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Patent Application of: Dayton T. Reardan et al.
Title: **SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD**
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PATENT APPLICATION TRANSMITTAL

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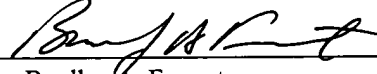
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- CONTINUATION** of prior Patent Application No. (10/322,348) (under 37 CFR 1.53(b)) comprising:
 - Specification (18 pgs, including claims numbered 1 through 25 and a 1 page Abstract).
 - Formal Drawing(s) (16 sheets).
 - Copy of signed Combined Declaration and Power of Attorney (4 pgs) from prior application.
 - 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.*
- Prior application is assigned of record to Orphan Medical, Inc.
- Pre-Examination Statement for Petition to Make Special Under 37 CFR 1.102(d) (6 pgs.).
- Petition to Make Special Under 37 CFR 1.102(d) (1 pg.)
- Appendix I (1 pg.).
- Preliminary Amendment (7pgs.).
- Information Disclosure Statement (2 pgs.); PTO 1449 (2 pgs.).
- Authorization to Charge Deposit Account No. 19-0743 in the amount of \$500.00 for the filing fee.
- Authorization to Charge Deposit Account No. 19-0743 in the amount of \$130.00 for the petition fee.

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Sensitive Drug Distribution System and Method

Field of the Invention

5 The present invention relates to distribution of drugs, and in particular to the distribution of sensitive drugs.

Background of the Invention

10 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.

15 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.

20 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.

25

Summary of the Invention

30 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.
- 5 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.
- 10 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.
- 15 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.
- 20 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
25 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
30 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.

5 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
10 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.

15 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
20 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,
25 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
30 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.

5 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
10 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
15 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.

20 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
25 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.

30 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.

5 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
10 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
15 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.

20 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
25 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
30 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
5 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.

10 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
15 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
20 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,
25 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.

30 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.

5 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.

10 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.

15

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 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

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
5 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
10 sensitivity of the drug.

