Application or Docket Number

PATENT APPLICATION FEE DETERMINATION RECORD
Effective January 1, 2003

CLAIMS AS FILED - PART I

	(Column 1)		(Column 2)
TOTAL CLAIMS	25		
FOR	NUMBER FILED		NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	25 minus 20=	*	5
INDEPENDENT CLAIMS	4 minus 3 =	*	1
MULTIPLE DEPENDENT CLAIM PRESENT			☐

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

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE	$375	OR	BASIC FEE	$750
X$ 9=	45	OR	X$18=	
X42=	42	OR	X84=	
+140=		OR	+280=	
TOTAL	462	OR	TOTAL	

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

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

J1135 U.S. PTO
12/17/02

12-19-02

J1036 U.S. PTO
10/322348
12/17/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Dayton T. Reardan et al.
Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
Attorney Docket No.: 101.031US1

PATENT APPLICATION TRANSMITTAL

BOX PATENT APPLICATION
Commissioner for Patents
Washington, D.C. 20231

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

X Return postcard.
X Utility Patent Application under 37 CFR § 1.53(b) comprising:
  X Specification (18 pgs, including claims numbered 1 through 25 and a 1 page Abstract).
  X Formal Drawing(s) (16 sheets).
  X Unsigned Combined Declaration and Power of Attorney (4 pgs).
X Applicant claims small entity status under 37 C.F.R 1.27.

The filing fee (NOT ENCLOSED) will be calculated as follows:

	No. Filed	No. Extra	Rate	Fee
TOTAL CLAIMS	25 - 20 =	5	x 9 =	**$45.00**
INDEPENDENT CLAIMS	4 - 3 =	1	x 42 =	**$42.00**
[ ] MULTIPLE DEPENDENT CLAIMS PRESENTED				**$0.00**
BASIC FEE				**$370.00**
TOTAL				**$457.00**

THE FILING FEE WILL BE PAID UPON RECEIPT OF THE NOTICE TO FILE MISSING PARTS.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938, Minneapolis, MN 55402 (612-373-6900)

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

Customer Number 21186

"Express Mail" mailing label number: EV 149 506 149 US
Date of Deposit: December 17, 2002
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, Box Patent Application, Washington, D.C. 20231.

Sensitive Drug Distribution System and Method

Field of the Invention

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

Background of the Invention

Sensitive drugs are controlled to minimize risk and ensure that they are not abused, or cause adverse reactions. Such sensitive drugs are approved for specific uses by the Food and Drug Administration, and must be prescribed by a licensed physician in order to be purchased by consumers. Some drugs, such as cocaine and other common street drugs are the object of abuse and illegal schemes to distribute for profit. Some schemes include Dr. shopping, diversion, and pharmacy thefts. A locked cabinet or safe is a requirement for distribution of some drugs.

Certain agents, such as gamma hydroxy buterate (GHB) are also abused, yet also are effective for therapeutic purposes such as treatment of daytime cataplexy in patients with narcolepsy. Some patients however, will obtain prescriptions from multiple doctors, and have them filled at different pharmacies. Still further, an unscrupulous physician may actually write multiple prescriptions for a patient, or multiple patients, who use cash to pay for the drugs. These patients will then sell the drug to dealers or others for profit.

There is a need for a distribution system and method that directly addresses these abuses. There is a further need for such a system and method that provides education and limits the potential for such abuse.

Summary of the Invention

A drug distribution system and method utilizes a central pharmacy and database to track all prescriptions for a sensitive drug. Information is kept in a central database regarding all physicians allowed to prescribe the sensitive drug, and all patients receiving the drug. Abuses are identified by monitoring data in the database for prescription patterns by physicians and prescriptions obtained by patients. Further verification is

made that the physician is eligible to prescribe the drug by consulting a separate database for a valid DEA license, and optionally state medical boards to determine whether any corrective or approved disciplinary actions relating to controlled substances have been brought against the physician. Multiple controls beyond those for traditional drugs are imposed on the distribution depending on the sensitivity of the drug.

Education is provided to both physician and patient. Prior to shipping the drug for the first time, the patient is contacted to ensure that product and abuse related educational materials have been received and/or read. The patient may provide the name of a designee to the central pharmacy who is authorized to accept shipment of the drug. Receipt of the initial drug shipment is confirmed by contacting the patient. Either a phone call or other communication to the patient within a set time after delivery may be made to ensure receipt. Further, a courier service's tracking system is used to confirm delivery in further embodiments. If a shipment is lost, an investigation is launched to find it.

In one embodiment, the drug may be shipped by the central pharmacy to another pharmacy for patient pick-up. The second pharmacy's ability to protect against diversion before shipping the drug must be confirmed. This ability may be checked through NTIS and State Boards of Pharmacy.

Prescription refills are permitted in the number specified in the original prescription. In addition, if a prescription refill is requested by the patient prior to the anticipated due date, such refills will be questioned. A lost, stolen, destroyed or spilled prescription/supply is documented and replaced to the extent necessary to honor the prescription, and will also cause a review or full investigation.

The exclusive central database contains all relevant data related to distribution of the drug and process of distributing it, including patient, physician and prescription information. Several queries and reports are run against the database to provide information which might reveal potential abuse of the sensitive drug, such as early refills.

Brief Description of the Drawings

FIG. 1 is a block diagram of a computer system for use in implementing the system and method of the present invention.

FIG.s 2A, 2B and 2C are a flowchart describing a method for sensitive drug distribution at least partially utilizing a computer system such as that shown in FIG. 1.

FIG. 3 is a flowchart of a physician success program at least partially implemented on a computer system such as that shown in FIG. 1.

FIG.s 4A and 4B are a flowchart describing a method for handling refill requests at least partially utilizing a computer system such as that shown in FIG. 1.

FIG. 5 is a flowchart of a process for requesting special reimbursement when a patient is uninsured or underinsured at least partially utilizing a computer system as that shown in FIG. 1.

FIG. 6 is a flowchart of a process for inventory control at least partially utilizing a computer system such as that shown in FIG. 1.

FIG. 7 is a block diagram of database fields.

FIG. 8 is a block diagram showing a list of queries against the database fields.

FIG. 9 is a copy of one example prescription and enrollment form.

FIG. 10 is a copy of one example of a NORD application request form for patient financial assistance.

FIG. 11 is a copy of one example voucher request for medication for use with the NORD application request form of FIG. 10.

FIG. 12 is a copy of certificate of medical need.

FIG.s 13A, 13B and 13C are descriptions of sample reports obtained by querying a central database having fields represented in FIG. 7.

Detailed Description of the Invention

In the following description, reference is made to the accompanying drawings that form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that structural, logical and electrical changes may be made without departing from the scope of the present invention. The following description is, therefore, not to be taken in a limited sense, and the scope of the present invention is defined by the appended claims.

The functions or algorithms described herein are implemented in software or a combination of software and human implemented procedures in one embodiment. The software comprises computer executable instructions stored on computer readable media such as memory or other type of storage devices. The term "computer readable media" is also used to represent carrier waves on which the software is transmitted. Further, such functions correspond to modules, which are software, hardware, firmware of any combination thereof. Multiple functions are performed in one or more modules as desired, and the embodiments described are merely examples. The software is executed on a digital signal processor, ASIC, microprocessor, or other type of processor operating on a computer system, such as a personal computer, server or other computer system.

A sensitive drug is one which can be abused, or has addiction properties or other properties that render the drug sensitive. One example of such a drug is sodium oxybate, also known as gamma hydroxy butyrate (GHB $C_4H_7NaO_3$) which is useful for treatment of cataplexy in patients with narcolepsy. GHB is marketed under the trademark of Xyrem® (sodium oxybate oral solution), which trademark can be used interchangeably with GHB herein. Sensitive drugs also include narcotics or other drugs which require controls on their distribution and use to monitor behaviors to prevent abuse and adverse side effects.

In one embodiment, Xyrem® is subject to a restricted distribution program. One aspect of the program is to educate physicians and patients about the risks and benefits of Xyrem, including support via ongoing contact with patients and a toll free helpline. Initial prescriptions are filled only after a prescriber and patient have received and read the educational materials. Further, patient and prescribing physician registries are maintained and monitored to ensure proper distribution.

In a further embodiment, bulk sodium oxybate is manufactured at a single site, as is the finished drug product. Following manufacture of the drug product, it is stored at a facility compliant with FDA Schedule III regulations, where a consignment inventory is maintained. The inventory is owned by a company, and is managed by a central pharmacy, which maintains the consignment inventory. Xyrem® is distributed and dispensed through a primary and exclusive central pharmacy, and is not stocked in retail

pharmacy outlets. It is distributed by overnight carriers, or by US mail in one embodiment to potentially invoke mail fraud laws if attempts of abuse occur.

FIG. 1 is a simplified block diagram of a computer system 100, such as a personal computer for implementing at least a portion of the methods described herein. A central processing unit (CPU) 110 executes computer programs stored on a memory 120. Memory 120 in one embodiment comprises one or more levels of cache as desired to speed execution of the program and access to data on which the programs operate. The CPU is directly coupled to memory 120 in one embodiment. Both CPU 110 and memory 120 are coupled to a bus 130. A storage 140, I/O 150 and communications 160 are also coupled to the bus 130. Storage 140 is usually a long term storage device, such as a disk drive, tape drive, DVD, CD or other type of storage device. In one embodiment, storage 140 is used to house a database for use with the present invention. I/O 150 comprises keyboards, sound devices, displays and other mechanisms by which a user interacts with the computer system 100. Communications 160 comprises a network, phone connection, local area network, wide area network or other mechanism for communicating with external devices. Such external devices comprise servers, other peer computers and other devices. In one embodiment, such external device comprises a database server that is used in place of the database on storage 140. Other computer system architectures capable of executing software and interacting with a database and users may also be used. Appropriate security measures such as encryption are used to ensure confidentiality. Further, data integrity and backup measures are also used to prevent data loss.

FIG.s 2A, 2B and 2C represent an initial prescription order entry process for a sensitive drug, such as Xyrem. At 202, a medical doctor (MD) sends a Rx/enrollment form via mail, fax, email or other means to an intake/reimbursement specialist at 204, who makes a copy of the RX/enrollment form that is stamped "copy". The original fax is forwarded to a pharmacy team. The enrollment form contains prescriber information, prescription information, checkboxes for the prescriber indicating they have read materials, educated the patient, understand the use in treatment, and understand certain safety information, and also contains patient information.

The prescriber information contains standard contact information as well as license number, DEA number and physician specialty. Patient and prescription

information includes name, social security number, date of birth, gender, contact information, drug identification, patient's appropriate dosage, and number of refills allowed, along with a line for the prescriber's signature. Patient insurance information is also provided.

There are two workflows involved at the pharmacy team, intake reimbursement 206 and pharmacy workflow 208, which may proceed in parallel or serially. The intake work flow 206 starts with an intake reimbursement specialist entering the patient and physician information into an application/database referred to as CHIPS, which is used to maintain a record of a client home infusion program (CHIP) for Xyrem®. A check is made to ensure the information is complete at 212. If not, at 214, an intake representative attempts to reach the MD or prescriber to obtain the missing information. If the missing information has not been obtained within a predetermined period of time, such as 24 hours at 216, the Rx/Enrollment form is sent back to the MD with a rejection explanation. A note is entered in CHIPS that the application was rejected.

If the information is complete at 212, the MD is contacted at 220 to verify receipt and accuracy of the patient's Rx. This contact is recorded in CHIPS. The intake and reimbursement specialist then sends a consent form and a cover letter to the patient at 224. The insurance provider is contacted at 226 to verify coverage and benefits. At 228, a determination is made regarding coverage for the drug. If it is not available, it is determined at 230 whether the patient is willing and able to pay. If not, a process is performed for handling patients who are uninsured or underinsured. In one embodiment, the process is referred to as a NORD process.

If the patient is willing and able to pay at 230, the patient is informed of the cost of the product and is given payment options at 234. At 236, once payment is received, the intake reimbursement specialist submits a coverage approval form with the enrollment form to the pharmacy team as notification to process the patient's prescription. If coverage is approved at 228, the intake reimbursement specialist also submits the coverage approval form with the enrollment form to the pharmacy team as notification to process the patient's prescription. Processing of the prescription is described below.

Upon receipt and initial processing of the prescription enrollment form and sending an original to the pharmacy work flow block 208, the patient is shipped a Xyrem® success packet via mail. In one embodiment, the Xyrem® success packet contains educational material for a patient that advises of the proper use, care and handling of the drug and consequences of diversion at 268. The medical doctor's credentials are checked to determine if the physician has a current DEA license to prescribe controlled substances and if he or she has had any actions related to misuse/misprescribing of controlled drugs against him or her, within a predetermined time, such as three months at 270. If they have, a pharmacist holds the prescription until receiving a coverage approval form from the intake reimbursement specialist at 272.

If the credentials have not been recently checked, the pharmacist verifies the credentials and enters all findings in the database at 274. If the credentials are approved at 276, the physician is indicated as approved in a physician screen populated by information from the database at 280. The prescription is then held pending coverage approval at 282.

If any disciplinary actions are identified, as referenced at block 278, management of the pharmacy is notified and either approves processing of the prescription with continued monitoring of the physician, or processing of the prescription is not performed, and the physician is noted in the database as unapproved at 284. The enrollment form is then mailed back to the physician with a cover letter reiterating that the prescription cannot be processed at 288. The patient is also sent a letter at 290 indicating that the prescription cannot be processed and the patient is instructed to contact their physician.

Actual filling of the approved prescription begins with receipt of the coverage approval form as indicated at 240. The patient is contacted by the pharmacy, such as by a technician to complete a technician section of a patient counseling checklist. If a pharmacist verifies that the program materials were not read at 242, the receipt of the material is confirmed at 244 and another call is scheduled to counsel the patient before the drug is shipped.

If the program materials were read at 242, the checklist is completed at 246 and the technician transfers the patient to the pharmacist who reviews the entire checklist and completes remaining pharmacist specified sections. At 248, the pharmacist indicates in

the database that the patient counseling and checklist was successfully completed, indicating the date completed.

At 250, the pharmacist schedules the patient's shipment for the next business day or the next business day that the patient or designee is able to sign for the package. Further, as indicated at 252, the shipment must be sent to the patient's home address unless the patient is traveling or has moved. In that event, the pharmacist may determine that an exception may be made. The patient or the patient's designee who is at least 18 years old, must sign for the package upon delivery.

At 254, the pharmacist enters the prescription order in the database, creating an order number. The pharmacist then verifies at 256 the prescription and attaches a verification label to the hard copy prescription. At 258, a pick ticket is generated for the order and the order is forwarded to the pharmacy for fulfillment. The shipment is confirmed in the database at 260, and the order is shipped by USPS Express Mail. Use of the US mail invokes certain criminal penalties for unauthorized diversion. Optionally, other mail services may be used. Potential changes in the law may also bring criminal penalties into play. Following shipment, the patient is called by the central pharmacy to confirm that the prescription was received.

As noted at 266, for the sensitive drug, Xyrem, all inventory is cycle counted and reconciled with the database system quantities before shipments for the day are sent. This provides a very precise control of the inventor.

A physician success program materials request process begins at 310 in FIG. 3. At 320, the MD calls to the central pharmacy to request program materials. A special phone number is provided. MD demographics, DEA number, and data or request are entered into the database at 330. At 340, a request is made to ship the materials to the MD via a fulfillment website, or other mechanism. The request process ends at 350.

A refill request process begins at 302 in FIG.s 4A and 4B. There are two different paths for refills. A first path beginning at 404 involves generating a report from the central database of patients with a predetermined number of days or product remaining. A second path beginning at 406 is followed when a patient calls to request an early refill.

In the first path, a copy of the report is provided to an intake reimbursement specialist at 408. No sooner than 8 days before the medication depletion, a pharmacy

technician contacts the patient at 410 to complete the pre-delivery checklist. At 412, if the patient is not reached, a message is left mentioning the depletion, and a return number at 414. A note is also entered into the database indicating the date the message was left at 416.

If the patient is reached at 412, the next shipment is scheduled at 418, the prescription is entered into the database creating an order at 420, the pharmacist verifies the prescription and attaches a verification label at 422 and the shipment is confirmed in the database at 424. Note at 426 that the inventory is cycle counted and reconciled with the database quantities before the shipments for a day or other time period are sent. A pick ticket is generated for the order and the order is forwarded for fulfillment at 428, with the first path ending at 430.

The second path, beginning at 406 results in a note code being entered into the database on a patient screen indicating an early refill request at 432. The pharmacist evaluates the patient's compliance with therapy or possible product diversion, misuse or over-use at 436. In one embodiment, cash payers are also identified. The pharmacist then contacts the prescribing physician to alert them of the situation and confirm if the physician approves of the early refill at 438. If the physician does not approve as indicated at 440, the patient must wait until the next scheduled refill date to receive additional product as indicated at 442, and the process ends at 444.

If the physician approves at 440, the pharmacist enters a note in the database on a patient screen that the physician approves the request at 446. The pharmacist notifies an intake reimbursement specialist to contact the patient's insurance provider to verify coverage for the early refill at 448. If the insurance provider will pay as determined at 450, the specialist submits the coverage approval form as notification that the refill may be processed at 452. At 454, the pharmacy technician contacts the patient to schedule shipment of the product for the next business day, and the process of filling the order is continued at 456 by following the process beginning at 240.

If the insurance provider will not pay at 450, it is determined whether the patient is willing and/or able to pay at 458. If not, the patient must wait until the next scheduled refill date to receive additional product at 460. If it was determined at 458 that the patient was willing and able to pay, the patient is informed of the cost of the product and is given

payment options at 462. Once payment is received as indicated at 464, the specialist submits a coverage approval form to the pharmacy team as notification that the refill request can be processed at 466. At 468, the pharmacy technician contacts the patient to schedule shipment. The process of filling the order is continued at 470 by following the process beginning at 240.

A process, referred to as a NORD process in one embodiment is used to determine whether donated, third party funds are available for paying for prescriptions where neither insurance will, nor the patient can pay. The process begins at 510 upon determining that a patient is uninsured or underinsured. A reimbursement specialist explains the NORD program to the patient and faxes an application request form to NORD for the patient. At 515, the intake reimbursement specialist documents in the database that an application has been received through NORD. At 520, NORD mails an application to the patient within one business day.

A determination is made at 525 by NORD whether the patient is approved. If not, at 530, NORD sends a denial letter to the patient, and it is documented in the database at 540 that the patient was denied by NORD. If the patient is approved, NORD sends an acceptance letter to the patient and faxes a voucher to the central pharmacy (SDS in one embodiment) to indicate the approval at 545. At 550, an intake reimbursement specialist submits a coverage approval form to the pharmacy team as notification that the patient has been approved for coverage. The process of filling the order is continued at 555 by following the process beginning at 240.

An inventory control process is illustrated in FIG. 6 beginning at 610. Each week, a responsible person at the central pharmacy, such as the director of the pharmacy transfers inventory for the week's shipments to a segregated warehouse location for production inventory. At 620, a purchase order is generated for the inventory transferred to the production location and is sent, such as by fax, to a controller, such as the controller of the company that obtained approval for distribution and use of the sensitive drug. At 630, the controller invoices the central pharmacy for the product moved to production. The process ends at 640.

The central database described above is a relational database running on the system of FIG. 1, or a server based system having a similar architecture coupled to

workstations via a network, as represented by communications 160. The database is likely stored in storage 140, and contains multiple fields of information as indicated at 700 in FIG. 7. The organization and groupings of the fields are shown in one format for convenience. It is recognized that many different organizations or schemas may be utilized. In one embodiment, the groups of fields comprise prescriber fields 710, patient fields 720, prescription fields 730 and insurance fields 740. For purposes of illustration, all the entries described with respect to the above processes are included in the fields. In further embodiments, no such groupings are made, and the data is organized in a different manner.

