Other If POA is established by a list of practitioners, the list may not compromise more than 10 practitioners (37 CFR 1.32(c)(3)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dayton T. Reardan et al.	Examiner: Lena Najarian	
Serial No.:	11/097,985	Group Art Unit: 3686	
Filed:	April 1, 2005	Docket No.: 101.031US4	
Customer No.: 21186		Confirmation No.: 5403	

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

TERMINAL DISCLAIMER

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

I, Bradley A. Forrest, am an attorney of record for the above identified patent application as evidenced by the Power of Attorney filed in the present application on April 1, 2005. This Terminal Disclaimer is submitted on behalf of Orphan Medical, Inc., the assignee of the present invention. As an attorney of record, I am empowered to act on behalf of the assignee and, in accordance with 37 C.F.R. § 1.321(b)(iv), to sign this Terminal Disclaimer.

Certificate Under 37 C.F.R. § 3.73(b)

The assignee, Orphan Medical, Inc., hereby certifies that it is the owner of the entire right, title and interest in and to both the captioned application (U.S. Application Serial No. 11/097,985) and to U.S. Serial No. 11/097,651, by virtue of the executed and filed assignment transferring title of both of these applications. The assignment for U.S. Serial No. 10/322,348 was recorded on at Reel 014869, Frames 0244-0250. That assignment assigned the application underlying U.S. Serial No. 10/322,348, as well as, *inter alia*, all continuations and divisionals based upon that application. The captioned application is a divisional of U.S. Serial No. 10/322,348, and U.S. Serial No. 11/097,651 is a continuation of U.S. Serial No. 10/322,348. Both applications were thus assigned to the assignee by the identified assignment.

The undersigned representative of the assignee has reviewed the evidentiary documents of title and certifies that to the best of assignee's knowledge and belief, title is in the assignee seeking to take the action set forth in this disclaimer.

Terminal Disclaimer

The assignee of the captioned application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified patent application, which would extend beyond the expiration date of the full statutory term, as presently shortened by any terminal disclaimers, of any patent issuing from U.S. Serial No. 11/097,651. The assignee hereby agrees that any patent to be granted on the captioned application shall be enforceable only for and during such period as such patent is commonly owned with any patent issuing from U.S. Serial No. 11/097,651. This agreement shall run with any patent granted on the above-identified application and shall be binding upon the assignee's successors and assigns.

Limitations on the Disclaimer

The assignee does not disclaim any terminal part of any patent granted on the above-identified application prior to the expiration date of the full statutory term as presently shortened by any terminal disclaimer of any patent issuing from U.S. Serial No. 11/097,651 in the event that it later expires before such term for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed, is the subject of a reexamination certificate cancelling all claims, or is otherwise terminated prior to the expiration date of its statutory term as presently shortened by any terminal disclaimer.

Fee Status

Please charge Deposit Account 19-0743 in the amount of $70.00 which is required under 37 C.F.R. § 1.20(d) to file a statutory disclaimer. The Commissioner of Patents and Trademarks is hereby authorized to charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402--0938
(612) 373-6972

Date 22 January 2010 By /Bradley A. Forrest/

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: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 22, 2010.

John D. Gustav-Wrathall
Name

/John D. Gustav-Wrathall/
Signature

Electronic Patent Application Fee Transmittal

Application Number:	11097985
Filing Date:	01-Apr-2005
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Filer:	Gregory M. Stark/John Gustav-Wrathall
Attorney Docket Number:	101.031US4

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Statutory disclaimer	2814	2	70	140
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**140**

Electronic Acknowledgement Receipt

EFS ID:	6861235
Application Number:	11097985
International Application Number:	
Confirmation Number:	5403
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Gregory M. Stark/John Gustav-Wrathall
Filer Authorized By:	Gregory M. Stark
Attorney Docket Number:	101.031US4
Receipt Date:	22-JAN-2010
Filing Date:	01-APR-2005
Time Stamp:	12:09:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$140
RAM confirmation Number	8554
Deposit Account	190743
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		101031us4_tds_012210.pdf	204970 ff087d2ba8c60bf8b3d583d12e170025e004922e	yes	7

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Terminal Disclaimer Filed	2	4
	Terminal Disclaimer Filed	5	7

Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	30001 4766149e917a0522233d99258df444f69b29d68b	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	234971		

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.

<u>New Applications Under 35 U.S.C. 111</u>
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.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
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.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.:	101.031US4	Serial No.:	11/097,985
Filed:	April 1, 2005	Due Date:	N/A
Examiner:	Lena Najarian	Group Art Unit:	3686
Customer No.:	21186	Confirmation No.:	5403

Mail Stop 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 Terminal Disclaimer for U.S. Application Serial No. 10/979,665 (3 pgs.)
X Terminal Disclaimer for U.S. Application Serial No. 11/097,651 (3 pgs.)
X Authorization to charge Deposit Account 19-0743 in the amount of $140.00 to cover the fee for two Terminal Disclaimers

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, P.A.
Customer No.: 21186

By: /Bradley A. Forrest/
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 for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 22 day of January, 2010.

John D. Gustav-Wrathall
Name

/John D. Gustav-Wrathall/
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dayton T. Reardan et al.	Examiner: Lena Najarian	
Serial No.:	11/097,985	Group Art Unit: 3686	
Filed:	April 1, 2005	Docket No.: 101.031US4	
Customer No.: 21186		Confirmation No.: 5403	

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

TERMINAL DISCLAIMER

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

I, Bradley A. Forrest, am an attorney of record for the above identified patent application as evidenced by the Power of Attorney filed in the present application on April 1, 2005. This Terminal Disclaimer is submitted on behalf of Orphan Medical, Inc., the assignee of the present invention. As an attorney of record, I am empowered to act on behalf of the assignee and, in accordance with 37 C.F.R. § 1.321(b)(iv), to sign this Terminal Disclaimer.

Certificate Under 37 C.F.R. § 3.73(b)

The assignee, Orphan Medical, Inc., hereby certifies that it is the owner of the entire right, title and interest in and to both the captioned application (U.S. Application Serial No. 11/097,985) and to U.S. Serial No. 10/979,665, by virtue of the executed and filed assignment transferring title of both of these applications. The assignment for U.S. Serial No. 10/322,348 was recorded on at Reel 014869, Frames 0244-0250. That assignment assigned the application underlying U.S. Serial No. 10/322,348, as well as, *inter alia*, all continuations and divisionals based upon that application. The captioned application is a divisional of U.S. Serial No. 10/322,348, and U.S. Serial No. 10/979,665 is a divisional of U.S. Serial No. 10/322,348. Both applications were thus assigned to the assignee by the identified assignment.

The undersigned representative of the assignee has reviewed the evidentiary documents of title and certifies that to the best of assignee's knowledge and belief, title is in the assignee seeking to take the action set forth in this disclaimer.

Terminal Disclaimer

The assignee of the captioned application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified patent application, which would extend beyond the expiration date of the full statutory term, as presently shortened by any terminal disclaimers, of any patent issuing from U.S. Serial No. 10/979,665. The assignee hereby agrees that any patent to be granted on the captioned application shall be enforceable only for and during such period as such patent is commonly owned with any patent issuing from U.S. Serial No. 10/979,665. This agreement shall run with any patent granted on the above-identified application and shall be binding upon the assignee's successors and assigns.

Limitations on the Disclaimer

The assignee does not disclaim any terminal part of any patent granted on the above-identified application prior to the expiration date of the full statutory term as presently shortened by any terminal disclaimer of any patent issuing from U.S. Serial No. 10/979,665 in the event that it later expires before such term for failure to pay a maintenance fee, is held unenforceable, is found invalid, is statutorily disclaimed, is the subject of a reexamination certificate cancelling all claims, or is otherwise terminated prior to the expiration date of its statutory term as presently shortened by any terminal disclaimer.

Fee Status

Please charge Deposit Account 19-0743 in the amount of $70.00 which is required under 37 C.F.R. § 1.20(d) to file a statutory disclaimer. The Commissioner of Patents and Trademarks is hereby authorized to charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402--0938
(612) 373-6972

Date 22 January 2010 By /Bradley A. Forrest/

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: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 22, 2010.

John D. Gustav-Wrathall
Name

/John D. Gustav-Wrathall/
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner: Lena Najarian
Serial No.:	11/097,985	Group Art Unit: 3686
Filed:	April 1, 2005	Docket No.: 101.031US4
Customer No.:	21186	Confirmation No.: 5403
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD	

AMENDMENT & RESPONSE UNDER 37 C.F.R. § 1.111

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

In response to the Office Action mailed September 14, 2009, please amend the application as follows.

IN THE CLAIMS

Please amend the claims as follows:

Claims 1-25 (Cancelled)

26. (Currently Amended) A computerized method to control abuse of a sensitive drug comprising:

~~by~~ controlling with a computer processor the distribution of said sensitive drug ~~thereof~~ via an exclusive central pharmacy that maintains a central database that tracks all prescriptions of said sensitive drug and analyzes for potential abuse situations~~, the method comprising:~~ ;

receiving in the computer processor all prescription requests, for any and all patients being prescribed the sensitive drug, only at the exclusive central pharmacy, from any and all medical doctors allowed to prescribe the sensitive drug;

processing with the computer processor all prescriptions for the sensitive drug only by the exclusive central pharmacy using only the central database;

determining with the computer processor current and anticipated patterns of potential prescription abuse of said sensitive drug from periodic reports generated only by the central database based on prescription request data from a particular medical doctor and further based on filling of prescriptions by a particular patient, wherein said request data contain information identifying the patient, the drug prescribed, and credentials of the medical doctor; and

selecting with the computer processor multiple controls for distribution by said exclusive central pharmacy, the controls comprising ~~selected from the group consisting of~~ communicating prescriptions from a physician to the central pharmacy; identifying the ~~physicians~~ physician's name, license, and DEA (Drug Enforcement Agency) registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive printed materials to the physician; contacting the patient's insurance company if any; verifying patient registry information; providing

comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address of the patient; shipping via US postal service or a commercial ~~similar~~ shipping service; receiving the name of an at least 18 year old designee to receive the drug; confirming receipt of an initial shipment of the drug to the patient returning the drug to the pharmacy after two attempts to deliver; launching an investigation when a shipment is lost; shipping to another pharmacy for delivery; requiring manufacture at a single location; releasing inventory in a controlled manner to the central pharmacy; questioning early refills; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; limiting the prescription to a one month supply; requiring rewriting of the prescription periodically; and making the database available to the DEA for checking for abuse patterns in the data, for cash payments, and for inappropriate questions.

27. (Currently Amended) The method of claim 26 wherein initially selected controls comprise communicating prescriptions from a physician to the central pharmacy; identifying the ~~physicians~~ physician's name, license, and DEA registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; verifying patient registry information; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address of the patient; shipping via US postal service; confirming receipt of an initial shipment of the drug to the patient; releasing inventory in a controlled manner to the central pharmacy; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; and making the database available to the DEA for checking for abuse patterns in the data.

28. (Previously presented) The method of claim 26 which further comprises consulting a separate database to verify that the medical doctor is eligible to prescribe the drug.

29. (Currently Amended) A computerized method to control abuse of gamma hydroxy butyrate (GHB) comprising:

~~by~~ controlling with a computer processor the distribution of GHB via an exclusive central pharmacy that maintains a central database that tracks all prescriptions of GHB and analyzes for potential abuse situations~~, the method comprising:~~;

receiving in the computer processor all prescription requests, for any and all patients being prescribed GHB, only at the exclusive central pharmacy, from any and all medical doctors allowed to prescribe GHB;

processing in the computer processor all prescriptions for GHB only by the exclusive central pharmacy using only the central database;

determining with the computer processor current and anticipated patterns of potential prescription abuse of GHB from periodic reports generated only by the central database based on prescription request data from a particular medical doctor and based on filling of prescriptions by a particular patient, wherein said request data contain information identifying the patient, GHB as the drug prescribed, and credentials of the medical doctor; and

selecting with the computer processor multiple controls for distribution by said exclusive central pharmacy, the controls comprising ~~selected from the group consisting of~~ communicating prescriptions from a physician to the central pharmacy; identifying the ~~physicians~~ physician's name, license, and DEA (Drug Enforcement Agency) registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the GHB ~~sensitive drug~~ by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive printed materials to the physician; contacting the patient's insurance company if any; verifying patient registry information; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address of the patient; shipping via US postal service or a commercial ~~similar~~ shipping service; receiving the name of an at least 18 year old designee to receive the drug; confirming receipt of an initial shipment of the drug to the patient returning the drug to the pharmacy after two attempts to deliver; launching an investigation when a shipment is lost; shipping to another pharmacy for delivery; requiring manufacture at a single location; releasing inventory in a controlled manner to the central pharmacy; questioning early refills; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; limiting the

prescription to a one month supply; requiring rewriting of the prescription periodically; and making the database available to the DEA for checking for abuse patterns in the data, for cash payments, and for inappropriate questions.

30. (Currently Amended) The method of claim 29 wherein initially selected controls comprise

communicating prescriptions from a physician to the central pharmacy; identifying the ~~physicians~~ physician's name, license, and DEA registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the GHB ~~sensitive drug~~ by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; verifying patient registry information; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address of the patient; shipping via US postal service; confirming receipt of an initial shipment of the drug to the patient; releasing inventory in a controlled manner to the central pharmacy; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; and making the database available to the DEA for checking for abuse patterns in the data.

31. (Previously presented) The method of claim 29 which further comprises consulting a separate database to verify that the medical doctor is eligible to prescribe the drug.

REMARKS

This responds to the Office Action mailed on September 14, 2009.

Claims 26, 27, 29, and 30 are currently amended, no claims are currently canceled, and no claims are currently added; as a result, claims 26-31 are now pending and subject to examination in this application.

Interview Summary

The Applicant expresses its gratitude to Examiner Najarian for the courtesies extended to the Applicant's representatives Mr. Bradley Forrest and Mr. David D'Zurilla during an in-person interview at the United States Patent Office on October 15, 2009.

The Applicant's representatives discussed with Examiner Najarian the Board decision of August 31, 2009, and in particular the Board's holding that the Lilly reference disclosed an exclusive data storage because in the Board's view the database in Lilly contains all relevant data related to the distribution of a drug and the process of distributing it. The Applicant's representatives discussed with Examiner Najarian the amendment to the claims in response to this holding by the Board. Specifically, the Applicant has amended the claims so that the prescriptions are received only at the central pharmacy and that all prescriptions are processed only by the exclusive pharmacy and using only the exclusive computer database.

The Applicant's representatives discussed with Examiner Najarian a further amendment to the claims in which the computerized method determines potential patterns of abuse based on prescription request data from the particular medical doctor and further based on the filling of prescriptions by the particular patient. The Applicant's representatives further explained that no potential abuse is found when no abuse has been found by both the patient and the doctor.

The Applicant's representatives further discussed the extensive approval process that the Applicant and the Food and Drug Administration (FDA) were involved in relating to a new indication for the drug gamma hydroxyl butyrate (GHB), and how the patent application was borne out of this FDA approval process.

Examiner Najarian expressed her concerns that the Ukens reference disclosed a single pharmacy, that the claims did not specifically recite that the computer system executed the steps

of the claimed method, that the claims did not identify the potential abuse, and that the Lilly reference discloses in paragraph [0054] multi-source interstate prescriptive medication abuse.

No agreement on the claims or the claim amendments was reached.

Claim Objections

Claims 26, 27, 29, and 30 are objected to because of the following informalities: "the physicians name" should be changed to "the physician's name" (note line 11 of claims 26 & 29, line 3 of claim 27, and lines 3-4 of claim 30). Appropriate correction has been made.

Double Patenting Rejection

Claims 26-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 19, 20, 22, 32-34, and 36 of copending Application No. 11/097651. The Office Action alleges that although the conflicting claims are not identical, they are not patentably distinct from each other because "GHB" is a form of "sensitive drug" and "selecting multiple controls for distribution by said exclusive central pharmacy" is a form of "selecting multiple controls for distribution while maintaining a central database."

Applicant does not admit that the claims are obvious in view of U.S. Patent Application No. 11/097651. Notwithstanding, a Terminal Disclaimers in compliance with 37 C.F.R. § 1.321(b)(iv) is being submitted to obviate this rejection.

Claims 26-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 33-36 of copending Application No. 10/979665. The Office Action alleges that although the conflicting claims are not identical, they are not patentably distinct from each other because "selecting multiple controls for distribution by said exclusive central pharmacy" is a form of "controlling the distribution of said sensitive drug via an exclusive central pharmacy."

Applicant does not admit that the claims are obvious in view of U.S. Patent Application No. 10/979665. Notwithstanding, a Terminal Disclaimers in compliance with 37 C.F.R. § 1.321(b)(iv) is being submitted to obviate this rejection.

§ 101 Rejection of the Claims

Claims 26-31 are rejected under 35 U.S.C. 101 because the claimed invention is allegedly directed to non-statutory subject matter.

The Applicant has amended the claims to recite that the method is a computerized method and that a computer processor executes that claimed method. Support for these amendments to the claims can be found in the specification on page 5, lines 3-21 and in FIG. 1.

§ 112 Rejection of the Claims

Claims 26-31 are rejected under 35 U.S.C. 112, second paragraph, as allegedly 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. The Applicant respectfully submits that the amendments to the claims overcome the rejection of the claims under 35 U.S.C. § 112, and respectfully requests the withdrawal of the rejection of the claims.

§ 103 Rejection of the Claims

Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as allegedly 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 Ukens ("Specialty Pharmacy").

The Applicant has amended claim 26 to recite

". . . receiving in the computer processor all prescription requests, for any and all patients being prescribed the sensitive drug, only at the exclusive central pharmacy, from any and all medical doctors allowed to prescribe the sensitive drug;

processing in the computer processor all prescriptions for the sensitive drug only by the exclusive central pharmacy using only the central database;

determining with the computer processor current and anticipated patterns of potential prescription abuse of said sensitive drug from periodic reports generated only by the central database based on prescription request data from a particular medical doctor and based on

filling of prescriptions by a particular patient, wherein said request data contain information identifying the patient, the drug prescribed, and credentials of the doctor; and

selecting with the computer processor multiple controls for distribution by said exclusive central pharmacy, the controls comprising ~~selected from the group consisting of~~ . . . ".

Support for the amendment that recites "receiving in the computer processor all prescription requests, for any and all patients being prescribed the sensitive drug, only at the exclusive central pharmacy, from any and all medical doctors allowed to prescribe the sensitive drug" can be found in the specification at page 1, lines 27-29.

Support for the amendment that recites "processing in the computer processor all prescriptions for the sensitive drug only by the exclusive central pharmacy using only the central database" can be found in the specification at page 1, lines 27-28 and page 4, line 29 – page 5, line 1.

Support for the amendment that recites "determining with the computer processor current and anticipated patterns of potential prescription abuse of said sensitive drug from periodic reports generated only by the central database based on prescription request data from a particular medical doctor and based on filling of prescriptions by a particular patient, wherein said request data contain information identifying the patient, the drug prescribed, and credentials of the doctor" can be found in the specification at at page 1, lines 27-31.

The Applicant respectfully submits that these amendments differentiate claim 26 over the references of record at least because none of the references of record, either alone or in combination, discloses "processing . . . all prescriptions for the sensitive drug only by the exclusive central pharmacy using only the central database" and "determining . . . current and anticipated patterns of potential prescription abuse of said sensitive drug . . . based on prescription request data from a particular medical doctor and based on filling of prescriptions by a particular patient."

The Moradi reference does not disclose these features. While the Moradi reference discloses a central service station that is used in an automated prescription delivery system,[1] Moradi does not disclose that all prescriptions for a sensitive drug, or all prescriptions for any

[1] Moradi, ¶ [0006].

other drug for that matter, are processed only by the central service station. That is, Moradi does not disclose, teach, or suggest requiring that a drug be distributed only through its disclosed system, and therefore does not disclose at least this claimed feature. Moradi further does not disclose "determining . . . current and anticipated patterns of potential prescription abuse of said sensitive drug . . . based on prescription request data from a particular medical doctor and based on filling of prescriptions by a particular patient" as is recited in claim 26.

The Lilly reference does not disclose these features. The Lilly reference discloses a data storage 122, and even states that it relates to a centralized method for tracking and managing prescriptive medication information.[2] However, Lilly does not disclose that all drugs are processed by its system or method using its data storage 122. Rather, as disclosed by Lilly, each user (such as a doctor, hospital, or pharmacy) may maintain its own database, and the data storage 122 can maintain a copy of this data which is used by the system, or the system can obtain the data by accessing a user's database.[3] In other words, Lilly discloses that each user maintains its own database, and while a user can access the data storage 122 to try to find out information about a patient, there is no disclosure in Lilly that all prescriptions for a particular drug must use only the database 122. Rather, a user could simply use its own database, without any concern for abuse or liability, or use its own database and the database 122. In contrast, the claimed subject matter recites processing all prescriptions for the sensitive drug only by the exclusive central pharmacy using only the central database. As noted above, the claims further recite "determining . . . current and anticipated patterns of potential prescription abuse of said sensitive drug . . . based on prescription request data from a particular medical doctor and based on filling of prescriptions by a particular patient," which is not disclosed in Lilly either.

The Ukens reference does not disclose the feature of "determining . . . current and anticipated patterns of potential prescription abuse of said sensitive drug . . . based on prescription request data from a particular medical doctor and based on filling of prescriptions by a particular patient."

Moreover, even if all the elements of the claimed subject matter were disclosed in the cited references, and the Applicant respectfully reiterates that none of the references, either alone or in combination, discloses "processing all prescriptions for the sensitive drug only by the

[2] Lilly, ¶¶ [0050] and [0061].
[3] Lilly, ¶ [0061].

exclusive central pharmacy using only the central database" and "determining . . . current and anticipated patterns of potential prescription abuse of said sensitive drug . . . based on prescription request data from a particular medical doctor and based on filling of prescriptions by a particular patient," the Applicant respectfully submits that a *prima facie* case of obviousness still does not exist. The cited references, taken as a whole, simply would not have lead one of skill in the art to come up with the claimed subject matter.