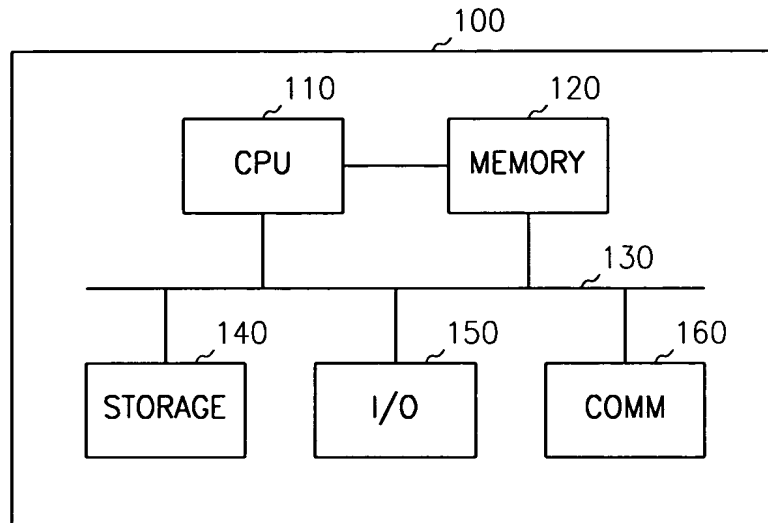


FIG. 1

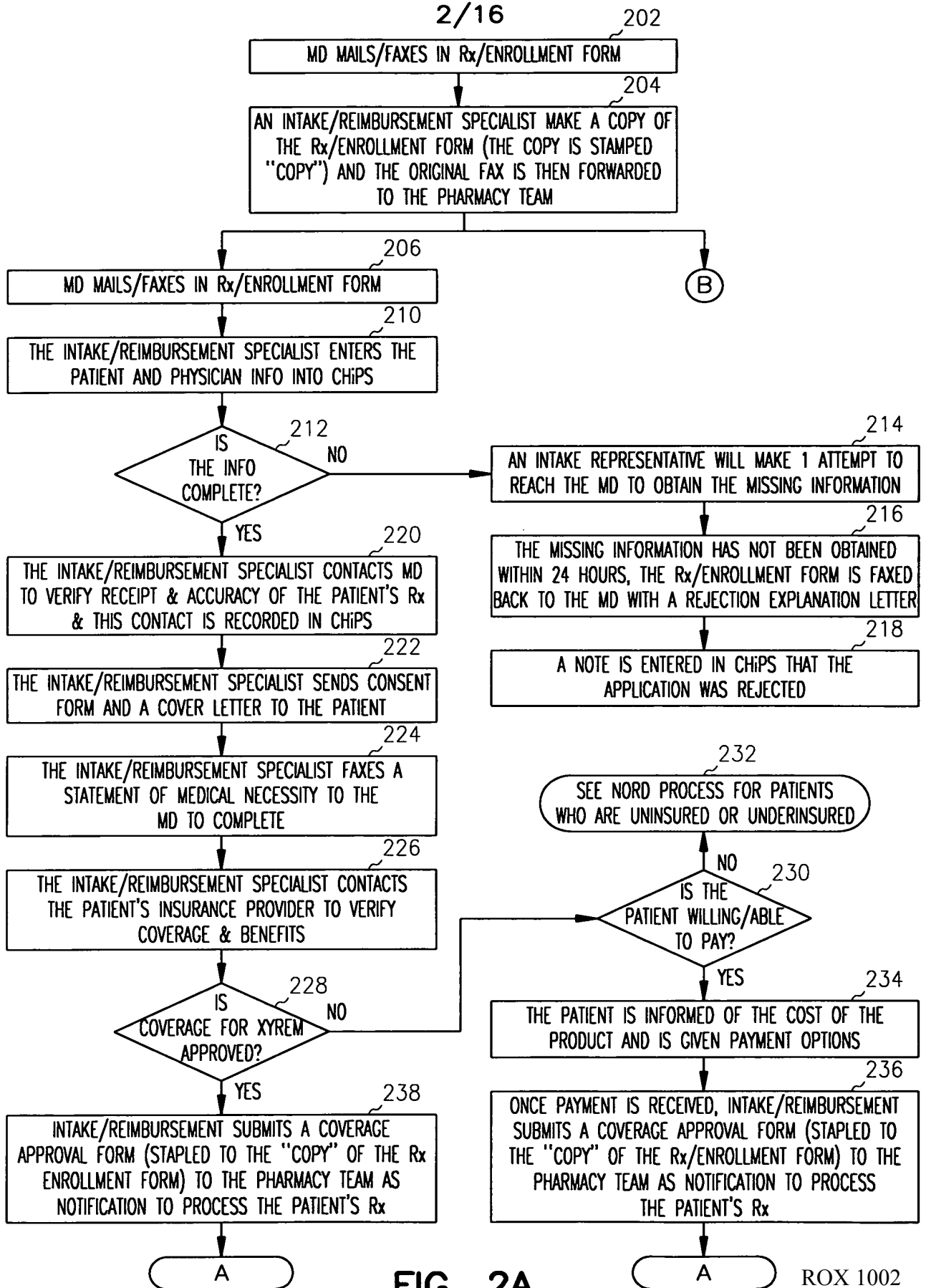


FIG. 2A

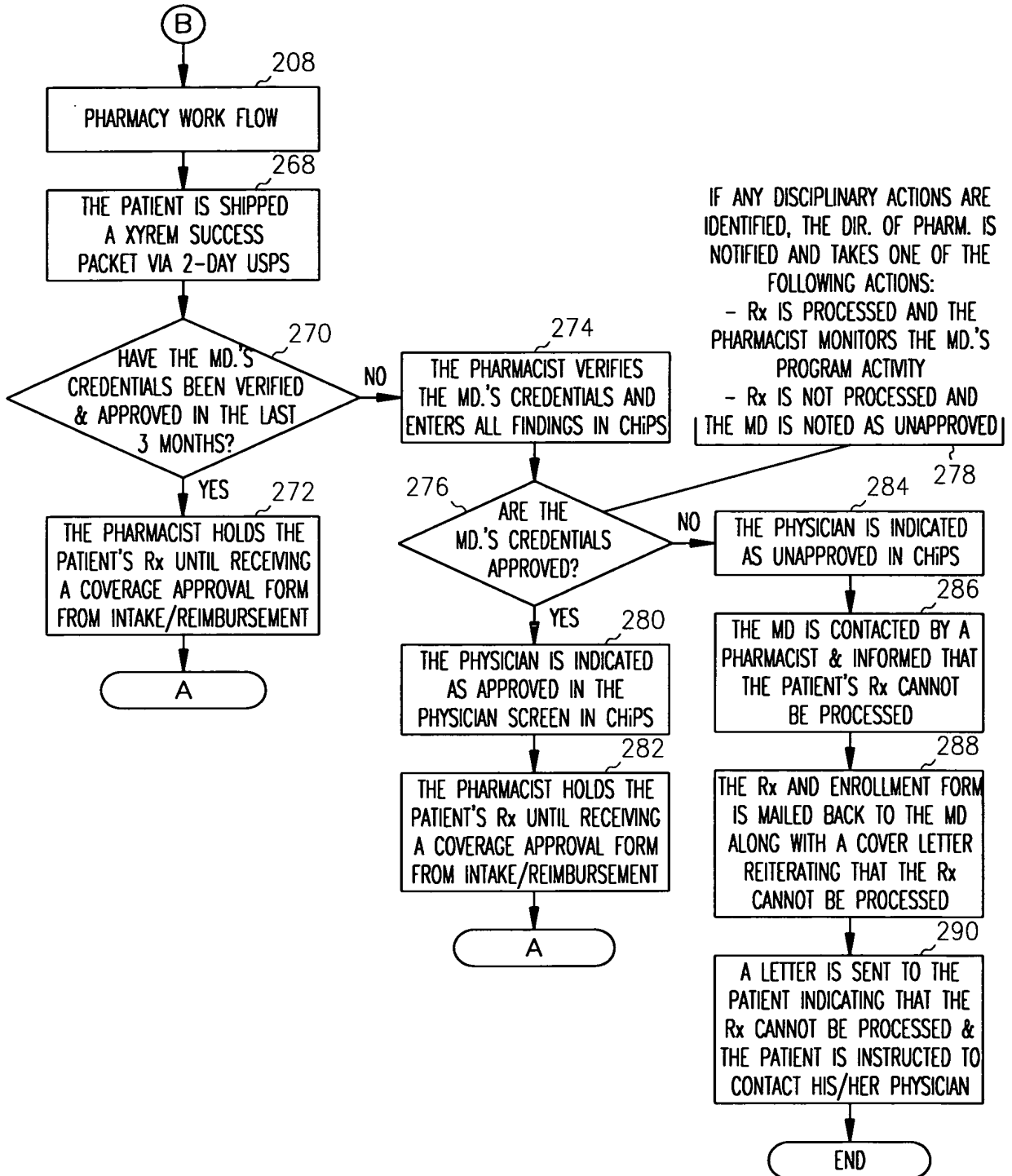


FIG. 2B

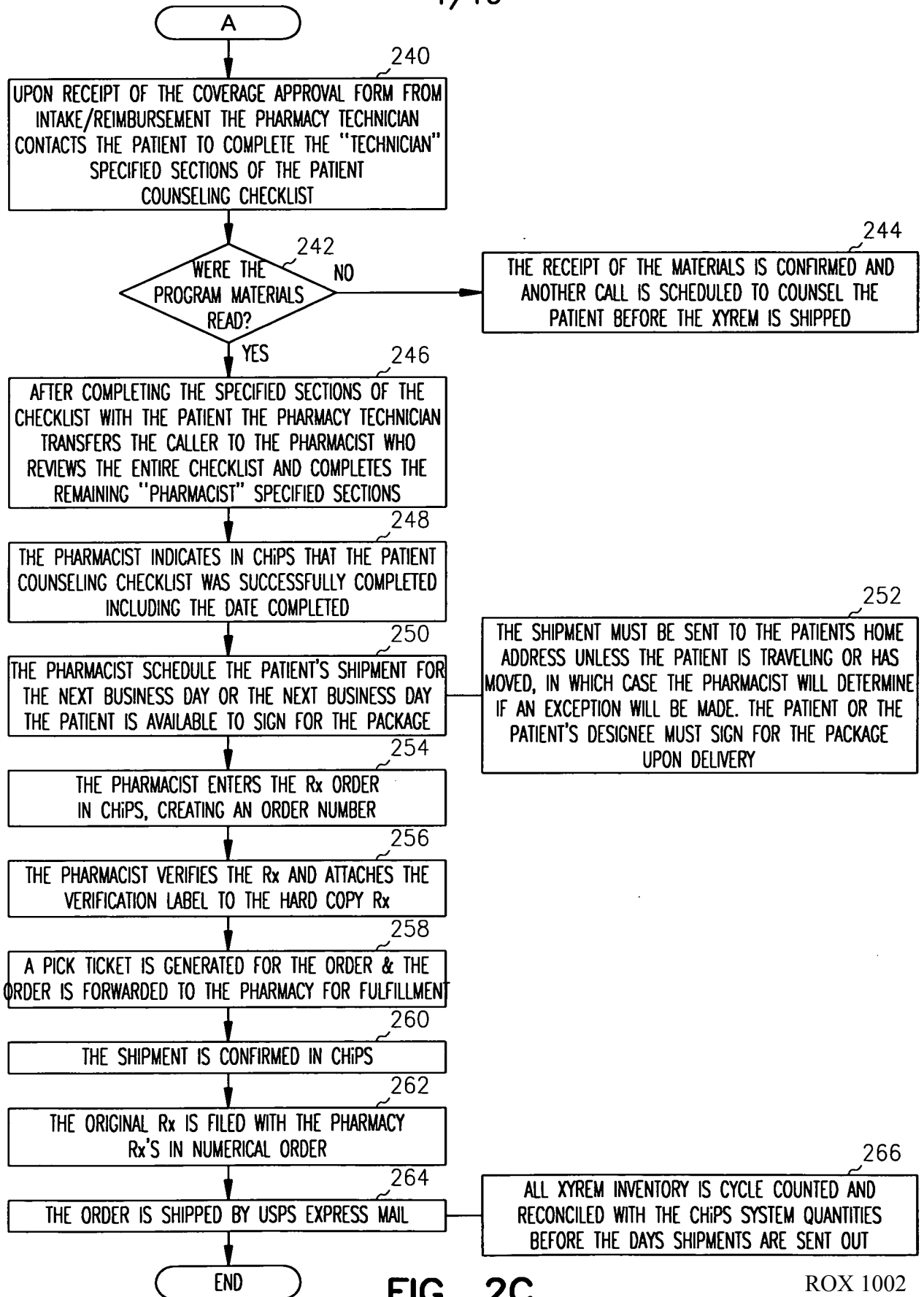


FIG. 2C

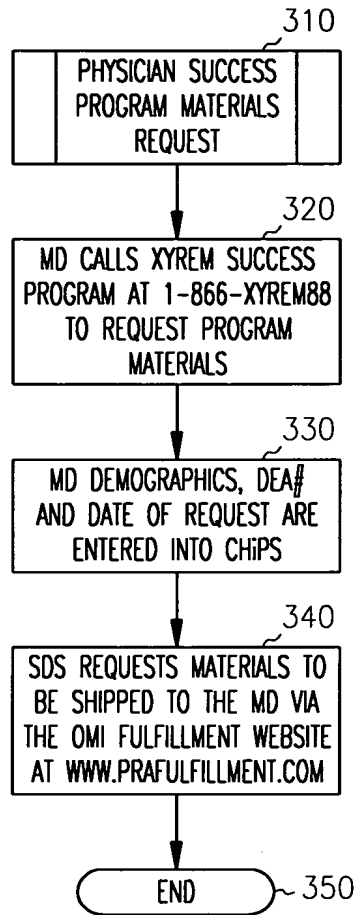


FIG. 3

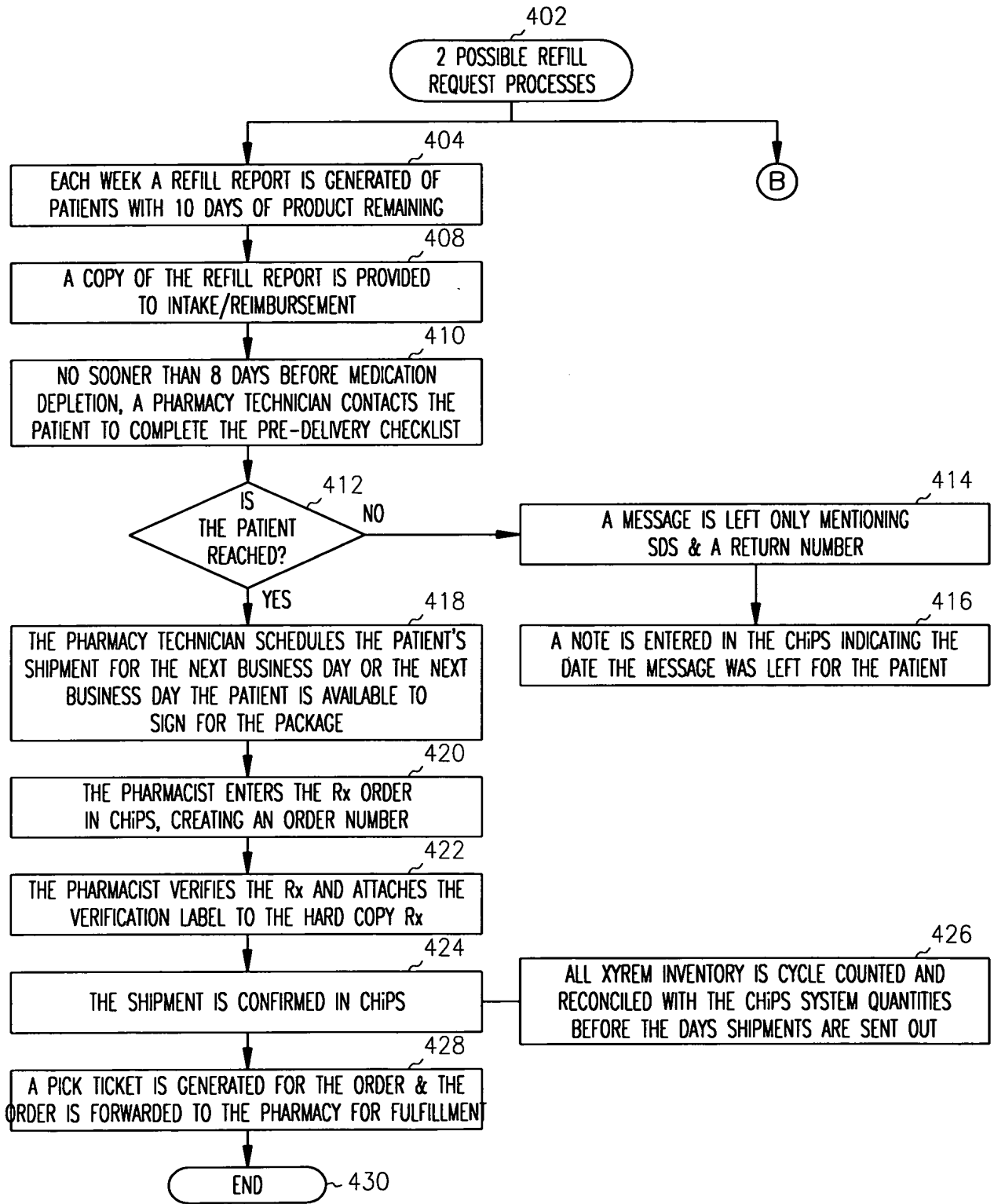


FIG. 4A

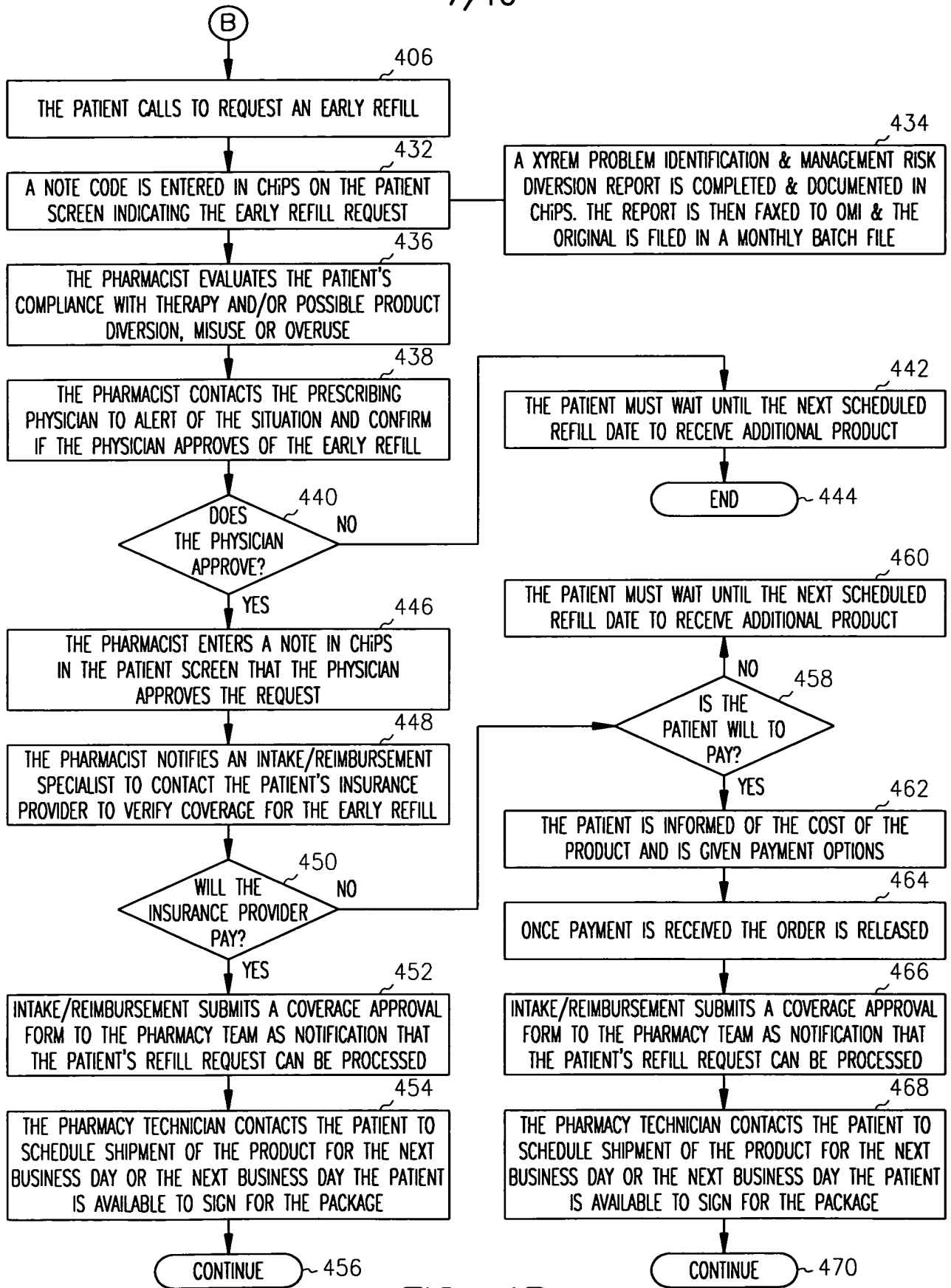


FIG. 4B

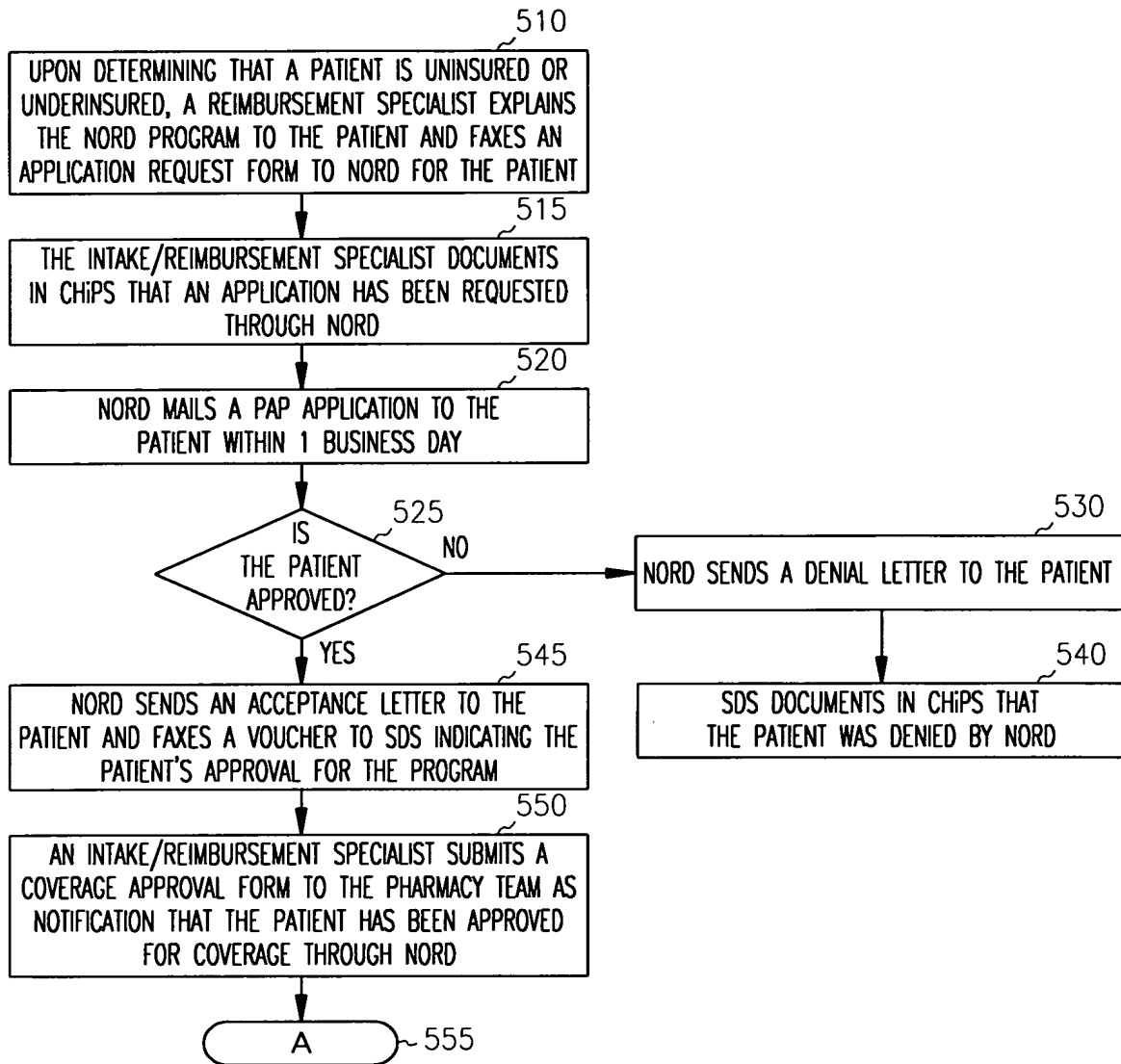


FIG. 5

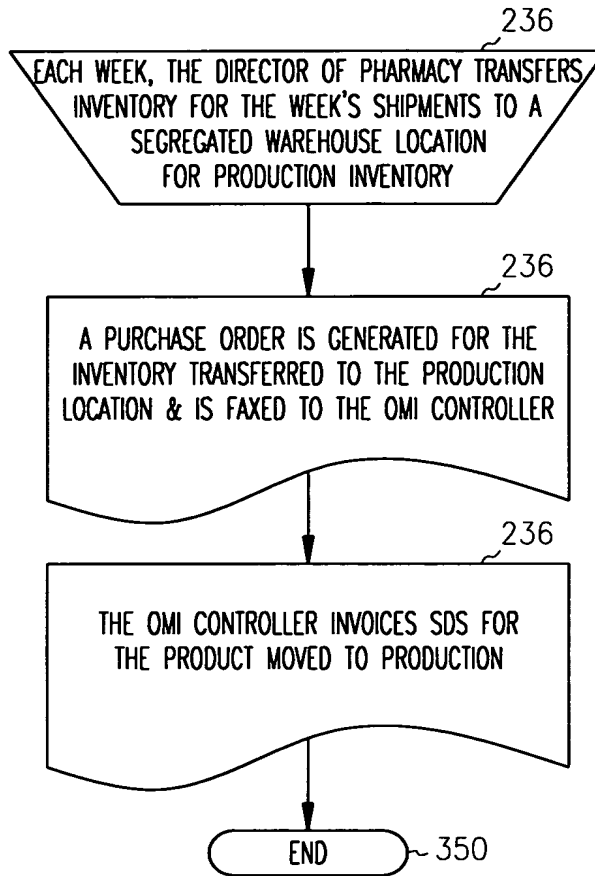


FIG. 6

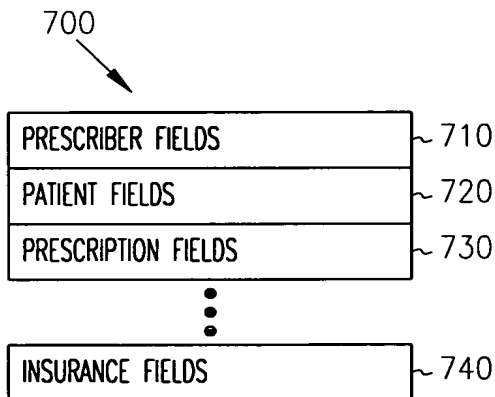


FIG. 7

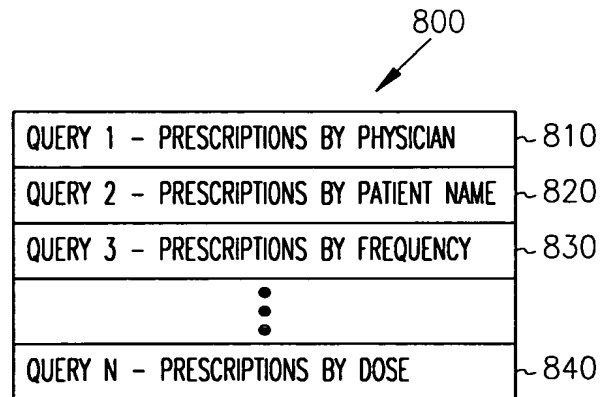


FIG. 8

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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
<input type="checkbox"/> I HAVE READ THE MATERIALS IN THE XYREM PHYSICIAN SUCCESS PROGRAM	
<input type="checkbox"/> I VERIFY THAT THE PATIENT HAS BEEN EDUCATED WITH RESPECT TO XYREM PREPARATION, DOSING AND SCHEDULING.	
<input type="checkbox"/> 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.	
<input type="checkbox"/> I UNDERSTAND THAT THE SAFETY OF DOSES GREATER THAN 9gm/DAY HAS NOT BEEN ESTABLISHED	

PATIENT INFORMATION	
BEST TIME TO CONTACT PATIENT: <input type="checkbox"/> DAY <input type="checkbox"/> NIGHT	
DAY #: _____	EVENING #: _____
INSURANCE COMPANY NAME: _____	PHONE #: _____