Several queries are illustrated at 800 in FIG. 8. There may be many other queries as required by individual state reporting requirements. A first query at 810 is used to identify prescriptions written by physician. The queries may be written in structured query language, natural query languages or in any other manner compatible with the database. A second query 820 is used to pull information from the database related to prescriptions by patient name. A third query 830 is used to determine prescriptions by frequency, and a n^{th} query finds prescriptions by dose at 840. Using query languages combined with the depth of data in the central database allows many other methods of investigating for potential abuse of the drugs. The central database ensures that all prescriptions, prescribers and patients are tracked and subject to such investigations. In further embodiments, the central database may be distributed among multiple computers provided a query operates over all data relating to such prescriptions, prescribers and patients for the drug.

An example of one prescription and enrollment form is shown at 900 in FIG. 9. As previously indicated, several fields are included for prescriber information, prescription information and patient information.

FIG. 10 is a copy of one example NORD application request form 1000 used to request that an application be sent to a patient for financial assistance.

FIG. 11 is a copy of one example application 1100 for financial assistance as requested by form 1000. The form requires both patient and physician information. Social security number information is also requested. The form provides information for approving the financial assistance and for tracking assistance provided.

FIG. 12 is a copy of one example voucher request for medication for use with the NORD application request form of FIG. 10. In addition to patient and physician information, prescription information and diagnosis information is also provided.

FIG.s 13A, 13B and 13C are descriptions of sample reports obtained by querying a central database having fields represented in FIG. 7. The activities grouped by sales, regulatory, quality assurance, call center, pharmacy, inventory, reimbursement, patient care and drug information. Each report has an associated frequency or frequencies. The reports are obtained by running queries against the database, with the queries written in one of many query languages.

While the invention has been described with respect to a Schedule III drug, it is useful for other sensitive drugs that are DEA or Federally scheduled drugs in Schedule II-V, as well as still other sensitive drugs where multiple controls are desired for distribution and use.

Claims

1. A method of distributing a sensitive drug, the method comprising:

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

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

checking the credentials of the doctor;

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

confirming receipt of the sensitive drug; and

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

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

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

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

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

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

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

8. The method of claim 1 wherein prescription refills requested prior to an anticipated date are questioned by the pharmacist.

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

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

11. A method of monitoring potential abuse of a sensitive drug by use of an exclusive central database, the method comprising:

generating queries of prescription information from a database containing selected information for all prescriptions of the sensitive drug, wherein the queries comprise prescriptions by physician specialty, prescriptions by patient name, prescriptions by frequency and prescriptions by dose.

12. The method of claim 11 and further comprising running multiple predetermined reports based on data in the exclusive central database.

13. The method of claim 12 wherein such reports are selected from groups of reports consisting of sales, regulatory, quality assurance, pharmacy, inventory, reimbursement, patient care, and drug information.

14. The method of claim 13 wherein sales reports are selected from the group consisting of prescriptions by zip code, prescriptions by physician by zip code and total dollars by zip code.

15. The method of claim 13 wherein regulatory reports are selected from the group consisting of number of physician registries, number of denied physician registries and reasons, number of completed patient registries, number of problem identification, number of cycle counts performed.

16. The method of claim 13 wherein inventory reports are selected from the group consisting of number of returned products and reasons, number of outdated bottles of product, inventory counts of consignment and production inventory, number of units received, and lots received.

17. The method of claim 13 wherein patient care reports are selected from the group consisting of number of adverse events, number of dosing problems and type, number of noncompliance episodes and reason, number of patients counseled and reason, number of discontinued and reason, number of patients referred to physician and reason, number of active patients, number of new patents, number of restart patients, and number of discontinued patients and reason.

18. The method of claim 13 wherein selected reports are run weekly, monthly or quarterly.

19. A method of obtaining FDA (Food and Drug Administration) approval for a sensitive drug, the method comprising:

determining current and anticipated patterns of potential abuse of the sensitive drug;

selecting multiple controls for distribution by an exclusive central pharmacy maintaining a central database, the controls selected from the group consisting of communicating prescriptions from a physician to the central pharmacy, identifying the physicians name, license and DEA (Drug Enforcement Agency) registration information, verifying the prescription; obtaining patient information, verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and check on whether any actions are pending against the physician, provide comprehensive printed materials to the physician, contacting the patient's insurance company if any, verifying patient registry information, providing comprehensive education information to the patient, verifying the patient has reviewed the educational materials, verifying the home

address of the patient, shipping via US postal service or similar shipping service, receiving the name of an at least 18 year old designee to receive the drug, confirming receipt of an initial shipment of the drug to the patient, returning the drug to the pharmacy after two attempts to deliver, launching an investigation when a shipment is lost, shipping to another pharmacy for delivery, requiring manufacture at a single location, releasing inventory in a controlled manner to the central pharmacy, questioning early refills, flagging repeat instances of lost, stolen, destroyed or spilled prescriptions, limiting the prescription to a one month supply, requiring rewriting of the prescription periodically, making the database available to the DEA for checking for abuse patterns in the data, cash payments, inappropriate questions; and

negotiating with the FDA by adding further controls from the group until approval is obtained.

20. The method of claim 19 wherein initially selected controls comprise communicating prescriptions from a physician to the central pharmacy, identifying the physicians name, license and DEA registration information, verifying the prescription; obtaining patient information, verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and check on whether any actions are pending against the physician, verifying 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 the drug. Abuses are identified by monitoring data in the database for prescription patterns by physicians and prescriptions obtained by patients. Further verification is made that the physician is eligible to prescribe the drug by consulting a separate database, and optionally whether any actions are taken against the physician. Multiple controls beyond those for normal drugs are imposed on the distribution depending on the sensitivity of the drug.

TITLE: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

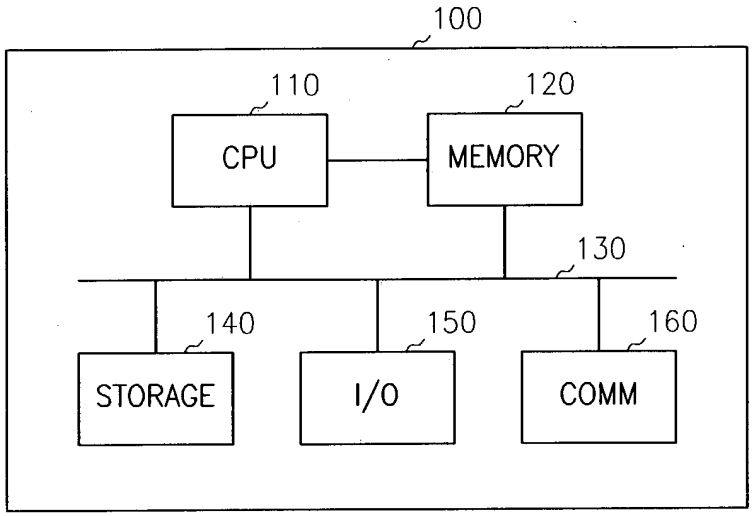

FIG. 1

10322345 121702

TITLE: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

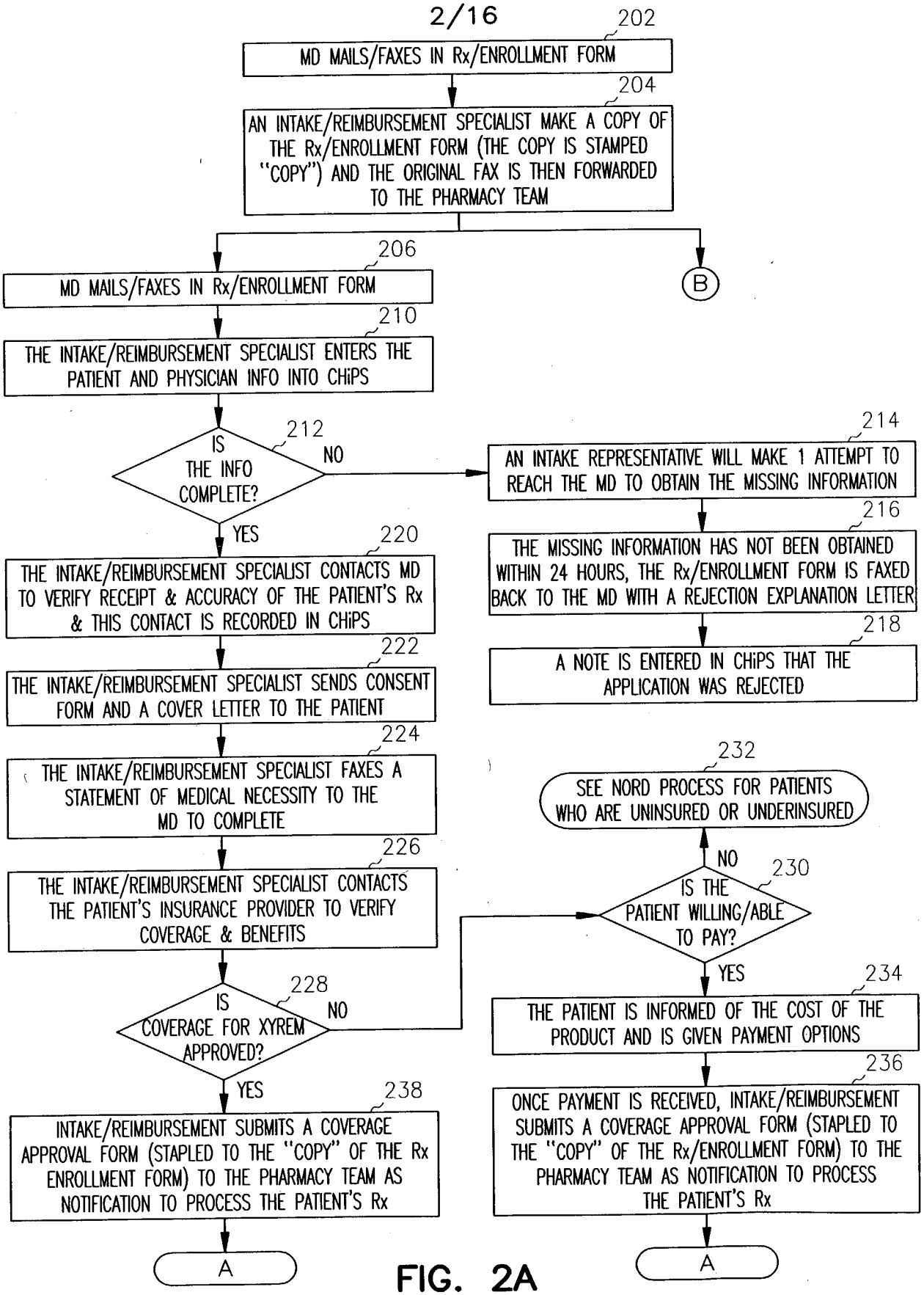

FIG. 2A

TITLE: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

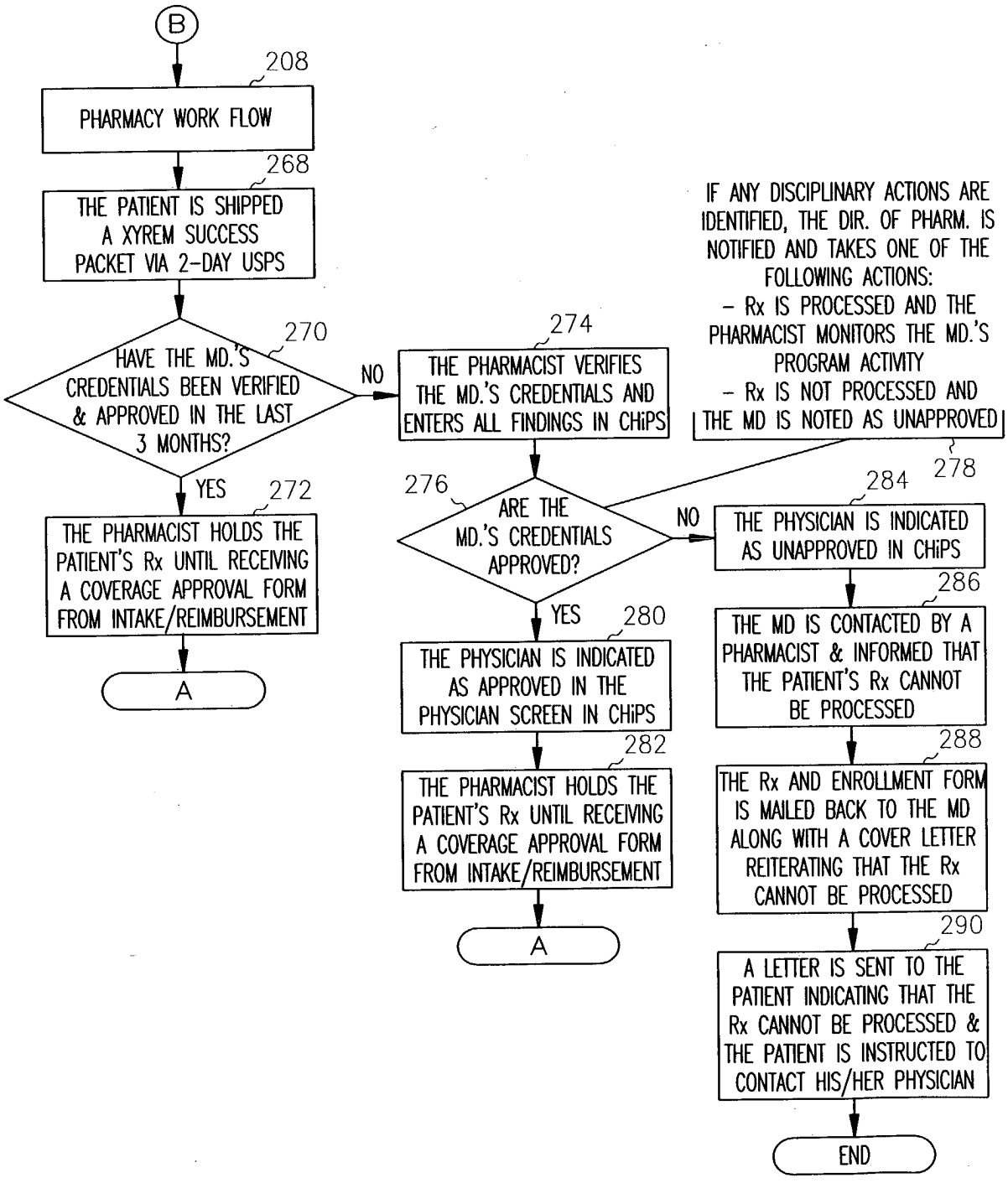

FIG. 2B

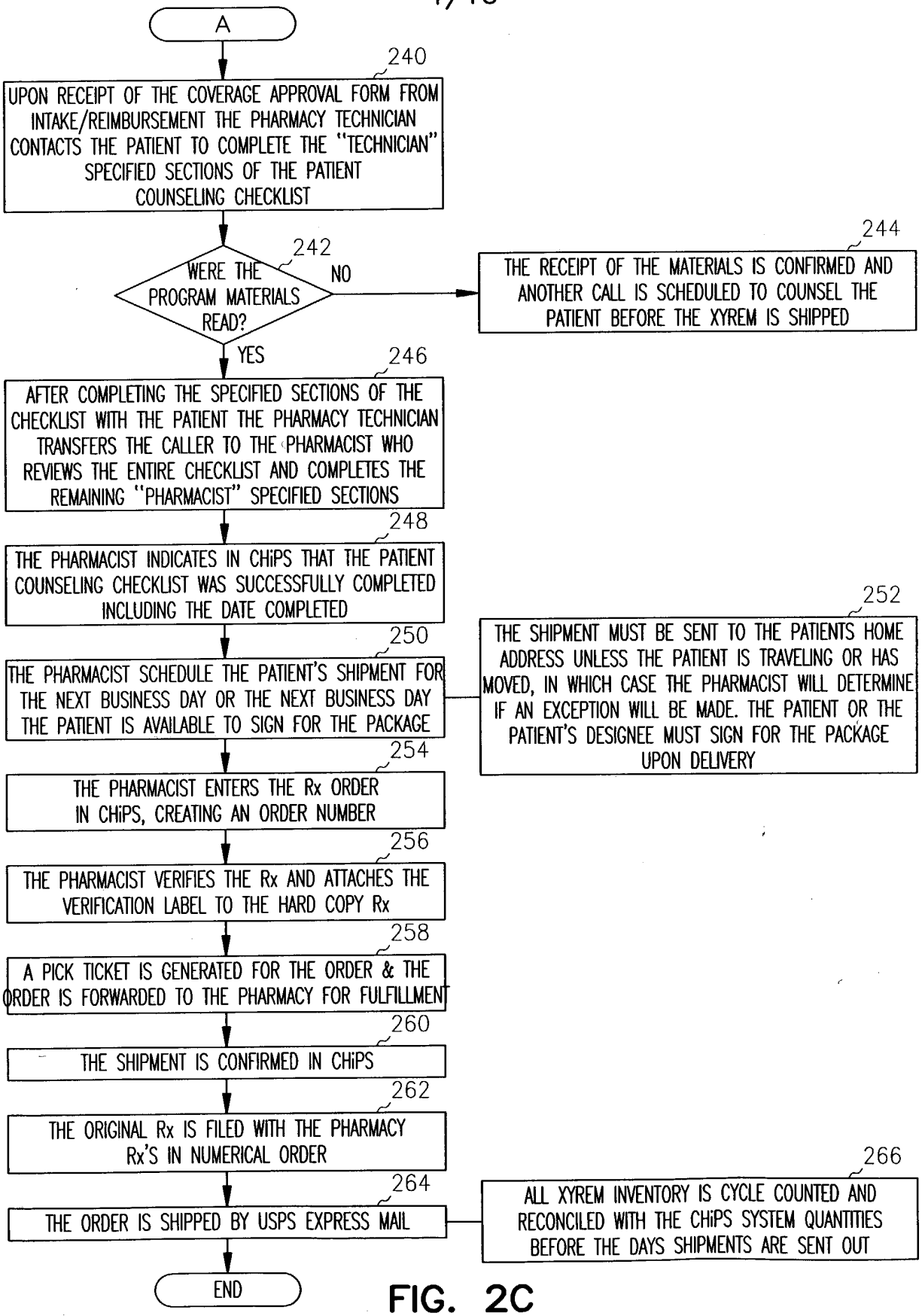
A
240
UPON RECEIPT OF THE COVERAGE APPROVAL FORM FROM INTAKE/REIMBURSEMENT THE PHARMACY TECHNICIAN CONTACTS THE PATIENT TO COMPLETE THE "TECHNICIAN" SPECIFIED SECTIONS OF THE PATIENT COUNSELING CHECKLIST
242
WERE THE PROGRAM MATERIALS READ?
NO
244
THE RECEIPT OF THE MATERIALS IS CONFIRMED AND ANOTHER CALL IS SCHEDULED TO COUNSEL THE PATIENT BEFORE THE XYREM IS SHIPPED
YES
246
AFTER COMPLETING THE SPECIFIED SECTIONS OF THE CHECKLIST WITH THE PATIENT THE PHARMACY TECHNICIAN TRANSFERS THE CALLER TO THE PHARMACIST WHO REVIEWS THE ENTIRE CHECKLIST AND COMPLETES THE REMAINING "PHARMACIST" SPECIFIED SECTIONS
248
THE PHARMACIST INDICATES IN CHIPS THAT THE PATIENT COUNSELING CHECKLIST WAS SUCCESSFULLY COMPLETED INCLUDING THE DATE COMPLETED
252
THE SHIPMENT MUST BE SENT TO THE PATIENTS HOME ADDRESS UNLESS THE PATIENT IS TRAVELING OR HAS MOVED, IN WHICH CASE THE PHARMACIST WILL DETERMINE IF AN EXCEPTION WILL BE MADE. THE PATIENT OR THE PATIENT'S DESIGNEE MUST SIGN FOR THE PACKAGE UPON DELIVERY
250
THE PHARMACIST SCHEDULE THE PATIENT'S SHIPMENT FOR THE NEXT BUSINESS DAY OR THE NEXT BUSINESS DAY THE PATIENT IS AVAILABLE TO SIGN FOR THE PACKAGE
254
THE PHARMACIST ENTERS THE Rx ORDER IN CHIPS, CREATING AN ORDER NUMBER
256
THE PHARMACIST VERIFIES THE Rx AND ATTACHES THE VERIFICATION LABEL TO THE HARD COPY Rx
258
A PICK TICKET IS GENERATED FOR THE ORDER & THE ORDER IS FORWARDED TO THE PHARMACY FOR FULFILLMENT
260
THE SHIPMENT IS CONFIRMED IN CHIPS
262
THE ORIGINAL Rx IS FILED WITH THE PHARMACY Rx'S IN NUMERICAL ORDER
266
ALL XYREM INVENTORY IS CYCLE COUNTED AND RECONCILED WITH THE CHIPS SYSTEM QUANTITIES BEFORE THE DAYS SHIPMENTS ARE SENT OUT
264
THE ORDER IS SHIPPED BY USPS EXPRESS MAIL
END