Specifically, the Moradi reference relates to the distribution of a plurality of prescription medicines, and in particular, after validating the prescription and selecting a delivery location based on the location of the patient, the prescribed medicine is delivered to the patient.[4] And while there is a check in Moradi to prevent prescription abuse, the check is only of an individual patient to determine if that patient is permitted to have a prescription filled twice.[5] This is much different than a system in which "all prescriptions for [a] sensitive drug are processed only by [an] exclusive central pharmacy using only [an] exclusive computer database" and in which "current and anticipated patterns of potential prescription abuse of said sensitive drug . . . [are] based on prescription request data from a particular medical doctor and based on filling of prescriptions by a particular patient" as is recited in claim 26.

Similarly, the Lilly reference relates to tracking prescriptions only on a per patient basis. Specifically, the Lilly system and method allows a determination of a "complete prescriptive medication history of ***the*** patient"[6] by "obtaining a medication history of ***a selected prescription medication purchaser*** for all prescriptive medicines purchased by ***the selected prescriptive medication purchaser*** from all of the plurality of unaffiliated pharmacies based on the transferred pharmaceutical computer data."[7] So, like in Moradi, Lilly focuses on a single patient. This is much different than a system in which "all prescriptions for [a] sensitive drug are processed only by [an] exclusive central pharmacy using only [an] exclusive computer database" and in which "current and anticipated patterns of potential prescription abuse of said sensitive drug . . . [are] based on prescription request data from a particular medical doctor and based on filling of prescriptions by a particular patient" as is recited in claim 26.

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[4] Moradi, Abstract.
[5] Moradi, ¶ [0045].
[6] Lilly, Abstract (*Emphasis Added*).
[7] Lilly, ¶ [0037] (*Emphasis Added*).

In summary, these references simply do not relate to the tracking of a particular sensitive drug using an exclusive central pharmacy and an exclusive central database to determine potential abuse by a particular doctor who is permitted to prescribe such sensitive drugs and a particular patient to whom prescriptions are written. Consequently, a *prima facie* case of obviousness does not exist, and the Applicant respectfully requests a withdrawal of the rejection of the claims.

In response to the concerns expressed by Examiner Najarian during the Interview of October 15, 2009, the Applicant offers the following.

Examiner Najarian stated that the Ukens reference discloses a single pharmacy. The Applicant respectfully replies that Ukens does not disclose determining current and anticipated patterns of potential prescription abuse of a sensitive drug based on prescription request data from a particular medical doctor permitted to prescribe the sensitive drug and further based on filling of prescriptions by a particular patient to whom the sensitive drug is prescribed. The Applicant further respectfully submits that no other reference of record discloses this feature.

Examiner Najarian stated that the claims recited that the computer system was used to perform the steps, not that the computer system performed the steps. The Applicant has amended the claims, and respectfully submits that the amendments address and overcome the concerns of Examiner Najarian.

Examiner Najarian stated that the claims did not identify the potential abuse. The Applicant respectfully submits that the particular type of abuse is not what the Applicant considers its invention to be, and therefore respectfully submits that the claims should not be limited by any particular type of abuse. The specification provides examples of abuse such as reselling drugs for profit,[8] and the Applicant respectfully submits that one of skill in the art would realize that the claimed subject matter could be applied to other abuse situations.

In response to the Applicant's amendment of "determining . . . current and anticipated patterns of potential prescription abuse of said sensitive drug . . . based on prescription request data from a particular medical doctor and further based on filling of prescriptions by a particular patient," Examiner Najarian brought to the attention of the Applicant's representatives paragraph

[8] Applicant's specification, page 1, lines 9-21.

[0054] of Lilly that discusses "multi-source interstate prescriptive medication abuse." The Applicant respectfully submits that this is not a disclosure of the claimed feature of determining current and anticipated patterns of potential prescription abuse of said sensitive drug based on prescription request data from a particular medical doctor and further based on filling of prescriptions by a particular patient. Indeed, the Applicant respectfully submits that Lilly is directed to obtaining a medication history of a selected prescriptive medication purchaser,[9] and that any multi-source interstate feature of Lilly is for that selected purchaser, not a particular patient ***and*** a particular medical doctor as recited in the claims.

Claim 27 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1), in view of Ukens ("Specialty Pharmacy"), in view of Califano et al. (US 2003/0033168 A1), in view of Wallace et al. (US 6,564,121 B1), in view of Andreasson et al. (US 2003/0160698 A1), and further in view of Official Notice.

Claim 27 is dependent on claim 26, which as indicated above, is believed allowable. The Applicant respectfully submits that claim 27 is allowable also, and respectfully requests the withdrawal of the rejection of claim 27.

Claims 29 and 31 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1), in view of Ukens ("Specialty Pharmacy"), and further in view of Melker et al. (US 2002/017732 A1).

Claim 30 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1), in view of Ukens ("Specialty Pharmacy"), in view of Melker et al. (US 2002/017732 A1), in view of Califano et al. (US 2003/0033168 A1), in view of Wallace et al. (US 6,564,121 B1), in view of Andreasson et al. (US 2003/0160698 A1), and further in view of Official Notice.

Independent claim 29 has been amended in a substantially similar fashion as claim 26. The Applicant respectfully submits that these amendments place claim 29, and claims 30 and 31

[9] Lilly, paragraph [0037].

which are dependent on claim 29, into a condition for allowance, and respectfully requests the withdrawal of the rejection of claim 29.

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 representative at (612) 371-2140 to facilitate prosecution of this application.

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

Respectfully submitted,

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Date November 3, 2009 By / /
David D'Zurilla
Reg. No. 36,776

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John D. Gustav-Wrathall / John D. Gustav-Wrathall /
Name Signature

Electronic Patent Application Fee Transmittal

Application Number:	11097985
Filing Date:	01-Apr-2005
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Filer:	Gregory M. Stark/John Gustav-Wrathall
Attorney Docket Number:	101.031US4

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	6384583
Application Number:	11097985
International Application Number:	
Confirmation Number:	5403
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Gregory M. Stark/John Gustav-Wrathall
Filer Authorized By:	Gregory M. Stark
Attorney Docket Number:	101.031US4
Receipt Date:	03-NOV-2009
Filing Date:	01-APR-2005
Time Stamp:	16:54:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	3051
Deposit Account	190743
Authorized User	

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		101031us4_resp_110309.pdf	389848 62dd6c087cdd18ed211a0f571539a08dd3bd9bdc	yes	19

Multipart Description/PDF files in .zip description

Document Description	Start	End
Miscellaneous Incoming Letter	1	1
Transmittal Letter	2	3
Information Disclosure Statement (IDS) Filed (SB/08)	4	4
Amendment/Req. Reconsideration-After Non-Final Reject	5	5
Claims	6	9
Applicant Arguments/Remarks Made in an Amendment	10	19

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	30290 88f3aa731a844b9ad95f2e071e2753afe09ab86e	no	2

Warnings:

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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.

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.:	101.031US4	Serial No.:	11/097,985
Filed:	April 1, 2005	Due Date:	December 14, 2009
Examiner:	Lena Najarian	Group Art Unit:	3686
Customer No.:	21186	Confirmation No.:	5403

Mail Stop 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 under 37 C.F.R. § 1.111 (15 pgs.)
X Supplemental Information Disclosure Statement (2 pgs.), Form 1449 (1 pg.) Copies of Cited References (13).
X Authorization to charge Deposit Account 19-0743 in the amount of $180.00 to cover the fee for consideration of Information Disclosure Statement.

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, P.A.
Customer No.: 21186

By: _____
David D'Zurilla
Reg. No. 36,776

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John D. Gustav-Wrathall
Name

/John D. Gustav-Wrathall/
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dayton T. Reardan et al.	Examiner:	Lena Najarian
Serial No.:	11/097,985	Group Art Unit:	3686
Filed:	April 1, 2005	Docket:	101.031US4
Customer No.:	21186	Confirmation No.:	5403
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached PTO 1449 Form be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the PTO 1449 Form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. § 1.97(c)(2), Applicants hereby authorize the Commissioner to charge the fee of $180.00 as set forth in 37 C.F.R. § 1.17(p), to Deposit Account No. 19-0743. Please charge any additional fees or deficiencies, or credit any overpayment to Deposit Account No. 19-0743.

Pursuant to 37 C.F.R. § 1.98(a)(2), copies of cited U.S. Patents and Published Applications, and Non-Published Applications identifiable by USPTO Serial Number, are no longer required to be provided to the Office. Applicants acknowledge the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R § 1.98(a)(2).

The Examiner is invited to contact the Applicants' Representative at the telephone number indicated if there are any questions regarding this communication.

Respectfully submitted,

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(612) 373-2140

Date November 3, 2009 By /David D'Zurilla/

David D'Zurilla
Reg. No. 36,776

BAF:jdgw

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John D. Gustav-Wrathall
Name

/John D. Gustav-Wrathall/
Signature

Modified form approved for use through 09/30/2007. OMB 651-0031
US Patent & 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 contains a valid OMB control number.

Substitute for form 1449A/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** (Use as many sheets as necessary)	*Complete if Known*	
	Application Number	11/097,985
	Filing Date	April 1, 2005
	First Named Inventor	Dayton T. Reardan
	Group Art Unit	3686
	Examiner Name	Lena Najarian
Sheet 1 of 1	Attorney Docket No: 101.031US4	

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Filing Date If Appropriate

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	T [1]

OTHER DOCUMENTS – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T [1]
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Advisory Action mailed 02-05-07", 3 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Amendment and Response to Final Office Action mailed 01-17-07", 17 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Amendment and Response to Final Office Action mailed 03-29-06", 11 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Final Office Action mailed 10-18-06", 14 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Final Office Action mailed 12-29-05", 11 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Non Final Office Action mailed 06-17-05", 26 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Non Final Office Action mailed 06-29-05", 12 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Non Final Office Action Response mailed 08-08-06", 10 pgs	
	"Application Serial No. 10/322,348 (Atty Ref 101.031US1), Preliminary Amendment mailed 09-30-04", 11 pgs	
	"Application Serial No. 10/731,915 (Atty Ref 101.031US1) Non Final Office Action mailed 10-05-04", 21 pgs	
	"Application Serial No. 10/731,915 (Atty Ref 101.031US1), Non Final Office Action mailed 08-12-05", 22 pgs	
	"Application Serial No. 10/731,915 (Atty Ref 101.031US1), Non Final Office Action Response mailed 02-02-05", 17 pgs	
	"Application Serial No. 101.031US1 (Atty Ref 101.031US1), Non Final Office Action mailed 06-19-06", 18 pgs	

EXAMINER **DATE CONSIDERED**

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant is to place a check mark here if English language Translation is attached

Electronic Acknowledgement Receipt

EFS ID:	6384933
Application Number:	11097985
International Application Number:	
Confirmation Number:	5403
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Gregory M. Stark/John Gustav-Wrathall
Filer Authorized By:	Gregory M. Stark
Attorney Docket Number:	101.031US4
Receipt Date:	03-NOV-2009
Filing Date:	01-APR-2005
Time Stamp:	17:14:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	NPL Documents	001_101031us1_adar_020507.pdf	217120 d3d92d7725e606e154971a460fe8ee36eb87bc9d	no	3

Warnings:	
Information:	

2	NPL Documents	002_101031us1_aarf_011707.pdf	1006603 cf52910908cf88168cfe9ebd5e26e1121db6d7ff	no	17
Warnings:					
Information:					
3	NPL Documents	003_101031us1_aarf_032906.pdf	601582 59ba2ae7f50e8f0c83131efe732bf482c169a723	no	11
Warnings:					
Information:					
4	NPL Documents	004_101031us1_foar_101806.pdf	360766 9e6561f54a6d6df13e58ac0f1dfa62792a34ec89	no	14
Warnings:					
Information:					
5	NPL Documents	006_101031us1_oarn_061705.pdf	1636633 43d0533c86b4663e46498cd2ec50afd5a5af2010	no	26
Warnings:					
Information:					
6	NPL Documents	007_101031us1_oarn_062905.pdf	311579 e1f719a2a65e6a22b4cfabf65d0ffaaa860005aa	no	12
Warnings:					
Information:					
7	NPL Documents	008_101031us1_aarn_080806.pdf	529072 583e5451104473d640792c1d13648c733b12ad08	no	10
Warnings:					
Information:					
8	NPL Documents	009_1303021us2oarn5506.pdf	267390 f58c488c174dc037ad9edab53379fdd52a317eda	no	10
Warnings:					
Information:					
9	NPL Documents	010_899009us2_oarn_100504.pdf	944694 2aba732765ac6235af4cabf3033d15525207b1a7	no	21
Warnings:					
Information:					
10	NPL Documents	011_899009us2_oarn_081205.pdf	627878 6df1012c69ebbb3ad2f46cf3a40bc4b9519e548b	no	22
Warnings:					
Information:					

11	NPL Documents	012_899009us2_aarn_020205.pdf	859394 1baf1b5eaca7de48e613235ad48efed91f429a0f	no	17
Warnings:					
Information:					
12	NPL Documents	013_101031us1_oarn_061906.pdf	1144215 3b38890335567fcfbe9b15d910ed17aa5ddd9301	no	18
Warnings:					
Information:					
13	NPL Documents	005_101031us1_foar_122905.pdf	668248 30660b047cd0a6bd707f09eac83bb3c57e1d1521	no	11
Warnings:					
Information:					
		Total Files Size (in bytes):	9175174		

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.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/097,985	04/01/2005	

APPLICATION 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), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 11/03/2009	(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(i))	* 6	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(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(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							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.

Legal Instrument Examiner:
/ROZENIA HARMON/

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/097,985	04/01/2005	Dayton T. Reardan	101.031US4	5403

21186 7590 09/14/2009

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
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EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
09/14/2009	ELECTRONIC

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

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
request@slwip.com

Office Action Summary	Application No.	Applicant(s)	
	11/097,985	REARDAN ET AL.	
	Examiner	Art Unit	
	LENA NAJARIAN	3686	

-- 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 *01 April 2005*.

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) *26-31* 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) *26-31* 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 *20050401; 20061010; 20070104*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 26-31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Under the statute, the claimed invention must fall into one of the four recognized statutory classes of invention, namely, a process (or method); a machine (or system); an article of manufacture; or a composition of matter.

In the present case, claims 26-31 only recite mental steps. In order to qualify as a statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state. The recited steps of independent claim 26 of merely determining current and anticipated patterns of potential prescription abuse of a drug from periodic reports and selecting multiple controls for distribution by an exclusive central pharmacy are not tied to another statutory class (such as a particular apparatus) and do not transform underlying subject matter (such as an article or materials) to a different state or thing. Similar analysis applies for independent claim 29. Therefore, claims 26-31 are deemed to be directed to non-statutory subject matter.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 26-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19, 20, 22, 32-34, and 36 of copending Application No. 11/097651. Although the conflicting claims are not identical, they are not patentably distinct from each other because "GHB" is a form of "sensitive drug" and "selecting multiple controls for distribution by said exclusive central pharmacy" is a form of "selecting multiple controls for distribution while maintaining a central database."

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 26-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-36 of copending Application No. 10/979665. Although the conflicting claims are not identical, they are not patentably distinct from each other because "selecting multiple controls for distribution by said exclusive central pharmacy" is a form of "controlling the distribution of said sensitive drug via an exclusive central pharmacy."

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

6. Claims 26, 27, 29, and 30 are objected to because of the following informalities: "the physicians name" should be changed to "the physician's name" (note line 11 of claims 26 & 29, line 3 of claim 27, and lines 3-4 of claim 30). Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. 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.

8. Claims 26-31 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.

9. Regarding claims 26 and 29, the phrase "or similar shipping service" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or similar shipping service"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

10. Claims 26 and 29 recite the limitation "the patient" in lines 7-8, 17-19, and 21 of claim 26 and lines 7, 17-19, and 21 of claim 29. There is insufficient antecedent basis for this limitation in the claims.

11. Claims 27 and 30 recite the limitation "the patient" in lines 8-11 of each claim. There is insufficient antecedent basis for this limitation in the claims.

12. Claims 26 and 29 recite the limitation "the patient's" in line 16 of each claim. There is insufficient antecedent basis for this limitation in the claims.

13. Claims 29 and 30 recite the limitation "the sensitive drug" in line 13 of claim 29 and line 5 of claim 30. There is insufficient antecedent basis for this limitation in the claims.

14. Claims 28 and 31 incorporate the deficiencies of claims 26 and 31, through dependency, and are also rejected.

Claim Rejections - 35 USC § 103

15. 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.

16. Claims 26 and 28 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), and further in view of Ukens ("Specialty Pharmacy").

(A) Referring to claim 26, Moradi discloses a method to control abuse of a drug by controlling the distribution thereof via a central pharmacy that maintains a central database that tracks all prescriptions of said drug and analyzes for potential abuse situations, the method comprising (para. 22-24, para. 43, and para. 99 of Moradi):

receiving prescription request data from a medical doctor, wherein said request data contain information identifying the patient, the drug prescribed, and credentials of the doctor (para. 35-36 and para. 116-118 of Moradi); and

selecting multiple controls for distribution by said central pharmacy, controls including verifying the prescription and obtaining patient information (para. 24 and para. 35 of Moradi).

Moradi does not disclose an exclusive central pharmacy, that the drug is a sensitive drug, and determining current and anticipated patterns of potential prescription abuse of said sensitive drug from periodic reports generated by the central database based on prescription request data.

Lilly discloses that the drug is a sensitive drug (para. 2 of Lilly; the Examiner interprets "controlled substance" to be a form of "sensitive drug") and determining current and anticipated patterns of potential prescription abuse of said sensitive drug from periodic reports generated by the central database based on prescription request data (para. 54, para. 57-58, para. 61, para. 69, para. 71, and Fig. 2 of Lilly).

Moradi and Lilly do not expressly disclose an *exclusive* central pharmacy.

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 Lilly and Ukens within Moradi. The motivation for doing so would have been to provide an accurate view of patient use of prescription drugs, to help protect professionals from lawsuits and other potential liabilities (para. 58 of Lilly) and to limit access to dangerous drugs (page 3, paragraph 5 of Ukens).

Insofar as the claim recites "selected from the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(B) Referring to claim 28, Moradi discloses consulting a separate database to verify that the medical doctor is eligible to prescribe the drug (para. 118 of Moradi).

17. Claim 27 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), in view of Ukens ("Specialty Pharmacy"), in view of Califano et al. (US 2003/0033168 A1), in view of Wallace et al. (US 6,564,121 B1), in view of Andreasson et al. (US 2003/0160698 A1), and further in view of *Official Notice*.

(A) Referring to claim 27, Moradi discloses wherein initially selected controls comprise communicating prescriptions from a physician to the central pharmacy (para. 23-24 of Moradi); identifying the physicians name, license, and DEA registration information (para. 116-118 of Moradi); verifying the prescription (para. 24 of Moradi); obtaining patient information (para. 35 of Moradi); verifying patient registry information (para. 27 and para. 31 of Moradi); verifying the home address of the patient (para. 40 of Moradi); shipping the drug (para. 6 of Moradi); confirming receipt of an initial shipment of the drug to the patient (abstract of Moradi);

Moradi does not disclose verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; shipping via US postal service; releasing inventory in a controlled manner to the central pharmacy; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; and making the database available to the DEA for checking for abuse patterns in the data.

Lilly discloses making the database available to the DEA for checking for abuse patterns in the data (para. 54 of Lilly).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the aforementioned feature of Lilly within Moradi. The motivation for doing so would have been to determine areas where violations may be occurring (para. 54 of Lilly).

Moradi, Lilly, and Ukens do not disclose verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; shipping via US postal service; releasing inventory in a controlled manner to the central pharmacy; and flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions.

Califano discloses providing comprehensive education information to the patient and verifying the patient has reviewed the educational materials (para. 84 of Califano).

Wallace discloses releasing inventory in a controlled manner to the central pharmacy (col. 26, lines 36-60 of Wallace).

Andreasson discloses flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions (para. 79 of Andreasson).

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 Califano,

Wallace, and Andreasson within Moradi, Lilly, and Ukens. 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), so that unauthorized individuals do not have access to the drugs (col. 26, lines 36-55 of Wallace), and to reduce the risk of lost or stolen medical products (para. 79 of Andreasson).

The Examiner takes *Official Notice* that it is old and well-known to ship via the US postal service and to verify the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician.

It would have been obvious to one of ordinary skill in the art at the time of the invention, to ship via US postal service with the motivation of using a reliable shipping service and to consult the National Technical Information Services with the motivation of protecting patients from unethical physicians.

18. Claims 29 and 31 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 Ukens ("Specialty Pharmacy"), and further in view of Melker et al. (US 2002/017732 A1).

(A) Referring to claim 29, Moradi discloses a method to control abuse of a drug by controlling the distribution thereof via a central pharmacy that maintains a central database that tracks all prescriptions of said drug and analyzes for

potential abuse situations, the method comprising (para. 22-24, para. 43, and para. 99 of Moradi):

receiving prescription request data from a medical doctor, wherein said request data contain information identifying the patient, the drug prescribed, and credentials of the doctor (para. 35-36 and para. 116-118 of Moradi); and

selecting multiple controls for distribution by said central pharmacy, controls including verifying the prescription and obtaining patient information (para. 24 and para. 35 of Moradi).

Moradi does not disclose an exclusive central pharmacy, that the drug is a sensitive drug, and determining current and anticipated patterns of potential prescription abuse of said sensitive drug from periodic reports generated by the central database based on prescription request data.