INSURED'S NAME: _____	RELATIONSHIP TO PATIENT: _____
IDENTIFICATION NUMBER: _____	POLICY/GROUP NUMBER: _____
PRESCRIPTION CARD: <input type="checkbox"/> NO <input type="checkbox"/> 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

TITLE: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
INVENTOR NAME: Dayton T. Reardon et al.
DOCKET NO.: 101.031US4

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1000
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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

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SENSITIVE DRUG PATIENT ASSISTANCE PROGRAM
VOUCHER REQUEST FOR MEDICATION

1100

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

TITLE: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
INVENTOR NAME: Dayton T. Reardon et al.
DOCKET NO.: 101.031US4

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1200
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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

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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/ENROLLMENT 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 PENDING 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:

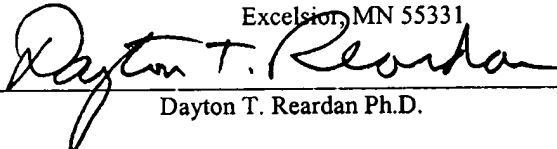
No such claim for priority is being made at this time.

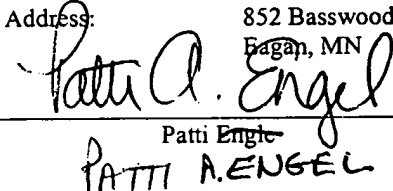
I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

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:  Date: April 3, 2003
Dayton T. Reardan Ph.D.

Full Name of joint inventor number 2 : A. Patti Engle ENGEL
Citizenship: United States of America Residence: Eagan, MN
Post Office Address: 852 Basswood Lane
Eagan, MN
Signature:  Date: May 13, 2003
Patti Engle
PATTI A. ENGEL

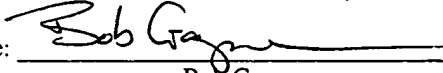
Additional inventors are being named on separately numbered sheets, attached hereto.

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**
Post Office Address: **202 So. Wheeler Street**
St. Paul, MN 55015

Residence: **St. Paul, MN**

Signature: _____


Bob Gagne

Date: 1 May 2003

§ 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.

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

PRELIMINARY AMENDMENT

Serial Number: Unknown

Filing Date: Herewith

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Page 6

Docket No: 101.031US4

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,

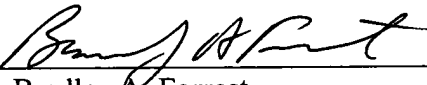
DAYTON T. REARDAN ET AL.