FIG. 2C

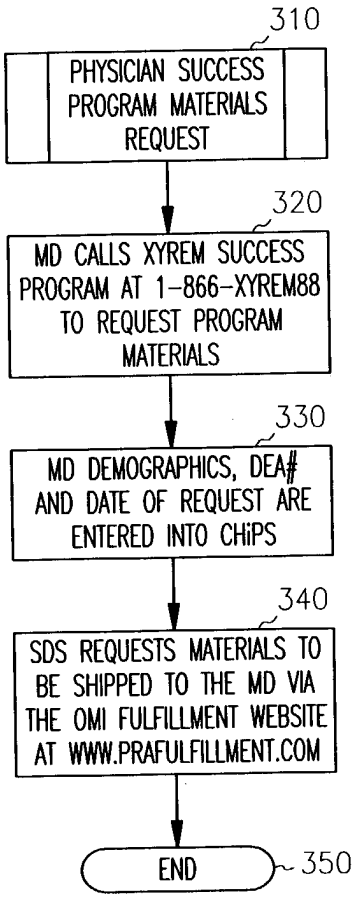
310
PHYSICIAN SUCCESS PROGRAM MATERIALS REQUEST
320
MD CALLS XYREM SUCCESS PROGRAM AT 1-866-XYREM88 TO REQUEST PROGRAM MATERIALS
330
MD DEMOGRAPHICS, DEA# AND DATE OF REQUEST ARE ENTERED INTO CHIPS
340
SDS REQUESTS MATERIALS TO BE SHIPPED TO THE MD VIA THE OMI FULFILLMENT WEBSITE AT WWW.PRAFULFILLMENT.COM
END
350

FIG. 3

TITLE: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

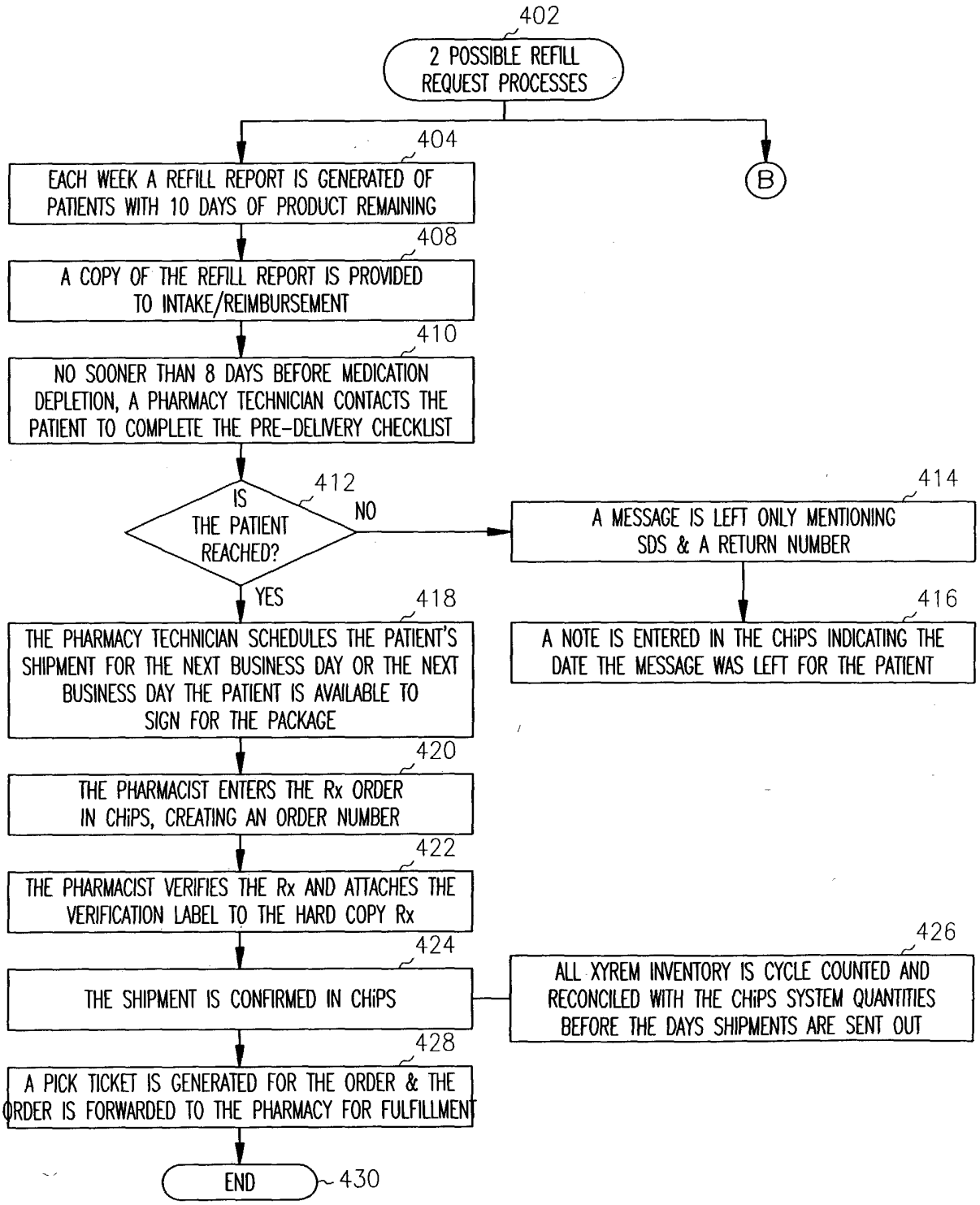

FIG. 4A

TITLE: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

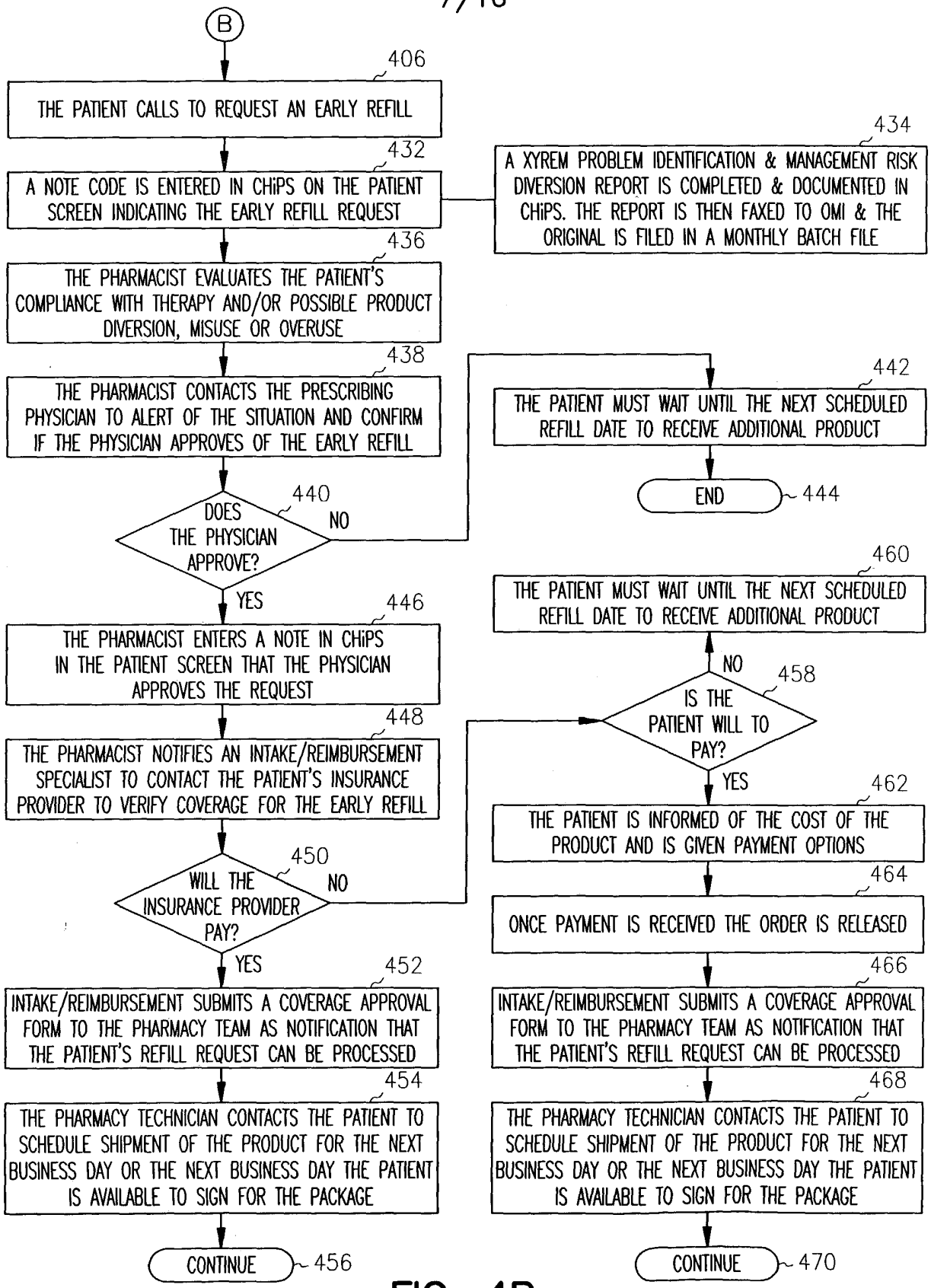

FIG. 4B

TITLE: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

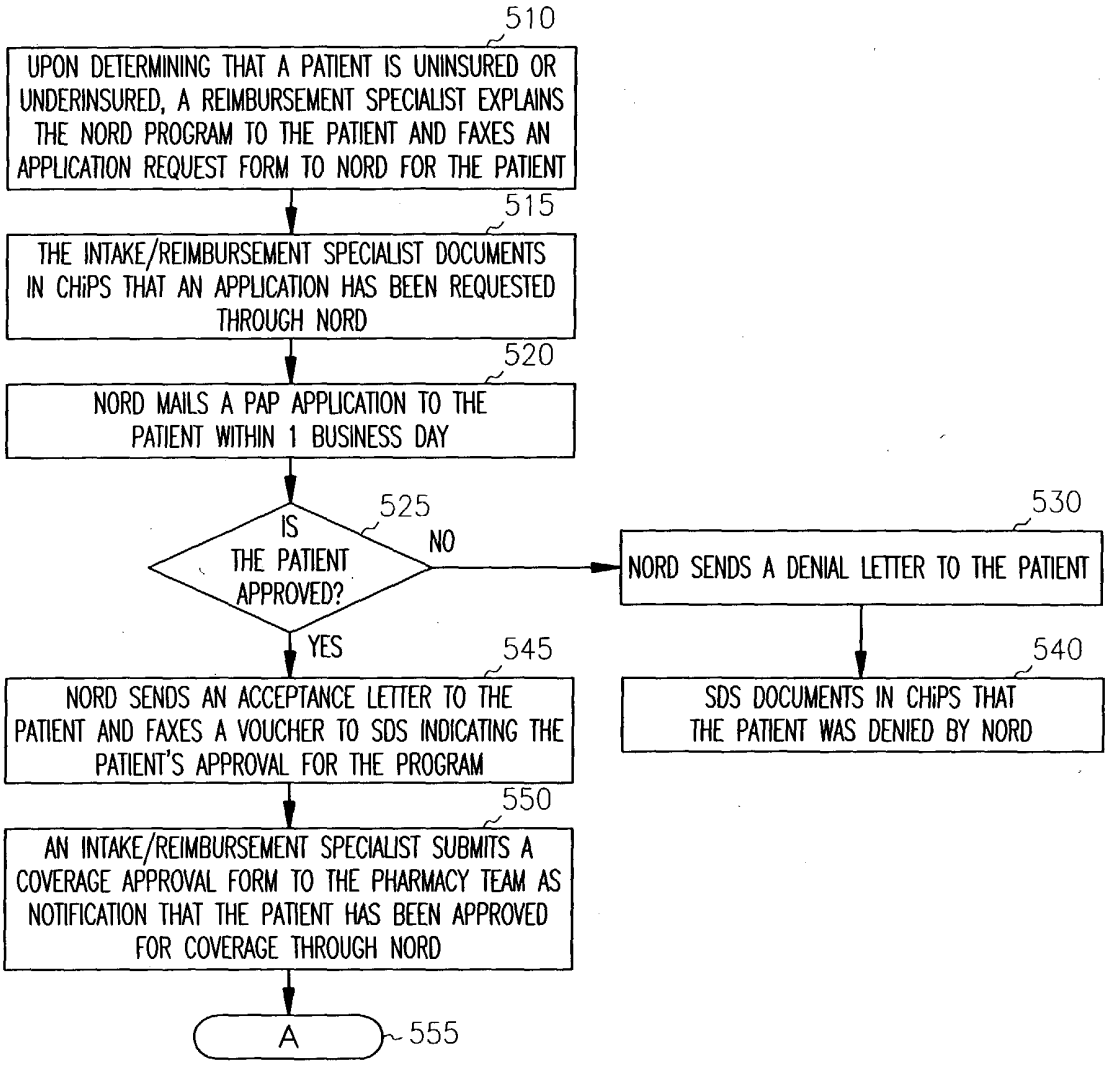

FIG. 5

TITLE: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

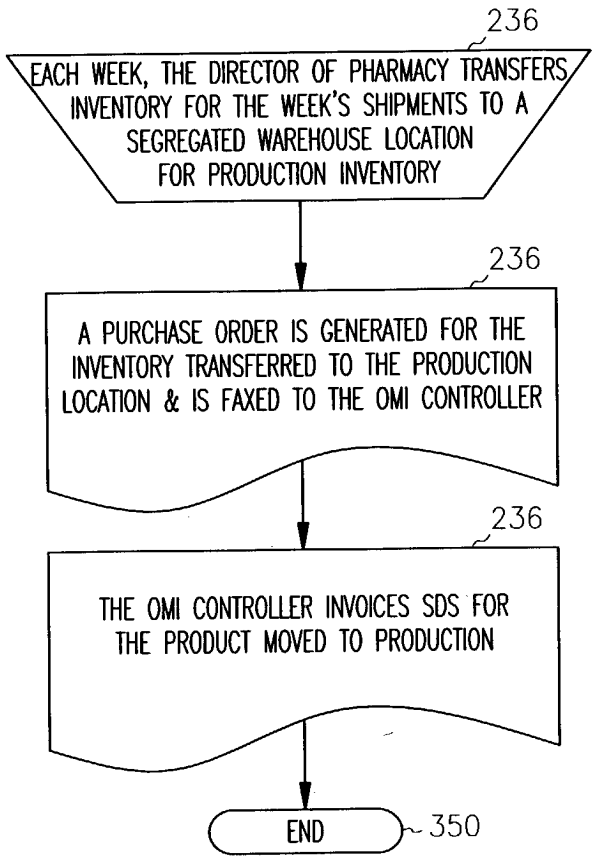

FIG. 6

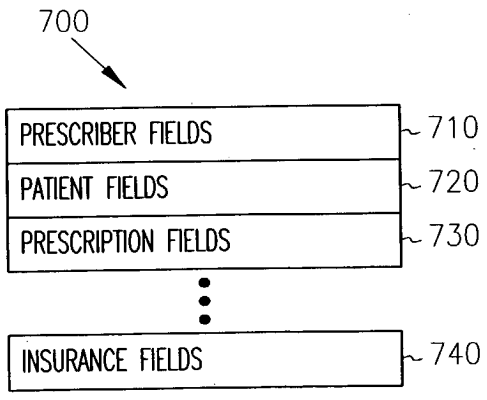

FIG. 7

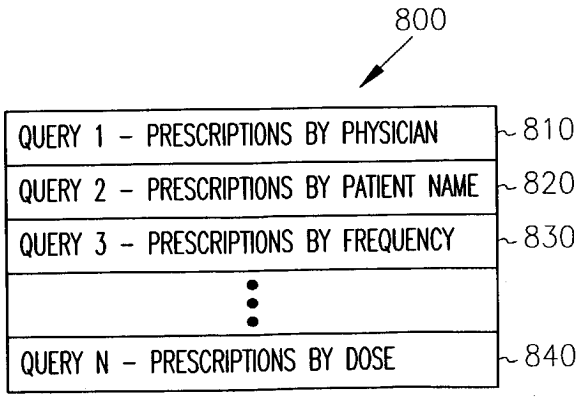

FIG. 8

TITLE: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

900

PRESCRIPTION AND ENROLLMENT FORM

PRESCRIBER INFORMATION

PRESCRIBER'S NAME: _____ OFFICE CONTACT: _____
STREET ADDRESS: _____
CITY: _____ STATE: _____ ZIP: _____
PHONE: _____ FAX: _____
LICENSE NUMBER: _____ DEA NUMBER: _____
MD SPECIALTY: _____

PRESCRIPTION FORM

PATIENT NAME: _____ SS#: _____ DOB: _____ SEX M / F
ADDRESS: _____
CITY: _____ STATE: _____ ZIP: _____
Rx: XYREM ORAL SOLUTION (500 mg/mL) 180 Ml. BOTTLE QUANTITY: _____ MONTHS SUPPLY
SIG: TAKE _____ GMS P.O. DILUTED IN 60 mL WATER AT H.S. AND THEN AGAIN 2 1/2 TO 4 HOURS LATER
REFILLS (CIRCLE ONE): 0 1 2 (MAXIMUM OF 3 MONTH SUPPLY)
_____ DATE: ____/____/____
PRESCRIBER'S SIGNATURE

PHYSICIAN DECLARATION–PLEASE CHECK EACH BOX | TO BE COMPLETED AT INITIAL PRESCRIPTION ONLY

☐ I HAVE READ THE MATERIALS IN THE XYREM PHYSICIAN SUCCESS PROGRAM
☐ I VERIFY THAT THE PATIENT HAS BEEN EDUCATED WITH RESPECT TO XYREM PREPARATION, DOSING AND SCHEDULING.
☐ I UNDERSTAND THAT XYREM IS APPROVED FOR THE TREATMENT OF CATAPLEXY IN PATIENTS WITH NARCOLEPSY, AND THAT SAFETY OR EFFICACY HAS NOT BEEN ESTABLISHED FOR ANY OTHER INDICATION.
☐ I UNDERSTAND THAT THE SAFETY OF DOSES GREATER THAN 9gm/DAY HAS NOT BEEN ESTABLISHED

PATIENT INFORMATION

BEST TIME TO CONTACT PATIENT: ☐ DAY ☐ NIGHT
DAY #: _____ EVENING #: _____
INSURANCE COMPANY NAME: _____ PHONE #: _____
INSURED'S NAME: _____ RELATIONSHIP TO PATIENT: _____
IDENTIFICATION NUMBER: _____ POLICY/GROUP NUMBER: _____
PRESCRIPTION CARD: ☐ NO ☐ YES IF YES, CARRIER: _____ POLICY #: _____ GROUP: _____

PLEASE ATTACH COPIES OF PATIENT'S INSURANCE CARDS

FAX COMPLETED FORM TO XYREM SUCCESS PROGRAM (TOLL-FREE) 1-866-470-1744
FOR INFORMATION, CALL THE XYREM TEAM (TOLL FREE) AT 1-866-XYREM88 (1-866-997-3688)

FIG. 9

TITLE: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

1000

PATIENT ASSISTANCE APPLICATION REQUEST FORM

DATE:

TO: PATIENT ASSISTANCE ORGANIZATION
FROM: SDS

FAX #: 203-798-2291

PLEASE SEND A XYREM PATIENT ASSISTANCE PROGRAM APPLICATION TO:

PATIENT NAME _____

ADDRESS _____

_____

_____

TELEPHONE: ( ) _____

PATIENT DOSAGE: _____ (GRAMS) TWICE NIGHTLY FOR A TOTAL DOSAGE OF _____ (GRAMS)

_____ BOTTLES (THREE MONTHS SUPPLY)

BACKGROUND INFORMATION:

_____

_____

_____

_____

_____

_____

FIG. 10

TITLE: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

12/16

SENSITIVE DRUG PATIENT ASSISTANCE PROGRAM 1100

VOUCHER REQUEST FOR MEDICATION

PATIENT INFORMATION
<FIRST NAME><LAST NAME>
<ADDRESS 1>
<ADDRESS 2>
<CITY, STATE ZIP CODE>

PHONE: <123-456-7890
DOB: 01/01/1900
SSN: 123-45-6789
DRUG ALLOTMENT: 100%
LRD: 03/01/2001

CASE CODE: ********

PHYSICIAN INFORMATION
<PHYSICIAN NAME>
<ADDRESS 1>
<ADDRESS 2>
<CITY, STATE ZIP CODE>

PHONE: <123-456-7890

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

CASE CODE: ********

PHYSICIAN INFORMATION
<PHYSICIAN NAME>
<ADDRESS 1>
<ADDRESS 2>
<CITY, STATE ZIP CODE>

PHONE: <123-456-7890

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: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

1200

SENSITIVE DRUG PHYSICIAN'S CERTIFICATE OF MEDICAL NEED

PATIENT INFORMATION

DATE: _____

NAME: _____
LAST FIRST M

DATE OF BIRTH: _____

DRUG BEING PRESCRIBED: XYREM

DIAGNOSIS/CONDITION FOR WHICH DRUG IS BEING PRESCRIBED: _____

ICD-9: _____

PHYSICIAN INFORMATION

PHYSICIAN'S NAME (PLEASE PRINT): _____

PHYSICIAN'S SIGNATURE: _____ DATE: _____

PLEASE FAX BACK TO SENSITIVE DRUG SUCCESS PROGRAM: (1-800-TOLL FREE NUMBER)

FIG. 12

TITLE: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

ACTIVITY REPORTS

	REPORT FREQUENCY		
	WEEKLY	MONTHLY	QUARTERLY
SALES			
Rx BY ZIP (NEW AND TOTAL)	X	X	X
Rx BY PHYSICIAN BY ZIP	X	X	
$ BY ZIP	X	X	X
REGULATORY			
# OF PHYSICIAN REGISTRIES		X	
# OF DENIED PHYSICIAN REGISTRIES AND REASON		X	
# OF COMPLETED PATIENT REGISTRIES		X	
# OF PROBLEM IDENTIFICATION & MANAGEMENT RISK DIVERSION REPORTS COMPLETED	X		
# OF CYCLE COUNTS PERFORMED & ACCURACY OF EACH		X	
QUALITY ASSURANCE			
# OF PRODUCT DEFECTS/COMPLAINTS REPORTED, TYPE AND LOT #		X	
CALL CENTER			
# OF CALLS RECEIVED		X	
# OF CALLS INITIATED		X	
# OF CALLS ANSWERED IN 30 SECONDS, ETC.		X	
PERCENTAGE OF CALLS ANSWERED IN 30 SECONDS		X	
# OF ABANDONED CALLS		X	
% OF ABANDONED CALLS		X	
AVERAGE CALL LENGTH		X	
PHARMACY			
# OF FAXED Rx/ENROLLMENT FORMS		X	
# OF MAILED Rx/ENROLLEMENT FORMS		X	
# OF RxS SHIPPED W/IN 1, 2, 3, 4 ETC. DAYS (FROM THE TIME INITIAL RECEIPT TO SHIPMENT OF Rx)		X	
# OF PATIENT SUCCESS PACKETS SHIPPED		X	

FIG. 13A

TITLE: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

ACTIVITY REPORTS

PHARMACY			
# OF PHYSICIAN SUCCESS PACKETS SHIPPED			X
# OF COMPLETED SHIPMENTS			X
# OF INCOMPLETE SHIPMENTS AND REASON			X
# OF SHIPPING ERRORS			X
# OF PAP SHIPMENTS			X
# OF PAP APPLICATIONS			X
# OF PAP APPROVALS			X
# OF CANCELED ORDERS			X
# OF USPS ERRORS			X
INVENTORY			X
# OF RETURNED PRODUCTS AND REASON			X
# OF OUTDATED BOTTLES OF PRODUCT			X
INVENTORY COUNTS OF CONSIGNMENT & PRODUCTION INVENTORY			X
# OF UNITS RECEIVED			X
LOTS RECEIVED			X
REIMBURSEMENT			X
# OF PENDED AND WHY			X
# OF APPROVALS			X
# OF DENIALS			X
# OF REJECTIONS			X
PAYOR TYPES			X

FIG. 13B

TITLE: METHOD OF DISTRIBUTION OF CONTROLLED DRUG
INVENTORS NAME: Dayton T. Reardan et al.
DOCKET NO.: 101.031US1

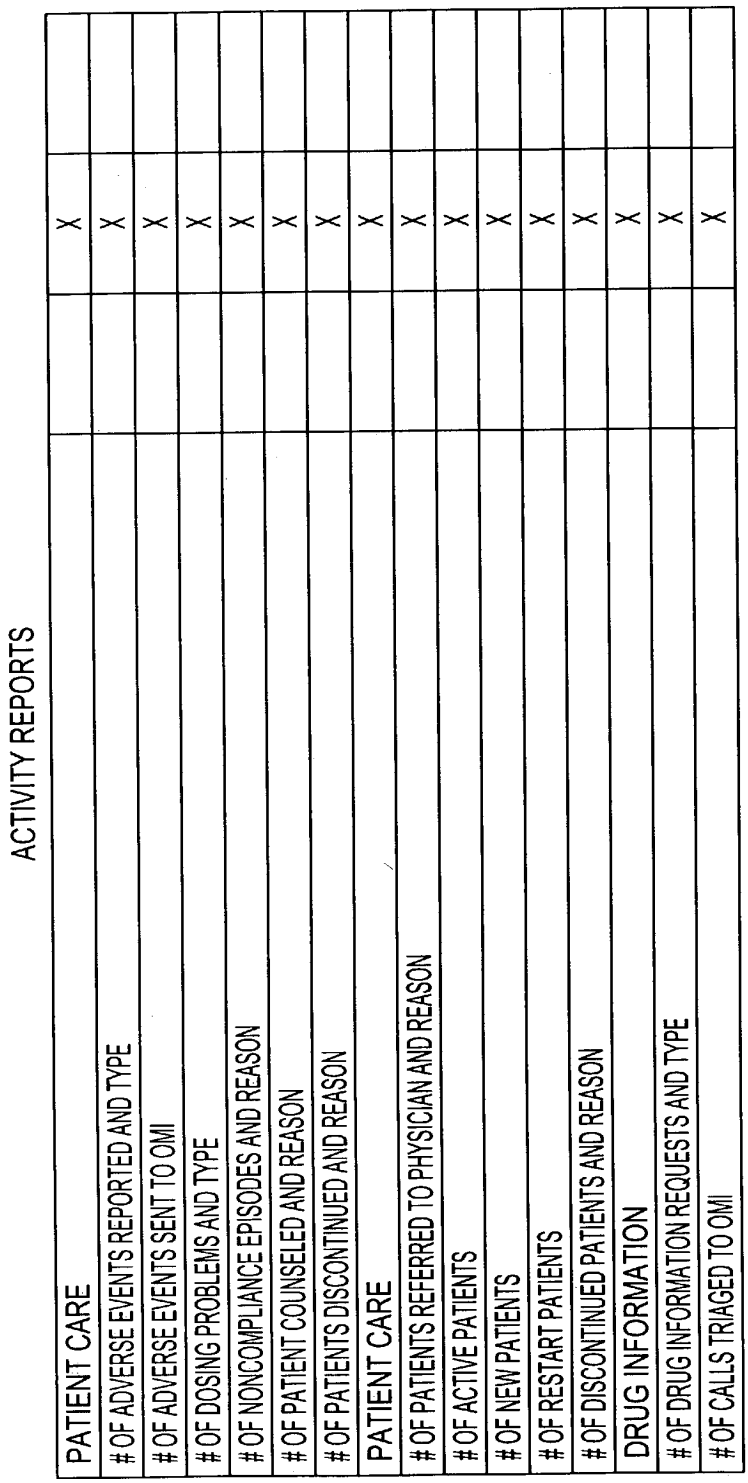

FIG. 13C

Attorney Docket No.101.031US1

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 is attached hereto.

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. Michael	Reg. No. 24,916	Haack, John L.	Reg. No. 36,154	Nama, Kash	Reg. No. 44,255
Arora, Suneel	Reg. No. 42,267	Harris, Robert J.	Reg. No. 37,346	Nelson, Albin J.	Reg. No. 28,650
Beekman, Marvin L.	Reg. No. 38,377	Jackson Huebsch, Katharine A.	Reg. No. 47,670	Nielsen, Walter W.	Reg. No. 25,539
Bianchi, Timothy E.	Reg. No. 39,610	Jurkovich, Patti J.	Reg. No. 44,813	Padys, Danny J.	Reg. No. 35,635
Billion, Richard E.	Reg. No. 32,836	Kalis, Janal M.	Reg. No. 37,650	Parker, J. Kevin	Reg. No. 33,024
Black, David W.	Reg. No. 42,331	Klima-Silberg, Catherine I.	Reg. No. 40,052	Perdok, Monique M.	Reg. No. 42,989
Brennan, Thomas F.	Reg. No. 35,075	Kluth, Daniel J.	Reg. No. 32,146	Peret, Andrew R.	Reg. No. 41,246
Chadwick, Robin A.	Reg. No. 36,477	Lacy, Rodney L.	Reg. No. 41,136	Peterson, David C.	Reg. No. 47,857
Clark, Barbara J.	Reg. No. 38,107	Lemaire, Charles A.	Reg. No. 36,198	Prout, William F.	Reg. No. 33,995
Clise, Timothy B.	Reg. No. 40,957	LeMoine, Dana B.	Reg. No. 40,062	Schumm, Sherry W.	Reg. No. 39,422
Cochran, David R.	Reg. No. 46,632	Lundberg, Steven W.	Reg. No. 30,568	Schwegman, Micheal L.	Reg. No. 25,816
Dahl, John M.	Reg. No. 44,639	Maki, Peter C.	Reg. No. 42,832	Speier, Gary J.	Reg. No. 45,458
Drake, Eduardo E.	Reg. No. 40,594	Malen, Peter L.	Reg. No. 44,894	Steffey, Charles E.	Reg. No. 25,179
Embretson, Janet E.	Reg. No. 39,665	Mates, Robert E.	Reg. No. 35,271	Stordal, Leif T.	Reg. No. 46,251
Forrest, Bradley A.	Reg. No. 30,837	McCrackin, Ann M.	Reg. No. 42,858	Terry, Kathleen R.	Reg. No. 31,884
Gamon, Owen J.	Reg. No. 36,143	McGough, Kevin J.	Reg. No. 31,279	Tong, Viet V.	Reg. No. 45,416
Gorrie, Gregory J.	Reg. No. 36,530	McTavish, Hugh E.	Reg. No. 48,341	Viksnins, Ann S.	Reg. No. 37,748
Gortych, Joseph E.	Reg. No. 41,791	Mehrle, Joseph P.	Reg. No. 45,535	Woessner, Warren D.	Reg. No. 30,440
Greaves, John N.	Reg. No. 40,362	Muller, Mark V.	Reg. No. 37,509		

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**
Citizenship: **United States of America** Residence: **Excelsior, MN**
Post Office Address: 22345 Bracketts Road
Excelsior, MN 55331

Signature: _____ Date: _____
Dayton T. Reardan

Full Name of joint inventor number 2 : **Patti Engel**
Citizenship: **United States of America** Residence: **Eagen, MN**
Post Office Address: 852 Basswood Lane
Eagen, MN 55123

Signature: _____ Date: _____
Patti Engel

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

[redacted]

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of joint inventor number 3 : **Bob Gagne**
Citizenship: **United States of America** Residence: **St. Paul, MN**
Post Office Address: 202 So. Wheeler Street
St. Paul, MN 55015

Signature: _____ Date: _____
Bob Gagne

Full Name of inventor:
Citizenship: Residence:
Post Office Address:

Signature: _____ Date: _____

Full Name of inventor:
Citizenship: Residence:
Post Office Address:

Signature: _____ Date: _____

Full Name of inventor:
Citizenship: Residence:
Post Office Address:

Signature: _____ Date: _____

[redacted]

§ 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.

[redacted]

UNITED STATES
PATENT AND
TRADEMARK OFFICE

Commissioner for Patents
Washington, DC 20231
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/322,348	12/17/2002	Dayton T. Reardan	101.031US1

CONFIRMATION NO. 5446

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

FORMALITIES LETTER

OC000000009686927

Date Mailed: 03/24/2003

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 $ **375** *to complete the basic filing fee for a small entity.*
- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of $65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

Items Required To Avoid Processing Delays:

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- Additional claim fees of $**87** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is $**527** for a Small Entity

- $**375** Statutory basic filing fee.
- $**65** Late oath or declaration Surcharge.
- Total additional claim fee(s) for this application is $**87**
  - $**45** for **5** total claims over 20 .

- **$42** for **1** independent claims over 3 .

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

Customer Service Center
Initial Patent Examination Division (703) 308-1202
PART 3 - OFFICE COPY

1743

3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

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

Serial No.: 10/322,348
Due Date: N/A
Group Art Unit: 1743

Commissioner for Patents
Washington, D.C. 20231

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

X A return postcard.
X An Information Disclosure Statement (1 pg.), Form 1449 (1 pg.), and copies of 7 cited documents.

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.
P.O. Box 2938, Minneapolis, MN 55402 (612-373-6900)

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

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: Commissioner for Patents, Washington, D.C. 20231, on this 8 day of April, 2003.

MEREDITH MESCHER
Name

Meredith Mescher
Signature

Customer Number 21186
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. Box 2938, Minneapolis, MN 55402 (612-373-6900)
(GENERAL)

S/N 10/322348 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan Ph.D. et al.	Examiner:	Unknown
Serial No.:	10/322,348	Group Art Unit:	1743
Filed:	December 17, 2002	Docket:	101.031US1
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

OIPE
APR 14 2003
PATENT & TRADEMARK OFFICE 2826

RECEIVED
APR 16 2003
TC 1700

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

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.

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.

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 PH.D. ET AL.

By their Representatives,

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

Date 4-8-2003 By _____
Bradley A. Forrest
Reg. No. 30,837

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: Commissioner of Patents, Washington, D.C. 20231, on this 8 day of April, 2003

MEREDITH MESCHER
Name

Meredith Mescher
Signature

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

OIPE JC26 APR 14 2003 PATENT & TRADEMARK OFFICE

Sheet 1 of 1

Complete if Known	
Applicati n Number	10/322,348
Filing Date	December 17, 2002
First Nam d Invent r	Reardan Ph.D., Dayton
Group Art Unit	1743
Examiner Name	Unknown
Attorney Docket No: 101.031US1	

RECEIVED APR 16 2003 TC 1700

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
	US-6,045,501	04/04/2000	Elsayed, Marc , et al			08/28/1998
	US-6,315,720	11/13/2001	Williams, Bruce A., et al			10/23/2000

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T[2]

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		NASCSA National Conference, (November 2000),8 pages	
		"Diversion Prevention Through Responsible Distribution", NADDI Regional Training, (May 2001),12 pages	
		"Diversion Prevention Through Responsible Distribution", NADDI Regional Training Tennessee, (June 2001),14 Pages	
		"Diversion Prevention Through Responsible Distribution", NADDI National Conference, (November 2001),15 pages	
		"Peripheral and Central Nervous System Drugs Advisory Committee", Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research, Holiday Inn, Bethesda, Maryland,(06/06/2001),7 pages	

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

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

4

OIPE
MAY 27 2003

Attorney Docket No.101.031US1

SCHWEGMAN ■ LUNDBERG ■ WOESSNER ■ KLUTH

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: **SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD**.

The specification of which was filed on December 17, 2002 as application serial no. 10/322,348.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 C.F.R. § 1.56 (attached hereto). I also acknowledge my duty to disclose all information known to be material to patentability which became available between a filing date of a prior application and the national or PCT international filing date in the event this is a Continuation-In-Part application in accordance with 37 C.F.R. § 1.63(e).

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

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

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

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

I hereby claim the benefit under 35 U.S.C. § 120 or 365(c) of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. § 1.56(a) which became available between the filing date of the prior application and the national or PCT international filing date of this application:

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

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

Anglin, J. M	Reg. No. 24,916	Harris, Robert J	Reg. No. 37,346	Nielsen, Walter W	Reg. No. 25,539
Arora, Suneel	Reg. No. 42,267	Jackson Huebsch, Katharine A	Reg. No. 47,670	Padys, Danny J	Reg. No. 35,635
Beekman, Marvin L	Reg. No. 38,377	Jurkovich, Patti J	Reg. No. 44,813	Parker, J. K	Reg. No. 33,024
Bianchi, Timothy E	Reg. No. 39,610	Kalis, Janal M	Reg. No. 37,650	Peacock, Gregg A	Reg. No. 45,001
Billion, Richard E	Reg. No. 32,836	Klima-Silberg, Catherine I	Reg. No. 40,052	Perdok, Monique M	Reg. No. 42,989
Black, David W	Reg. No. 42,331	Kluth, Daniel J	Reg. No. 32,146	Peret, Andrew R	Reg. No. 41,246
Brennan, Thomas F	Reg. No. 35,075	Lacy, Rodney L	Reg. No. 41,136	Peterson, David C	Reg. No. 47,857
Chadwick, Robin A	Reg. No. 36,477	Lemaire, Charles A	Reg. No. 36,198	Prout, William F	Reg. No. 33,995
Clark, Barbara J	Reg. No. 38,107	Lundberg, Steven W	Reg. No. 30,568	Puckett, Ph. D., Craig L	Reg. No. 43,023
Clise, Timothy B	Reg. No. 40,957	Maki, Peter C	Reg. No. 42,832	Schumm, Sherry W	Reg. No. 39,422
Cochran, David R	Reg. No. 46,632	Malen, Peter L	Reg. No. 44,894	Schwegman, Micheal L	Reg. No. 25,816
Dahl, John M	Reg. No. 44,639	Mates, Robert E	Reg. No. 35,271	Speier, Gary J	Reg. No. 45,458
Drake, Eduardo E	Reg. No. 40,594	McCrackin, Ann M	Reg. No. 42,858	Steffey, Charles E	Reg. No. 25,179
Embretson, Janet E	Reg. No. 39,665	McGough, Kevin J	Reg. No. 31,279	Stordal, Leif T	Reg. No. 46,251
Forrest, Bradley A	Reg. No. 30,837	McTavish, Hugh E	Reg. No. 48,341	Terry, Kathleen R	Reg. No. 31,884
Gorrie, Gregory J	Reg. No. 36,530	Mehrle, Joseph P	Reg. No. 45,535	Tong, Viet V	Reg. No. 45,416
Gortych, Joseph E	Reg. No. 41,791	Muller, Mark V	Reg. No. 37,509	Viksnins, Ann S	Reg. No. 37,748
Greaves, John N	Reg. No. 40,362	Nama, Prakash	Reg. No. 44,255	Woessner, Warren D	Reg. No. 30,440
Haack, John L	Reg. No. 36,154	Nelson, A. J	Reg. No. 28,650		

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/organization/who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Schwegman, Lundberg, Woessner & Kluth, P.A. to the contrary.