Lilly discloses that the drug is a sensitive drug (para. 2 of Lilly; the Examiner interprets "controlled substance" to be a form of "sensitive drug") and determining current and anticipated patterns of potential prescription abuse of said sensitive drug from periodic reports generated by the central database based on prescription request data (para. 54, para. 57-58, para. 61, para. 69, para. 71, and Fig. 2 of Lilly).

Moradi and Lilly do not expressly disclose an *exclusive* central pharmacy.

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 Lilly and Ukens

within Moradi. The motivation for doing so would have been to ensure that prescribers have an accurate view of their patients' use of prescription drugs, to help protect professionals from lawsuits and other potential liabilities (para. 58 of Lilly) and to limit access to dangerous drugs (page 3, paragraph 5 of Ukens).

Moradi, Lilly, and Ukens do not disclose that the sensitive drug is gamma hydroxy butyrate (GHB).

Melker teaches that gamma hydroxy butyrate (GHB) is an illicit substance (para. 3 of Melker).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to include the aforementioned feature of Melker within Moradi, Lilly, and Ukens. The motivation for doing so would have been to include drugs of recent concern, such as GHB (para. 3 of Melker).

Insofar as the claim recites "selected from the group consisting of," it is immaterial whether or not the other elements are also disclosed.
(B) Referring to claim 31, Moradi discloses consulting a separate database to verify that the medical doctor is eligible to prescribe the drug (para. 118 of Moradi).

19. Claim 30 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), in view of Ukens ("Specialty Pharmacy"), in view of Melker et al. (US 2002/017732 A1), in view of Califano et al. (US 2003/0033168 A1), in view of

Wallace et al. (US 6,564,121 B1), in view of Andreasson et al. (US 2003/0160698 A1), and further in view of *Official Notice*.

(A) Referring to claim 30, Moradi discloses wherein initially selected controls comprise communicating prescriptions from a physician to the central pharmacy (para. 23-24 of Moradi); identifying the physicians name, license, and DEA registration information (para. 116-118 of Moradi); verifying the prescription (para. 24 of Moradi); obtaining patient information (para. 35 of Moradi); verifying patient registry information (para. 27 and para. 31 of Moradi); verifying the home address of the patient (para. 40 of Moradi); shipping the drug (para. 6 of Moradi); confirming receipt of an initial shipment of the drug to the patient (abstract of Moradi);

Moradi does not disclose verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; shipping via US postal service; releasing inventory in a controlled manner to the central pharmacy; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; and making the database available to the DEA for checking for abuse patterns in the data.

Lilly discloses making the database available to the DEA for checking for abuse patterns in the data (para. 54 of Lilly).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the aforementioned feature of Lilly within Moradi. The motivation for doing so would have been to determine areas where violations may be occurring (para. 54 of Lilly).

Moradi, Lilly, Ukens, and Melker do not disclose verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; shipping via US postal service; releasing inventory in a controlled manner to the central pharmacy; and flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions.

Califano discloses providing comprehensive education information to the patient and verifying the patient has reviewed the educational materials (para. 84 of Califano).

Wallace discloses releasing inventory in a controlled manner to the central pharmacy (col. 26, lines 36-60 of Wallace).

Andreasson discloses flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions (para. 79 of Andreasson).

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 Califano, Wallace, and Andreasson within Moradi, Lilly, Ukens, and Melker. 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), so that unauthorized individuals do not have access to the drugs (col. 26, lines 36-55 of Wallace), and to reduce the risk of lost or stolen medical products (para. 79 of Andreasson).

The Examiner takes *Official Notice* that it is old and well-known to ship via the US postal service and to verify the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician.

It would have been obvious to one of ordinary skill in the art at the time of the invention, to ship via US postal service with the motivation of using a reliable shipping service and to consult the National Technical Information Services with the motivation of protecting patients from unethical physicians.

Conclusion

20. 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 a kit for distributing pharmaceutical products (4,976,351).

21. 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, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. 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.

/LENA NAJARIAN/
Examiner, Art Unit 3686
9/9/09

Notice of References Cited	Application/Control No. 11/097,985	Applicant(s)/Patent Under Reexamination REARDAN ET AL.	
	Examiner LENA NAJARIAN	Art Unit 3686	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,564,121	05-2003	Wallace et al.	700/231
*	B	US-4,976,351	12-1990	Mangini et al.	206/232
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11097985	REARDAN ET AL.
	Examiner	Art Unit
	LENA NAJARIAN	3686

SEARCHED			
Class	Subclass	Date	Examiner
705	2, 3	8/7/09	LN

SEARCH NOTES		
Search Notes	Date	Examiner
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	8/7/09	LN
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	8/14/09	LN
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	9/3/09	LN
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	9/9/09	LN

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11097985	REARDAN ET AL.
	Examiner	Art Unit
	LENA NAJARIAN	3686

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/09/2009								
	1	-								
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	28	✓								
	29	✓								
	30	✓								
	31	✓								

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CONFIRMATION NO. 5403

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/097,985	04/01/2005	705	3686	101.031US4

APPLICANTS

Dayton T. Reardan, Excelsior, MN;
Patti A. Engel, Eagan, MN;
Bob Gagne, St. Paul, MN;

**** CONTINUING DATA ***************************

This application is a DIV of 10/322,348 12/17/2002

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
05/31/2005

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /LENA NAJARIAN/ Examiner's Signature	☐ Met after Allowance LN Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		MN	16	6	2

ADDRESS

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

TITLE

Sensitive drug distribution system and method

FILING FEE RECEIVED		
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	Unknown
Filing Date	Even Date Herewith
First Named Inventor	Reardan, Dayton
Group Art Unit	Unknown
Examiner Name	Unknown

Sheet 1 of 2

Attorney Docket No: 101.031US4

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EXAMINER /Lena Najarian/ **DATE CONSIDERED** 08/06/2009

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	Application Number	Unknown
	Filing Date	Even Date Herewith
	First Named Inventor	Reardan, Dayton
	Group Art Unit	Unknown
	Examiner Name	Unknown
Sheet 2 of 2	Attorney Docket No: 101.031US4	

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Examiner Initials*	**Foreign Document No**	**Publication Date**	**Name of Patentee or Applicant of cited Document**	**T[2]**

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	**Cite No[1]**	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T[2]**
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		"Diversion Prevention Through Responsible Distribution", NADDI Regional Training, (May 2001),12 pages	
		"Diversion Prevention Through Responsible Distribution", NADDI Regional Training Tennessee, (June 2001),14 Pages	
		"Diversion Prevention Through Responsible Distribution", NADDI National Conference, (November 2001),15 pages	
		"Peripheral and Central Nervous System Drugs Advisory Committee", Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research, Holiday Inn, Bethesda, Maryland,(06/06/2001),7 pages	

EXAMINER	/Lena Najarian/	**DATE CONSIDERED**	08/06/2009

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known	
Application Number	11/097,985
Filing Date	April 1, 2005
First Named Inventor	Reardan, Dayton
Group Art Unit	3626
Examiner Name	Unknown

Sheet 1 of 1

Attorney Docket No: 101.031US4

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Examiner Initials*	**Cite No [1]**	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T[2]**
		"Preliminary Amendment Pursuant to 37 CFR Sec. 1.115", U.S. Application Ser. No. 11/104,013, filed April 12, 2005, (June 17, 2005), 3 pgs.	
		"System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) Starter Kit", Celgene Corporation, (2001), 103 pgs.	

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Application Number	11/097,985
Filing Date	April 1, 2005
First Named Inventor	Reardan, Dayton
Group Art Unit	3626
Examiner Name	Unknown

Sheet 1 of 1

Attorney Docket No: 101.031US4

US PATENT DOCUMENTS				
Examiner Initial *	**USP Document Number**	**Publication Date**	**Name of Patentee or Applicant of cited Document**	**Filing Date If Appropriate**
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OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
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		"An Interview with Orphan Medical about Xyrem", http://www.talkaboutsleep.com/sleepdisorders/archives/Narcolepsy_xyrem_interview.htm,(February 12, 2001), 3 pgs.	
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S5	36	(single or one or exclusive) same pharmacy same (distribut$) same (sensitive or controlled) same (substance or drug or prescription or medication or pharmaceutical)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/08/07 14:34
S10	19	(single or one or exclusive) adj2 pharmacy same (sensitive or controlled) same (substance or drug or prescription or medication or pharmaceutical)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/08/07 14:39
S11	439	(single or one or exclusive) adj2 pharmacy	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/08/07 14:41
S12	273	(single or one or exclusive) adj1 pharmacy	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/08/07 14:41
S16	88	(exclusive or specialty or single) adj2 pharmacy	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/08/07 14:42
S17	50	national adj1 technical adj1 information adj1 services	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/07 15:48
S18	4	national adj1 technical adj1 information adj1 services same dea	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/07 15:48

S26	483	pattern same (drug or prescription or medicine or medication or pharmaceutical) same abuse	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/14 11:46
S27	49	pattern same (drug or prescription or medicine or medication or pharmaceutical) same abuse same report	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/14 11:46
S28	65	pattern same (drug or prescription or medicine or medication or pharmaceutical) same abuse and generat$ same report	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/14 11:47
S45	4	(prescription or drug or medication or medicine or pharmaceutical) with abuse same report same (generat$ or creat $) same (database or data adj1 base or databank or data adj1 bank) same request same prescription	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/14 16:43
S46	4	(prescription or drug or medication or medicine or pharmaceutical) with abuse same report same (database or data adj1 base or databank or data adj1 bank) same request same prescription	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/14 16:44
S47	5	(prescription or drug or medication or medicine or pharmaceutical)same abuse same report same (database or data adj1 base or databank or data adj1 bank) same request same prescription	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/14 16:44
S48	13	(prescription or drug or medication or medicine or pharmaceutical)same abuse same report same (database or data adj1 base or databank or data adj1 bank) same prescription	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/14 16:45

S49	32	(prescription or drug or medication or medicine or pharmaceutical)same abuse same report same (database or data adj1 base or databank or data adj1 bank)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/14 16:46
S85	547	releas$ same (prescription or drug or substance) same pharmacy same (secure or controlled)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/03 14:29
S86	4	releas$ same (prescription or drug or substance) same pharmacy same (secure or controlled) and (report$ or flag$) same (lost or stolen or destroyed or spilled) same (prescription)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/03 14:30
S89	28	releas$ same (prescription or drug or substance) same pharmacy same (secure or controlled) and (missing or damaged or lost or stolen or destroyed or spilled) same (delivery or pharmaceutical or pills or prescription)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/03 14:30
S90	75	(deliver$ or ship$ or releas$ or mail$) same (prescription or drug or substance) same pharmacy same (secure or controlled) and (missing or damaged or lost or stolen or destroyed or spilled) same (delivery or pharmaceutical or pills or prescription)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/03 14:31
S91	456	(deliver$ or ship$ or releas$ or mail$) same (prescription or drug or substance) with pharmacy same (secure or controlled)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/03 14:56

S92	353	(deliver$ or ship$ or releas$ or mail$) with (prescription or drug or substance) with pharmacy same (secure or controlled)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/03 14:57
S93	248	(deliver$ or ship$ or releas$ or mail$) with (prescription or drug or substance) with pharmacy with (secure or controlled)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/03 14:57
S94	1	manufacturer same (deliver$ or ship$ or releas$ or mail$) with (prescription or drug or substance) with pharmacy with (secure or controlled)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/03 15:04
S95	2	manufacturer same (deliver$ or ship$ or releas$ or mail$) same (prescription or drug or substance) with pharmacy with (secure or controlled)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/03 15:04
S96	196	pharmacy same receiv$ same (pharmaceutical or drug or substance) same manufacturer	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/03 15:05
S97	6	pharmacy same receiv$ same (pharmaceutical or drug or substance) same manufacturer same (secur$ or controlled)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/03 15:05
S98	50	pharmacy same receiv$ same (pharmaceutical or drug or substance) same manufacturer and inventory	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/03 15:10
S99	366	(flag$ or alert$ or track $) same (lost or stolen or destroy$ or spill$) same (Prescription or drug or medication or pharmaceutical)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/09 12:14

S100	14	(flag$ or alert$ or track $) same (repeat) same (lost or stolen or destroy $ or spill$) same (Prescription or drug or medication or pharmaceutical)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/09 12:15
S101	28	(flag$ or alert$ or track $) same (repeat or multiple) same (lost or stolen or destroy$ or spill$) same (Prescription or drug or medication or pharmaceutical)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/09 12:15
S102	66	(flag$ or alert$ or track $) same (repeat or multiple or several) same (lost or stolen or destroy$ or spill$) same (Prescription or drug or medication or pharmaceutical)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/09 12:17
S103	71	(flag$ or alert$ or track $) same (repeat or multiple or several) same (lost or stolen or destroy$ or spill$) same (Prescription or drug or medication or pharmaceutical or medicine)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/09 12:19
S104	16	(flag$ or alert$ or track $) same (abuse or fraud) same (lost or stolen or destroy$ or spill$) same (Prescription or drug or medication or pharmaceutical or medicine)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/09 12:19
S105	57	(flag$ or alert$ or track $) same (lost or stolen or destroy$ or spill$) same (Prescription or drug or medication or pharmaceutical or medicine) and (abuse or fraud$)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/09 12:20

S107	14	(flag$ or alert$ or track $) same (repeat) same (lost or stolen or destroy $ or spill$ or missing) same (Prescription or drug or medication or pharmaceutical)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/09 14:34
S108	471	(flag$ or alert$ or track $) same (lost or stolen or destroy$ or spill$ or missing) same (Prescription or drug or medication or pharmaceutical)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/09 14:35
S109	137	(flag$ or alert$ or track $) same (missing) same (Prescription or drug or medication or pharmaceutical)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/09/09 14:35

EAST Search History (Interference)

< This search history is empty>

9/9/2009 3:40:59 PM
C:\Documents and Settings\lnajarian2\My Documents\EAST\Workspaces\11097985.wsp

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	11/097,985	Group Art Unit:	3626
Filed:	April 01, 2005	Docket:	101.031US4
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Supplemental Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Supplemental Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 19-0743 in order to have this Supplemental Information Disclosure Statement considered.

Pursuant to 37 C.F.R. §1.98(d), copies of the listed documents are not provided as these references were previously cited by or submitted to the U.S. Patent Office in connection with Applicants' prior U.S. application, Serial No. 10/322,348, filed on December 17, 2002, which is relied upon for an earlier filing date under 35 U.S.C. §120.

Pursuant to 37 C.F.R. 1.98(a)(2), Applicants believe that copies of cited U.S. Patents and Published Applications, and Non-Published Applications identifiable by USPTO Serial Number, are no longer required to be provided to the Office. Notification of this change to this effect was provided in the United States Patent and Trademark Office OG Notices dated October 12, 2004 and October 19, 2004. Thus, Applicants have not included copies of any US Patents or US Patent Applications identifiable by serial number that may be cited with this submission. Should the Office require copies to be provided, Applicants respectfully request that notice of such requirement be directed to Applicants' below-signed representative. Applicants acknowledge the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

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 1-3-2007

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: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexendria, VA 22313-1450 on this 4TH day of January 2007.

JAMES KANYSIK
Name

_____
Signature

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	11/097,985
Filing Date	April 1, 2005
First Named Inventor	Reardan, Dayton
Group Art Unit	3626
Examiner Name	Unknown

Sheet 1 of 1

Attorney Docket No: 101.031US4

US PATENT DOCUMENTS				
Examiner Initial *	**USP Document Number**	**Publication Date**	**Name of Patentee or Applicant of cited Document**	**Filing Date If Appropriate**
	US-6,952,681	10/04/2005	McQuade, R., et al.	08/30/2001
	US-7,058,584	06/06/2006	Kosinski, D. L., et al.	01/28/2002

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	**Cite No [1]**	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T[2]**
		"An Interview with Orphan Medical about Xyrem", http://www.talkaboutsleep.com/sleepdisorders/archives/Narcolepsy_xyrem_interview.htm,(February 12, 2001), 3 pgs.	
		UKENS, C., "Specialty Pharmacy", Drug Topics, 144, (June 5, 2000), 40-47	

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional) [2] Applicant is to place a check mark here if English language Translation is attached

Electronic Acknowledgement Receipt

EFS ID:	1417491
Application Number:	11097985
International Application Number:	
Confirmation Number:	5403
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Eduardo Enrique Drake/James Kanyusik
Filer Authorized By:	Eduardo Enrique Drake
Attorney Docket Number:	101.031US4
Receipt Date:	04-JAN-2007
Filing Date:	01-APR-2005
Time Stamp:	17:58:22
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		101_031US4_sids.pdf	194673	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Information Disclosure Statement (IDS) Filed	2	4
Warnings:			
Information:			
	Total Files Size (in bytes):	194673	

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.: 101.031US4
Filed: April 1, 2005
Examiner: Unknown

Serial No.: 11/097,985
Due Date: N/A
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 Supplemental Information Disclosure Statement (2 pgs.), Form 1449 (1 pg.). Documents NOT enclosed, cited in parent application.

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 4TH day of January, 2007.

JAMES KAUKSIK
Name

_____
Signature

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	11/097,985	Group Art Unit:	3626
Filed:	April 01, 2005	Docket:	101.031US4
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Supplemental Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Supplemental Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 19-0743 in order to have this Supplemental Information Disclosure Statement considered.

Pursuant to 37 C.F.R. §1.98(d), copies of the listed documents are not provided as these references were previously cited by or submitted to the U.S. Patent Office in connection with Applicants' prior U.S. application, Serial No. 10/322,348, filed on December 17, 2002, which is relied upon for an earlier filing date under 35 U.S.C. §120.

Pursuant to 37 C.F.R. 1.98(a)(2), Applicants believe that copies of cited U.S. Patents and Published Applications, and Non-Published Applications identifiable by USPTO Serial Number, are no longer required to be provided to the Office. Notification of this change to this effect was provided in the United States Patent and Trademark Office OG Notices dated October 12, 2004 and October 19, 2004. Thus, Applicants have not included copies of any US Patents or US Patent Applications identifiable by serial number that may be cited with this submission. Should the Office require copies to be provided, Applicants respectfully request that notice of such requirement be directed to Applicants' below-signed representative. Applicants acknowledge the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

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 10/10/2006

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: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexendria, VA 22313-1450 on this 10TH day of October 2006.

JAMES KANYUSIK
Name

_____
Signature

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & 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 contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	11/097,985
Filing Date	April 1, 2005
First Named Inventor	Reardan, Dayton
Group Art Unit	3626
Examiner Name	Unknown

Sheet 1 of 1

Attorney Docket No: 101.031US4

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Filing Date If Appropriate
	US-2002/0010661A1	01/24/2002	Waddington, S. G., et al.	05/30/2001
	US-2002/0177232A1	11/28/2002	Melker, R. J., et al.	05/22/2002
	US-2003/0033168A1	02/13/2003	Califano, A., et al.	04/15/2002
	US-2003/0160698A1	08/28/2003	Andreasson, C. O., et al.	02/26/2002
	US-2003/0197366A1	10/23/2003	Kusterbeck, S.	04/17/2003
	US-2004/0008123A1	01/15/2004	Carrender, C., et al.	07/15/2002
	US-2004/0019794A1	01/29/2004	Moradi, A., et al.	07/29/2002
	US-2004/0176985A1	09/09/2004	Lilly, R. B., et al.	03/18/2004
	US-3,556,342	01/19/1971	Joseph, S. G.	05/05/1969
	US-4,847,764	07/11/1989	Halvorson, J. L.	05/21/1987

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T [2]
		"Preliminary Amendment Pursuant to 37 CFR Sec. 1.115", U.S. Application Ser. No. 11/104,013, filed April 12, 2005, (June 17, 2005), 3 pgs.	
		"System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) Starter Kit", Celgene Corporation, (2001), 103 pgs.	

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Electronic Acknowledgement Receipt

EFS ID:	1244529
Application Number:	11097985
Confirmation Number:	5403
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor:	Dayton T. Reardan
Customer Number:	21186
Filer:	Eduardo Enrique Drake/James Kanyusik
Filer Authorized By:	Eduardo Enrique Drake
Attorney Docket Number:	101.031US4
Receipt Date:	10-OCT-2006
Filing Date:	01-APR-2005
Time Stamp:	14:32:36
Application Type:	Utility
International Application Number:	

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part	Pages
1		101_031US4_SIDS.pdf	213040	yes	4

	Multipart Description		
	Doc Desc	**Start**	**End**
	Transmittal letter	1	1
	Information Disclosure Statement (IDS) Filed	2	4
Warnings:			
Information:			
	Total Files Size (in bytes):	213040	

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New Applications Under 35 U.S.C. 111
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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.: 101.031US4
Filed: April 1, 2005
Examiner: Unknown

Serial No.: 11/097,985
Due Date: N/A
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 Supplemental Information Disclosure Statement (2 pgs.), Form 1449 (1 pg.). Documents NOT enclosed, cited in parent application.

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: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 10TH day of October, 2006.

JAMES KANYUSIK
Name

Signature

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

IFW/S

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 NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/097,985	04/01/2005	Dayton T. Reardan	101.031US4

CONFIRMATION NO. 5403

21186
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402-0938

FORMALITIES LETTER

OC000000016165194

Date Mailed: 06/02/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

06/15/2005 MBERHE 00000023 11097985

01 FC:2011 150.00 OP
02 FC:2111 250.00 OP
03 FC:2311 100.00 OP
04 FC:2051 65.00 OP

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
  Applicant must submit $ **150** *to complete the basic filing fee for a small entity.*
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(f) of $65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$565** for a Small Entity

- **$150** Statutory basic filing fee.
- **$65** Late oath or declaration Surcharge.

- The application search fee has not been paid. Applicant must submit **$250** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **$100** to complete the examination fee for a small entity in compliance with 37 CFR 1.27

Replies should be mailed to: Mail Stop Missing Parts

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

A copy of this notice MUST be returned with the reply.