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.

INFORMATION DISCLOSURE STATEMENT

Serial No :Unknown

Filing Date: Herewith

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Page 2

Dkt: 101.031US4

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

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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)	<i>Complete if Known</i>	
	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

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
	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
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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
		<u>NASCSA National Conference, (November 2000), 8 pages</u>	
		<u>"Diversion Prevention Through Responsible Distribution", NADDI Regional Training, (May 2001), 12 pages</u>	
		<u>"Diversion Prevention Through Responsible Distribution", NADDI Regional Training Tennessee, (June 2001), 14 Pages</u>	
		<u>"Diversion Prevention Through Responsible Distribution", NADDI National Conference, (November 2001), 15 pages</u>	
		<u>"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</u>	

EXAMINER

DATE CONSIDERED

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

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,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
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(612)373-6935

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.

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

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:

<u>Class</u>	<u>Subclasses</u>	<u>Description</u>
700/		DATA PROCESSING: GENERIC CONTROL SYSTEMS OR SPECIFIC APPLICATIONS
	237Authorization (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

PRE-EXAMINATION STATEMENT

Serial Number: Unknown

Filing Date: Herewith

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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

PRE-EXAMINATION STATEMENT

Serial Number: Unknown

Filing Date: Herewith

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

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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.

PRE-EXAMINATION STATEMENT

Serial Number: Unknown

Filing Date: Herewith

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

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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

PRE-EXAMINATION STATEMENT

Serial Number: Unknown

Filing Date: Herewith

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Page 6

Dkt: 101.031US4

distribution of a sensitive drug by an exclusive central pharmacy. This feature is not disclosed in Lilly et al.

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.

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 <input type="checkbox"/>		

SMALL ENTITY TYPE OR

OTHER THAN SMALL ENTITY

RATE	FEE
BASIC FEE	
X\$ 25=	
X100=	
+180=	
TOTAL	

RATE	FEE
BASIC FEE	
X\$50=	
X200=	
+360=	
TOTAL	

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR
	Total	*	**
	Independent	*	***
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

SMALL ENTITY OR

OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
TOTAL ADDIT. FEE	

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR
	Total	*	**
	Independent	*	***
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
TOTAL ADDIT. FEE	

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR
	Total	*	**
	Independent	*	***
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
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.

ROX 1002
CBM of U.S. Patent No. 7,765,107


UNITED STATES PATENT AND TRADEMARK OFFICE

 UNITED STATES DEPARTMENT OF COMMERCE
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 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

 21186
 SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
 P.O. BOX 2938
 MINNEAPOLIS, MN 55402-0938

CONFIRMATION NO. 5403
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

 ROX 1002
 CBM of U.S. Patent No. 7,765,107
 60 of 265

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

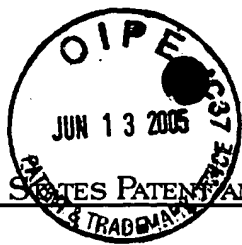
*A copy of this notice **MUST** be returned with the reply.*

A handwritten signature in black ink, appearing to be 'A. J. ...', written over a horizontal line.

Office of Initial Patent Examination (703) 308-1202

PART 3 - OFFICE COPY

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

21186
 SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
 P.O. BOX 2938
 MINNEAPOLIS, MN 55402-0938

CONFIRMATION NO. 5403

FORMALITIES LETTER



OC00000016165194

Date Mailed: 06/02/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

06/15/2005 MBERHE 00000023 11097985

FILED UNDER 37 CFR 1.53(b)

01 FC:2011	150.00 OP
02 FC:2111	250.00 OP
03 FC:2311	100.00 OP
04 FC:2051	65.00 OP

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

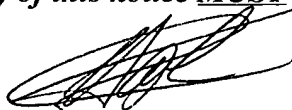
- **\$150** Statutory basic filing fee.
- **\$65** Late oath or declaration Surcharge.
- The application search fee has not been paid. Applicant must submit **\$250** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **\$100** to complete the examination fee for a small entity in compliance with 37 CFR 1.27

Replies should be mailed to: Mail Stop Missing Parts

ROX 1002
 CBM of U.S. Patent No. 7,765,107
 62 of 265

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

Serial No.: 11/097,985

Filed: April 1, 2005

Due Date: August 2, 2005

Examiner: Unknown

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:

- A return postcard.
- A check in the amount of \$65.00 to cover the small entity surcharge.
- A check in the amount of \$500.00 to cover the Basic Filing Fee and Additional Claims Fee.
- Communication Re: Missing Parts (1 pg.).
- 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.

By: 

Customer Number: 21186

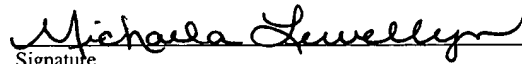
Name: Bradley A. Forrest

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


Signature



S/N 11/097,985

PATENT

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
Alexandria, VA 22313-1450

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.

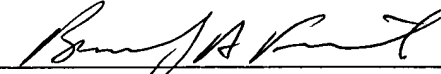
Respectfully submitted,

Dayton T. Reardan et al.

By their Representatives,

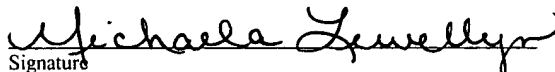
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6972

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


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 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.

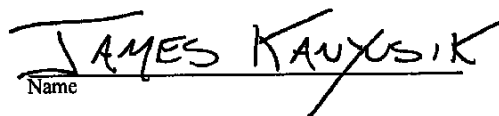
By their Representatives,

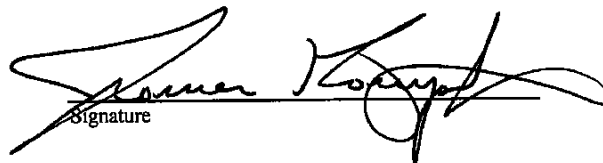
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6972

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, Alexandria, VA 22313-1450 on this 10TH day of October 2006.


Name


Signature

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 809. 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

ROX 1002
CBM of U.S. Patent No. 7,765,107

68 of 265

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
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part	Pages
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Multipart Description			
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	Transmittal letter	1	1
	Information Disclosure Statement (IDS) Filed	2	4

Warnings:

Information:

Total Files Size (in bytes):	213040
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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

Serial No.: 11/097,985

Filed: April 1, 2005

Due Date: N/A

Examiner: Unknown

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"):

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.

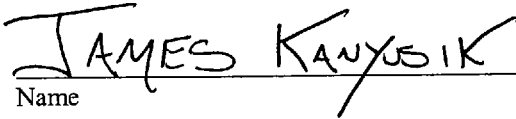
Customer Number 21186

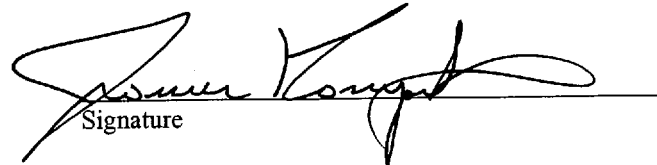
By: 

Atty: Bradley A. Forrest

Reg. No. 30,837

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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,

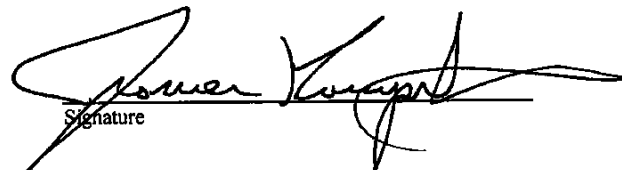
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6972

Date 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, Alexandria, VA 22313-1450 on this 4TH day of January 2007.


Name


Signature

Under the Paperwork Reduction Act of 1996, 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-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.talkaboutsleap.com/sleepdisorders/archives/Narcolepsy_xyrem_interview.htm , (February 12, 2001), 3 pgs.	
		UKENS, C., "Specialty Pharmacy", <i>Drug Topics</i> , 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 attachedBOX 1002
CBM of U.S. Patent No. 7,765,107

74 of 265

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
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
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ROX 1002

CBM of U.S. Patent No. 7,765,107

75 of 265

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
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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

Serial No.: 11/097,985

Filed: April 1, 2005

Due Date: N/A

Examiner: Unknown

Group Art Unit: 3626

MS Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

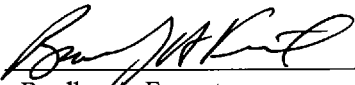
We are transmitting herewith the following attached items (as indicated with an "X"):

Supplemental Information Disclosure Statement (2 pgs.), Form 1449 (1 pg.). Documents NOT enclosed, cited in parent application.