Please direct all correspondence in this case to **Schwegman, Lundberg, Woessner & Kluth, P.A.** at the address indicated below:

P.O. Box 2938, Minneapolis, MN 55402
Telephone No. (612)373-6900

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of joint inventor number 1 : **Dayton T. Reardan Ph.D.**
Citizenship: **United States of America** Residence: **Excelsior, MN**
Post Office Address: 22345 Bracketts Road
Excelsior, MN 55331

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

Full Name of joint inventor number 2 : **Patti ~~Engle~~ A. ENGEL**
Citizenship: **United States of America** Residence: **Eagan, MN**
Post Office Address: 852 Basswood Lane
~~Eagan~~, MN

Signature: Patti A. Engel Date: May 13, 2003
Patti ~~Engle~~
PATTI A. ENGEL

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

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of joint inventor number 3 : **Bob Gagne**
Citizenship: **United States of America** Residence: **St. Paul, MN**
Post Office Address: 202 So. Wheeler Street
St. Paul, MN 55015

Signature: Bob Gagne Date: 1 May 2003
Bob Gagne

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application:

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

OIPE JC141 OCT 04 2004 PATENT & TRADEMARK OFFICE

S/N 10/322,348

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	10/322,348 ✓	Group Art Unit:	Unknown
Filed:	December 17, 2002	Docket No:	101.031US1
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:

10/06/2004 MBELETE1 00000032 10322348

01 FC:2201 86.00 OP
02 FC:2202 54.00 OP

IN THE CLAIMS

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

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

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

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

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

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

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

11. (Original) 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. (Original) The method of claim 11 and further comprising running multiple predetermined reports based on data in the exclusive central database.

13. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) The method of claim 13 wherein selected reports are run weekly, monthly or quarterly.

19. (Original) 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. (Original) 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. (Original) The method of claim 19 wherein the sensitive drug is a scheduled drug in Schedule II-V.

22. (Original) 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. (Original) 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. (Original) 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. (Original) 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.

26. (New) 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. (New) 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. (New) 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. (New) 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. (New) The method of claim 29 wherein initially selected controls comprise communicating prescriptions from a physician to the central pharmacy; identifying the physicians name, license, and DEA registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; verifying patient registry information; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address of the patient; shipping via US postal service; confirming receipt of an initial shipment of the drug to the patient; releasing inventory in a controlled manner to the central pharmacy; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; and making the database available to the DEA for checking for abuse patterns in the data.

31. (New) 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 added new claims 26 to 31. No new matter has been added. Support for claim 26 appears in the specification at page 1(in the Summary of the Invention) and in original claim 19. Support for claim 27 appears in original claim 20. Support for claim 28 appears in the specification at page 2, line 1. Support for claim 29 appears at page 4, line 13, in the specification at page 1 (in the Summary of the Invention), and in original claim 19. Support for claim 30 appears at page 4, line 13 and in original claim 20. Support for claim 31 appears at page 4, line 13 and at page 2, line 1.

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 (703) 239-9592 to facilitate prosecution of this application.

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

Respectfully Submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

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Date 9/30/2004 By _____
Bradley A. Forrest
Reg. No. 30,837

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 envelop addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 30th day of September 2004.

Name Dawn M. Ridle Signature _____

OIPE JC147 OCT 04 2004 PATENT & TRADEMARK OFFICE

S/N 10/322348 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:
Serial No.:	10/322348	Group Art Unit:
Filed:	December 17, 2002	Docket: 101.031US1
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. 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), is enclosed. 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). Copies of the references deemed most closely related to the subject matter are enclosed in the accompanying Information Disclosure Statement and Form 1449.

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

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Date 9/30/2004 By _____
Bradley A. Forrest
Reg. No. 36,530

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on **September 30th, 2004**.

Name: Dawn M. Poole

Signature _____

10/06/2004 MBELETE1 00000032 10322348

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S/N 10/322348 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:
Serial No.:	10/322348	Group Art Unit:
Filed:	December 17, 2002	Docket: 101.031US1
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 1-31 of the above-identified Application.

The search was conducted in the USPTO classes/subclasses listed below:

Class	Subclasses	Description
700/		**DATA PROCESSING: GENERIC CONTROL SYSTEMS OR SPECIFIC APPLICATIONS**
	237	....Authorization (e.g., password, time usage limit, personal identification number (PIN)
705/		**DATA PROCESSING: FINANCIAL, BUSINESS PRACTICE, MANAGEMENT, OR COST/PRICE DETERMINATION**
	1	AUTOMATED ELECTRICAL FINANCIAL OR BUSINESS PRACTICE OR MANAGEMENT ARRANGEMENT
	2	. Health care management (e.g., record management, ICDA billing)
	3	.. Patient record management
707/		**DATA PROCESSING: DATABASE AND FILE MANAGEMENT OR DATA STRUCTURES**
	1	DATABASE OR FILE ACCESSING
	10	. Distributed or remote access
	104.1	. Application of database or data structure (e.g., distributed, multimedia, image)
709/		**ELECTRICAL COMPUTERS AND DIGITAL PROCESSING SYSTEMS: MULTICOMPUTER DATA TRANSFERRING OR PLURAL PROCESSOR SYNCHRONIZATION**
	200	MULTICOMPUTER DATA TRANSFERRING
	201	. Distributed data processing

217	. Remote data accessing
218	.. Using interconnected networks
219	.. Accessing a remote server

The references found to be relevant to claims 1-31 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 1-31 are patentable over the relevant references.

In summary, the present claims relate to a new paradigm for 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 an exclusive 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.

Instant claims 19 and 26 recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by an exclusive central pharmacy. This feature is not disclosed in Mayaud.

Patents 5,924,074 and 6,347,329 B1 to Evans provide for an **ELECTRONIC MEDICAL RECORDS SYSTEM.** Disclosed is reference database **104**, which includes

diagnosis module **300**, medication manager **302**, and procedure module **304**. A healthcare provider may use the reference database for assistance in diagnosing a patient's disease and prescribing medications to treat the disease. Medication manager **302** provides information on medications, such as proper dosages, allergies, contraindications, adverse interactions, and side effects. This system also provides instant access to a patient's electronic record by any authorized healthcare provider from any geographical location.

Instant claim 19 recites a feature that embodies the new distribution model, namely the distribution of a sensitive drug by an exclusive central pharmacy. This feature is not disclosed in Evans.

Patent 6,021,392 to Lester et al. provides for a **SYSTEM AND METHOD FOR DRUG MANAGEMENT**. Disclosed is a system for health care supply distribution from a central location.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Lester et al. These features do more than simply manage the distribution of health care supplies as in Lester et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

Patent 6,055,507 to Cunningham provides for a **METHOD AND SYSTEM FOR DISPENSING TRACKING AND MANAGING PHARMACEUTICAL TRIAL PRODUCTS**. Disclosed is a centralized pharmaceutical sample distribution management system for controlling dispensing of samples among prescribers, patients, and pharmacies.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Cunningham. These features do more than simply manage the distribution of pharmaceutical samples as in Cunningham. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

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.

Instant claims 19 and 26 recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by an exclusive central pharmacy. This feature is not disclosed in 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.

Instant claims 19 and 26 recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by an exclusive central pharmacy. This feature is not disclosed in Williams et al.

Patent 6,687,676 B1 and related published application 2004/0107117 A1 to Denny provide a **PRESCRIPTION VERIFICATION SYSTEM.** Disclosed is a method for verifying/confirming prescription fulfillment, whereby a hosted database receives/provides prescription information including health care provider codes, patient codes, pharmacy system identification codes, and reports having prescription data summarized by patient name, social security numbers, the names of the prescribing health care providers, and the physician's Drug Enforcement Agency (DEA) number as means for minimizing fraud, abuse, and errors associated with prescription drugs.

Instant claim 1 recites features that embody the new distribution model. For example,

among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Denny. These features do more than simply verify and confirm fulfillment of prescriptions, as in Denny. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

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.

Instant claims 19 and 26 recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by an exclusive central pharmacy. This feature is not disclosed in Kapp.

Published patent application 2001/0042050 A1 to Fletcher et al. provides a **SECURE ELECTRONIC PROCUREMENT SYSTEM AND METHOD.** Disclosed is a secure, Internet-based electronic procurement system allowing a user (e.g., pharmacist) to order and confirm receipt of goods normally subject to a verifiable chain of custody (e.g., narcotics, controlled drugs and substances).

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Fletcher et al. These features do more than simply facilitate the ordering and receipt of drugs as in Fletcher et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

Published patent application 2001/0047281 A1 to Keresman et al. provides a **SECURE ON-LINE AUTHENTICATION SYSTEM FOR PROCESSING PRESCRIPTION DRUG FULFILLMENT**. Disclosed is a centralized database providing identity authentication over a

communication network, whereby network users/vendors are registered and provided with a uniquely defined identity as means for allowing ID authentication prior to closing a transaction. For doctors **40** and pharmacies **30**, the evaluation preferably includes a verification of their credentials and/or licenses by comparing collected registration data **114** corresponding to data made available from a government office or agency which issued the credentials and/or granted licenses.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Keresman et al. These features do more than simply authenticate identity as in Keresman et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

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.

Instant claim 19 recites a feature that embodies the new distribution model, namely the distribution of a sensitive drug by an exclusive central pharmacy in order to obtain FDA approval. This feature is not disclosed in Reitberg.

Published patent application 2002/0032582 A1 to Feeney et al. provides for a **SYSTEM FOR MEDICATION DISPENSING AND INTEGRATED DATA MANAGEMENT.** Disclosed is a medical system for integrating data management with the process of controllably dispensing products including medications, and whereby a central server connected via a network to a prescription subsystem is configured to receive and process data including DEA, FDA, and drug interactions as means to determine whether the medication is appropriate for a patient.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or

suggested by Feeney et al. These features do more than simply control dispensing of drugs at the point of care as in Feeney et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

Published patent application 2002/0042762 A1 to McQuade et al. provides for **TRACKING THE DISTRIBUTION OF PRESCRIPTION DRUGS AND OTHER CONTROLLED ARTICLES**. Disclosed is a method for tracking the distribution of controlled articles from a central inventory.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by McQuade et al. These features do more than simply control the distribution and inventory of pharmaceutical samples as in McQuade et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

Published patent application 2002/0052762 A1 to Kobylevsky et al. provides for a **REMOTE PRESCRIPTION REFILL SYSTEM.** Disclosed is a central pharmacy system having software for automatically processing pharmacy orders.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Kobylevsky et al. These features do more than simply process refills automatically so as to relieve the burden on pharmacists as in Kobylevsky et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

Published patent application 2002/0161607 A1 to Subich provides for a **PHARMACEUTICAL DRUG SAMPLE TRACKING AND CONTROL METHOD.** Disclosed is a pharmaceutical drug sample tracking and control method for storing patient information, adverse reaction information experienced by a patient, and patient recovery state, when a patient is treated with a drug sample.

Instant claim 1 recites features that embody the new distribution model. For example,

among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports to evaluate potential abuse patterns are not discussed or suggested by Subich. These features do more than simply store prescription information so that interested parties may access the information.

Published patent application 2003/0046110 A1 to Gogolak provides for a **METHOD AND SYSTEM FOR CREATING, STORING, AND USING PATIENT SPECIFIC AND POPULATION-BASED GENOMIC DRUG SAFETY DATA.** Disclosed is drug safety database **10**, which may be accessed by users as a single virtual database. This source data covers three general areas: adverse event database **20**, drug information database **30**, and patient or genomic database **40**. Adverse event data are acquired by accessing, soliciting, or assembling data on patients experiencing adverse drug reactions, and comparing the data against data from a control set. This data may be provided from pharmaceutical corporations, hospitals, physicians, and government agencies.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Gogolak. These features do more than simply provide a database as in Gogolak. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

Published patent application 2003/0050802 A1 to Jay et al. provides for a **MEDICAL SERVICE AND PRESCRIPTION MANAGEMENT SYSTEM.** Disclosed is point-of-care device **112**, which may connect to health plan database **104**. The system allows a doctor to search for drugs and perform drug interaction checking. It helps in dispensing of medication by presenting a warning message when the doctor selects a drug that is likely to cause drug-to-drug interactions or drug-allergy interactions for the patient. The drug interaction warnings may also include an analysis of the patient's family history and living habits.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or

suggested by Jay et al. These features do more than simply allowing a doctor to search for drugs and perform drug interaction checking as in Jay et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

Published patent application 2003/0093295 A1 to Lilly et al. provides a **CONTROLLED SUBSTANCE TRACKING SYSTEM AND METHOD.** Disclosed is a system and method for providing access to potential medication abuse information comprising identification of prescription duplications, potential drug interactions, multi-source interstate prescriptive medication abuse, and fraudulent prescriptive medications. Data storage **122** provides means for storing/receiving various types of data comprising: a doctor's name, DEA number, patient name, patient ID, patient address, patient phone number, drugs prescribed, dosage, frequency, start/end date, duration, quantity, number refills, whether substitution is allowed, generic allowed, notes, aberrant use flag, date prescription filed, location prescription was filled, pharmacist's name, phone number, and DEA number.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Lilly et al. These features do more than simply providing access to potential medication abuse information as in Lilly et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

Published patent application 2003/0110060 A1 to Clementi provides for a **METHOD OF PROVIDING COMPREHENSIVE DRUG COMPLIANCE INFORMATION.** Disclosed is database **20**, which constructs patient report **12**. Patient **10** may access this report to see basic personal information, a record of all medicines being used, interactions between the medicines, and side effects of the medicine. The drug manufacturer **50** may also receive a number of such reports and note the side effect in a future product warning.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, and analysis of potential abuse are not discussed or suggested by Clementi. These

features do more than simply provide information as in Clementi. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

Published patent application 2003/0127508 A1 to Jones provides a **METHOD OF INDIVIDUALLY TRACKING AND IDENTIFYING A DRUG DELIVERY DEVICE.** Disclosed is a method and system for identifying an individual drug delivery device and for tracing its ownership, whereby a coded unique identifier is stored in a database for subsequent association/identification of distributing entities (e.g., transferee and a prescribing physician). Additional information added to the database may include the address of a patient, the RX number, the MD number, the identity of the prescribing physician, the DEA number, the pharmacy number, and the date of dispensation or transfer.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Jones. These features do more than simply track and identify a particular drug delivery device as in Jones. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

Published patent application 2003/0144876 A1 to Kosinski et al. provides for an **APPARATUS AND METHOD FOR PROCESSING PHONE-IN PRESCRIPTION.** Disclosed is central or regional pharmacy **138** and prescription processing network **100,** whereby identification information including DEA data may be utilized as means to prevent prescription fraud.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Kosinski et al. These features do more than simply process audible, fax, or e-mail prescription requests as in Kosinski et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

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.

Instant claims 19 and 26 recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by an exclusive central pharmacy. This feature is not disclosed in Eidex et al.

Published patent application 2003/0233256 A1 to Cardenas et al. provides **SECURE MEDICAL PRESCRIPTIONS.** Disclosed is a centralized method and system for producing a secure medical prescription by converting the physician's DEA number into an encrypted code for placement onto a medical prescription.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Cardenas et al. These features do more than simply producing secure medical prescriptions as in Cardenas et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

Published patent application 2004/0019567 A1 to Herceg et al. provides for an **ELECTRONIC PRESCRIPTION ORDERING METHOD, SYSTEM, AND PROGRAM PRODUCT.** Disclosed is Web-based central pharmaceutical computer **12** having database **24** as means for providing electronic prescription ordering.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Herceg et al. These features do more than ordering prescriptions electronically. In

contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

Published patent application 2004/0019794 A1 to Moradi et al. provides a **METHOD AND SYSTEM FOR DELIVERING PRESCRIPTION MEDICINE**. Disclosed is a system and method of distributing medicine, whereby the method provides for: accepting a prescription and a delivery address from a central server, wherein the prescription is for a medicine and wherein the delivery address is associated with a person; delivering the medicine to the delivery address; receiving a confirmation from the person that the medicine was delivered; and communicating the confirmation to the central server. In addition, the system provides for registering information relevant to the identification of a prescription issuing physician, patient, and fulfillment pharmacy.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Moradi et al. These features do more than prevent receipt of too much medicine as in Moradi et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

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.

Instant claims 19 and 26 recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by an exclusive central pharmacy. This feature is not disclosed in 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.

Instant claim 19 recites a feature that embodies the new distribution model, namely the distribution of a sensitive drug by an exclusive central pharmacy in order to obtain FDA approval. This feature is not disclosed in Fetterman et al.

Published patent applications 2004/0122712 A1 and 2004/0122713 A1 to Hill et al. provide a **SYSTEM AND METHOD FOR PRESCRIPTION MANAGEMENT**. Disclosed is a prescription filling system for allowing physicians **102** and patients **104** to interact with pharmacy system **112** and central fill facility **124** to fill prescriptions. In addition, filled prescriptions may be delivered by central fill facility **124** to pharmacies **106** or home delivered for purchase by patient **104**.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Hill et al. These features do more than provide a prescription filling system to bypass manual filling as in Hill et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

Published patent application 2004/0162740 A1 to Ericsson et al. provides for a **DIGITIZED PRESCRIPTION SYSTEM.** Disclosed is an apparatus comprising an electronic database containing a plurality of transaction records for transactions in which a prescription medicinal substance is dispensed to a patient. Additionally, a method is utilized in conjunction with FDA and DEA drug information to: obtain a patient's medication history comprising searching the electronic database by the patient's social security number; determine whether a proposed refill or remaining fill transaction is indicative of potential overuse; determine whether a medicinal substance in a proposed transaction will result in possible interactions with a patient's recently dispensed medicinal substances; and identify potential counterfeiting or illicit importation of prescription medicinal substances.

Instant claim 1 recites features that embody the new distribution model. For example,

among other distinctions recited in claim 1, patient education is not discussed or suggested by Ericsson et al. This feature does more than facilitate exchange of data as in Ericsson et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions and uses patient education as a control on the distribution of a sensitive drug.

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.

Instant claim 1 recites features that embody the new distribution model. For example, among other distinctions recited in claim 1, checking the credentials of the doctor, patient education, analysis of potential abuse, and generating periodic reports are not discussed or suggested by Lilly et al. These features do more than generate a medication history for a particular purchaser as in Lilly et al. In contrast, the present model analyses for and determines potential abuse situations and current and anticipated patterns of potential adverse reactions.

In addition, instant claims 19 and 26 recite a feature that embodies the new distribution model, namely the distribution of a sensitive drug by an exclusive central pharmacy. This feature is not disclosed in Lilly et al.

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(703) 239-9592

Date: 9/30/2004

By _____
Bradley A. Forrest
Registration No. 36,530

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on **September 30th, 2004**.

Dawn M. Poole
Name:

Dawn M. Poole
Signature

OIPE JC141 OCT 04 2004 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.:	101.031US1	Serial No.:	10/322,348
Filed:	December 17, 2002	Due Date:	N/A
Examiner:	Unknown	Group Art Unit:	1743

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

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

X A return postcard.
X Petition to Make Special Under 37 CFR 1.102(d) (1 Pg.).
X Appendix I (2 pgs.).
X An Information Disclosure Statement (2 pgs.), Form 1449 (2 pgs.). Documents NOT enclosed.
X A check in the amount of $140.00 to cover the fee for additional claims as calculated below.
X Preliminary Amendment (11 pgs.).
X Pre-Examination Statement For Petition To Make Special Under 37 CFR 1.102(d) (15 pgs.).
X A check in the amount of $130.00 to cover the Petition Fee.

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

CLAIMS AS AMENDED						
	(1) Claims Remaining After Amendment		(2) Highest Number Previously Paid For	(3) Present Extra	Rate	Fee
TOTAL CLAIMS	31	-	25	6	x 9.00 =	$54.00
INDEPENDENT CLAIMS	6	-	4	2	x 43.00 =	$86.00
[]MULTIPLE DEPENDENT CLAIMS PRESENTED						$0.00
TOTAL						$140.00

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

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

By: _____
Atty: Bradley A. Forrest
Reg. No. 36,530

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: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 30th day of September, 2004.

Dawn M. Poole
Name

Dawn M. Poole
Signature

OIPE JC141 OCT 04 2004 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	10/322,348	Group Art Unit:	1743
Filed:	December 17, 2002	Docket:	101.031US1
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.

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.

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
(703) 239-9592

Date 9/30/2004 By _____
Bradley A. Forrest
Reg. No. 36,530

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: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 30th day of September, 2004.