Office of Initial Patent Examination (703) 308-1202
PART 2 - COPY TO BE RETURNED WITH RESPONSE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.: 101.031US4
Filed: April 1, 2005
Examiner: Unknown

Serial No.: 11/097,985
Due Date: August 2, 2005
Group Art Unit: 3626

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

We are transmitting herewith the attached:

X A return postcard.
X A check in the amount of $65.00 to cover the small entity surcharge.
X A check in the amount of $500.00 to cover the Basic Filing Fee and Additional Claims Fee.
X Communication Re: Missing Parts (1 pg.).
X Notice to File Missing Parts (2 pgs.).

Applicant claims small entity status under 37 C.F.R. 1.27.

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 required fees or credit overpayment to Deposit Account No. 19-0743.

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

By: _____
Name: Bradley A. Forrest
Reg. No. 30,837
BAF:CMG:mrl

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Attn: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 10th day of June, 2005

Michaela R. Lewellyn
Name

Michaela Lewellyn
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner: Unknown	
Serial No.:	11/097,985	Group Art Unit: 3626	
Filed:	April 1, 2005	Docket: 101.031US4	
Customer No.:	21186	Confirmation No.:	5403
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

COMMUNICATION RE: MISSING PARTS

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
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In response to the "Notice to File Missing Parts" (see enclosed copy), we submit a check in the amount of $65.00 to cover the Small entity surcharge, and a check in the amount of $500.00 to cover the small entity basic filing fee and additional claims fee.

Applicants assume the application is now in proper order and in condition for examination. Please direct any inquiries to the undersigned attorney at (612) 373-6972.

If necessary, please charge any additional fees or credit overpayment to Deposit Account 19-0743.

Respectfully submitted,

Dayton T. Reardan et al.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
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Date 6/10/2005

By _____
Bradley A. Forrest
Reg. No. 30,837
BAF:CMG:mrl

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Attn: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 10th day of June, 2005

Michaela R. Lewellyn
Name

Michaela Lewellyn
Signature

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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/097,985	04/01/2005	Dayton T. Reardan	101.031US4

CONFIRMATION NO. 5403

21186
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FORMALITIES LETTER

OC000000016165194

Date Mailed: 06/02/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
  Applicant must submit $ **150** *to complete the basic filing fee for a small entity.*
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(f) of $65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$565** for a Small Entity

- **$150** Statutory basic filing fee.
- **$65** Late oath or declaration Surcharge.

- The application search fee has not been paid. Applicant must submit **$250** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **$100** to complete the examination fee for a small entity in compliance with 37 CFR 1.27

Replies should be mailed to: Mail Stop Missing Parts

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

A copy of this notice MUST be returned with the reply.

Office of Initial Patent Examination (703) 308-1202

PART 3 - OFFICE COPY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Dayton T. Reardan et al.
Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
Attorney Docket No.: 101.031US4
Customer No.: 21186

PATENT APPLICATION TRANSMITTAL

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

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

X Return postcard.
X **CONTINUATION** of prior Patent Application No.(10/322,348) (under 37 CFR 1.53(b)) comprising:
  X Specification (18 pgs, including claims numbered 1 through 25 and a 1 page Abstract).
  X Formal Drawing(s) (16 sheets).
  X Copy of signed Combined Declaration and Power of Attorney (4 pgs) from prior application.
  X Incorporation by Reference: *The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied herewith, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.*
X Prior application is assigned of record to Orphan Medical, Inc..
X Pre-Examination Statement for Petition to Make Special Under 37 CFR 1.102(d) (6 pgs.).
X Petition to Make Special Under 37 CFR 1.102(d) (1 pg.)
X Appendix I (1 pg.).
X Preliminary Amendment (7pgs.).
X Information Disclosure Statement (2 pgs.); PTO 1449 (2 pgs.).
X Authorization to Charge Deposit Account No. 19-0743 in the amount of $500.00 for the filing fee.
X Authorization to Charge Deposit Account No. 19-0743 in the amount of $130.00 for the petition fee.

The filing fee (NOT ENCLOSED) will be calculated as follows:

	No. Filed	No. Extra	Rate	Fee
TOTAL CLAIMS	6-20	0	x 25.00 =	$0.00
INDEPENDENT CLAIMS	2-3	0	x 100.00 =	$0.00
[]MULTIPLE DEPENDENT CLAIMS PRESENTED				$0.00
BASIC FEE				$150.00
SEARCH FEE				$250.00
EXAMINATION FEE				$100.00
APPLICATION SIZE FEE				$0.00
TOTAL				$500.00

THE FILING FEE WILL BE PAID UPON RECEIPT OF THE NOTICE TO FILE MISSING PARTS.

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

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

"Express Mail" mailing label number: EV 553 984 061 US
Date of Deposit: April 1, 2005
This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to The Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Sensitive Drug Distribution System and Method

Field of the Invention

The present invention relates to distribution of drugs, and in particular to the distribution of sensitive drugs.

Background of the Invention

Sensitive drugs are controlled to minimize risk and ensure that they are not abused, or cause adverse reactions. Such sensitive drugs are approved for specific uses by the Food and Drug Administration, and must be prescribed by a licensed physician in order to be purchased by consumers. Some drugs, such as cocaine and other common street drugs are the object of abuse and illegal schemes to distribute for profit. Some schemes include Dr. shopping, diversion, and pharmacy thefts. A locked cabinet or safe is a requirement for distribution of some drugs.

Certain agents, such as gamma hydroxy buterate (GHB) are also abused, yet also are effective for therapeutic purposes such as treatment of daytime cataplexy in patients with narcolepsy. Some patients however, will obtain prescriptions from multiple doctors, and have them filled at different pharmacies. Still further, an unscrupulous physician may actually write multiple prescriptions for a patient, or multiple patients, who use cash to pay for the drugs. These patients will then sell the drug to dealers or others for profit.

There is a need for a distribution system and method that directly addresses these abuses. There is a further need for such a system and method that provides education and limits the potential for such abuse.

Summary of the Invention

A drug distribution system and method utilizes a central pharmacy and database to track all prescriptions for a sensitive drug. Information is kept in a central database regarding all physicians allowed to prescribe the sensitive drug, and all patients receiving the drug. Abuses are identified by monitoring data in the database for prescription patterns by physicians and prescriptions obtained by patients. Further verification is

made that the physician is eligible to prescribe the drug by consulting a separate database for a valid DEA license, and optionally state medical boards to determine whether any corrective or approved disciplinary actions relating to controlled substances have been brought against the physician. Multiple controls beyond those for traditional drugs are imposed on the distribution depending on the sensitivity of the drug.

Education is provided to both physician and patient. Prior to shipping the drug for the first time, the patient is contacted to ensure that product and abuse related educational materials have been received and/or read. The patient may provide the name of a designee to the central pharmacy who is authorized to accept shipment of the drug. Receipt of the initial drug shipment is confirmed by contacting the patient. Either a phone call or other communication to the patient within a set time after delivery may be made to ensure receipt. Further, a courier service's tracking system is used to confirm delivery in further embodiments. If a shipment is lost, an investigation is launched to find it.

In one embodiment, the drug may be shipped by the central pharmacy to another pharmacy for patient pick-up. The second pharmacy's ability to protect against diversion before shipping the drug must be confirmed. This ability may be checked through NTIS and State Boards of Pharmacy.

Prescription refills are permitted in the number specified in the original prescription. In addition, if a prescription refill is requested by the patient prior to the anticipated due date, such refills will be questioned. A lost, stolen, destroyed or spilled prescription/supply is documented and replaced to the extent necessary to honor the prescription, and will also cause a review or full investigation.

The exclusive central database contains all relevant data related to distribution of the drug and process of distributing it, including patient, physician and prescription information. Several queries and reports are run against the database to provide information which might reveal potential abuse of the sensitive drug, such as early refills.

Brief Description of the Drawings

FIG. 1 is a block diagram of a computer system for use in implementing the system and method of the present invention.

FIG.s 2A, 2B and 2C are a flowchart describing a method for sensitive drug distribution at least partially utilizing a computer system such as that shown in FIG. 1.

FIG. 3 is a flowchart of a physician success program at least partially implemented on a computer system such as that shown in FIG. 1.

FIG.s 4A and 4B are a flowchart describing a method for handling refill requests at least partially utilizing a computer system such as that shown in FIG. 1.

FIG. 5 is a flowchart of a process for requesting special reimbursement when a patient is uninsured or underinsured at least partially utilizing a computer system as that shown in FIG. 1.

FIG. 6 is a flowchart of a process for inventory control at least partially utilizing a computer system such as that shown in FIG. 1.

FIG. 7 is a block diagram of database fields.

FIG. 8 is a block diagram showing a list of queries against the database fields.

FIG. 9 is a copy of one example prescription and enrollment form.

FIG. 10 is a copy of one example of a NORD application request form for patient financial assistance.

FIG. 11 is a copy of one example voucher request for medication for use with the NORD application request form of FIG. 10.

FIG. 12 is a copy of certificate of medical need.

FIG.s 13A, 13B and 13C are descriptions of sample reports obtained by querying a central database having fields represented in FIG. 7.

Detailed Description of the Invention

In the following description, reference is made to the accompanying drawings that form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that structural, logical and electrical changes may be made without departing from the scope of the present invention. The following description is, therefore, not to be taken in a limited sense, and the scope of the present invention is defined by the appended claims.

The functions or algorithms described herein are implemented in software or a combination of software and human implemented procedures in one embodiment. The software comprises computer executable instructions stored on computer readable media such as memory or other type of storage devices. The term "computer readable media" is also used to represent carrier waves on which the software is transmitted. Further, such functions correspond to modules, which are software, hardware, firmware of any combination thereof. Multiple functions are performed in one or more modules as desired, and the embodiments described are merely examples. The software is executed on a digital signal processor, ASIC, microprocessor, or other type of processor operating on a computer system, such as a personal computer, server or other computer system.

A sensitive drug is one which can be abused, or has addiction properties or other properties that render the drug sensitive. One example of such a drug is sodium oxybate, also known as gamma hydroxy butyrate (GHB $C_4H_7NaO_3$) which is useful for treatment of cataplexy in patients with narcolepsy. GHB is marketed under the trademark of Xyrem® (sodium oxybate oral solution), which trademark can be used interchangeably with GHB herein. Sensitive drugs also include narcotics or other drugs which require controls on their distribution and use to monitor behaviors to prevent abuse and adverse side effects.

In one embodiment, Xyrem® is subject to a restricted distribution program. One aspect of the program is to educate physicians and patients about the risks and benefits of Xyrem, including support via ongoing contact with patients and a toll free helpline. Initial prescriptions are filled only after a prescriber and patient have received and read the educational materials. Further, patient and prescribing physician registries are maintained and monitored to ensure proper distribution.

In a further embodiment, bulk sodium oxybate is manufactured at a single site, as is the finished drug product. Following manufacture of the drug product, it is stored at a facility compliant with FDA Schedule III regulations, where a consignment inventory is maintained. The inventory is owned by a company, and is managed by a central pharmacy, which maintains the consignment inventory. Xyrem® is distributed and dispensed through a primary and exclusive central pharmacy, and is not stocked in retail

pharmacy outlets. It is distributed by overnight carriers, or by US mail in one embodiment to potentially invoke mail fraud laws if attempts of abuse occur.

FIG. 1 is a simplified block diagram of a computer system 100, such as a personal computer for implementing at least a portion of the methods described herein. A central processing unit (CPU) 110 executes computer programs stored on a memory 120. Memory 120 in one embodiment comprises one or more levels of cache as desired to speed execution of the program and access to data on which the programs operate. The CPU is directly coupled to memory 120 in one embodiment. Both CPU 110 and memory 120 are coupled to a bus 130. A storage 140, I/O 150 and communications 160 are also coupled to the bus 130. Storage 140 is usually a long term storage device, such as a disk drive, tape drive, DVD, CD or other type of storage device. In one embodiment, storage 140 is used to house a database for use with the present invention. I/O 150 comprises keyboards, sound devices, displays and other mechanisms by which a user interacts with the computer system 100. Communications 160 comprises a network, phone connection, local area network, wide area network or other mechanism for communicating with external devices. Such external devices comprise servers, other peer computers and other devices. In one embodiment, such external device comprises a database server that is used in place of the database on storage 140. Other computer system architectures capable of executing software and interacting with a database and users may also be used. Appropriate security measures such as encryption are used to ensure confidentiality. Further, data integrity and backup measures are also used to prevent data loss.

FIG.s 2A, 2B and 2C represent an initial prescription order entry process for a sensitive drug, such as Xyrem. At 202, a medical doctor (MD) sends a Rx/enrollment form via mail, fax, email or other means to an intake/reimbursement specialist at 204, who makes a copy of the RX/enrollment form that is stamped "copy". The original fax is forwarded to a pharmacy team. The enrollment form contains prescriber information, prescription information, checkboxes for the prescriber indicating they have read materials, educated the patient, understand the use in treatment, and understand certain safety information, and also contains patient information.

The prescriber information contains standard contact information as well as license number, DEA number and physician specialty. Patient and prescription

information includes name, social security number, date of birth, gender, contact information, drug identification, patient's appropriate dosage, and number of refills allowed, along with a line for the prescriber's signature. Patient insurance information is also provided.

There are two workflows involved at the pharmacy team, intake reimbursement 206 and pharmacy workflow 208, which may proceed in parallel or serially. The intake work flow 206 starts with an intake reimbursement specialist entering the patient and physician information into an application/database referred to as CHIPS, which is used to maintain a record of a client home infusion program (CHIP) for Xyrem®. A check is made to ensure the information is complete at 212. If not, at 214, an intake representative attempts to reach the MD or prescriber to obtain the missing information. If the missing information has not been obtained within a predetermined period of time, such as 24 hours at 216, the Rx/Enrollment form is sent back to the MD with a rejection explanation. A note is entered in CHIPS that the application was rejected.

If the information is complete at 212, the MD is contacted at 220 to verify receipt and accuracy of the patient's Rx. This contact is recorded in CHIPS. The intake and reimbursement specialist then sends a consent form and a cover letter to the patient at 224. The insurance provider is contacted at 226 to verify coverage and benefits. At 228, a determination is made regarding coverage for the drug. If it is not available, it is determined at 230 whether the patient is willing and able to pay. If not, a process is performed for handling patients who are uninsured or underinsured. In one embodiment, the process is referred to as a NORD process.

If the patient is willing and able to pay at 230, the patient is informed of the cost of the product and is given payment options at 234. At 236, once payment is received, the intake reimbursement specialist submits a coverage approval form with the enrollment form to the pharmacy team as notification to process the patient's prescription. If coverage is approved at 228, the intake reimbursement specialist also submits the coverage approval form with the enrollment form to the pharmacy team as notification to process the patient's prescription. Processing of the prescription is described below.

Upon receipt and initial processing of the prescription enrollment form and sending an original to the pharmacy work flow block 208, the patient is shipped a Xyrem® success packet via mail. In one embodiment, the Xyrem® success packet contains educational material for a patient that advises of the proper use, care and handling of the drug and consequences of diversion at 268. The medical doctor's credentials are checked to determine if the physician has a current DEA license to prescribe controlled substances and if he or she has had any actions related to misuse/misprescribing of controlled drugs against him or her, within a predetermined time, such as three months at 270. If they have, a pharmacist holds the prescription until receiving a coverage approval form from the intake reimbursement specialist at 272.

If the credentials have not been recently checked, the pharmacist verifies the credentials and enters all findings in the database at 274. If the credentials are approved at 276, the physician is indicated as approved in a physician screen populated by information from the database at 280. The prescription is then held pending coverage approval at 282.

If any disciplinary actions are identified, as referenced at block 278, management of the pharmacy is notified and either approves processing of the prescription with continued monitoring of the physician, or processing of the prescription is not performed, and the physician is noted in the database as unapproved at 284. The enrollment form is then mailed back to the physician with a cover letter reiterating that the prescription cannot be processed at 288. The patient is also sent a letter at 290 indicating that the prescription cannot be processed and the patient is instructed to contact their physician.

Actual filling of the approved prescription begins with receipt of the coverage approval form as indicated at 240. The patient is contacted by the pharmacy, such as by a technician to complete a technician section of a patient counseling checklist. If a pharmacist verifies that the program materials were not read at 242, the receipt of the material is confirmed at 244 and another call is scheduled to counsel the patient before the drug is shipped.

If the program materials were read at 242, the checklist is completed at 246 and the technician transfers the patient to the pharmacist who reviews the entire checklist and completes remaining pharmacist specified sections. At 248, the pharmacist indicates in

the database that the patient counseling and checklist was successfully completed, indicating the date completed.

At 250, the pharmacist schedules the patient's shipment for the next business day or the next business day that the patient or designee is able to sign for the package. Further, as indicated at 252, the shipment must be sent to the patient's home address unless the patient is traveling or has moved. In that event, the pharmacist may determine that an exception may be made. The patient or the patient's designee who is at least 18 years old, must sign for the package upon delivery.

At 254, the pharmacist enters the prescription order in the database, creating an order number. The pharmacist then verifies at 256 the prescription and attaches a verification label to the hard copy prescription. At 258, a pick ticket is generated for the order and the order is forwarded to the pharmacy for fulfillment. The shipment is confirmed in the database at 260, and the order is shipped by USPS Express Mail. Use of the US mail invokes certain criminal penalties for unauthorized diversion. Optionally, other mail services may be used. Potential changes in the law may also bring criminal penalties into play. Following shipment, the patient is called by the central pharmacy to confirm that the prescription was received.

As noted at 266, for the sensitive drug, Xyrem, all inventory is cycle counted and reconciled with the database system quantities before shipments for the day are sent. This provides a very precise control of the inventor.

A physician success program materials request process begins at 310 in FIG. 3. At 320, the MD calls to the central pharmacy to request program materials. A special phone number is provided. MD demographics, DEA number, and data or request are entered into the database at 330. At 340, a request is made to ship the materials to the MD via a fulfillment website, or other mechanism. The request process ends at 350.

A refill request process begins at 302 in FIG.s 4A and 4B. There are two different paths for refills. A first path beginning at 404 involves generating a report from the central database of patients with a predetermined number of days or product remaining. A second path beginning at 406 is followed when a patient calls to request an early refill.

In the first path, a copy of the report is provided to an intake reimbursement specialist at 408. No sooner than 8 days before the medication depletion, a pharmacy

technician contacts the patient at 410 to complete the pre-delivery checklist. At 412, if the patient is not reached, a message is left mentioning the depletion, and a return number at 414. A note is also entered into the database indicating the date the message was left at 416.

If the patient is reached at 412, the next shipment is scheduled at 418, the prescription is entered into the database creating an order at 420, the pharmacist verifies the prescription and attaches a verification label at 422 and the shipment is confirmed in the database at 424. Note at 426 that the inventory is cycle counted and reconciled with the database quantities before the shipments for a day or other time period are sent. A pick ticket is generated for the order and the order is forwarded for fulfillment at 428, with the first path ending at 430.

The second path, beginning at 406 results in a note code being entered into the database on a patient screen indicating an early refill request at 432. The pharmacist evaluates the patient's compliance with therapy or possible product diversion, misuse or over-use at 436. In one embodiment, cash payers are also identified. The pharmacist then contacts the prescribing physician to alert them of the situation and confirm if the physician approves of the early refill at 438. If the physician does not approve as indicated at 440, the patient must wait until the next scheduled refill date to receive additional product as indicated at 442, and the process ends at 444.

If the physician approves at 440, the pharmacist enters a note in the database on a patient screen that the physician approves the request at 446. The pharmacist notifies an intake reimbursement specialist to contact the patient's insurance provider to verify coverage for the early refill at 448. If the insurance provider will pay as determined at 450, the specialist submits the coverage approval form as notification that the refill may be processed at 452. At 454, the pharmacy technician contacts the patient to schedule shipment of the product for the next business day, and the process of filling the order is continued at 456 by following the process beginning at 240.

If the insurance provider will not pay at 450, it is determined whether the patient is willing and/or able to pay at 458. If not, the patient must wait until the next scheduled refill date to receive additional product at 460. If it was determined at 458 that the patient was willing and able to pay, the patient is informed of the cost of the product and is given

payment options at 462. Once payment is received as indicated at 464, the specialist submits a coverage approval form to the pharmacy team as notification that the refill request can be processed at 466. At 468, the pharmacy technician contacts the patient to schedule shipment. The process of filling the order is continued at 470 by following the process beginning at 240.

A process, referred to as a NORD process in one embodiment is used to determine whether donated, third party funds are available for paying for prescriptions where neither insurance will, nor the patient can pay. The process begins at 510 upon determining that a patient is uninsured or underinsured. A reimbursement specialist explains the NORD program to the patient and faxes an application request form to NORD for the patient. At 515, the intake reimbursement specialist documents in the database that an application has been received through NORD. At 520, NORD mails an application to the patient within one business day.

A determination is made at 525 by NORD whether the patient is approved. If not, at 530, NORD sends a denial letter to the patient, and it is documented in the database at 540 that the patient was denied by NORD. If the patient is approved, NORD sends an acceptance letter to the patient and faxes a voucher to the central pharmacy (SDS in one embodiment) to indicate the approval at 545. At 550, an intake reimbursement specialist submits a coverage approval form to the pharmacy team as notification that the patient has been approved for coverage. The process of filling the order is continued at 555 by following the process beginning at 240.

An inventory control process is illustrated in FIG. 6 beginning at 610. Each week, a responsible person at the central pharmacy, such as the director of the pharmacy transfers inventory for the week's shipments to a segregated warehouse location for production inventory. At 620, a purchase order is generated for the inventory transferred to the production location and is sent, such as by fax, to a controller, such as the controller of the company that obtained approval for distribution and use of the sensitive drug. At 630, the controller invoices the central pharmacy for the product moved to production. The process ends at 640.