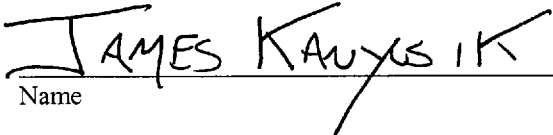
If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

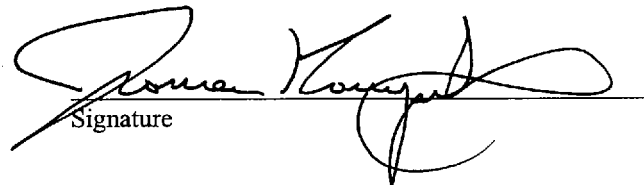
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

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.


Name


Signature

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

(GENERAL)



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Table with 5 columns: 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.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

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. 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 --

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: _____

ROX 1002

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.

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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.

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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

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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 negated 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.

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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).

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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.

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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,

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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

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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

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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

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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).

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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

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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

Art Unit: 3686

(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

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	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. 11097985	Applicant(s)/Patent Under Reexamination REARDAN ET AL.
	Examiner LENA NAJARIAN	Art Unit 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

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

✓	Rejected
=	Allowed

-	Cancelled
÷	Restricted

N	Non-Elected
I	Interference

A	Appeal
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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	22	-								
	23	-								
	24	-								
	25	-								
	26	✓								
	27	✓								
	28	✓								
	29	✓								
	30	✓								
	31	✓								



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BIB DATA SHEET

CONFIRMATION NO. 5403

SERIAL NUMBER 11/097,985	FILING or 371(c) DATE 04/01/2005 RULE	CLASS 705	GROUP ART UNIT 3686	ATTORNEY DOCKET NO. 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 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Verified and Acknowledged <u>/LENA NAJARIAN/</u> Examiner's Signature	<input type="checkbox"/> Met after Allowance LN Initials	STATE OR COUNTRY MN	SHEETS DRAWINGS 16	TOTAL CLAIMS 6	INDEPENDENT CLAIMS 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:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit		

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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	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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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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		<u>"Diversion Prevention Through Responsible Distribution", NADDI Regional Training, (May 2001), 12 pages</u>	
		<u>"Diversion Prevention Through Responsible Distribution", NADDI Regional Training Tennessee, (June 2001), 14 Pages</u>	
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EXAMINER /Lena Najarian/ DATE CONSIDERED 08/06/2009

* 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. Applicant's unique citation designation number (optional). 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)	<i>Complete if Known</i>	
	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
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EXAMINER /Lena Najarian/ DATE CONSIDERED 08/06/2009

Under the Paperwork Reduction Act of 1996, 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)	<i>Complete if Known</i>	
	Application Number	11/097,985
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	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
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EXAMINER /Lena Najarian/ **DATE CONSIDERED** 08/06/2009

Substitute Disclosure Statement Form (PTO-1448)
 * 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./

ROX 1002
 CBM 2005 Patent No. 7,765,107
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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

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CBM of U.S. Patent No. 7,765,107

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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

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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

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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 (I nterference)

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CBM of U.S. Patent No. 7,765,107

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S/N 11/097,985

PATENT

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 prescriptive 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.

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

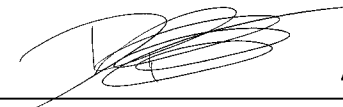
Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 371-2140 to facilitate prosecution of this application.

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

Respectfully submitted,

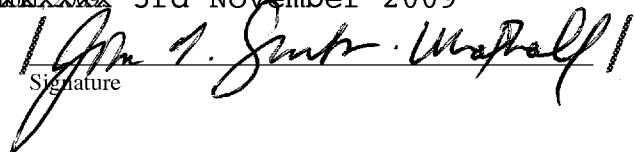
SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402--0938
(612) 371-2140

Date November 3, 2009

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 Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this ~~XXXXXX~~ 3rd November 2009

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:				

ROX 1002

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	

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) 1002

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) 7,765,107

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

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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.)
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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 <small>88f3aa731a844b9ad95f2e071e2753afe09ab86e</small>	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			420138		

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
Filed: April 1, 2005
Examiner: Lena Najarian
Customer No.: 21186

Serial No.: 11/097,985
Due Date: December 14, 2009
Group Art Unit: 3686
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"):

- Amendment and Response under 37 C.F.R. § 1.111 (15 pgs.)
- Supplemental Information Disclosure Statement (2 pgs.), Form 1449 (1 pg.) Copies of Cited References (13).
- 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

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 3 day of November, 2009.

John D. Gustav-Wrathall
Name


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,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-2140

Date November 3, 2009 By 

David D'Zurilla
Reg. No. 36,776

BAF:jdgw

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John D. Gustav-Wrathall
Name


Signature

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	<i>Complete if Known</i>
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. 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
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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 <small>d3d92d7725e606e154971a460fe8ee36eb87bc9d</small>	no	3

Warnings:

ROX 1002

Information:

CBM of U.S. Patent No. 7,765,107

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Warnings:					
Information:					

ROX 1002

CBM of U.S. Patent No. 7,765,107

134 of 265

11	NPL Documents	012_899009us2_aarn_020205.pdf	859394 1baf1b5eaca7de48e613235ad48efed91f429a0f	no	17
Warnings:					
Information:					
12	NPL Documents	013_101031us1_oarn_061906.pdf	1144215 3b38890335567fcb9b15d910ed17aa5dd49301	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.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/097,985	Filing Date 04/01/2005	<input type="checkbox"/> To be Mailed
---	---	----------------------------------	---------------------------------------

APPLICATION AS FILED – PART I			OTHER THAN SMALL ENTITY				
(Column 1)		(Column 2)	SMALL ENTITY <input checked="" type="checkbox"/>		OR	SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)		RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>	N/A	N/A	N/A			N/A	
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>	N/A	N/A	N/A			N/A	
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>	N/A	N/A	N/A			N/A	
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>	minus 20 =	*	X \$ =		OR	X \$ =	
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>	minus 3 =	*	X \$ =			X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>	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).						
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II					OTHER THAN SMALL ENTITY				
(Column 1)		(Column 2)	(Column 3)		SMALL ENTITY		OR	SMALL ENTITY	
AMENDMENT	11/03/2009	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(i))</small>	* 6	Minus	** 20 = 0	X \$26 =	0	OR	X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>	* 2	Minus	*** 3 = 0	X \$110 =	0	OR	X \$ =	
<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>									
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

APPLICATION AS AMENDED – PART II					OTHER THAN SMALL ENTITY				
(Column 1)		(Column 2)	(Column 3)		SMALL ENTITY		OR	SMALL ENTITY	
AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)	
	Total <small>(37 CFR 1.16(i))</small>	*	Minus	** =	X \$ =		OR	X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>	*	Minus	*** =	X \$ =		OR	X \$ =	
<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>									
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>							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/

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

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

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.

TERMINAL DISCLAIMER

Serial Number:11/097,985

Filing Date: April 1, 2005

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Page 3

Dkt: 101.031US4


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
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


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

ROX 1002

Extension-of-Time:

CBM of U.S. Patent No. 7,765,107

140 of 265

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:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) 1002

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) 7,765,107

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 ff087d2ba8c60b8b3d583d12e170025e004922e	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
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Warnings:

Information:

Total Files Size (in bytes): 234971

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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

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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
Filed: April 1, 2005
Examiner: Lena Najarian
Customer No.: 21186

Serial No.: 11/097,985
Due Date: N/A
Group Art Unit: 3686
Confirmation No.: 5403

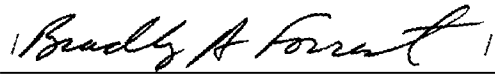
Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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

- Terminal Disclaimer for U.S. Application Serial No. 10/979,665 (3 pgs.)
- Terminal Disclaimer for U.S. Application Serial No. 11/097,651 (3 pgs.)
- 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
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


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.

TERMINAL DISCLAIMER

Serial Number:11/097,985

Filing Date: April 1, 2005

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Page 3

Dkt: 101.031US4

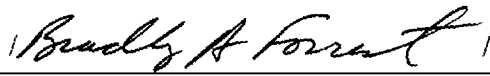
Fee Status

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,

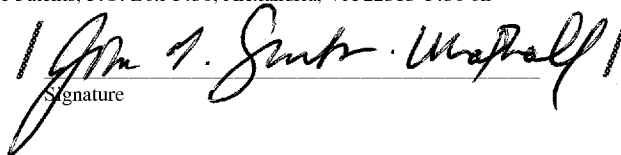
SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402--0938
(612) 373-6972


Date 22 January 2010

By 
Bradley A. Forrest
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


Signature

Application Number 	Application/Control No. 11/097,985	Applicant(s)/Patent under Reexamination REARDAN ET AL.