Name _____ Signature _____

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

OIPE JC141 OCT 04 2004 PATENT & TRADEMARK OFFICE

Sheet 1 of 2

Complete if Known

Application Number	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan, Dayton
Group Art Unit	1743
Examiner Name	Unknown

Attorney Docket No: 101.031US1

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
	US-2001/ 0001144	05/10/2001	Kapp, Thomas L.			12/22/2000
	US-2001/ 0042050	11/15/2001	Fletcher, Robert J., et al.			01/05/2001
	US-2001/ 0047281	11/29/2001	Keresman, III, Michael A., et al.			03/06/2001
	US-2002/ 0032581	03/14/2002	Reitberg, donald P.			06/01/2001
	US-2002/ 0032582	03/14/2002	Feeney, Jr., Robert J., et al.			08/15/2001
	US-2002/ 0042725	04/11/2002	Mayaud, Christian			08/30/2001
	US-2002/ 0042762	04/11/2002	McQuade, Richard , et al.			08/30/2001
	US-2002/ 0052762	05/02/2002	Kobylevsky, Paul , et al.			05/15/2001
	US-2002/ 0161607	10/31/2002	Subich, David C.			02/23/2001
	US-2003/ 0046110	03/06/2003	Gogolak, Victor			08/28/2002
	US-2003/ 0050802	03/13/2003	Jay, Richard , et al.			04/03/2002
	US-2003/ 0110060	06/12/2003	Clementi, William A.			12/12/2001
	US-2003/ 0127508	07/10/2003	Jones, William N.			01/21/2003
	US-2003/ 0144876	07/31/2003	Kosinski, Diana L., et al.			01/28/2002
	US-2003/ 0229519	12/11/2003	Eidex, Brian H., et al.			05/16/2003
	US-2003/ 0233256	12/18/2003	Cardenas, Rodolfo , et al.			06/13/2002
	US-2004/ 0019567	01/29/2004	Herceg, Michael J., et al.			07/23/2002
	US-2004/ 0019794	01/29/2004	Moradi, Ahmad , et al.			07/29/2002
	US-2004/ 0078237	04/22/2004	Kaafarani, William , et al.			08/28/2003
	US-2004/ 0107117	06/03/2004	Denny, Lawrence A.			11/25/2003

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

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

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 851-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

OIPE
OCT 04 2004
PATENT & TRADEMARK OFFICE
TC/A.U. 1743

Sheet 2 of 2

Complete if Known

Application Number	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan, Dayton
Group Art Unit	1743
Examiner Name	Unknown

Attorney Docket No: 101.031US1

	US-2004/0117126	06/17/2004	Fetterman, Jeffrey E., et al.			11/25/2003
	US-2004/0122712	06/24/2004	Hill, Sr., Kenneth A., et al.			12/20/2002
	US-2004/0122713	06/24/2004	Hill, Sr., Kenneth A., et al.			12/20/2002
	US-2004/0162740	08/19/2004	Ericsson, Arthur D., et al.			02/14/2003
	US-2004/0176985	09/09/2004	Lilly, Ralph B., et al.			03/18/2004
	US-5,845,255	12/01/1998	Mayaud, C.	705	3	10/02/1997
	US-5,924,074	07/13/1999	Evans, J. A.	705	3	09/27/1996
	US-6,021,392	02/01/2000	Lester, Douglas D., et al.			12/08/1997
	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-6,755,784	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	Class	Subclass	T[2]

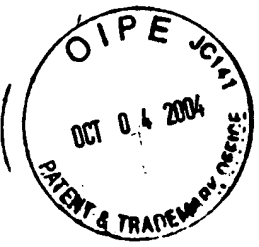
OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

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]

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

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



Appendix I
Copies of Prior Art References

The thirty-six (36) references include:

1. 5,845,255
2. 5,924,074
3. 6,347,329
4. 6,021,392
5. 6,055,507
6. 6,112,182
7. 6,315,720
8. 6,561,977
9. 6,755,784
10. 6,687,676
11. 2001/0001144
12. 2001/0042050
13. 2001/0047281
14. 2002/0032581
15. 2002/0032582
16. 2002/0042725
17. 2002/0042762
18. 2002/0052762
19. 2002/0161607
20. 2003/0046110
21. 2003/0050802
22. 2003/0093295
23. 2003/0110060
24. 2003/0127508
25. 2003/0144876
26. 2003/0229519
27. 2003/0233256
28. 2004/0019567
29. 2004/0019794

30. 2004/0078237
31. 2004/0107117
32. 2004/0117126
33. 2004/0122712
34. 2004/0122713
35. 2004/0162740
36. 2004/0176985

PATENT APPLICATION FEE DETERMINATION RECORD
Effective January 1, 2003

Application or Docket Number: 10/322348

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	25	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	25 minus 20=	* 5
INDEPENDENT CLAIMS	4 minus 3 =	* 1
MULTIPLE DEPENDENT CLAIM PRESENT		☐

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

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE	$375	OR	BASIC FEE	$750
X$ 9=	45	OR	X$18=	
X42=	42	OR	X84=	
+140=		OR	+280=	
TOTAL	462	OR	TOTAL	

CLAIMS AS AMENDED - PART II

10.4.04

AMENDMENT A	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 31	Minus	** 25	= 6
Independent	* 6	Minus	*** 4	= 2
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=	54	OR	X$18=	
~~X42=~~	86	OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE	140	OR	TOTAL ADDIT. FEE	

AMENDMENT B	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

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

Index of Claims

Application/Control No.	Applicant(s)/Patent under Reexamination
~~10/000,000~~ 10/322348	~~LIGHT~~
Examiner	**Art Unit**
~~***~~	1743

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

Claim		Date								
Final	Original									
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.:	101.031US1	Serial No.:	10/322,348
Filed:	December 17, 2002	Due Date:	N/A
Examiner:	Unknown	Group Art Unit:	1743

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

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

X A return postcard.
X A Supplemental Information Disclosure Statement (2 pgs.), Form 1449 (2 pgs.), and copies of 33 cited documents.

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

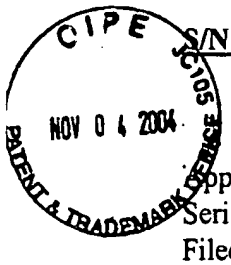
By: _____
Atty: Bradley A. Forrest
Reg. No. 30,837

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 2nd day of November, 2004.

Dawn M. Vode
Name

Dawn M. Vode
Signature

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



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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	10/322,348	Group Art Unit:	1743
Filed:	December 17, 2002	Docket:	101.031US1
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.

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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 11/2/2004 By _____
Bradley A. Forrest
Reg. No. 30,837

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Name Dawn M. Poole

Signature _____

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

OIPE JC105 NOV 0 4 2004 PATENT & TRADEMARK OFFICE

Sheet 1 of 2

Complete if Known

Application Number	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan, Dayton
Group Art Unit	1743
Examiner Name	Unknown
Attorney Docket No: 101.031US1	

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	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/ 0,110,060	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
	US-2004/ 0,107,117	06/03/2004	Denny, Lawrence A.			11/25/2003

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's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

Application Number	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan, Dayton
Group Art Unit	1743
Examiner Name	Unknown
Attorney Docket No:	101.031US1

	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.	705	3	10/02/1997
	US-5,924,074	07/13/1999	Evans, J. A.	705	3	09/27/1996
	US-6,021,392	02/01/2000	Lester, Douglas D., et al.			12/08/1997
	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-6,755,784	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	Class	Subclass	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]

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

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

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JUN 17 2005

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

In re application of : **DECISION ON PETITION**
Dayton T. Reardan, et al. : **TO MAKE SPECIAL**
Application No. 10/322,348 : **(ACCELERATED**
Filed: December 17, 2002 : **EXAMINATION)**
For: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

This is in response to the renewed petition filed on October 4, 2004 to make the above-identified application special on the basis of special examining procedure for certain new applications - accelerated examination as set forth in MPEP § 708.02 VIII.

The requirements for granting special status under this section are: (A) a petition to make special accompanied by the fee set forth in 37 CFR 1.17(i); (B) all claims being directed to a single invention, or an election without traverse if the Office determines that all the claims are not directed to a single invention; (C) a statement that a pre-examination search was made listing the field of search; (D) one copy of each of the references deemed most closely related to the subject matter encompassed by the claims if said references are not already of record; and (E) a detailed discussion of how the claimed subject matter is patentable over the references in accordance with 37 CFR 1.111 (b) and (c).

Since all of the requirements for special status under MPEP § 708.02 VIII have been met, the petition is **GRANTED**.

The examiner is directed (1) to make an interference search for possible interfering applications, (2) to promptly examine this application out of turn, and (3) if any interfering application is discovered, to examine such application simultaneously and state in the first official letter of such application that it is being taken out of turn because of a possible interference.

Petitioner is advised that this application will continue to be special, throughout its entire prosecution and pendency, including interference or appeal, if any, only if petitioner makes a prompt ***bona fide*** effort, in response to each Office action, to place the application in condition for allowance, even if it is necessary to conduct an interview with the examiner to accomplish this purpose.

SUMMARY: Petition to Make Special **GRANTED.**

Randolph A. Reese
Special Programs Examiner
Technology Center 3600
571-272-6619

RAR/dcg: 6/1/05

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L12	37	(educational or printed) adj1 (material) same (prescriber or physician or doctor) same (new or first adj1 time or no adj1 experience or never adj1 before)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 14:53 looked at titles/abstracts
L15	22	(sensitive or controlled) and (drug or medication or medicine or prescription) same (first adj1 time) same (prescriber or doctor or physician) same (information or instruction or direction)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 14:57 considered 1
L16	39	(drug or medication or medicine or prescription) same (first adj1 time) same (prescriber or doctor or physician) same (information or instruction or direction)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 15:19 considered 1
S1	66586	(distribut$3 or provid$3 or supply$3 or deliver$3 or dispens$3) and ((sensitive or abuse or abusive or addictive) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 14:21
S2	4281	((705/2) or (705/3) or (600/300)). CCLS.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2005/06/17 13:13
S3	348	S1 and S2	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/17 13:14

S4	116	(data adj1 base or database or data adj1 bank or databank) and (enter$3 or submit$4 or input$4 or prompt) and (credential$3 or certif$7 or licens$3) and (refill or re adj1 fill) and (address or residence) and (educational adj1 (material or information or data) or brochure or pamphlet) and (pattern or track$3 or monitor$3) and (report or update) and (evaluat$3 or analy$4) and (doctor or physician or prescriber)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/17 13:35
S5	8	S1 and S4	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON looked at titles/abstracts	2005/06/17 13:19
S6	159939	(distribut$3 or provid$3 or supply$3 or deliver$3 or dispens$3) and ((sensitive or abuse or abusive or addictive or controlled) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:31
S7	14343	(distribut$3 or provid$3 or supply$3 or deliver$3 or dispens$3) and ((sensitive or abuse or abusive or addictive or controlled) adj1 (drug or medicine or medication or ointment or pharmaceutical or pill or agent) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/17 13:24
S8	8	S4 and S7	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON looked at titles/abstracts	2005/06/17 13:24

S9	119	(data adj1 base or database or data adj1 bank or databank) and (enter$3 or submit$4 or input$4 or prompt) and (credential$3 or certif$7 or licens$3) and (refill or re adj1 fill or reorder or re adj1 order) and (address or residence) and (educational adj1 (material or information or data) or brochure or pamphlet) and (pattern or track$3 or monitor$3) and (report or update) and (evaluat$3 or analy$4) and (doctor or physician or prescriber)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/17 13:36
S10	41	(data adj1 base or database or data adj1 bank or databank) and (enter$3 or submit$4 or input$4 or prompt) and (credential$3 or certif$7 or licens$3) and (refill or re adj1 fill or reorder or re adj1 order) and (address or residence) and (educational adj1 (material or information or data) or brochure or pamphlet) and (pattern or track$3 or monitor$3) and (report or update) and (evaluat$3 or analy$4) and (doctor or physician or prescriber) and (patient)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/17 13:37
S11	8	(data adj1 base or database or data adj1 bank or databank) and (enter$3 or submit$4 or input$4 or prompt) and (credential$3 or certif$7 or licens$3) and (refill or re adj1 fill or reorder or re adj1 order) and (address or residence) and (educational adj1 (material or information or data) or brochure or pamphlet) and (pattern or track$3 or monitor$3) and (report or update) and (evaluat$3 or analy$4) and (doctor or physician or prescriber) and (patient) and ((sensitive or abuse or abusive or addictive) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/17 13:38

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S12	32	(data adj1 base or database or data adj1 bank or databank) and (enter$3 or submit$4 or input$4 or prompt) and (credential$3 or certif$7 or licens$3) and (refill or re adj1 fill or reorder or re adj1 order) and (address or residence) and (educational adj1 (material or information or data) or brochure or pamphlet) and (pattern or track$3 or monitor$3) and (report or update) and (evaluat$3 or analy$4) and (doctor or physician or prescriber) and (patient) and ((sensitive or abuse or abusive or addictive or controlled) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/17 17:26
S54	4	S53 or S51	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 15:17

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Considered 1

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L12	37	(educational or printed) adj1 (material) same (prescriber or physician or doctor) same (new or first adj1 time or no adj1 experience or never adj1 before)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 14:53 looked at titles/abstracts
L15	22	(sensitive or controlled) and (drug or medication or medicine or prescription) same (first adj1 time) same (prescriber or doctor or physician) same (information or instruction or direction)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 14:57 looked at titles/abstracts
L16	39	(drug or medication or medicine or prescription) same (first adj1 time) same (prescriber or doctor or physician) same (information or instruction or direction)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 15:19 looked at titles/abstracts
S1	66586	(distribut$3 or provid$3 or supply$3 or deliver$3 or dispens$3) and ((sensitive or abuse or abusive or addictive) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 14:21
S2	4281	((705/2) or (705/3) or (600/300)). CCLS.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2005/06/17 13:13
S3	348	S1 and S2	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/17 13:14

S12	32	(data adj1 base or database or data adj1 bank or databank) and (enter$3 or submit$4 or input$4 or prompt) and (credential$3 or certif$7 or licens$3) and (refill or re adj1 fill or reorder or re adj1 order) and (address or residence) and (educational adj1 (material or information or data) or brochure or pamphlet) and (pattern or track$3 or monitor$3) and (report or update) and (evaluat$3 or analy$4) and (doctor or physician or prescriber) and (patient) and ((sensitive or abuse or abusive or addictive or controlled) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/17 17:26
S24	4	(data adj1 base or database or data adj1 bank or databank) and (enter$3 or submit$4 or input$4 or prompt) and (credential$3 or certif$7 or licens$3) and (refill or re adj1 fill or reorder or re adj1 order) and (address or residence) and (educational adj1 (material or information or data) or brochure or pamphlet) and (pattern or track$3 or monitor$3) and (report or update) and (evaluat$3 or analy$4) and (doctor or physician or prescriber) and (patient) and ((sensitive or abuse or abusive or addictive or controlled) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer)) and (state adj1 licens$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/17 17:32

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looked at titles/abstracts

S25	8	(physician or doctor or medical adj1 professional or practitioner) same (request$3 or submit$4 or order$2) same (prescription or medication or medicine or drug or pill) and (central or main) adj1 (database or data adj1 base or databank or data adj1 bank) and (abuse or fraud or abusing or abusive) and (check$3 or verif$7 or confirm$5) same (credential$3 or certif$7 or licens$3) and (ship$4 or distribut$3 or supply$3 or deliver$3 or dispens$3) and (receiv$3 or receipt)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:20 looked at titles/abstracts
S26	118162	((sensitive or abuse or abusive or addictive) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer or cocaine or marijuana))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/17 17:38
S27	5	S25 and S26	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/17 17:39 looked at titles/abstracts
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S29	24	(physician or doctor or medical adj1 professional or practitioner or prescriber) same (request$3 or submit$4 or order$2 or enter$3 or input$4) same (prescription or medication or medicine or drug or pill or pharmaceutical) and (central or main) adj1 (database or data adj1 base or databank or data adj1 bank) and (check$3 or verif$7 or confirm$5) same (credential$3 or certif$7 or licens$3) and (ship$4 or distribut$3 or supply$3 or deliver$3 or dispens$3) and (generat$3 or creat$3) same (report or analy$3 or conclusion or summary or finding or document$5)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:26
S30	19	(physician or doctor or medical adj1 professional or practitioner or prescriber) same (request$3 or submit$4 or order$2 or enter$3 or input$4) same (prescription or medication or medicine or drug or pill or pharmaceutical) and (central or main) adj1 (database or data adj1 base or databank or data adj1 bank) and (check$3 or verif$7 or confirm$5) same (credential$3 or certif$7 or licens$3) and (ship$4 or distribut$3 or supply$3 or deliver$3 or dispens$3) and (generat$3 or creat$3) same (report or analy$3 or conclusion or summary or finding or document$5) and (pharmacy)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 13:39
S31	63501	((sensitive or abuse or abusive or addictive or controlled) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer)) same (pattern or finding or analy$3 or conclusion or result or track$3 or monitor$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:34
S32	4281	((705/2) or (705/3) or (600/300)).CCLS.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2005/06/20 11:33

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S33	303	S31 and S32	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:33
S34	25010	((sensitive or abuse or abusive or addictive or controlled) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer)) same (pattern or finding or analy$3 or track$3 or monitor$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:34
S35	25010	(((sensitive or abuse or abusive or addictive or controlled) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent)) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer)) same (pattern or finding or analy$3 or track$3 or monitor$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:34
S36	1028	(((sensitive or abuse or abusive or addictive or controlled) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent)) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer)) same (pattern or finding or analy$3 or track$3 or monitor$3) and (prescription or prescribing or medication adj1 order)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:35
S37	485	(((sensitive or abuse or abusive or addictive or controlled) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent)) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer)) same (pattern or finding or analy$3 or track$3 or monitor$3) and (prescription or prescribing or medication adj1 order) same (doctor or physician)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:36
S38	103	S32 and S37	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:35

S39	102	(((sensitive or abuse or abusive or addictive or controlled) adj2 (drug or medicine or medication or ointment or pharmaceutical or pill or agent)) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer)) same (pattern or finding or analy$3 or track$3 or monitor$3) and (prescription or prescribing or medication adj1 order) same (doctor or physician)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:41
S40	97	(((sensitive abusive or addictive or controlled) adj2 (drug or medicine or medication or ointment or pharmaceutical or pill or agent)) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer)) same (pattern or finding or analy$3 or track$3 or monitor$3) and (prescription or prescribing or medication adj1 order) same (doctor or physician)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:42
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looked at titles/abstracts

S43	131	(((sensitive or abusive or addictive or controlled) adj2 (drug or medicine or medication or ointment or pharmaceutical or pill or agent or substance)) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer)) same (pattern or finding or analy$3 or track$3 or monitor$3) and (prescription or prescribing or medication adj1 order) same (doctor or physician)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:57
S44	1072	(((sensitive or abusive or addictive or controlled) adj2 (drug or medicine or medication or ointment or pharmaceutical or pill or agent or substance)) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer)) same (abuse or abusive or fraud$5)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 11:58
S45	143	(((sensitive or abusive or addictive or controlled) adj2 (drug or medicine or medication or ointment or pharmaceutical or pill or agent or substance)) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer)) same (abuse or abusive or fraud$5) same (analy$4 or pattern or track$3 or monitor$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 12:00
S46	44	(((sensitive or abusive or addictive or controlled) adj2 (drug or medicine or medication or ointment or pharmaceutical or pill or agent or substance)) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer)) same (abuse or abusive or fraud$5) same (analy$4 or pattern or track$3 or monitor$3) and (prescription or prescrib$3 or medication adj1 order)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 13:32