The central database described above is a relational database running on the system of FIG. 1, or a server based system having a similar architecture coupled to

workstations via a network, as represented by communications 160. The database is likely stored in storage 140, and contains multiple fields of information as indicated at 700 in FIG. 7. The organization and groupings of the fields are shown in one format for convenience. It is recognized that many different organizations or schemas may be utilized. In one embodiment, the groups of fields comprise prescriber fields 710, patient fields 720, prescription fields 730 and insurance fields 740. For purposes of illustration, all the entries described with respect to the above processes are included in the fields. In further embodiments, no such groupings are made, and the data is organized in a different manner.

Several queries are illustrated at 800 in FIG. 8. There may be many other queries as required by individual state reporting requirements. A first query at 810 is used to identify prescriptions written by physician. The queries may be written in structured query language, natural query languages or in any other manner compatible with the database. A second query 820 is used to pull information from the database related to prescriptions by patient name. A third query 830 is used to determine prescriptions by frequency, and a n^{th} query finds prescriptions by dose at 840. Using query languages combined with the depth of data in the central database allows many other methods of investigating for potential abuse of the drugs. The central database ensures that all prescriptions, prescribers and patients are tracked and subject to such investigations. In further embodiments, the central database may be distributed among multiple computers provided a query operates over all data relating to such prescriptions, prescribers and patients for the drug.

An example of one prescription and enrollment form is shown at 900 in FIG. 9. As previously indicated, several fields are included for prescriber information, prescription information and patient information.

FIG. 10 is a copy of one example NORD application request form 1000 used to request that an application be sent to a patient for financial assistance.

FIG. 11 is a copy of one example application 1100 for financial assistance as requested by form 1000. The form requires both patient and physician information. Social security number information is also requested. The form provides information for approving the financial assistance and for tracking assistance provided.

FIG. 12 is a copy of one example voucher request for medication for use with the NORD application request form of FIG. 10. In addition to patient and physician information, prescription information and diagnosis information is also provided.

FIG.s 13A, 13B and 13C are descriptions of sample reports obtained by querying a central database having fields represented in FIG. 7. The activities grouped by sales, regulatory, quality assurance, call center, pharmacy, inventory, reimbursement, patient care and drug information. Each report has an associated frequency or frequencies. The reports are obtained by running queries against the database, with the queries written in one of many query languages.

While the invention has been described with respect to a Schedule III drug, it is useful for other sensitive drugs that are DEA or Federally scheduled drugs in Schedule II-V, as well as still other sensitive drugs where multiple controls are desired for distribution and use.

Claims

1. A method of distributing a sensitive drug, the method comprising:

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

entering the information into a central 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 database to evaluate potential abuse patterns.

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

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

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

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

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

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

8. The method of claim 1 wherein prescription refills requested prior to an anticipated date are questioned by the pharmacist.

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

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

11. A method of monitoring potential abuse of a sensitive drug by use of an exclusive central database, the method comprising:

generating queries of prescription information from a database containing selected information for all prescriptions of the sensitive drug, wherein the queries comprise prescriptions by physician specialty, prescriptions by patient name, prescriptions by frequency and prescriptions by dose.

12. The method of claim 11 and further comprising running multiple predetermined reports based on data in the exclusive central database.

13. The method of claim 12 wherein such reports are selected from groups of reports consisting of sales, regulatory, quality assurance, pharmacy, inventory, reimbursement, patient care, and drug information.

14. The method of claim 13 wherein sales reports are selected from the group consisting of prescriptions by zip code, prescriptions by physician by zip code and total dollars by zip code.

15. The method of claim 13 wherein regulatory reports are selected from the group consisting of number of physician registries, number of denied physician registries and reasons, number of completed patient registries, number of problem identification, number of cycle counts performed.

16. The method of claim 13 wherein inventory reports are selected from the group consisting of number of returned products and reasons, number of outdated bottles of product, inventory counts of consignment and production inventory, number of units received, and lots received.

17. The method of claim 13 wherein patient care reports are selected from the group consisting of number of adverse events, number of dosing problems and type, number of noncompliance episodes and reason, number of patients counseled and reason, number of discontinued and reason, number of patients referred to physician and reason, number of active patients, number of new patents, number of restart patients, and number of discontinued patients and reason.

18. The method of claim 13 wherein selected reports are run weekly, monthly or quarterly.

19. A method of obtaining FDA (Food and Drug Administration) approval for a sensitive drug, the method comprising:

determining current and anticipated patterns of potential abuse of the sensitive drug;

selecting multiple controls for distribution by an exclusive central pharmacy maintaining a central database, the controls selected from the group consisting of communicating prescriptions from a physician to the central pharmacy, identifying the physicians name, license and DEA (Drug Enforcement Agency) registration information, verifying the prescription; obtaining patient information, verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and check on whether any actions are pending against the physician, provide comprehensive printed materials to the physician, contacting the patient's insurance company if any, verifying patient registry information, providing comprehensive education information to the patient, verifying the patient has reviewed the educational materials, verifying the home

address of the patient, shipping via US postal service or similar shipping service, receiving the name of an at least 18 year old designee to receive the drug, confirming receipt of an initial shipment of the drug to the patient, returning the drug to the pharmacy after two attempts to deliver, launching an investigation when a shipment is lost, shipping to another pharmacy for delivery, requiring manufacture at a single location, releasing inventory in a controlled manner to the central pharmacy, questioning early refills, flagging repeat instances of lost, stolen, destroyed or spilled prescriptions, limiting the prescription to a one month supply, requiring rewriting of the prescription periodically, making the database available to the DEA for checking for abuse patterns in the data, cash payments, inappropriate questions; and

negotiating with the FDA by adding further controls from the group until approval is obtained.

20. The method of claim 19 wherein initially selected controls comprise communicating prescriptions from a physician to the central pharmacy, identifying the physicians name, license and DEA registration information, verifying the prescription; obtaining patient information, verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and check on whether any actions are pending against the physician, verifying pátient registry information, providing comprehensive education information to the patient, verifying the patient has reviewed the educational materials, verifying the home address of the patient, shipping via US postal service, confirming receipt of an initial shipment of the drug to the patient releasing inventory in a controlled manner to the central pharmacy, flagging repeat instances of lost, stolen, destroyed or spilled prescriptions, and making the database available to the DEA for checking for abuse patterns in the data

21. The method of claim 19 wherein the sensitive drug is a scheduled drug in Schedule II-V.

22. A method of distributing a sensitive drug, the method comprising:

determining current and anticipated patterns of potential abuse of the sensitive drug;

selecting multiple controls for distribution of the sensitive drug; and

adding additional controls to provide sufficient reassurance to a governmental regulatory body that the sensitive drug distribution can be adequately controlled in order to obtain marketing approval by the governmental regulatory body.

23. The method of claim 22 wherein the system allows marketing of a drug product pursuant to FDA subpart 4 regulation embodied in Title 21, CFR Part 314.

24. The method of claim 22 wherein distribution of the sensitive drug is controlled by a central distribution center sufficient to allow the DEA (Drug Enforcement Agency) to approve the central distribution center.

25. The method of claim 22 wherein the governmental regulatory body comprises a state regulatory agency that approves distribution of the sensitive drug in a state.

Abstract of the Disclosure

A drug distribution system and method utilizes a central pharmacy and database to track all prescriptions for a sensitive drug. Information is kept in the database regarding all physicians allowed to prescribe the sensitive drug, and all patients receiving the drug. Abuses are identified by monitoring data in the database for prescription patterns by physicians and prescriptions obtained by patients. Further verification is made that the physician is eligible to prescribe the drug by consulting a separate database, and optionally whether any actions are taken against the physician. Multiple controls beyond those for normal drugs are imposed on the distribution depending on the sensitivity of the drug.

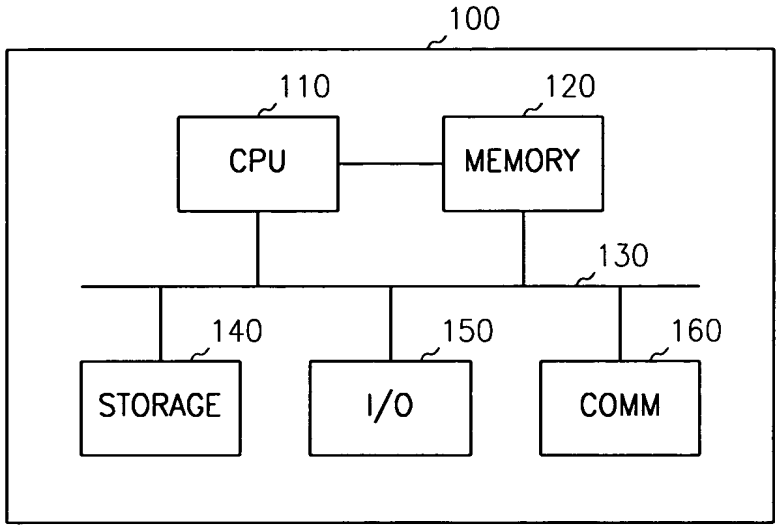


FIG. 1

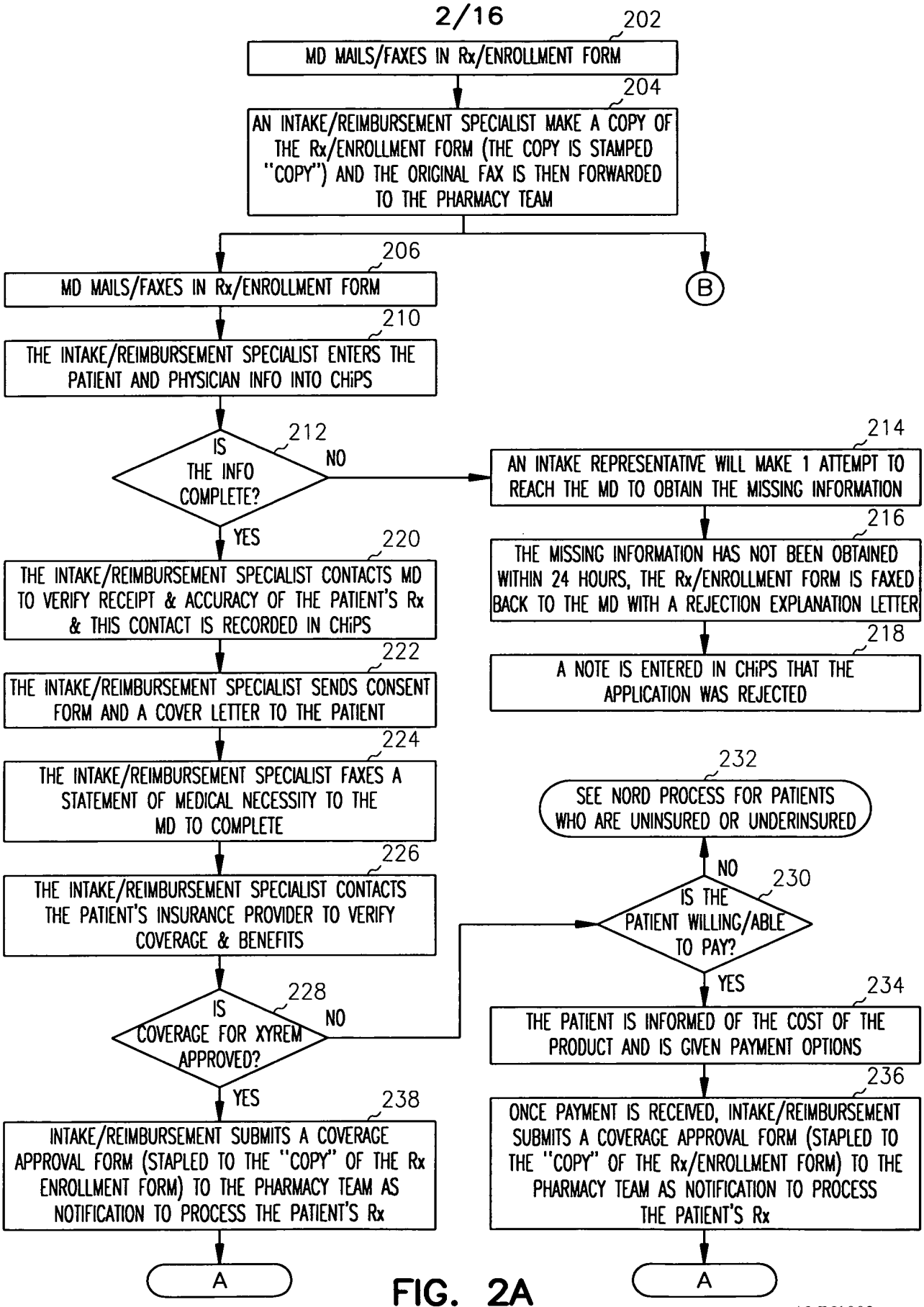

202
MD MAILS/FAXES IN Rx/ENROLLMENT FORM
204
AN INTAKE/REIMBURSEMENT SPECIALIST MAKE A COPY OF THE Rx/ENROLLMENT FORM (THE COPY IS STAMPED "COPY") AND THE ORIGINAL FAX IS THEN FORWARDED TO THE PHARMACY TEAM
206
MD MAILS/FAXES IN Rx/ENROLLMENT FORM
B
210
THE INTAKE/REIMBURSEMENT SPECIALIST ENTERS THE PATIENT AND PHYSICIAN INFO INTO CHiPS
212
IS THE INFO COMPLETE?
NO
214
AN INTAKE REPRESENTATIVE WILL MAKE 1 ATTEMPT TO REACH THE MD TO OBTAIN THE MISSING INFORMATION
216
THE MISSING INFORMATION HAS NOT BEEN OBTAINED WITHIN 24 HOURS, THE Rx/ENROLLMENT FORM IS FAXED BACK TO THE MD WITH A REJECTION EXPLANATION LETTER
218
A NOTE IS ENTERED IN CHiPS THAT THE APPLICATION WAS REJECTED
YES
220
THE INTAKE/REIMBURSEMENT SPECIALIST CONTACTS MD TO VERIFY RECEIPT & ACCURACY OF THE PATIENT'S Rx & THIS CONTACT IS RECORDED IN CHiPS
222
THE INTAKE/REIMBURSEMENT SPECIALIST SENDS CONSENT FORM AND A COVER LETTER TO THE PATIENT
224
THE INTAKE/REIMBURSEMENT SPECIALIST FAXES A STATEMENT OF MEDICAL NECESSITY TO THE MD TO COMPLETE
226
THE INTAKE/REIMBURSEMENT SPECIALIST CONTACTS THE PATIENT'S INSURANCE PROVIDER TO VERIFY COVERAGE & BENEFITS
228
IS COVERAGE FOR XYREM APPROVED?
NO
232
SEE NORD PROCESS FOR PATIENTS WHO ARE UNINSURED OR UNDERINSURED
NO
230
IS THE PATIENT WILLING/ABLE TO PAY?
YES
234
THE PATIENT IS INFORMED OF THE COST OF THE PRODUCT AND IS GIVEN PAYMENT OPTIONS
236
ONCE PAYMENT IS RECEIVED, INTAKE/REIMBURSEMENT SUBMITS A COVERAGE APPROVAL FORM (STAPLED TO THE "COPY" OF THE Rx/ENROLLMENT FORM) TO THE PHARMACY TEAM AS NOTIFICATION TO PROCESS THE PATIENT'S Rx
YES
238
INTAKE/REIMBURSEMENT SUBMITS A COVERAGE APPROVAL FORM (STAPLED TO THE "COPY" OF THE Rx ENROLLMENT FORM) TO THE PHARMACY TEAM AS NOTIFICATION TO PROCESS THE PATIENT'S Rx
A
A

FIG. 2A

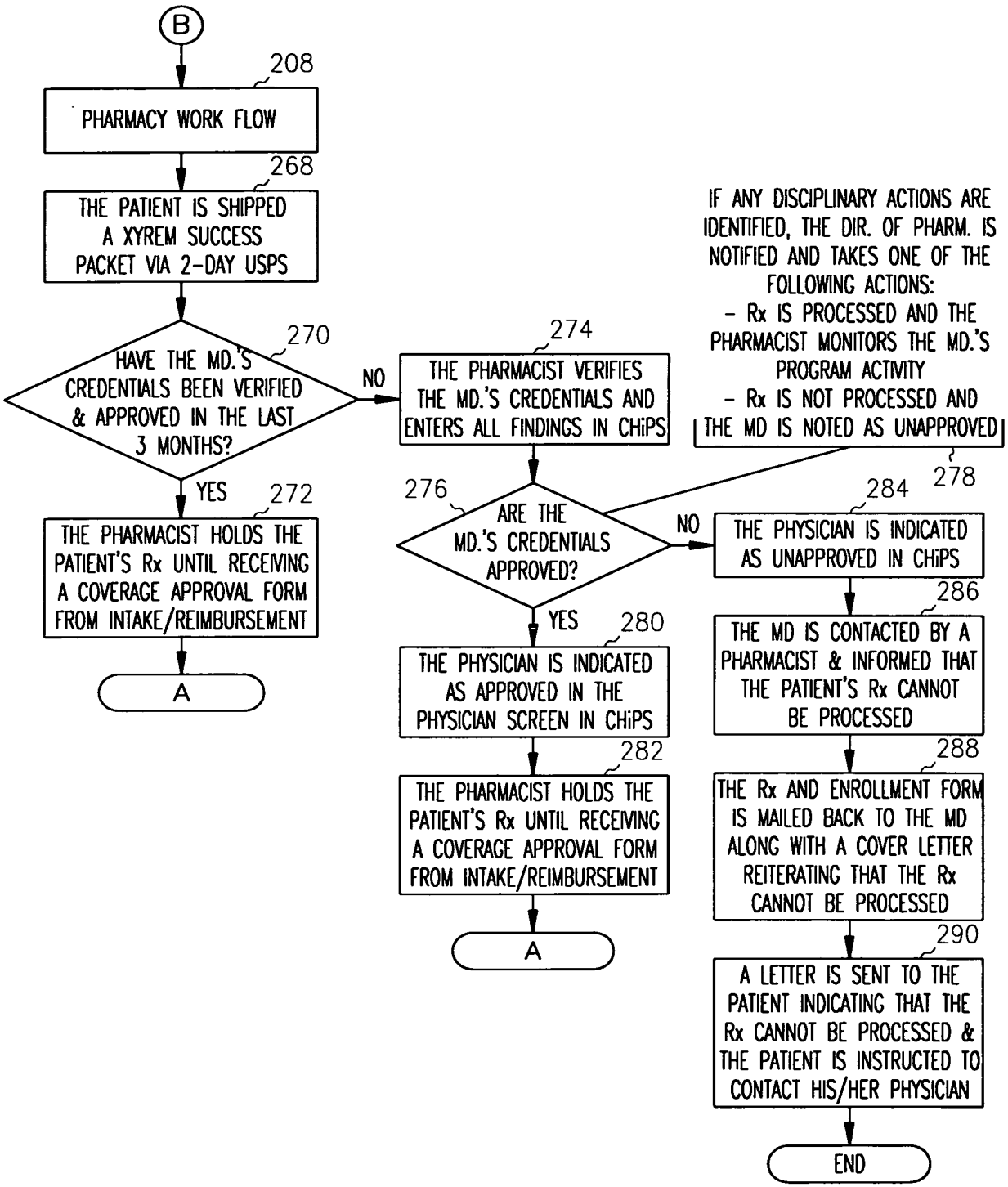

B
208
PHARMACY WORK FLOW
268
THE PATIENT IS SHIPPED A XYREM SUCCESS PACKET VIA 2-DAY USPS
270
HAVE THE MD.'S CREDENTIALS BEEN VERIFIED & APPROVED IN THE LAST 3 MONTHS?
NO
YES
272
THE PHARMACIST HOLDS THE PATIENT'S Rx UNTIL RECEIVING A COVERAGE APPROVAL FORM FROM INTAKE/REIMBURSEMENT
A
274
THE PHARMACIST VERIFIES THE MD.'S CREDENTIALS AND ENTERS ALL FINDINGS IN CHiPS
276
ARE THE MD.'S CREDENTIALS APPROVED?
NO
YES
280
THE PHYSICIAN IS INDICATED AS APPROVED IN THE PHYSICIAN SCREEN IN CHiPS
282
THE PHARMACIST HOLDS THE PATIENT'S Rx UNTIL RECEIVING A COVERAGE APPROVAL FORM FROM INTAKE/REIMBURSEMENT
A
IF ANY DISCIPLINARY ACTIONS ARE IDENTIFIED, THE DIR. OF PHARM. IS NOTIFIED AND TAKES ONE OF THE FOLLOWING ACTIONS:
- Rx IS PROCESSED AND THE PHARMACIST MONITORS THE MD.'S PROGRAM ACTIVITY
- Rx IS NOT PROCESSED AND THE MD IS NOTED AS UNAPPROVED
278
284
THE PHYSICIAN IS INDICATED AS UNAPPROVED IN CHiPS
286
THE MD IS CONTACTED BY A PHARMACIST & INFORMED THAT THE PATIENT'S Rx CANNOT BE PROCESSED
288
THE Rx AND ENROLLMENT FORM IS MAILED BACK TO THE MD ALONG WITH A COVER LETTER REITERATING THAT THE Rx CANNOT BE PROCESSED
290
A LETTER IS SENT TO THE PATIENT INDICATING THAT THE Rx CANNOT BE PROCESSED & THE PATIENT IS INSTRUCTED TO CONTACT HIS/HER PHYSICIAN
END