Document Code - DISQ	Internal Document – DO NOT MAIL
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TERMINAL DISCLAIMER	<input type="checkbox"/> APPROVED	<input checked="" type="checkbox"/> 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

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)

ROX 1002

CBM of U.S. Patent No. 7,765,107

149 of 265

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))

S/N 11/097,985

PATENT

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.

TERMINAL DISCLAIMER

Serial Number: 11/097,985

Filing Date: April 1, 2005

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Page 3

Dkt: 101.031US4

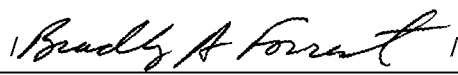
Fee Status

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
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


Signature

S/N 11/097,985

PATENT

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.

TERMINAL DISCLAIMER

Serial Number: 11/097,985

Filing Date: April 1, 2005

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Page 3

Dkt: 101.031US4

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
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


Signature

S/N 11/097,985

PATENT

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: 
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:

ROX 1002
CBM of U.S. Patent No. 7,765,107

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) 1002

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) 65,107

GBM of U.S. Patent No. 7,765,107

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 d76d4eda6179d4e932704591851cc43315d36f7f	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
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Warnings:

Information:

Total Files Size (in bytes):	317981
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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.

ROX 1002

CBM of U.S. Patent No. 7,765,107

161 of 265

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

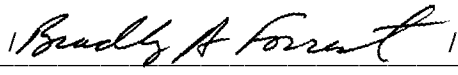
Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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

- Terminal Disclaimer for U.S. Application Serial No. 10/979,665 (3 pgs.)
- Terminal Disclaimer for U.S. Application Serial No. 11/097,651 (3 pgs.)
- Power of Attorney (1 pg.)
- Authorization to charge Deposit Account 19-0743 in the amount of \$140.00 to cover the fee for two Terminal Disclaimers

If not provided 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
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


Signature

Application Number 	Application/Control No. 11097985	Applicant(s)/Patent Under Reexamination REARDAN ET AL.
Document Code - DISQ		Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	<input checked="" type="checkbox"/> APPROVED	<input type="checkbox"/> DISAPPROVED
Date Filed: 02/10/2010	<p style="text-align: center;">This patent is subject to a Terminal Disclaimer</p>	

Approved/Disapproved by:	
karen c. approved 2 td's 2/13/10	

U.S. Patent and Trademark Office



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

Table with 5 columns: 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

Table with 7 columns: 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.

ROX 1002

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

<p>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</p> <p><input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</p> <p><input type="checkbox"/> "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.</p>	<p>2. For printing on the patent front page, list</p> <p>(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____</p> <p>(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 _____</p> <p>3 _____</p>
---	---

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

<p>4a. The following fee(s) are submitted:</p> <p><input type="checkbox"/> Issue Fee</p> <p><input type="checkbox"/> Publication Fee (No small entity discount permitted)</p> <p><input type="checkbox"/> Advance Order - # of Copies _____</p>	<p>4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)</p> <p><input type="checkbox"/> A check is enclosed.</p> <p><input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><input type="checkbox"/> 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).</p>
---	--

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

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
Rows include application numbers 11/097,985 and 21186, filing dates 04/01/2005 and 03/10/2010, inventor Dayton T. Reardan, docket number 101.031US4, and examiner NAJARIAN, LENA.

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 Draftsperson'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
In
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 11/097,985	FILING or 371(c) DATE 04/01/2005 RULE	CLASS 705	GROUP ART UNIT 3686	ATTORNEY DOCKET NO. 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 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Verified and Acknowledged <u>/LENA NAJARIAN/</u> Examiner's Signature	<input type="checkbox"/> Met after Allowance LN Initials	STATE OR COUNTRY MN	SHEETS DRAWINGS 16	TOTAL CLAIMS 6	INDEPENDENT CLAIMS 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:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit		

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

✓	Rejected
=	Allowed

-	Cancelled
÷	Restricted

N	Non-Elected
I	Interference

A	Appeal
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	-	-						
	5	-	-						
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	20	-	-						
	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

ROX 1002

CBM of U.S. Patent No. 7,765,107

176 of 265

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 (I nterference)

< This search history is empty >

2/ 18/ 2010 5:16:06 PM

C:\ Documents and Settings\ Inajarian2\ My Documents\ EAST\ Workspaces\ 11097985.wsp

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)	<i>Complete if Known</i>	
	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. Applicant is to place a check mark here if English Language Translation is attached.

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

ROX 1002
 CBM of U.S. Patent No. 7,765,187
 179 of 265

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	3
A.	Dialog	3
II.	INVENTOR SEARCH RESULTS FROM DIALOG	5
III.	TEXT SEARCH RESULTS FROM DIALOG.....	10
A.	Full-Text Databases I.....	10
IV.	TEXT SEARCH RESULTS FROM DIALOG.....	27
A.	Full-Text Databases I I.....	27
V.	TEXT SEARCH RESULTS FROM DIALOG.....	45
A.	Abstract Databases	45

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
(c) 2010 Gale/Cengage. All rights reserved.

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 1 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 1 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)
(c) 2010 Wolters Kluwer Pharma Sol. All rights reserved.

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
(c) 2010 Thomson Reuters. All rights reserved.

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 Application
Number Kind Date 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
(c) 2010 Thomson Reuters. All rights reserved.

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 Application

Number	Kind	Date	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
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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

Application

Number	Kind	Date	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
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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
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US 20040117205	A1	20040617	US 2002322348	A	20021217	200449 B
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Priority Applications (no., kind, date): US 2002322348 A 20021217

Patent Details

Number	Kind	Lan	Pg	Dwg	Filing	Notes
--------	------	-----	----	-----	--------	-------

US 20040117205	A1	EN	23	13		
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...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
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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
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File 637:Journal of Commerce 1986-2010/Jan 15
(c) 2010 UBM Global Trade

File 635:Business Dateline(R) 1985-2010/Jan 15
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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)
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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)
(c) 2010 Gale/Cengage. All rights reserved.

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)
(c) 2010 Gale/Cengage. All rights reserved.

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)
(c) 2010 Gale/Cengage. All rights reserved.

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)
(c) 2010 Gale/Cengage. All rights reserved.

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)
(c) 2010 Gale/Cengage. All rights reserved.

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)
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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
(c) 2010 Gale/Cengage. All rights reserved.

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
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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
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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
(c) 2010 Dialog. All rights reserved.

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
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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)
(c) 2010 ProQuest Info&Learning. All rights reserved.

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.
(c) 2010 MCT Information Svc. All rights reserved.

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
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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
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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
(c) 2010 WIPO/Thomson. All rights reserved.

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
(c) 2010 WIPO/Thomson. All rights reserved.

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 information,

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)
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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
(c) 1999 PR Newswire Association Inc. All rights reserved.

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
(c) 2010 Gale/Cengage. All rights reserved.

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
(c) 2010 Gale/Cengage. All rights reserved.

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
(c) 2010 Dialog. All rights reserved.

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** **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)
(c) 2010 ProQuest Info&Learning. All rights reserved.

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
(c) 2010 Gale/Cengage. All rights reserved.

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
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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 1 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 1 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
(c) 2010 WIPO/Thomson. All rights reserved.

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:

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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)
(c) 2010 Wolters Kluwer Pharma Sol. All rights reserved.

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: PsyclNFO(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
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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
 (c) 2010 Elsevier B.V. All rights reserved.

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
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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
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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
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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
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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 Evaluation 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
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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
(c) 2010 Elsevier B.V. All rights reserved.

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
(c) 2010 Elsevier B.V. All rights reserved.

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
(c) 2010 Elsevier B.V. All rights reserved.

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)
(c) 2010 Gale/Cengage. All rights reserved.

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)
(c) 2010 Gale/Cengage. All rights reserved.

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)
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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)
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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)
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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)
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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)
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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)
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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)
(c) 2010 Gale/Cengage. All rights reserved.

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)
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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)
(c) format only 2009 Dialog. All rights reserved.

14029226 PMID: 11155636
Not for **nurses** only. A NIDSEC (Nursing Information and
Data Set Evaluation Center&I
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&I
t;/ B>) primer.**

18/3,K/22 (Item 2 from file: 154)
DIALOG(R)File 154: MEDLINE(R)
(c) format only 2009 Dialog. All rights reserved.