S48	8	(physician or doctor or medical adj1 professional or practitioner or prescriber) same (request$3 or submit$4 or order$2 or enter$3 or input$4) same (prescription or medication or medicine or drug or pill or pharmaceutical) and (central or main) adj1 (database or data adj1 base or databank or data adj1 bank) and (check$3 or verif$7 or confirm$5) same (credential$3 or certif$7 or licens$3) and (ship$4 or distribut$3 or supply$3 or deliver$3 or dispens$3) and (generat$3 or creat$3) same (report or analy$3 or conclusion or summary or finding or document$5) and (pharmacy) and (educational adj1 (material or information or data) or (brochure) or (pamphlet))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 13:44
S54	4	S53 or S51	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 15:17

looked at titles/abstracts

considered 2

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S64	23	(confirm$3 or verif$7) same (prescription) same (read) same (instruction or advice)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 16:02 looked at titles/abstracts
S65	1	(call$3) same (patient) same (verif$7 or confirm$5) same (prescription or medication adj1 order) same (instructions or guidelines or education)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 16:08 looked at title/abstract
S66	275	(patient) same (verif$7 or confirm$5 or check$3) same (prescription or medication adj1 order) same (read or instructions or guidelines or education)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/20 16:10
S67	152	(patient) same (verif$7 or confirm$5 or check$3) same (prescription or medication adj1 order) same (instructions or guidelines or educational adj1 material)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 10:12
S68	36	(patient) same (verif$7 or confirm$5 or check$3) same (prescription or medication adj1 order) same (instructions or guidelines or educational adj1 material) same (database or data adj1 base or databank or data adj1 bank)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 10:17
S69	7	(patient) same (verif$7 or confirm$5 or check$3) same (prescription or medication adj1 order) same (instructions or guidelines or educational adj1 material) same (prior or before) same (ship$4 or dispens$3 or deliver$3 or send$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 10:20 looked at titles/abstracts
S70	29	(patient) same (verif$7 or confirm$5 or check$3) same (prescription or medication adj1 order or medication or pharmaceutical or drug or pill) same (instructions or guidelines or educational adj1 material) same (prior or before) same (ship$4 or dispens$3 or deliver$3 or send$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 10:28 looked at titles/abstracts

S71	53	(verif$7 or confirm$5 or check$3) same (prescription or medication adj1 order or medication or pharmaceutical or drug or pill) same (instructions or guidelines or educational adj1 material or prescription adj1 label) same (prior or before) same (ship$4 or dispens$3 or deliver$3 or send$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 12:21
S72	11	clark.inv. and (inform$2) adj1 consent	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 12:27 considered 1
S73	5	(educational adj1 material) same (prior or before) same (ship$4 or deliver$3 or dispens$3) same (medicine or medication or pharmaceutical or prescription or pill or drug)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 12:30
S74	15	(educational adj1 material) same (prior or before) same (ship$4 or deliver$3 or dispens$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 12:30 considered 1
S75	6	(educational adj1 material) same (prior or before) same (ship$4 or deliver$3 or dispens$3) and (medicine or medication or pharmaceutical or prescription or pill or drug)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 12:54
S83	98	(receipt or receiv$3 or deliver$3) same (confirm$5 or verif$7 or notif$7) same (call or phone or telephone) same (pharmacy)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 13:02
S84	91	(receipt or receiv$3 or deliver$3) same (confirm$5 or verif$7 or notif$7) same (call or phone or telephone) same (pharmacy) same (drug or prescription or medicine or medication)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 13:09
S85	16	(pharmacy) same (telephone or call or phone) same (patient) same (confirm$5 or verif$7) same (received or receipt or receiving) same (prescription or medication or medicine or drug or pharmaceutical)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 13:23 looked at titles/abstracts

S86	49	(pharmacy) same (telephone or call or phone) same (confirm$5 or verif$7 or ask or find adj1 out) same (received or receipt or receiving or delivered or sent) same (prescription or medication or medicine or drug or pharmaceutical)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 13:29 looked at titles/abstracts
S87	31	(pharmacist) same (telephone or call or phone) same (confirm$5 or verif$7 or ask or find adj1 out) same (received or receipt or receiving or delivered or sent) same (prescription or medication or medicine or drug or pharmaceutical)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 13:32 looked at titles/abstracts
S88	151	(pharmacist) same (confirm$5 or verif$7 or ask or find adj1 out) same (received or receipt or receiving or delivered or sent) same (prescription or medication or medicine or drug or pharmaceutical)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 13:32
S89	242	(pharmacist or pharmacy) same (confirm$5 or verif$7 or ask or find adj1 out) same (patient) same (received or receipt or receiving or delivered or sent) same (prescription or medication or medicine or drug or pharmaceutical)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 13:33
S90	162	(pharmacist or pharmacy) same (confirm$5 or verif$7 or ask or find adj1 out) same (patient) same (received or receipt or receiving or delivered or sent) same (prescription or medication or medicine or drug or pharmaceutical) and (phone or telephone or cellphone)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 13:33
S111	26	(investigat$3) same (lost) same (shipment or delivery or order) same (drug or medicine or medication or prescription or pharmaceutical)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 14:10 considered 1
S118	105	(stolen or lost or missing) same (drug or medication or pharmaceutical or prescription) same (investigat$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 14:17

S119	1066	(stolen or lost or missing) same ((sensitive or abuse or abusive or addictive) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 14:22
S120	37	(stolen or lost or missing) same ((sensitive or abuse or abusive or addictive) same (drug or medicine or medication or ointment or pharmaceutical or pill or agent) or (sodium adj1 oxybate or gamma adj1 hydroxy adj1 butyrate or narcotic or opium or pain adj1 killer)) same (shipment or delivery)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 14:23
S121	582	(stolen or lost or missing) same (drug or medicine or medication or pharmaceutical or prescription) same (shipment or delivery)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 14:23
S122	16	(stolen or lost or missing) same (drug or medicine or medication or pharmaceutical or prescription) same (shipment or delivery) same (investigat$3)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/06/21 14:23 Considered 1

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

21186 7590 06/29/2005

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EXAMINER	
NAJARIAN, LENA	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 06/29/2005

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

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

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) 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 the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- 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 *17 December 2002*.

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) *1-31* is/are pending in the application.

4a) Of the above claim(s) *11-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* 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 *17 December 2002* 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-1449 or PTO/SB/08) Paper No(s)/Mail Date *20030414*, 10/4/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a method of distributing a sensitive drug, classified in class 705, subclass 2.

II. Claims 11-18, drawn to a method of monitoring potential abuse of a sensitive drug by use of an exclusive central database, classified in class 707, subclass 3.

III. Claims 19-25, drawn to a method of obtaining FDA approval for a sensitive drug, classified in class 700, subclass 237.

IV. Claims 26-31, drawn to a method to control abuse of a sensitive drug, classified in class 705, subclass 4.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as a healthcare management system, invention II has separate utility such as query processing, invention III has separate utility such as authorization, and invention IV has separate utility such as an insurance processing system. See MPEP § 806.05(d).

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Richard Schwartz on 3/18/05 a provisional election was made without traverse to prosecute the invention of Group 1, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: items 232 & 238 (Fig. 2A), item 286 (Fig. 2B), items 262 & 264 (Fig. 2C), item 402 (Fig. 4A), item 434 (Fig. 4B), and item 1200 (Fig. 12). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the

specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

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

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

8. Claims 1-10 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. Claims 1-10 recite the limitations for which there is no antecedent basis in the claims. In particular, the following passages lack or have vague antecedent basis:

(i) "the patient": claim 1, lines 3 & 6

claim 2, line 2

claim 4, line 2

claim 6, line 2

(ii) "the patient's": claim 5, line 1

(iii) "the central pharmacy": claim 2, line 2

(iv) "the pharmacist": claim 8, line 2

(v) "the physician": claim 9, line 2

(vi) Claims 3, 7, and 10 incorporate the deficiencies of claim 1, through dependency, and are also rejected.

Claim Rejections - 35 USC § 101

10. Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

(1) whether the invention is within the technological arts; and

(2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

(A) In the present case, it is not clear whether or not the various elements of claims 1-10 clearly and definitely require technology. For example in exemplary claim 1, a database in its broadest sense, may simply be a paper-based table (e.g., chart) or paper files in a file cabinet. As such, the claims when given their broadest reasonable interpretation appear to be devoid of any technological device.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention generates periodic reports to evaluate potential abuse patterns. Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claims 1-10 are deemed to be directed to non-statutory subject matter.

Claim Rejections - 35 USC § 103

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

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

12. Claims 1-2, 4-8, and 10 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 Califano et al. (US 2003/0033168 A1).

(A) Referring to claim 1, Moradi discloses a method of distributing a drug, the method comprising (para. 3 of Moradi):

receiving prescription requests from a medical doctor containing information identifying the patient, the drug, and various credentials of the doctor (para. 35, para. 116, and para. 117 of Moradi);

checking the credentials of the doctor (para. 118 of Moradi); and

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

Moradi does not expressly disclose that the drug is a sensitive drug, entering the information into a central database for analysis of potential abuse situations, confirming with the patient that educational material has been read prior to shipping the sensitive drug, and generating periodic reports via the central database to evaluate potential abuse patterns.

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

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Lilly within Moradi. The motivation for doing so would have been to ensure that prescribers have an accurate view of their patients' use of prescription drugs and to help protect professionals from lawsuits and other potential liabilities (para. 58 of Lilly).

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

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

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

(B) Referring to claims 2 and 6, Moradi discloses wherein receipt of the drug is confirmed by telephone call from the central pharmacy to the patient (abstract, para. 42, para. 26, and para. 47 of Moradi) and recording a designee identified by the patient to receive the drug (para. 24 of Moradi; the Examiner interprets recipient's...name" to be a form of "designee").

Moradi does not expressly disclose that the drug is a sensitive drug.

Lilly et al. disclose that the drug is a sensitive drug (para. 33 of Lilly; the Examiner interprets "controlled substance" to be a form of "sensitive drug").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Lilly within Moradi. The motivation for doing so would have been for the distribution method to be used primarily for drugs that are likely to be abused (para. 9 of Lilly).

(C) Referring to claim 4, Moradi and Lilly do not disclose recording the confirmation with the patient that the educational material has been read in the central database.

Califano discloses recording the confirmation with the patient that the educational material has been read in the central database (para. 120 of Califano).

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

(D) Referring to claim 5, Moradi discloses verifying the patient's home address (para. 43 of Moradi).

(E) Referring to claim 7, Moradi discloses establishing a delivery date (para. 46 of Moradi).

(F) Referring to claim 8, Moradi discloses wherein prescription refills requested prior to an anticipated date are questioned by the pharmacist (para. 42 of Moradi).

(G) Referring to claim 10, Moradi discloses wherein the credentials of the doctor comprise DEA (Drug Enforcement Agency) and state license numbers (para. 116 and para. 117 of Moradi).

13. Claim 3 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 Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Andreasson et al. (US 2003/0160698 A1).

(A) Referring to claim 3, Moradi, Lilly, and Califano do not disclose launching an investigation of lost shipments.

Andreasson discloses disclose launching an investigation of lost shipments (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 feature of Andreasson within Moradi, Lilly, and Califano. The motivation for doing so would have been to reduce the risk of lost or stolen medical products by immediately notifying healthcare workers so that they may take appropriate action (para. 79 of Andreasson).

14. Claim 9 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 Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Mayaud (5,845,255).

(A) Referring to claim 9, Moradi, Lilly, and Califano do not disclose shipping comprehensive printed materials to the physician if the physician is a first time prescriber of the drug.

Mayaud discloses shipping comprehensive printed materials to the physician if the physician is a first time prescriber of the drug (col. 37, lines 6-31 of Mayaud).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Mayaud within Moradi, Lilly, and Califano. The motivation for doing so would have been to reduce the reluctance

of physicians to prescribe new drugs by providing them with the latest information about the drugs (col. 37, lines 6-23 of Mayaud).

Mayaud does not expressly disclose that the drug is a sensitive drug.

Lilly et al. disclose that the drug is a sensitive drug (para. 33 of Lilly; the Examiner interprets "controlled substance" to be a form of "sensitive drug").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Lilly within Mayaud, Moradi, and Califano. The motivation for doing so would have been for the distribution method to be used primarily for drugs that are likely to be abused (para. 9 of Lilly).

Conclusion

15. 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 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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).

In
6-21-05

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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PATENT & TRADEMARK OFFICE
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Sheet 1 of 1

Complete if Known	
Application Number	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan Ph.D., Dayton
Group Art Unit	~~1743~~ 3626
Examiner Name	Unknown
Attorney Docket No: 101.031US1	

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US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
LN	US-6,045,501	04/04/2000	Elsayed, Marc , et al	600	300	08/28/1998
LN	US-6,315,720	11/13/2001	Williams, Bruce A., et al	600	300	10/23/2000

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	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]
LN		NASCSA National Conference, (November 2000),8 pages	
LN		"Diversion Prevention Through Responsible Distribution", NADDI Regional Training, (May 2001),12 pages	
LN		"Diversion Prevention Through Responsible Distribution", NADDI Regional Training Tennessee, (June 2001),14 Pages	
LN		"Diversion Prevention Through Responsible Distribution", NADDI National Conference, (November 2001),15 pages	
LN		"Peripheral and Central Nervous System Drugs Advisory Committee", Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research, Holiday Inn, Bethesda, Maryland,(06/06/2001),7 pages	

EXAMINER Lena Nafarian DATE CONSIDERED 6-17-05

Substitute Disclosure Statement Form (PTO-1449)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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OIPE JC141 OCT 04 2004 PATENT & TRADEMARK OFFICE

Sheet 1 of 2

Complete if Known	
Application Number	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan, Dayton
Group Art Unit	~~1743~~ 3626
Examiner Name	Unknown
Attorney Docket No: 101.031US1	

US PATENT DOCUMENTS

Examiner Initial*	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
LN	US-2001/ 0001144	05/10/2001	Kapp, Thomas L.	705	3	12/22/2000
LN	US-2001/ 0042050	11/15/2001	Fletcher, Robert J., et al.	705	64	01/05/2001
LN	US-2001/ 0047281	11/29/2001	Keresman, III, Michael A., et al.	705	2	03/06/2001
LN	US-2002/ 0032581	03/14/2002	Reitberg, donald P.	705	2	06/01/2001
LN	US-2002/ 0032582	03/14/2002	Feeney, Jr., Robert J., et al.	705	2	08/15/2001
LN	US-2002/ 0042725	04/11/2002	Mayaud, Christian	705	2	08/30/2001
LN	US-2002/ 0042762	04/11/2002	McQuade, Richard , et al.	705	29	08/30/2001
LN	US-2002/ 0052762	05/02/2002	Kobylevsky, Paul , et al.	705	2	05/15/2001
LN	US-2002/ 0161607	10/31/2002	Subich, David C.	705	3	02/23/2001
LN	US-2003/ 0046110	03/06/2003	Gogolak, Victor	705	2	08/28/2002
LN	US-2003/ 0050802	03/13/2003	Jay, Richard , et al.	705	3	04/03/2002
LN	US-2003/ 0110060	06/12/2003	Clementi, William A.	705	2	12/12/2001
LN	US-2003/ 0127508	07/10/2003	Jones, William N.	235	375	01/21/2003
LN	US-2003/ 0144876	07/31/2003	Kosinski, Diana L., et al.	705	2	01/28/2002
LN	US-2003/ 0229519	12/11/2003	Eidex, Brian H., et al.	705	2	05/16/2003
LN	US-2003/ 0233256	12/18/2003	Cardenas, Rodolfo , et al.	705	3	06/13/2002
LN	US-2004/ 0019567	01/29/2004	Herceg, Michael J., et al.	705	64	07/23/2002
LN	US-2004/ 0019794	01/29/2004	Moradi, Ahmad , et al.	713	185	07/29/2002
LN	US-2004/ 0078237	04/22/2004	Kaafarani, William , et al.	705	2	08/28/2003
LN	US-2004/ 0107117	06/03/2004	Denny, Lawrence A.	705	2	11/25/2003

EXAMINER Lona Nafarian DATE CONSIDERED 6-17-05

Substitute Disclosure Statement Form (PTO-1449)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known	
Application Number	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan, Dayton
Group Art Unit	1743
Examiner Name	Unknown
Sheet 2 of 2	Attorney Docket No: 101.031US1

LN	US-2004/0117126	06/17/2004	Fetterman, Jeffrey E., et al.	702	19	11/25/2003
LN	US-2004/0122712	06/24/2004	Hill, Sr., Kenneth A., et al.	705	2	12/20/2002
LN	US-2004/0122713	06/24/2004	Hill, Sr., Kenneth A., et al.	705	2	12/20/2002
LN	US-2004/0162740	08/19/2004	Ericsson, Arthur D., et al.	705	3	02/14/2003
LN	US-2004/0176985	09/09/2004	Lilly, Ralph B., et al.	705	2	03/18/2004
LN	US-5,845,255	12/01/1998	Mayaud, C.	705	3	10/02/1997
LN	US-5,924,074	07/13/1999	Evans, J. A.	705	3	09/27/1996
LN	US-6,021,392	02/01/2000	Lester, Douglas D., et al.	705	2	12/08/1997
LN	US-6,055,507	04/25/2000	Cunningham, David W.	705	3	08/20/1998
LN	US-6,112,182	08/29/2000	Akers, William R., et al.	705	2	01/16/1996
LN	US-6,315,720	11/13/2001	Williams, Bruce A., et al.	600	300	10/23/2000
LN	US-6,347,329	02/12/2002	Evans, Jae A.	709	202	08/01/2000
LN	US-6,755,784	06/29/2004	Williams, Bruce A., et al.	600	300	03/07/2003

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

EXAMINER Lena Najarian DATE CONSIDERED 6-17-05

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

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-2004/0019794 A1	01-2004	Moradi et al.	713/185
	B	US-2003/0033168 A1	02-2003	Califano et al.	705/3
	C	US-2004/0176985 A1	09-2004	Lilly et al.	705/002
	D	US-5,845,255 A	12-1998	Mayaud, Christian	705/3
	E	US-2003/0160698 A1	08-2003	Andreasson et al.	340/573.1
	F	US-			
	G	US-			
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	N					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
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*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.

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Bib Data Sheet

CONFIRMATION NO. 5446

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
10/322,348	12/17/2002 RULE	705	3626	101.031US1

APPLICANTS

Dayton T. Reardan, Excelsior, MN;

Patti A. Eneel, Eagan, MN;
Bob Gagne, St. Paul, MN;

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

none LN 6-17-05

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

none LN 6-17-05

IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** SMALL ENTITY **
** 03/21/2003

Foreign Priority claimed ☐ yes ☒ no 35 USC 119 (a-d) conditions met ☐ yes ☒ no ☐ Met after Allowance Verified and Acknowledged Examiner's Signature Initials	STATE OR COUNTRY MN	SHEETS DRAWING 16	TOTAL CLAIMS 25	INDEPENDENT CLAIMS 4

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

TITLE
Sensitive drug distribution system and method

FILING FEE RECEIVED 667	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue)

		☐ Other _____
		☐ Credit

Index of Claims

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

√	Rejected	–	(Through numeral) Cancelled	N	Non-Elected	A	Appeal
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Claim		Date
Final	Original	6/21/05
	1	√
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Search Notes

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

SEARCHED			
Class	Subclass	Date	Examiner
705	2 3	6/17/2005	LN
600	300	6/17/2005	LN
705	2 3	6/20/2005	LN
600	300	6/20/2005	LN

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
East (see attached printout) USPAT; USOCR; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	6/17/2005	LN
East (see attached printout) USPAT; USOCR; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	6/20/2005	LN
East (see attached printout) USPAT; USOCR; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	6/21/2005	LN

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OCT 03 2005
PATENT & TRADEMARK OFFICE

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

RESPONSE TO RESTRICTION REQUIREMENT AND AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

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

This responds to the Office Action mailed on June 29, 2005. Please amend the above-identified patent application as follows.

IN THE SPECIFICATION

Please amend the paragraph on page 6, starting at line 17 as follows:

If the information is complete at 212, the MD is contacted at 220 to verify receipt and accuracy of the patient's Rx. This contact is recorded in CHIPS. The intake and reimbursement specialist then sends a consent form and a cover letter to the patient at 224. The insurance provider is contacted at 226 to verify coverage and benefits. At 228, a determination is made regarding coverage for the drug. If it is not available, it is determined at 230 whether the patient is willing and able to pay. If not, a process 232 is performed for handling patients who are uninsured or underinsured. In one embodiment, the process is referred to as a NORD process.