FIG. 2B

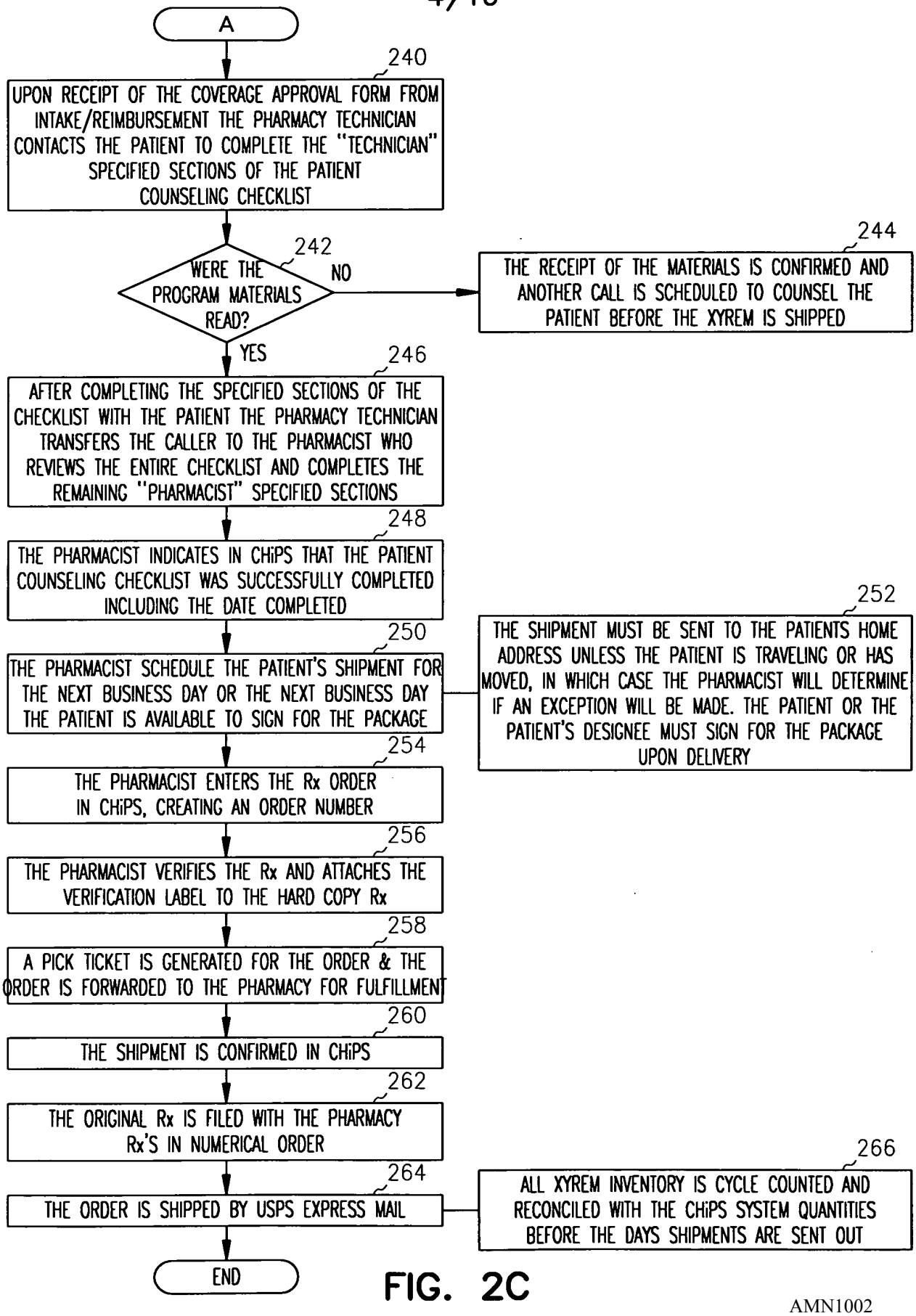

A
240
UPON RECEIPT OF THE COVERAGE APPROVAL FORM FROM INTAKE/REIMBURSEMENT THE PHARMACY TECHNICIAN CONTACTS THE PATIENT TO COMPLETE THE "TECHNICIAN" SPECIFIED SECTIONS OF THE PATIENT COUNSELING CHECKLIST
242
WERE THE PROGRAM MATERIALS READ?
NO
244
THE RECEIPT OF THE MATERIALS IS CONFIRMED AND ANOTHER CALL IS SCHEDULED TO COUNSEL THE PATIENT BEFORE THE XYREM IS SHIPPED
YES
246
AFTER COMPLETING THE SPECIFIED SECTIONS OF THE CHECKLIST WITH THE PATIENT THE PHARMACY TECHNICIAN TRANSFERS THE CALLER TO THE PHARMACIST WHO REVIEWS THE ENTIRE CHECKLIST AND COMPLETES THE REMAINING "PHARMACIST" SPECIFIED SECTIONS
248
THE PHARMACIST INDICATES IN CHiPS THAT THE PATIENT COUNSELING CHECKLIST WAS SUCCESSFULLY COMPLETED INCLUDING THE DATE COMPLETED
252
THE SHIPMENT MUST BE SENT TO THE PATIENTS HOME ADDRESS UNLESS THE PATIENT IS TRAVELING OR HAS MOVED, IN WHICH CASE THE PHARMACIST WILL DETERMINE IF AN EXCEPTION WILL BE MADE. THE PATIENT OR THE PATIENT'S DESIGNEE MUST SIGN FOR THE PACKAGE UPON DELIVERY
250
THE PHARMACIST SCHEDULE THE PATIENT'S SHIPMENT FOR THE NEXT BUSINESS DAY OR THE NEXT BUSINESS DAY THE PATIENT IS AVAILABLE TO SIGN FOR THE PACKAGE
254
THE PHARMACIST ENTERS THE Rx ORDER IN CHiPS, CREATING AN ORDER NUMBER
256
THE PHARMACIST VERIFIES THE Rx AND ATTACHES THE VERIFICATION LABEL TO THE HARD COPY Rx
258
A PICK TICKET IS GENERATED FOR THE ORDER & THE ORDER IS FORWARDED TO THE PHARMACY FOR FULFILLMENT
260
THE SHIPMENT IS CONFIRMED IN CHiPS
262
THE ORIGINAL Rx IS FILED WITH THE PHARMACY Rx'S IN NUMERICAL ORDER
266
ALL XYREM INVENTORY IS CYCLE COUNTED AND RECONCILED WITH THE CHiPS SYSTEM QUANTITIES BEFORE THE DAYS SHIPMENTS ARE SENT OUT
264
THE ORDER IS SHIPPED BY USPS EXPRESS MAIL
END

FIG. 2C

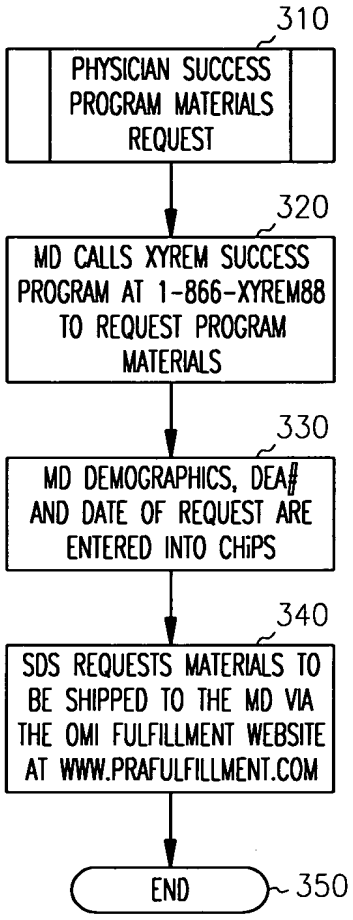

310
PHYSICIAN SUCCESS PROGRAM MATERIALS REQUEST
320
MD CALLS XYREM SUCCESS PROGRAM AT 1-866-XYREM88 TO REQUEST PROGRAM MATERIALS
330
MD DEMOGRAPHICS, DEA# AND DATE OF REQUEST ARE ENTERED INTO CHIPS
340
SDS REQUESTS MATERIALS TO BE SHIPPED TO THE MD VIA THE OMI FULFILLMENT WEBSITE AT WWW.PRAFULFILLMENT.COM
END
350

FIG. 3

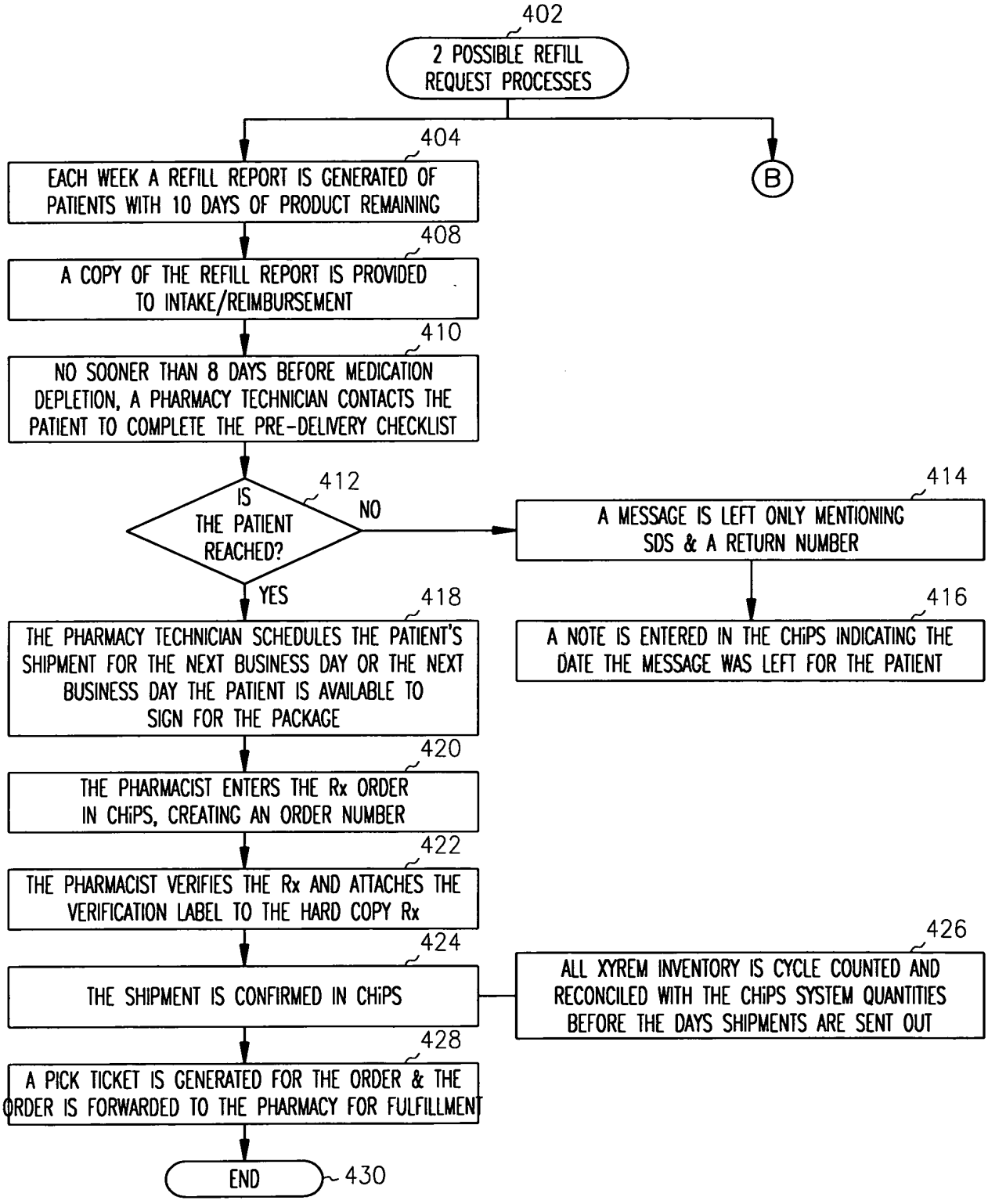

402
2 POSSIBLE REFILL REQUEST PROCESSES
404
EACH WEEK A REFILL REPORT IS GENERATED OF PATIENTS WITH 10 DAYS OF PRODUCT REMAINING
B
408
A COPY OF THE REFILL REPORT IS PROVIDED TO INTAKE/REIMBURSEMENT
410
NO SOONER THAN 8 DAYS BEFORE MEDICATION DEPLETION, A PHARMACY TECHNICIAN CONTACTS THE PATIENT TO COMPLETE THE PRE-DELIVERY CHECKLIST
412
IS THE PATIENT REACHED?
NO
414
A MESSAGE IS LEFT ONLY MENTIONING SDS & A RETURN NUMBER
416
A NOTE IS ENTERED IN THE CHiPS INDICATING THE DATE THE MESSAGE WAS LEFT FOR THE PATIENT
YES
418
THE PHARMACY TECHNICIAN SCHEDULES THE PATIENT'S SHIPMENT FOR THE NEXT BUSINESS DAY OR THE NEXT BUSINESS DAY THE PATIENT IS AVAILABLE TO SIGN FOR THE PACKAGE
420
THE PHARMACIST ENTERS THE Rx ORDER IN CHiPS, CREATING AN ORDER NUMBER
422
THE PHARMACIST VERIFIES THE Rx AND ATTACHES THE VERIFICATION LABEL TO THE HARD COPY Rx
424
THE SHIPMENT IS CONFIRMED IN CHiPS
426
ALL XYREM INVENTORY IS CYCLE COUNTED AND RECONCILED WITH THE CHiPS SYSTEM QUANTITIES BEFORE THE DAYS SHIPMENTS ARE SENT OUT
428
A PICK TICKET IS GENERATED FOR THE ORDER & THE ORDER IS FORWARDED TO THE PHARMACY FOR FULFILLMENT
END
430

FIG. 4A

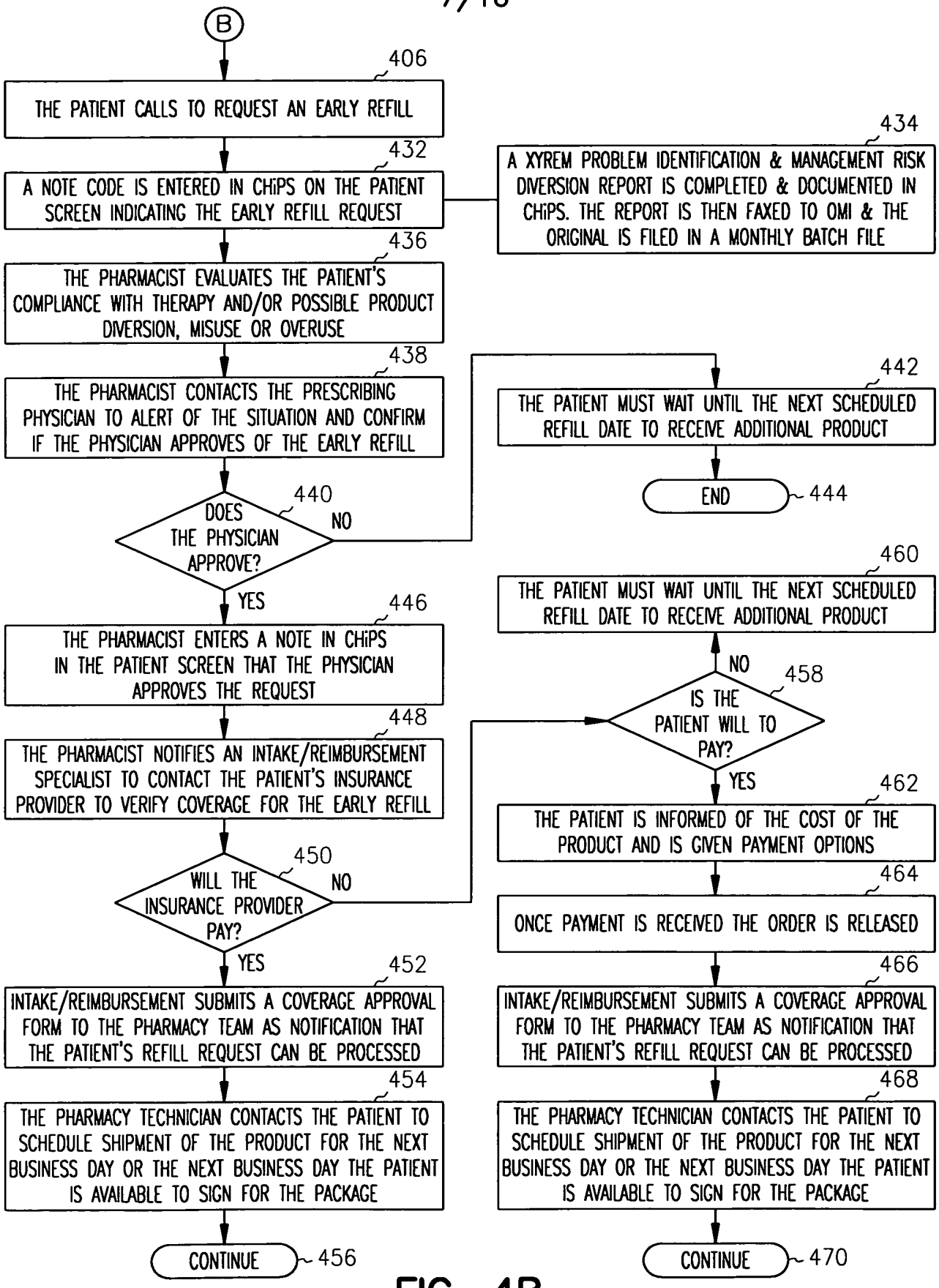

B
406
THE PATIENT CALLS TO REQUEST AN EARLY REFILL
432
A NOTE CODE IS ENTERED IN CHiPS ON THE PATIENT SCREEN INDICATING THE EARLY REFILL REQUEST
434
A XYREM PROBLEM IDENTIFICATION & MANAGEMENT RISK DIVERSION REPORT IS COMPLETED & DOCUMENTED IN CHiPS. THE REPORT IS THEN FAXED TO OMI & THE ORIGINAL IS FILED IN A MONTHLY BATCH FILE
436
THE PHARMACIST EVALUATES THE PATIENT'S COMPLIANCE WITH THERAPY AND/OR POSSIBLE PRODUCT DIVERSION, MISUSE OR OVERUSE
438
THE PHARMACIST CONTACTS THE PRESCRIBING PHYSICIAN TO ALERT OF THE SITUATION AND CONFIRM IF THE PHYSICIAN APPROVES OF THE EARLY REFILL
440
DOES THE PHYSICIAN APPROVE?
NO
442
THE PATIENT MUST WAIT UNTIL THE NEXT SCHEDULED REFILL DATE TO RECEIVE ADDITIONAL PRODUCT
END
444
YES
446
THE PHARMACIST ENTERS A NOTE IN CHiPS IN THE PATIENT SCREEN THAT THE PHYSICIAN APPROVES THE REQUEST
448
THE PHARMACIST NOTIFIES AN INTAKE/REIMBURSEMENT SPECIALIST TO CONTACT THE PATIENT'S INSURANCE PROVIDER TO VERIFY COVERAGE FOR THE EARLY REFILL
450
WILL THE INSURANCE PROVIDER PAY?
NO
YES
452
INTAKE/REIMBURSEMENT SUBMITS A COVERAGE APPROVAL FORM TO THE PHARMACY TEAM AS NOTIFICATION THAT THE PATIENT'S REFILL REQUEST CAN BE PROCESSED
454
THE PHARMACY TECHNICIAN CONTACTS THE PATIENT TO SCHEDULE SHIPMENT OF THE PRODUCT FOR THE NEXT BUSINESS DAY OR THE NEXT BUSINESS DAY THE PATIENT IS AVAILABLE TO SIGN FOR THE PACKAGE
CONTINUE
456
460
THE PATIENT MUST WAIT UNTIL THE NEXT SCHEDULED REFILL DATE TO RECEIVE ADDITIONAL PRODUCT
NO
458
IS THE PATIENT WILL TO PAY?
YES
462
THE PATIENT IS INFORMED OF THE COST OF THE PRODUCT AND IS GIVEN PAYMENT OPTIONS
464
ONCE PAYMENT IS RECEIVED THE ORDER IS RELEASED
466
INTAKE/REIMBURSEMENT SUBMITS A COVERAGE APPROVAL FORM TO THE PHARMACY TEAM AS NOTIFICATION THAT THE PATIENT'S REFILL REQUEST CAN BE PROCESSED
468
THE PHARMACY TECHNICIAN CONTACTS THE PATIENT TO SCHEDULE SHIPMENT OF THE PRODUCT FOR THE NEXT BUSINESS DAY OR THE NEXT BUSINESS DAY THE PATIENT IS AVAILABLE TO SIGN FOR THE PACKAGE
CONTINUE
470