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)
(c) format only 2009 Dialog. All rights reserved.

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)
(c) format only 2009 Dialog. All rights reserved.

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 ; 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)
(c) format only 2009 Dialog. All rights reserved.

14029226 PMID: 11155636
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.
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) primer.

18/3,K/26 (Item 2 from file: 155)
DIALOG(R)File 155: MEDLINE(R)
(c) format only 2009 Dialog. All rights reserved.

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)
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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 ; 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)
(c) format only 2009 Dialog. All rights reserved.

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 ; 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.
(c) 2010 Mass. Med. Soc. All rights reserved.

00106307
Copyright 1989 by the Massachusetts Medical Society

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
(c) 2009 The Thomson Corporation. All rights reserved.

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
(c) 2009 The Thomson Corporation. All rights reserved.

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

(c) 2009 The Thomson Corporation. All rights reserved.

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

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(c) 1999 NILS Publishing Co.
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(c) 2010 NTIS, Intl Cpyrgh All Rights Res
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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
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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 Application
Number Kind Date Number 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
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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 Application
Number Kind Date Number 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
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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
(c) 2010 Thomson Reuters. All rights reserved.

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 Application
Number Kind Date 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 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
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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

Application

Number	Kind	Date	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
(c) 2010 JPO & JAPIO. All rights reserved.

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
(c) 2010 JPO & JAPIO. All rights reserved.

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
(c) 2010 The IET. All rights reserved.

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 in 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

Copyright: 2003, IEE

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
(c) 2010 The IET. All rights reserved.

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
Copyright: 1998, IEE

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
(c) 2010 The IET. All rights reserved.

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
Copyright: 1983, IEE

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
(c) 2010 The IET. All rights reserved.

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
Copyright: 1980, IEE
Identifiers: information; **physicians**; Lister Hill National **Center** for Biomedical Communications; **data bases**; library

19/3,K/12 (Item 1 from file: 474)
DIALOG(R)File 474: New York Times Abs
(c) 2010 The New York Times. All rights reserved.

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
(c) 2010 The Thomson Corp. All rights reserved.

07538656 Genuine Article#: 178NP No. References: 14
Title: Chlorpyrifos: A ten-year US poison center exposure experience
Author: Kingston RL (REPRINT) ; Chen WL; Borrón 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
(c) 2010 The Thomson Corp. All rights reserved.

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)
(c) 2010 The Thomson Corp. All rights reserved.

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)
(c) 2010 The Thomson Corp. All rights reserved.

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. 11097985	Applicant(s)/Patent Under Reexamination REARDAN ET AL.
	Examiner LENA NAJARIAN	Art Unit 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

	ROX 1002
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Issue Classification 	Application/Control No. 11097985	Applicant(s)/Patent Under Reexamination REARDAN ET AL.
	Examiner LENA NAJARIAN	Art Unit 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																		

<input checked="" type="checkbox"/> Claims renumbered in the same order as presented by applicant <input type="checkbox"/> CPA <input checked="" type="checkbox"/> T.D. <input type="checkbox"/> 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 (Assistant Examiner)	2/19/10 (Date)	Total Claims Allowed: 6	
/Gerald J. O'Connor/ SPE, GAU 3686 (Primary Examiner)	2/26/2010 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 4B

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	<i>Complete if Known</i>	
	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.

ROX 1002
CBM of U.S. Patent No. 7,765,107

239 of 265

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:				

ROX 1002

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) 1002

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) 7,765,107

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 b38459cb0be0efa11312ded10b72d8f8027cd7a	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 adc5e6c5fab217855003c77e44d753917307bdf	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
Filed: April 1, 2005
Examiner: Lena Najarian
Customer No.: 21186

Serial No.: 11/097,985
Due Date: N/A
Group Art Unit: 3686
Confirmation No.: 5403

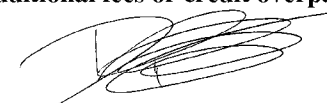
Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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

- Communication Concerning Prior and Copending Applications (2 pgs.)
- Supplemental Information Disclosure Statement under 37 C.F.R. 1.97(d) (2 pgs.), Form 1449 (1 pg.)
Copies of Cited References (1).
- 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 COPENING 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.

<u>Serial No./ Patent No.</u>	<u>Filing Date</u>	<u>Attorney Docket</u>	<u>Title</u>
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

Name

/John D. Gustav-Wrathall/

Signature

Receipt date: 04/01/2005

11097985 - GAU: 3686

PTO/SB/04 (10-01)
Approved for use through 10/31/2002, OMB 65-1-003
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 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-6,581,977	02/03/2004	Denny, Lawrence A. <i>W. P. REARDAN</i>	05/29/2002
	US-6,755,784	06/29/2004	Williams, Bruce A., et al.	03/07/2003

CP
514

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", <u>NADDI Regional Training</u> , (May 2001), 12 pages	
		"Diversion Prevention Through Responsible Distribution", <u>NADDI Regional Training Tennessee</u> , (June 2001), 14 Pages	
		"Diversion Prevention Through Responsible Distribution", <u>NADDI National Conference</u> , (November 2001), 15 pages	
		"Peripheral and Central Nervous System Drugs Advisory Committee", <u>Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research</u> , 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 808. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

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

CBM of U.S. Patent No. 7,765,107

250 of 265

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 3 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)

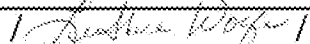
Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

21185 7590 03/19/2010

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

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)
 (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. Reardon	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 FEES 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 for(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-2039 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: 
 Typed or printed name: David D'Zurilla

Date: June 10, 2010
 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.

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.

ROX-1002

CBM of U.S. Patent No. 7,765,107

S/N 11/097,985

PATENT

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

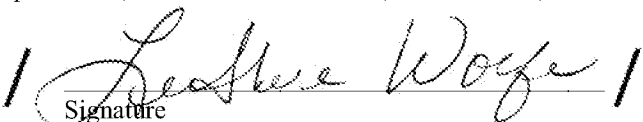
By 

David D'Zurilla
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


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	CBM of U.S. Patent No. 7,765,107	755	ROX 1002 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) 1002

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) 7,765,107

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
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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
Filed: April 1, 2005
Examiner: Lena Najarian
Customer No.: 21186

Serial No.: 11/097,985
Due Date: June 10, 2010
Group Art Unit: 3686
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:


- Authorization to charge Deposit 19-0743 in the amount of \$755.00 to cover the Small Entity Issue Fee Payment.
- Authorization to charge Deposit 19-0743 in the amount of \$300.00 to cover the Publication Fee Payment.
- Issue Fee Transmittal (Form PTOL-85).
- 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

Customer No.: 21186

DDZ:CMG:lrw

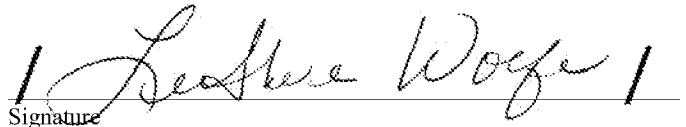


David D'Zurilla
Reg. No. 36,776

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 10th day of June, 2010.

LeShere Wolfe

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

Table with 5 columns: 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

Table with 2 columns: ART UNIT, PAPER NUMBER

3686

Table with 2 columns: 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.	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 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)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>20100512</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|--|---|

/Jerry O'Connor/
SPE, GAU 3686


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

	ROX 1002
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Index of Claims 	Application/Control No. 11097985	Applicant(s)/Patent Under Reexamination REARDAN ET AL.
	Examiner LENA NAJARIAN	Art Unit 3686

✓	Rejected
=	Allowed

-	Cancelled
÷	Restricted

N	Non-Elected
I	Interference

A	Appeal
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	-	-	-					
	3	-	-	-					
	4	-	-	-					
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	22	-	-	-					
	23	-	-	-					
	24	-	-	-					
	25	-	-	-					
1	26	✓	=	=					
2	27	✓	=	=					
3	28	✓	=	=					
4	29	✓	=	=					
5	30	✓	=	=					
6	31	✓	=	=					

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)	<i>Complete if Known</i>	
	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 11/097,985	FILING or 371(c) DATE 04/01/2005 RULE	CLASS 705	GROUP ART UNIT 3686	ATTORNEY DOCKET NO. 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 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Verified and Acknowledged <u>/LENA NAJARIAN/</u> Examiner's Signature	<input type="checkbox"/> Met after Allowance LN Initials	STATE OR COUNTRY MN	SHEETS DRAWINGS 16	TOTAL CLAIMS 6	INDEPENDENT CLAIMS 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:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit		



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;