FIG. 4B

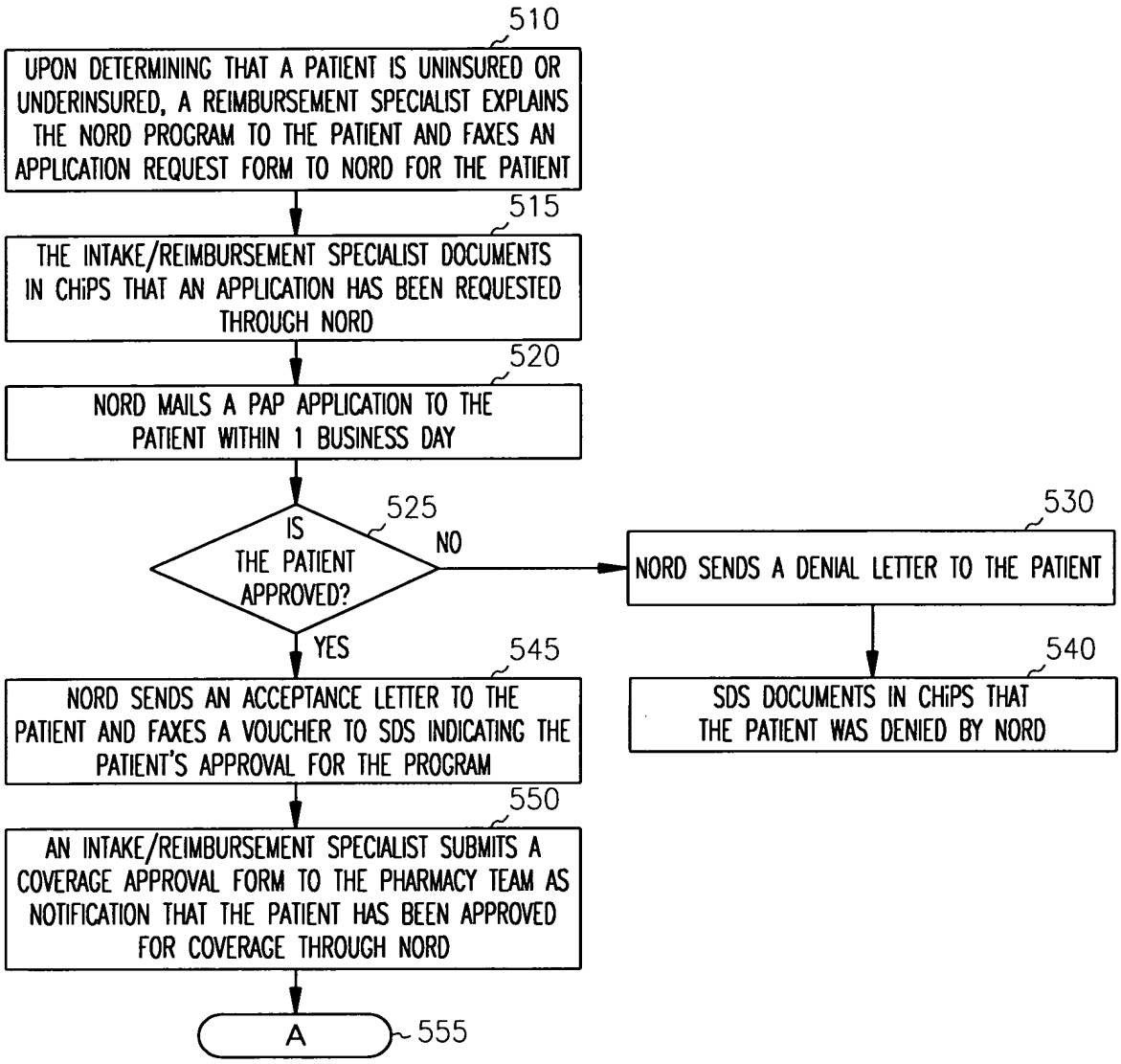

510
UPON DETERMINING THAT A PATIENT IS UNINSURED OR UNDERINSURED, A REIMBURSEMENT SPECIALIST EXPLAINS THE NORD PROGRAM TO THE PATIENT AND FAXES AN APPLICATION REQUEST FORM TO NORD FOR THE PATIENT
515
THE INTAKE/REIMBURSEMENT SPECIALIST DOCUMENTS IN CHiPS THAT AN APPLICATION HAS BEEN REQUESTED THROUGH NORD
520
NORD MAILS A PAP APPLICATION TO THE PATIENT WITHIN 1 BUSINESS DAY
525
IS THE PATIENT APPROVED?
NO
530
NORD SENDS A DENIAL LETTER TO THE PATIENT
540
SDS DOCUMENTS IN CHiPS THAT THE PATIENT WAS DENIED BY NORD
YES
545
NORD SENDS AN ACCEPTANCE LETTER TO THE PATIENT AND FAXES A VOUCHER TO SDS INDICATING THE PATIENT'S APPROVAL FOR THE PROGRAM
550
AN INTAKE/REIMBURSEMENT SPECIALIST SUBMITS A COVERAGE APPROVAL FORM TO THE PHARMACY TEAM AS NOTIFICATION THAT THE PATIENT HAS BEEN APPROVED FOR COVERAGE THROUGH NORD
A
555

FIG. 5

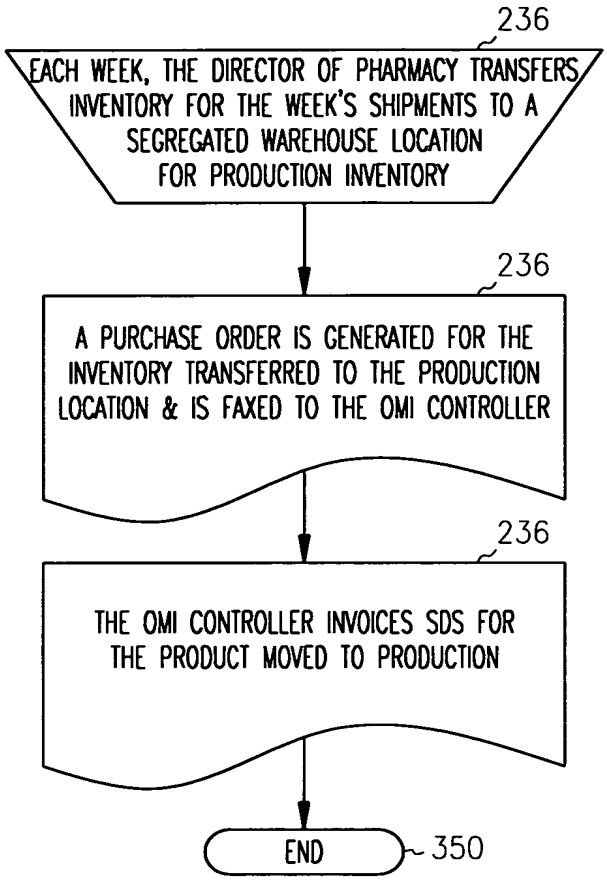


FIG. 6

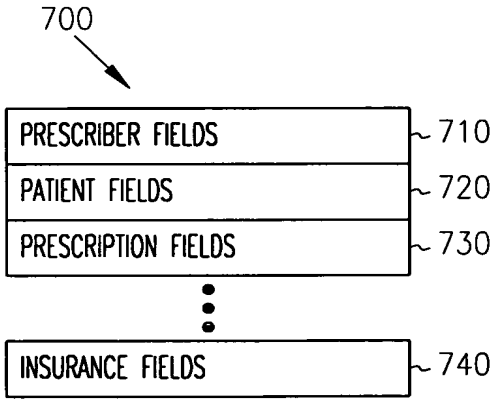


FIG. 7

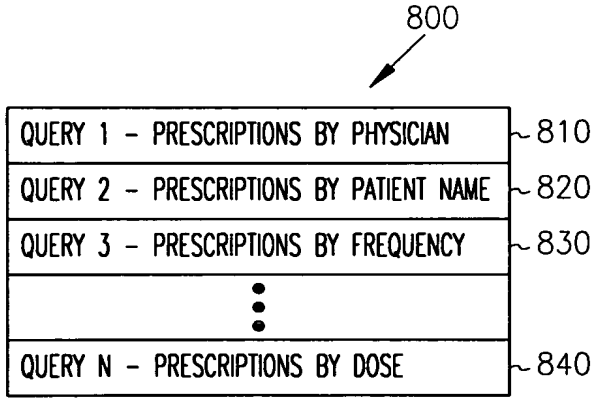


FIG. 8

900

PRESCRIPTION AND ENROLLMENT FORM

PRESCRIBER INFORMATION

PRESCRIBER'S NAME: _____ OFFICE CONTACT: _____
STREET ADDRESS: _____
CITY: _____ STATE: _____ ZIP: _____
PHONE: _____ FAX: _____
LICENSE NUMBER: _____ DEA NUMBER: _____
MD SPECIALTY: _____

PRESCRIPTION FORM

PATIENT NAME: _____ SS#: _____ DOB: _____ SEX M / F
ADDRESS: _____
CITY: _____ STATE: _____ ZIP: _____
Rx: XYREM ORAL SOLUTION (500 mg/mL) 180 Ml. BOTTLE QUANTITY: _____ MONTHS SUPPLY
SIG: TAKE _____ GMS P.O. DILUTED IN 60 mL WATER AT H.S. AND THEN AGAIN 2 1/2 TO 4 HOURS LATER
REFILLS (CIRCLE ONE): 0 1 2 (MAXIMUM OF 3 MONTH SUPPLY)
_____ DATE: _____/_____/_____
PRESCRIBER'S SIGNATURE

PHYSICIAN DECLARATION-PLEASE CHECK EACH BOX | TO BE COMPLETED AT INITIAL PRESCRIPTION ONLY

☐ I HAVE READ THE MATERIALS IN THE XYREM PHYSICIAN SUCCESS PROGRAM
☐ I VERIFY THAT THE PATIENT HAS BEEN EDUCATED WITH RESPECT TO XYREM PREPARATION, DOSING AND SCHEDULING.
☐ I UNDERSTAND THAT XYREM IS APPROVED FOR THE TREATMENT OF CATAPLEXY IN PATIENTS WITH NARCOLEPSY, AND THAT SAFETY OR EFFICACY HAS NOT BEEN ESTABLISHED FOR ANY OTHER INDICATION.
☐ I UNDERSTAND THAT THE SAFETY OF DOSES GREATER THAN 9gm/DAY HAS NOT BEEN ESTABLISHED

PATIENT INFORMATION

BEST TIME TO CONTACT PATIENT: ☐ DAY ☐ NIGHT
DAY #: _____ EVENING #: _____
INSURANCE COMPANY NAME: _____ PHONE #: _____
INSURED'S NAME: _____ RELATIONSHIP TO PATIENT: _____
IDENTIFICATION NUMBER: _____ POLICY/GROUP NUMBER: _____
PRESCRIPTION CARD: ☐ NO ☐ YES IF YES, CARRIER: _____ POLICY #: _____ GROUP: _____
PLEASE ATTACH COPIES OF PATIENT'S INSURANCE CARDS

FAX COMPLETED FORM TO XYREM SUCCESS PROGRAM (TOLL-FREE) 1-866-470-1744
FOR INFORMATION, CALL THE XYREM TEAM (TOLL FREE) AT 1-866-XYREM88 (1-866-997-3688)

FIG. 9

1000

PATIENT ASSISTANCE APPLICATION REQUEST FORM

DATE:

TO: PATIENT ASSISTANCE ORGANIZATION
FROM: SDS

FAX #: 203-798-2291

PLEASE SEND A XYREM PATIENT ASSISTANCE PROGRAM APPLICATION TO:

PATIENT NAME _____

ADDRESS _____

_____

_____

TELEPHONE: ( ) _____

PATIENT DOSAGE: _____ (GRAMS) TWICE NIGHTLY FOR A TOTAL DOSAGE OF _____ (GRAMS)

_____ BOTTLES (THREE MONTHS SUPPLY)

BACKGROUND INFORMATION:

_____

_____

_____

_____

_____

_____

FIG. 10

1100

SENSITIVE DRUG PATIENT ASSISTANCE PROGRAM

VOUCHER REQUEST FOR MEDICATION

PATIENT INFORMATION
<FIRST NAME><LAST NAME>
<ADDRESS 1>
<ADDRESS 2>
<CITY, STATE ZIP CODE>

PHONE: <123-456-7890
DOB: 01/01/1900
SSN: 123-45-6789
DRUG ALLOTMENT: 100%
LRD: 03/01/2001

PHYSICIAN INFORMATION
<PHYSICIAN NAME>
<ADDRESS 1>
<ADDRESS 2>
<CITY, STATE ZIP CODE>

PHONE: <123-456-7890

CASE CODE: ********

FIRST SHIPMENT THIS YEAR

DRUG	QUANTITY
XYREEM 180ml btl	1

VALIDATION DATE:	03/01/2001
EXPIRATION DATE:	05/31/2001
ISSUE DATE:	03/15/2001

APPROVED _____

PHARMACY USE

NORD COPY

****

(DETACH HERE)

PATIENT INFORMATION
<FIRST NAME><LAST NAME>
<ADDRESS 1>
<ADDRESS 2>
<CITY, STATE ZIP CODE>

PHONE: <123-456-7890
DOB: 01/01/1900
SSN: 123-45-6789
DRUG ALLOTMENT: 100%
LRD: 03/01/2001

PHYSICIAN INFORMATION
<PHYSICIAN NAME>
<ADDRESS 1>
<ADDRESS 2>
<CITY, STATE ZIP CODE>

PHONE: <123-456-7890

CASE CODE: ********

FIRST SHIPMENT THIS YEAR

DRUG	QUANTITY
XYREM 180ml btl	1

VALIDATION DATE:	03/01/2001
EXPIRATION DATE:	05/31/2001
ISSUE DATE:	03/15/2001

APPROVED _____

PHARMACY USE

FIG. 11

1200

SENSITIVE DRUG PHYSICIAN'S CERTIFICATE OF MEDICAL NEED

PATIENT INFORMATION

DATE: _____

NAME: _____
LAST FIRST M

DATE OF BIRTH: _____

DRUG BEING PRESCRIBED: XYREM

DIAGNOSIS/CONDITION FOR WHICH DRUG IS BEING PRESCRIBED: _____

ICD-9: _____

PHYSICIAN INFORMATION

PHYSICIAN'S NAME (PLEASE PRINT): _____

PHYSICIAN'S SIGNATURE: _____ DATE: _____

PLEASE FAX BACK TO SENSITIVE DRUG SUCCESS PROGRAM: (1-800-TOLL FREE NUMBER)

FIG. 12

ACTIVITY REPORTS

	REPORT FREQUENCY		
	WEEKLY	MONTHLY	QUARTERLY
SALES			
Rx BY ZIP (NEW AND TOTAL)	X	X	X
Rx BY PHYSICIAN BY ZIP	X	X	
$ BY ZIP	X	X	X
REGULATORY			
# OF PHYSICIAN REGISTRIES		X	
# OF DENIED PHYSICIAN REGISTRIES AND REASON		X	
# OF COMPLETED PATIENT REGISTRIES		X	
# OF PROBLEM IDENTIFICATION & MANAGEMENT RISK DIVERSION REPORTS COMPLETED	X		
# OF CYCLE COUNTS PERFORMED & ACCURACY OF EACH		X	
QUALITY ASSURANCE			
# OF PRODUCT DEFECTS/COMPLAINTS REPORTED, TYPE AND LOT #		X	
CALL CENTER			
# OF CALLS RECEIVED		X	
# OF CALLS INITIATED		X	
# OF CALLS ANSWERED IN 30 SECONDS, ETC.		X	
PERCENTAGE OF CALLS ANSWERED IN 30 SECONDS		X	
# OF ABANDONED CALLS		X	
% OF ABANDONED CALLS		X	
AVERAGE CALL LENGTH		X	
PHARMACY			
# OF FAXED Rx/ENROLLMENT FORMS		X	
# OF MAILED Rx/ENROLLEMENT FORMS		X	
# OF RxS SHIPPED W/IN 1, 2, 3, 4 ETC. DAYS (FROM THE TIME INITIAL RECEIPT TO SHIPMENT OF Rx)		X	
# OF PATIENT SUCCESS PACKETS SHIPPED		X	

FIG. 13A

ACTIVITY REPORTS

PHARMACY		X	
# OF PHYSICIAN SUCCESS PACKETS SHIPPED		X	
# OF COMPLETED SHIPMENTS		X	
# OF INCOMPLETE SHIPMENTS AND REASON		X	
# OF SHIPPING ERRORS		X	
# OF PAP SHIPMENTS		X	
# OF PAP APPLICATIONS		X	
# OF PAP APPROVALS		X	
# OF CANCELED ORDERS		X	
# OF USPS ERRORS		X	
INVENTORY		X	
# OF RETURNED PRODUCTS AND REASON		X	
# OF OUTDATED BOTTLES OF PRODUCT		X	
INVENTORY COUNTS OF CONSIGNMENT & PRODUCTION INVENTORY		X	
# OF UNITS RECEIVED		X	
LOTS RECEIVED		X	
REIMBURSEMENT		X	
# OF PENDED AND WHY		X	
# OF APPROVALS		X	
# OF DENIALS		X	
# OF REJECTIONS		X	
PAYOR TYPES		X	

FIG. 13B

ACTIVITY REPORTS

PATIENT CARE		X	
# OF ADVERSE EVENTS REPORTED AND TYPE		X	
# OF ADVERSE EVENTS SENT TO OMI		X	
# OF DOSING PROBLEMS AND TYPE		X	
# OF NONCOMPLIANCE EPISODES AND REASON		X	
# OF PATIENT COUNSELED AND REASON		X	
# OF PATIENTS DISCONTINUED AND REASON		X	
PATIENT CARE		X	
# OF PATIENTS REFERRED TO PHYSICIAN AND REASON		X	
# OF ACTIVE PATIENTS		X	
# OF NEW PATIENTS		X	
# OF RESTART PATIENTS		X	
# OF DISCONTINUED PATIENTS AND REASON		X	
DRUG INFORMATION		X	
# OF DRUG INFORMATION REQUESTS AND TYPE		X	
# OF CALLS TRIAGED TO OMI		X	

FIG. 13C

SCHWEGMAN ■ LUNDBERG ■ WOESSNER ■ KLUTH

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: **SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD**.

The specification of which was filed on December 17, 2002 as application serial no. 10/322,348.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 C.F.R. § 1.56 (attached hereto). I also acknowledge my duty to disclose all information known to be material to patentability which became available between a filing date of a prior application and the national or PCT international filing date in the event this is a Continuation-In-Part application in accordance with 37 C.F.R. § 1.63(e).

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

No such claim for priority is being made at this time.

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

No such claim for priority is being made at this time.

I hereby claim the benefit under 35 U.S.C. § 120 or 365(c) of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. § 1.56(a) which became available between the filing date of the prior application and the national or PCT international filing date of this application:

No such claim for priority is being made at this time.

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Anglin, J. M	Reg. No. 24,916	Harris, Robert J	Reg. No. 37,346	Nielsen, Walter W	Reg. No. 25,539
Arora, Suneel	Reg. No. 42,267	Jackson Huebsch, Katharine A	Reg. No. 47,670	Padys, Danny J	Reg. No. 35,635
Beekman, Marvin L	Reg. No. 38,377	Jurkovich, Patti J	Reg. No. 44,813	Parker, J. K	Reg. No. 33,024
Bianchi, Timothy E	Reg. No. 39,610	Kalis, Janal M	Reg. No. 37,650	Peacock, Gregg A	Reg. No. 45,001
Billion, Richard E	Reg. No. 32,836	Klima-Silberg, Catherine I	Reg. No. 40,052	Perdok, Monique M	Reg. No. 42,989
Black, David W	Reg. No. 42,331	Kluth, Daniel J	Reg. No. 32,146	Peret, Andrew R	Reg. No. 41,246
Brennan, Thomas F	Reg. No. 35,075	Lacy, Rodney L	Reg. No. 41,136	Peterson, David C	Reg. No. 47,857
Chadwick, Robin A	Reg. No. 36,477	Lemaire, Charles A	Reg. No. 36,198	Prout, William F	Reg. No. 33,995
Clark, Barbara J	Reg. No. 38,107	Lundberg, Steven W	Reg. No. 30,568	Puckett, Ph. D., Craig L	Reg. No. 43,023
Clise, Timothy B	Reg. No. 40,957	Maki, Peter C	Reg. No. 42,832	Schumm, Sherry W	Reg. No. 39,422
Cochran, David R	Reg. No. 46,632	Malen, Peter L	Reg. No. 44,894	Schwegman, Micheal L	Reg. No. 25,816
Dahl, John M	Reg. No. 44,639	Mates, Robert E	Reg. No. 35,271	Speier, Gary J	Reg. No. 45,458
Drake, Eduardo E	Reg. No. 40,594	McCrackin, Ann M	Reg. No. 42,858	Steffey, Charles E	Reg. No. 25,179
Embretson, Janet E	Reg. No. 39,665	McGough, Kevin J	Reg. No. 31,279	Stordal, Leif T	Reg. No. 46,251
Forrest, Bradley A	Reg. No. 30,837	McTavish, Hugh E	Reg. No. 48,341	Terry, Kathleen R	Reg. No. 31,884
Gorrie, Gregory J	Reg. No. 36,530	Mehrle, Joseph P	Reg. No. 45,535	Tong, Viet V	Reg. No. 45,416
Gortych, Joseph E	Reg. No. 41,791	Muller, Mark V	Reg. No. 37,509	Viksnins, Ann S	Reg. No. 37,748
Greaves, John N	Reg. No. 40,362	Nama, Prakash	Reg. No. 44,255	Woessner, Warren D	Reg. No. 30,440
Haack, John L	Reg. No. 36,154	Nelson, A. J	Reg. No. 28,650		

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/organization/who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Schwegman, Lundberg, Woessner & Kluth, P.A. to the contrary.

Please direct all correspondence in this case to **Schwegman, Lundberg, Woessner & Kluth, P.A.** at the address indicated below:

P.O. Box 2938, Minneapolis, MN 55402
Telephone No. (612)373-6900

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of joint inventor number 1 : **Dayton T. Reardan Ph.D.**
Citizenship: **United States of America** Residence: **Excelsior, MN**
Post Office Address: 22345 Bracketts Road
Excelsior, MN 55331

Signature: Dayton T. Reardan Date: April 3, 2003
Dayton T. Reardan Ph.D.

Full Name of joint inventor number 2 : **Patti ~~Engle~~ A. ENGEL**
Citizenship: **United States of America** Residence: **Eagan, MN**
Post Office Address: 852 Basswood Lane
Eagan, MN

Signature: Patti A. Engel Date: May 13, 2003
Patti ~~Engle~~
PATTI A. ENGEL

X Additional inventors are being named on separately numbered sheets, attached hereto.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of joint inventor number 3 : **Bob Gagne**
Citizenship: **United States of America** Residence: **St. Paul, MN**
Post Office Address: 202 So. Wheeler Street
St. Paul, MN 55015

Signature: Bob Gagne Date: 1 May 2003
Bob Gagne

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application:

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	Unknown	Group Art Unit:	Unknown
Filed:	Herewith	Docket No:	101.031US4
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

PRELIMINARY AMENDMENT

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

Prior to taking up this application for examination, please enter the following amendments:

IN THE SPECIFICATION

On page 1, line 4, please insert the following paragraph:

Related Application

This application is a divisional application of U.S. Patent Application Serial No.: 10/322,348, filed December 17, 2002, which application is incorporated herein by reference.

IN THE CLAIMS

Claims 1-25 (Cancelled)

26. (Previously presented) A method to control abuse of a sensitive drug by controlling the distribution thereof via an exclusive central pharmacy that maintains a central database that tracks all prescriptions of said sensitive drug and analyzes for potential abuse situations, the method comprising:

determining current and anticipated patterns of potential prescription abuse of said sensitive drug from periodic reports generated by the central database based on prescription request data from a medical doctor, wherein said request data contain information identifying the patient, the drug prescribed, and credentials of the doctor; and

selecting multiple controls for distribution by said exclusive central pharmacy, the controls selected from the group consisting of communicating prescriptions from a physician to the central pharmacy; identifying the physicians name, license, and DEA (Drug Enforcement Agency) registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive printed materials to the physician; contacting the patient's insurance company if any; verifying patient registry information; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address of the patient; shipping via US postal service or similar shipping service; receiving the name of an at least 18 year old designee to receive the drug; confirming receipt of an initial shipment of the drug to the patient returning the drug to the pharmacy after two attempts to deliver; launching an investigation when a shipment is lost; shipping to another pharmacy for delivery; requiring manufacture at a single location; releasing inventory in a controlled manner to the central pharmacy; questioning early refills; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; limiting the prescription to a one month supply; requiring rewriting of the prescription periodically; and making the database available to the DEA for checking for abuse

patterns in the data, for cash payments, and for inappropriate questions.

27. (Previously presented) The method of claim 26 wherein initially selected controls comprise

communicating prescriptions from a physician to the central pharmacy; identifying the physicians name, license, and DEA registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; verifying patient registry information; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address of the patient; shipping via US postal service; confirming receipt of an initial shipment of the drug to the patient; releasing inventory in a controlled manner to the central pharmacy; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; and making the database available to the DEA for checking for abuse patterns in the data.

28. (Previously presented) The method of claim 26 which further comprises consulting a separate database to verify that the medical doctor is eligible to prescribe the drug.

29. (Previously presented) A method to control abuse of gamma hydroxy butyrate (GHB) by controlling the distribution of GHB via an exclusive central pharmacy that maintains a central database that tracks all prescriptions of GHB and analyzes for potential abuse situations, the method comprising:

determining current and anticipated patterns of potential prescription abuse of GHB from periodic reports generated by the central database based on prescription request data from a medical doctor, wherein said request data contain information identifying the patient, GHB as the drug prescribed, and credentials of the doctor; and

selecting multiple controls for distribution by said exclusive central pharmacy, the controls selected from the group consisting of communicating prescriptions from a physician to

the central pharmacy; identifying the physicians name, license, and DEA (Drug Enforcement Agency) registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive printed materials to the physician; contacting the patient's insurance company if any; verifying patient registry information; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address of the patient; shipping via US postal service or similar shipping service; receiving the name of an at least 18 year old designee to receive the drug; confirming receipt of an initial shipment of the drug to the patient returning the drug to the pharmacy after two attempts to deliver; launching an investigation when a shipment is lost; shipping to another pharmacy for delivery; requiring manufacture at a single location; releasing inventory in a controlled manner to the central pharmacy; questioning early refills; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; limiting the prescription to a one month supply; requiring rewriting of the prescription periodically; and making the database available to the DEA for checking for abuse patterns in the data, for cash payments, and for inappropriate questions.

30. (Previously presented) The method of claim 29 wherein initially selected controls comprise

communicating prescriptions from a physician to the central pharmacy; identifying the physicians name, license, and DEA registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; verifying patient registry information; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address of the patient; shipping via US postal service; confirming receipt of an initial shipment of the drug to the patient; releasing inventory in a controlled manner to the central pharmacy; flagging repeat

instances of lost, stolen, destroyed, or spilled prescriptions; and making the database available to the DEA for checking for abuse patterns in the data.

31. (Previously presented) The method of claim 29 which further comprises consulting a separate database to verify that the medical doctor is eligible to prescribe the drug.

REMARKS

By this amendment, Applicants have cancelled claims 1-25. Claims 26-31 are now before the Examiner for examination.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' 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 4-1-2005 By _____
Bradley A. Forrest
Reg. No. 30,837

"Express Mail" mailing label number: EV 553 984 061 US
Date of Deposit: April 1, 2005
This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to The Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	Unknown	Group Art Unit:	Unknown
Filed:	Herewith	Docket:	101.031US4
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

INFORMATION DISCLOSURE STATEMENT

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

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

The attached documents were discovered as a result of a Search Report in Applicants' corresponding foreign patent application. Enclosed for the Examiner's information is a copy of the cited documents and the Search Report.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 19-0743 in order to have this Information Disclosure Statement considered.

Pursuant to 37 C.F.R. §1.98(d), copies of the listed documents are not provided as these references were previously cited by or submitted to the U.S. Patent Office in connection with Applicants' prior U.S. application, Serial No. 10/322348, filed on December 17, 2002, which is relied upon for an earlier filing date under 35 U.S.C. §120.

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Pursuant to 37 C.F.R. 1.98(a)(2), Applicant believes that copies of cited U.S. Patents and Published Applications are no longer required to be provided to the Office. Notification of this change was provided in the United States Patent and Trademark Office OG Notices dated October 12, 2004. Thus, Applicant has not included copies of any US Patents or Published Applications cited with this submission. Should the Office require copies to be provided, Applicant respectfully requests that notice of such requirement be directed to Applicant's below-signed representative. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

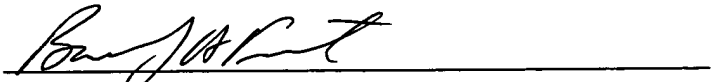
Respectfully submitted,

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 4-1-2005

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

"Express Mail" mailing label number: EV 553 984 061 US
Date of Deposit: April 1, 2005
This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to The Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & 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 contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	Unknown
Filing Date	Even Date Herewith
First Named Inventor	Reardan, Dayton
Group Art Unit	Unknown
Examiner Name	Unknown

Sheet 1 of 2

Attorney Docket No: 101.031US4

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Filing Date If Appropriate
	US-2001/ 0,001,144	05/10/2001	Kapp, Thomas L.	12/22/2000
	US-2001/ 0,042,050	11/15/2001	Fletcher, Robert J., et al.	01/05/2001
	US-2001/ 0,047,281	11/29/2001	Keresman, III, Michael A., et al.	03/06/2001
	US-2002/ 0,032,581	03/14/2002	Reitberg, donald P.	06/01/2001
	US-2002/ 0,032,582	03/14/2002	Feeney, Jr., Robert J., et al.	08/15/2001
	US-2002/ 0,042,725	04/11/2002	Mayaud, Christian	08/30/2001
	US-2002/ 0,042,762	04/11/2002	McQuade, Richard , et al.	08/30/2001
	US-2002/ 0,052,762	05/02/2002	Kobylevsky, Paul , et al.	05/15/2001
	US-2002/ 0,161,607	10/31/2002	Subich, David C.	02/23/2001
	US-2003/ 0,046,110	03/06/2003	Gogolak, Victor	08/28/2002
	US-2003/ 0,050,802	03/13/2003	Jay, Richard , et al.	04/03/2002
	US-2003/ 0,093,295	05/15/2003	Lilly, Ralph B., et al.	01/31/2002
	US-2003/ 0,110,060	06/12/2003	Clementi, William A.	12/12/2001
	US-2003/ 0,127,508	07/10/2003	Jones, William N.	01/21/2003
	US-2003/ 0,144,876	07/31/2003	Kosinski, Diana L., et al.	01/28/2002
	US-2003/ 0,229,519	12/11/2003	Eidex, Brian H., et al.	05/16/2003
	US-2003/ 0,233,256	12/18/2003	Cardenas, Rodolfo , et al.	06/13/2002
	US-2004/ 0,019,567	01/29/2004	Herceg, Michael J., et al.	07/23/2002
	US-2004/ 0,019,794	01/29/2004	Moradi, Ahmad , et al.	07/29/2002
	US-2004/ 0,078,237	04/22/2004	Kaafarani, William , et al.	08/28/2003

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	Unknown
Filing Date	Even Date Herewith
First Named Inventor	Reardan, Dayton
Group Art Unit	Unknown
Examiner Name	Unknown

Sheet 2 of 2

Attorney Docket No: 101.031US4

	US-2004/ 0,107,117	06/03/2004	Denny, Lawrence A.	11/25/2003
	US-2004/ 0,117,126	06/17/2004	Fetterman, Jeffrey E., et al.	11/25/2003
	US-2004/ 0,122,712	06/24/2004	Hill, Sr., Kenneth A., et al.	12/20/2002
	US-2004/ 0,122,713	06/24/2004	Hill, Sr., Kenneth A., et al.	12/20/2002
	US-2004/ 0,162,740	08/19/2004	Ericsson, Arthur D., et al.	02/14/2003
	US-2004/ 0,176,985	09/09/2004	Lilly, Ralph B., et al.	03/18/2004
	US-5,845,255	12/01/1998	Mayaud, C.	10/02/1997
	US-5,924,074	07/13/1999	Evans, Jae A.	09/27/1996
	US-6,021,392	02/01/2000	Lester, Douglas D., et al.	12/08/1997
	US-6,045,501	04/04/2000	Elsayed, Marc , et al.	08/28/1998
	US-6,055,507	04/25/2000	Cunningham, David W.	08/20/1998
	US-6,112,182	08/29/2000	Akers, William R., et al.	01/16/1996
	US-6,315,720	11/13/2001	Williams, Bruce A., et al.	10/23/2000
	US-6,347,329	02/12/2002	Evans, Jae A.	08/01/2000
	US-6,561,977	02/03/2004	Denny, Lawrence A.	05/29/2002
	US-6,755,784	06/29/2004	Williams, Bruce A., et al.	03/07/2003

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	T[2]

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		NASCSA National Conference, (November 2000),8 pages	
		"Diversion Prevention Through Responsible Distribution", NADDI Regional Training, (May 2001),12 pages	
		"Diversion Prevention Through Responsible Distribution", NADDI Regional Training Tennessee, (June 2001),14 Pages	
		"Diversion Prevention Through Responsible Distribution", NADDI National Conference, (November 2001),15 pages	
		"Peripheral and Central Nervous System Drugs Advisory Committee", Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research, Holiday Inn, Bethesda, Maryland,(06/06/2001),7 pages	

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Appendix I
Copies of Prior Art References

The fourteen (14) references include:

1. 5,845,255
2. 5,924,074
3. 6,347,329
4. 6,112,182
5. 6,315,720
6. 6,561,977
7. 6,755,784
8. 2001/0001144
9. 2002/0032581
10. 2002/0042725
11. 2003/0229519
12. 2004/0078237
13. 2004/0117126
14. 2004/0176985

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner: Unknown
Serial No.:	Unknown	Group Art Unit: Unknown
Filed:	Herewith	Docket: 101.031US4
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD	

PETITION TO MAKE SPECIAL UNDER 37 C.F.R. § 1.102(d)

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

Applicants hereby petition the Commissioner to advance the above-identified Application out of turn for accelerated examination under the provisions of 37 C.F.R. 1.102(d).

The Application meets the requirements of M.P.E.P. §708.02, section VIII. Please charge Deposit Account No. 19-0743 for the petition fee of $130.00 as set forth in § 1.17(i), which is required pursuant to 37 C.F.R. § 1.102(d). The Application is a new application, not yet having received any examination. Applicants believe that all of the claims are directed to a single invention; however, if the Office shall determine that they do not obviously encompass only a single invention, Applicants agree to make a telephone election without traverse. An enclosed Statement avers that a pre-examination search has been carried out, lists the field of the search, and discusses the relevant references, pointing out how the claimed subject matter is patentable over these references with the particularity required by 37 C.F.R. 1.111(b) and (c).

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

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Date 4-1-2005 By _____
Bradley A. Forrest
Reg. No. 30,837

"Express Mail" mailing label number: EV 553 984 061 US
Date of Deposit: April 1, 2005
This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to The Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PRE-EXAMINATION STATEMENT FOR PETITION TO MAKE SPECIAL UNDER 37 C.F.R. §1.102(d)

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

Dear Sir:

The undersigned Attorney for Applicant has caused a search to be made for the subject matter claimed in claims 26-31 of the above-identified Application.

The search was conducted in the USPTO classes/subclasses listed below:

Class	Subclasses	Description
700/		**DATA PROCESSING: GENERIC CONTROL SYSTEMS OR SPECIFIC APPLICATIONS**
	237	....Authorization (e.g., password, time usage limit, personal identification number (PIN)
705/		**DATA PROCESSING: FINANCIAL, BUSINESS PRACTICE, MANAGEMENT, OR COST/PRICE DETERMINATION**
	1	AUTOMATED ELECTRICAL FINANCIAL OR BUSINESS PRACTICE OR MANAGEMENT ARRANGEMENT
	2	. Health care management (e.g., record management, ICDA billing)
	3	.. Patient record management
707/		**DATA PROCESSING: DATABASE AND FILE MANAGEMENT OR DATA STRUCTURES**
	1	DATABASE OR FILE ACCESSING
	10	. Distributed or remote access
	104.1	. Application of database or data structure (e.g., distributed, multimedia, image)
709/		**ELECTRICAL COMPUTERS AND DIGITAL PROCESSING SYSTEMS: MULTICOMPUTER DATA TRANSFERRING OR PLURAL PROCESSOR SYNCHRONIZATION**
	200	MULTICOMPUTER DATA TRANSFERRING
	201	. Distributed data processing

217	. Remote data accessing
218	.. Using interconnected networks
219	.. Accessing a remote server

The references found to be relevant to claims 26-31 are listed on Form 1449 of the enclosed Information Disclosure Statement, and copies of each of these references are attached thereto. The following discussion sets forth with particularity the reasons why claims 26-31 are patentable over the relevant references.

In summary, the present claims relate to a new paradigm for controlling abuse by controlling distribution of a sensitive drug. Heretofore, sensitive drug access has been restricted via a computer readable storage medium containing information on the patient, the prescriber, and the pharmacy. The computer readable storage medium evaluates risk parameters and generates an approval code to the pharmacy after determining that the degree of risk of contraindications to the patient is acceptable.

The new distribution model of the present system and method permits analysis and control of abuse of the sensitive drug and control of adverse reactions to the sensitive drug. It further permits obtaining FDA approval for the sensitive drug. The new model employs a central pharmacy that relies upon imposition of controls for distribution of a sensitive drug after a central database has analyzed for potential abuse situations and/or current and anticipated patterns of potential adverse reactions to the drug.

Patent 5,845,255 and related published application 2002/0042725 A1 to Mayaud provide for a **PRESCRIPTION MANAGEMENT SYSTEM.** Disclosed is a remote source database that may provide prescription abuse monitoring parameters. Multiple physicians and/or pharmacists may have access to a patient's prescription history record so that when a patient presents a problem or condition to more than one physician, it may be known. The system also allows for access to comprehensive drug information including scientific literature.

The claims all recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by a central pharmacy. This feature is not disclosed in Mayaud.

Patents 5,924,074 and 6,347,329 B1 to Evans provide for an **ELECTRONIC MEDICAL RECORDS SYSTEM.** Disclosed is reference database **104**, which includes

diagnosis module **300**, medication manager **302**, and procedure module **304**. A healthcare provider may use the reference database for assistance in diagnosing a patient's disease and prescribing medications to treat the disease. Medication manager **302** provides information on medications, such as proper dosages, allergies, contraindications, adverse interactions, and side effects. This system also provides instant access to a patient's electronic record by any authorized healthcare provider from any geographical location.

The claims all recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by a central pharmacy. This feature is not disclosed in Evans.

Patent 6,112,182 to Akers et al. provides for a **METHOD AND APPARATUS FOR INTEGRATED MANAGEMENT OF PHARMACEUTICAL AND HEALTHCARE SERVICES.** Disclosed is a database for storing information on patients, doctors, drugs and prescriptions. Practice management system **102** checks for adverse interactions that the prescribed drug may have, and for possible adverse reactions of the patient to the drug due to allergies. The drug conflict information is maintained in conflict table **410**, and is displayed to the pharmacist. A prescription record is created and kept in the database for the practice management system **102** each time the drug is dispensed for reference.

The claims all recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by a central pharmacy. This feature is not disclosed in Akers et al.

Patents 6,315,720 B1, 6,561,977 B2, and 6,755,784 B2 to Williams et al. provide for **METHODS FOR DELIVERING A DRUG TO A PATIENT WHILE RESTRICTING ACCESS TO THE DRUG BY PATIENTS FOR WHOM THE DRUG MAY BE CONTRAINDICATED.** Disclosed is a computer readable storage medium in which the prescriber, pharmacy and patient may be registered. A storage medium is used to educate and reinforce the actions of patients who are taking a drug, as well as prescribers and pharmacies that distribute the drug. Based on information collected, patients are assigned to risk groups in order to limit unauthorized and inappropriate distribution of a drug.

The claims all recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by a central pharmacy. This feature is not disclosed in Williams

et al.

Published patent application 2001/0001144 A1 to Kapp provides for a **PHARMACY DRUG MANAGEMENT SYSTEM PROVIDING PATIENT SPECIFIC DRUG DOSING, DRUG INTERACTION ANALYSIS, ORDER GENERATION, AND PATIENT DATA MATCHING.** Disclosed is a pharmacy drug management system that includes drug interaction module **30**. Through the module, each drug to be prescribed will be examined for potential problems associated with other drugs and medical data of the patient such as the medical condition, allergy, and food of the patient. The module allows the input of medical history; allergies, diet, and prescribed drugs from all physicians being seen by the patient.

The claims all recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by a central pharmacy. This feature is not disclosed in Kapp.

Published patent application 2002/0032581 A1 to Reitberg provides **SINGLE-PATIENT DRUG TRIALS USED WITH ACCUMULATED DATABASE: RISK OF HABITUATION.** Disclosed is a method of predicting the abuse potential of a drug or substance when administered to an individual patient for chronic therapy or used habitually, and for gaining FDA approval and surveillance post-approval for new drugs which have been discovered for the treatment of chronic illnesses and conditions.

The claims all recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by a central pharmacy. This feature is not disclosed in Reitberg.

Published patent application 2003/0229519 A1 to Eidex et al. provides for **SYSTEMS AND METHODS FOR IDENTIFYING FRAUD AND ABUSE IN PRESCRIPTION CLAIMS.** Disclosed is a system for identifying fraudulent prescription claims. The system monitors prescription transactions and returns appropriate notification messages to pharmacists or other health care providers. Database **105** may store data relating to pharmacies, doctors, and consumers. This may include typical doses filled by consumers, the likelihood indicators of fraud and abuse screening processes, and reports relating to the results of fraud and abuse screening processes. An example of a method of preventing drug abuse is a comparison of the distance between the pharmacy and the patient with the statistical average distance that has been previously computed.

The claims all recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by a central pharmacy. This feature is not disclosed in Eidex et al.

Published patent application 2004/0078237 A1 to Kaafarani et al. provides for a **METHOD OF DISPENSING MEDICAL PRESCRIPTIONS.** Disclosed is a system which may protect against fraudulent or illegal re-use of a prescription. It includes steps of prompting the patient for personal information such as age, weight, telephone number, requested deliver time, and secret confirmation codes. Another method employs retaining a data slip with a mark of indelible ink or a patterned die cut.

The claims all recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by a central pharmacy. This feature is not disclosed in Kaafarani et al.

Published patent application 2004/0117126 A1 to Fetterman et al. provides a **METHOD OF ASSESSING AND MANAGING RISKS ASSOCIATED WITH A PHARMACEUTICAL PRODUCT.** Disclosed is method providing a continual and systematic assessment and management of the risks associated with the use of a pharmaceutical product as means for gaining regulatory approval and physician adoption. In addition, a hazard assessment is utilized for creating interventions to be utilized in mitigating the risk of the pharmaceutical product, whereby educational materials may be continually evaluated and revised to achieve an expected level of effectiveness on a target audience.

The claims all recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by a central pharmacy. This feature is not disclosed in Fetterman et al.

Published patent application 2004/0176985 A1 to Lilly et al. provides a **CONTROLLED SUBSTANCE TRACKING SYSTEM AND METHOD.** Disclosed is a method for tracking prescription medications, as means to address and control prescription drug abuse, whereby pharmaceutical information control organization **12** may be implemented as an independent information utility acting as a central service center for the management of prescriptive medication drugs.

The claims all recite a feature that embodies the new distribution model, namely the

distribution of a sensitive drug by an exclusive central pharmacy. This feature is not disclosed in Lilly et al.

Respectfully submitted,

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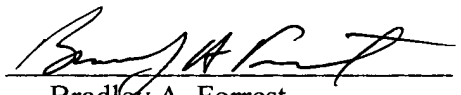
Date: 4-1-2005

By 
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PATENT APPLICATION FEE DETERMINATION RECORD

Effective December 8, 2004

11097985

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	6	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	6 minus 20=	*
INDEPENDENT CLAIMS	2 minus 3 =	*
MULTIPLE DEPENDENT CLAIM PRESENT		☐

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE		OR	BASIC FEE	
X$ 25=		OR	X$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL		OR	TOTAL	

CLAIMS AS AMENDED - PART II

AMENDMENT A	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 25=		OR	X$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 25=		OR	X$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 25=		OR	X$50=	
X100=		OR	X200=	
+180=		OR	+360=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. 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.

AMN1002
IPR of U.S. Patent No. 7,165,107