Please amend the paragraph on page 6, starting at line 25 as follows:

If the patient is willing and able to pay at 230, the patient is informed of the cost of the product and is given payment options at 234. At 236, once payment is received, the intake reimbursement specialist submits a coverage approval form with the enrollment form to the pharmacy team as notification to process the patient's prescription. If coverage is approved at 228, the intake reimbursement specialist also submits the coverage ~~coveral~~ approval form at 238 with the enrollment form to the pharmacy team as notification to process the patient's prescription. Processing of the prescription is described below.

Please amend the paragraph on page 7, starting at line 18 as follows:

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 MD is contacted by a pharmacist at 286, and informed that the patient's Rx cannot be processed. 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.

Please amend the paragraph on page 8, starting at line 12 as follows:

At 254, the pharmacist enters the prescription order in the database, creating an order number. The pharmacist then verifies at 256 the prescription and attaches a verification label to the hard copy prescription. At 258, a pick ticket is generated for the order and the order is forwarded to the pharmacy for fulfillment. The shipment is confirmed in the database at 260, the original Rx is filed with the pharmacy Rx's in numerical order at 262, and the order is shipped by USPS Express Mail 264. Use of the US mail invokes certain criminal penalties for unauthorized diversion. Optionally, other mail services may be used. Potential changes in the law may also bring criminal penalties into play. Following shipment, the patient is called by the central pharmacy to confirm that the prescription was received.

Please amend the paragraph on page 8, starting at line 29 as follows:

A refill request process begins at ~~302~~ 402 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.

Please amend the paragraph on page 9, starting at line 12 as follows:

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. At 434, a sensitive drug problem identification and management risk diversion report may be completed, documented and distributed. The pharmacist evaluates the patient's compliance with therapy or possible product diversion, misuse or over-use at 436. In one embodiment, cash payers are also identified. The pharmacist then contacts the prescribing physician to alert them of the situation and confirm if the physician approves of the early refill at 438. If the physician does not approve as indicated at 440, the patient must wait until the next scheduled refill date to receive additional product as indicated at 442, and the process ends at 444.

Please amend the paragraph on page 12, starting at line 5 as follows:

FIG. 12 is a copy of one example voucher request 1200 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.

IN THE CLAIMS

Please amend the claims as follows:

1. (Currently Amended) A method of distributing a sensitive drug, the method comprising:

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

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

checking the credentials of the doctor;

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

confirming receipt of the sensitive drug; and

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

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

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

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

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

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

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

8. (Currently Amended) The method of claim 1 wherein prescription refills requested prior to an anticipated date are questioned by a ~~the~~ pharmacist.

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

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

11. (Withdrawn) 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. (Withdrawn) The method of claim 11 and further comprising running multiple predetermined reports based on data in the exclusive central database.

13. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) The method of claim 13 wherein selected reports are run weekly, monthly or quarterly.

19. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) The method of claim 19 wherein the sensitive drug is a scheduled drug in Schedule II-V.

22. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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.

26. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) The method of claim 29 wherein initially selected controls comprise:

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

31. (Withdrawn) 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 June 29, 2005, and the references cited therewith.

Claims 1, 2, 4, 8 and 9 are amended. Claims 1-10 are now pending in this application.

Affirmation of Election

Restriction to one of the following claims was required:

As provisionally elected by Applicant's representative, Richard Schwartz on March 18, 2005, Applicant elects to prosecute the invention of Group I, claims 1-10.

The claims of the non-elected invention, claims 11-31, are hereby canceled. However, Applicant reserves the right to later file continuations or divisions having claims directed to the non-elected inventions.

Drawing Objection

The drawings were objected to as containing reference numbers not identified in the description. The description has been amended to include such reference numbers. Any text added to the description is fully supported by the drawings.

§112 Rejection of the Claims

Claims 1-10 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Amendments related solely to addressing antecedence have been made.

§101 Rejection of the Claims

Claims 1-10 were rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The claims have been amended to clarify that the database is a computer database. Thus, the recited process clearly involves the technological arts.

§103 Rejection of the Claims

Claims 1-2, 4-8 and 10 were 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 Califano et al. (US 2003/0033168 A1). Applicant reserves the right to swear behind each of the references at a later date. The rejection is respectfully traversed.

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). To do that the Examiner must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *Id.*

The *Fine* court stated that:

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

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

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

An invention can be obvious even though the suggestion to combine prior art teachings is not found in a specific reference. *In re Oetiker*, 24 USPQ2d 1443 (Fed. Cir. 1992). At the same time, however, although it is not necessary that the cited references or prior art specifically suggest making the combination, **there must be some teaching somewhere which provides the suggestion or motivation to combine prior art teachings and applies that combination to solve the same or similar problem which the claimed invention addresses** *(emphasis added)*.

One of ordinary skill in the art will be presumed to know of any such teaching. (See, e.g., *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) and *In re Wood*, 599 F.2d 1032, 1037, 202 USPQ 171, 174 (CCPA 1979)).

The suggestion to combine the reference in the Office Action is not directed to solving the same or similar problem which the claimed invention addresses. Further, there is no teaching in the prior art of application of the combination to solve the same or similar problems which the claimed invention addresses. The Office Action indicates that the motivation for combining the features of Lilly within Moradi would be "to ensure that prescribers have an accurate view of their patients' use of prescription drugs and to help protect professionals from lawsuits and other potential liabilities (para. 58 of Lilly)." The purpose of the presently claimed invention is to track sensitive drugs and reduce the potential for abuse. These are very different problems, and there is no suggestion to apply the combination to solve the same or similar problem which the claimed invention addresses.

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

Even if one were to combine multiple selected elements from each of Moradi and Lilly, an element of the claimed invention is still lacking. The Office Action indicates that the combination does not disclose "confirming with the patient that educational material has been read prior to shipping the drug." Califano is cited as providing this missing element, and that the

motivation for doing so "would have been to ensure that the patient knows about the risks and dangers associated with the drug (para. 43 of Califano)." Califano is directed to obtaining consent for a clinical trial. Abstract. The cited motivation is very different from the purpose of the presently claimed invention, making it very unlikely that one of skill in the art would be motivated to combine the references. As a proper prima facie case of obviousness has not been established, the rejection should be withdrawn.

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

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

Claims 2, 4-8 and 10 depend from claim 1 and distinguish the references for at least the same reasons as claim 1. In addition, claim 2 recites a central pharmacy. The Office Action

states that Moradi discloses confirming receipt by a telephone call from the central pharmacy. Applicant has reviewed the cited sections of Moradi, and cannot find the concept of a central pharmacy. As the term is used in the present application, a central pharmacy is a pharmacy that exclusively controls the distribution of a sensitive drug. While it may have branches and affiliates, it uses the central database to keep track of all distribution of the sensitive drug. This enables a much improved ability to monitor abuse situations. Patients seeking prescriptions from different doctors will be detected, because the drug is tracked in the central database. Each pharmacy that distributes the sensitive drug also uses the central database. Practically, this is accomplished by obtaining FDA approval that requires the use of the central database. Since any entity that distributes the sensitive drug requires the FDA approval, all must use the same central database. The term central database is used to encompass any real or virtual manifestation of a central database that facilitates evaluation of potential abuse patterns for distribution of the sensitive drug.

Claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Andreasson et al. (US 2003/0160698 A1). Applicant further reserves the right to swear behind each of the references. This rejection is also respectfully traversed. Claim 3 depends from claim 1 and distinguishes from the references at least in the same manner as claim 1. Andreasson et al. describe monitoring distribution of medical products within a facility as indicated by the title. Claim 3 recites launching an investigation of lost shipments, which implies that the shipments have already left a facility. Monitoring within the facility would not address a lost shipment that has left the facility. As such, there is no showing of a reasonable likelihood of success in making the combination. As a proper prima facie case of obviousness has not been established, the rejection should be withdrawn.

Claim 9 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Mayaud (U.S. Patent

No. 5,845,255). Claim 9 depends from claim 1 and distinguishes from the references at least in the same manner as claim 1. The Office Action cites a motivation to combine the four references as "to reduce the reluctance of physicians to prescribe new drugs by providing them with the latest information about the drugs". This motivation has nothing to do with the problems addressed by the currently claimed invention as identified above. As a proper prima facie case of obviousness has not been established, the rejection should be withdrawn.

CONCLUSION

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

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

Respectfully submitted,
DAYTON T. REARDAN ET AL.
By their Representatives,
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6972

Date 9-29-2005 By _____
Bradley A. Forrest
Reg. No. 30,837

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: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29th day of September, 2005.

PATRICIA A. HULTMAN _____

Name Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

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

Serial No.: 10/322,348
Due Date: September 29, 2005
Group Art Unit: 3626

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

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

X Return postcard.
X Response to Restriction Requirement and Amendment and Response Under 37 CFR 1.111 (19 pgs.).
X Supplemental Information Disclosure Statement (2 pgs.), Form 1449 (1 pg.), and copies of 1 cited document.
X Check in the amount of $180.00 to cover the fee for consideration of Information Disclosure Statement under 97(c).

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 deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29th day of September, 2005.

PATRICIA A.HULTMAN
Name

_____
Signature

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

1F 3626

S/N 10/322,348

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	10/322,348	Group Art Unit:	3626
Filed:	December 17, 2002	Docket:	101.031US1
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(c)(2), Applicants have included the fee of $180.00 as set forth in 37 C.F.R. §1.17(p). Please charge any additional fees or credit any overpayment to Deposit Account No. 19-0743.

10/04/2005 FMETEKI1 00000018 10322348
01 FC:1806 180.00 OP

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,

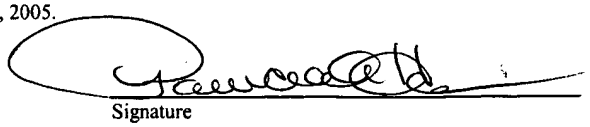
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6972

Date 9-29-2005

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

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: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29th day of September, 2005.

PATRICIA A. HULTMAN
Name


Signature

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

OIPE IAP26 OCT 03 2005 PATENT & TRADEMARK OFFICE

Sheet 1 of 1

Complete if Known

Application Number	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan, Dayton
Group Art Unit	3626
Examiner Name	Lena Najarian
Attorney Docket No: 101.031US1	

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[2]

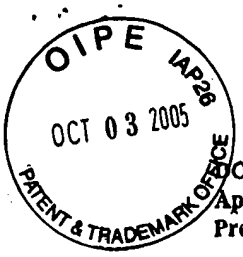
OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

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]
		Preliminary Amendment Pursuant to 37 CFR 1.115 filed with United States Patent and Trademark Office on June 17, 2005 in Application Serial No. 11/104,013 (3 pages).	

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

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



DOCKET NO.: CELG-0471 **PATENT**
Application No.: 11/104,013
Preliminary Amendment - First Action Not Yet Received

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Marc Elsayed and Bruce Williams

Confirmation No.: **Not yet assigned**

Application No.: **11/104,013**

Group Art Unit: **Not yet assigned**

Filing Date: **April 12, 2005**

Examiner: **Not yet assigned**

For: **Methods For Delivering A Drug To A Patient While Preventing The Exposure Of A Foetus Or Other Contraindicated Individual To The Drug**

DATE OF DEPOSIT: June 17, 2005

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Angela Verrecchio

TYPED NAME: Angela Verrecchio
REGISTRATION NO.: 54,510

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

Sir:

PRELIMINARY AMENDMENT PURSUANT TO 37 CFR § 1.115

Preliminary to examination of the above-captioned patent application, please amend the application as follows:

☐ **Amendments to the Specification** begin on page of this paper.

☒ **Amendments to the Claims** are reflected in the listing of the claims which begins on page 2 of this paper.

☐ **Amendments to the Drawings** begin on page of this paper and include an attached replacement sheet.

☒ **Remarks** begin on page 3 of this paper.

DOCKET NO.: CELG-0471 **PATENT**
Application No.: 11/104,013
Preliminary Amendment - First Action Not Yet Received

REMARKS

Claims 1-10 have been canceled, and claims 11-14 added. Support for these claims can be found throughout the specification as originally filed. No new matter has been added. Consideration and allowance of all pending claims is respectfully requested.

Date: June 17, 2005

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DOCKET NO.: CELG-0471 **PATENT**
Application No.: 11/104,013
Preliminary Amendment - First Action Not Yet Received

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claims 1-10 (Canceled)

11. (New) A method of distributing a drug, comprising:

a. receiving data from a prescriber for the drug, said data comprising information identifying a patient, the drug, and the prescriber;

b. entering the data into a computer database;

c. confirming the ability of the prescriber to prescribe the drug;

d. confirming that patient educational materials have been read; and

e. generating periodic reports regarding distribution of the drug via the computer database.

12. (New) The method of claim 11, further comprising the step of recording the confirmation that the educational materials have been read in the database.

13. (New) The method of claim 11, further comprising the step of blocking inappropriate refill requests.

14. (New) The method of claim 11, further comprising the step of shipping educational materials to the prescriber.

PATENT APPLICATION FEE DETERMINATION RECORD
Effective January 1, 2003

Application or Docket Number: 10/322348

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	25	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	25 minus 20=	* 5
INDEPENDENT CLAIMS	4 minus 3 =	* 1
MULTIPLE DEPENDENT CLAIM PRESENT		☐

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

SMALL ENTITY TYPE ☐			OTHER THAN SMALL ENTITY	
RATE	FEE	OR	RATE	FEE
BASIC FEE	$375	OR	BASIC FEE	$750
X$ 9=	45	OR	X$18=	
X42=	42	OR	X84=	
+140=		OR	+280=	
TOTAL	462	OR	TOTAL	

CLAIMS AS AMENDED - PART II

10/4/04

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 31	Minus	** 25	= 6
Independent	* 6	Minus	*** 4	= 2
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY			OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE	OR	RATE	ADDITIONAL FEE
X$ 9=	54	OR	X$18=	
~~X42=~~	86	OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE	140	OR	TOTAL ADDIT. FEE	

DN 10/3/05

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 31	Minus	** 25	=
Independent	* 6	Minus	*** 4	= 1
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

X$ 9=		OR	X$18=	
X42=	1	OR	X84=	1
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

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

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

21186 7590 12/29/2005

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH
1600 TCF TOWER
121 SOUTH EIGHT STREET
MINNEAPOLIS, MN 55402

EXAMINER	
NAJARIAN, LENA	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 12/29/2005

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

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

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *03 October 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) *1-10* 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) *1-10* 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-1449 or PTO/SB/08) Paper No(s)/Mail Date *20051003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 10/3/05. Claims 1-10 are pending. Claims 1, 2, 4, 8, and 9 have been amended.

Drawings

2. The objection to the drawings is hereby withdrawn due to the amendment filed 10/3/05.

Claim Rejections - 35 USC § 112

3. The rejection of claims 1-10 under 35 U.S.C. 112, second paragraph, is hereby withdrawn due to the amendment filed 10/3/05.

Claim Rejections - 35 USC § 101

4. The rejection of claims 1-10 under 35 U.S.C. 101 is hereby withdrawn due to the amendment filed 10/3/05.

Claim Rejections - 35 USC § 103

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

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

6. Claims 1-2, 4-8, and 10 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 Califano et al. (US 2003/0033168 A1).

(A) The amendments to claims 1, 2, 4, and 8 were apparently made to overcome 112, 2nd paragraph and/or 101 issues set forth in the prior Office Action. However, these changes do not affect the scope and breadth of the claims as originally presented and/or in the manner in which the claims were interpreted by the Examiner when applying prior art within the previous Office Action. As such, these claims are rejected under the same rationale given in the prior Office Action, and incorporated herein.

(B) Claims 5-7 and 10 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

7. Claim 3 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 Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Andreasson et al. (US 2003/0160698 A1).

(A) Claim 3 has not been amended and is rejected for the same reasons given in the previous Office Action, and incorporated herein.

8. Claim 9 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 Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Mayaud (5,845,255).

(A) The amendment to claim 9 was apparently made to overcome 112, 2nd paragraph issues set forth in the prior Office Action. However, these changes do not affect the scope and breadth of the claim as originally presented and/or in the manner in which the claim was interpreted by the Examiner when applying prior art within the previous Office Action. As such, this claim is rejected under the same rationale given in the prior Office Action, and incorporated herein.

Response to Arguments

9. Applicant's arguments filed 10/3/05 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 10/3/05.

(1) Applicant argues at page 15 that the suggestion to combine the reference in the Office Action is not directed to solving the same or similar problem which the claimed invention addresses.

(2) Applicant argues at page 16 that Califano is directed to obtaining consent for a clinical trial and that the cited motivation is very different from the purpose of the presently claimed invention, making it very unlikely that one of skill in the art would be motivated to combine the references.

(3) Applicant argues at page 16 that multiple elements from each of Moradi and Lilly were combined to make the rejection and that there is no reasonable

expectation of success in making the combination. Further, it points toward the improper use of hindsight, using the claims as a roadmap to make the combination.

(4) Applicant argues at page 16 that the prior art teaches away from the claimed combination. Lilly describes the cooperative use of a database by multiple different pharmacies, prescribers and patients, to keep track of the prescription history for a patient. It would be an extremely daunting task to get the cooperation of all these parties. The ambitious path set forth in Lilly would discourage one of skill in the art from considering using it to solve the problems addressed in the presently claimed invention.

(5) Applicant argues at page 17 that Applicant has reviewed the cited sections of Moradi and cannot find the concept of a central pharmacy. As the term is used in the present application, a central pharmacy is a pharmacy that exclusively controls the distribution of a sensitive drug.

(6) Applicant argues at page 17 that Andreasson et al. describe monitoring distribution of medical products within a facility as indicated by the title. Claim 3 recites launching an investigation of lost shipments, which implies that the shipments have already left a facility. Monitoring within the facility would not address a lost shipment that has left the facility. As such, there is no showing of a reasonable likelihood of success in making the combination.

(7) Applicant argues at page 18 that the Office Action cites a motivation to combine the four references "to reduce the reluctance of physicians to prescribe new drugs by providing them with the latest information about the drugs." This

motivation has nothing to do with the problems addressed by the currently claimed invention as identified above.

(A) As per the first argument, in response to applicant's argument that the suggestion to combine Moradi with Lilly is improper since the purpose stated is not related to the same or similar problem addressed by the claimed invention, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In addition, the Examiner respectfully submits that Applicant has failed to fully consider the Lilly reference. At para. 12, Lilly discloses reducing misused and abused prescriptions and the need for better tracking and management of prescriptions. As such, it is readily apparent that Lilly and Applicant's invention solve the same or similar problem.

(B) As per the second argument, in response to applicant's argument that Califano is directed to obtaining consent for a clinical trial, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's argument that the cited motivation is very different from the purpose of the presently claimed invention, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

(C) As per the third argument, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

(D) As per the fourth argument, whether or not the Lilly reference discloses tracking all prescriptions for a patient and not just sensitive drugs is immaterial to the issue at hand, especially since Lilly is directed to a tracking system for controlled substances. In addition, it is irrelevant whether the applied references contain elements in addition to or beyond those claimed by Applicant, and not required by Applicant, insofar as Applicant uses the word "comprising" at end of each preamble of the pending claims. The Examiner understands this claim language to mean "having at least". If Applicant desires to claim an invention that is exclusively limited to only those elements specifically recited in the claims,

the Examiner suggests that Applicant use the term "consisting of" rather than "comprising".

(E) As per the fifth argument, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "a central pharmacy is a pharmacy that exclusively controls the distribution of a sensitive drug") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(F) As per the sixth argument, the Examiner respectfully submits that para. 79 of Andreasson discloses tracking the delivery of medical products and immediately notifying healthcare workers and/or administrators of any missing medical products so that they make take appropriate action to recover and/or investigate the missing medical products. Para. 43 discloses comparing the information of the medical products shipped to the healthcare facility with the information received from the pharmacy terminal to verify that all of the medical products shipped to the healthcare facility were received by the pharmacy. As such, it is readily apparent that Andreasson teaches launching an investigation of lost shipments.

(G) As per the seventh argument, in response to applicant's argument that the motivation to combine the four references has nothing to do with the problems addressed by the currently claimed invention, the fact that applicant has recognized another advantage which would flow naturally from following the

suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

In
12-12-05

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

OIPE IAP28 OCT 03 2005 PATENT & TRADEMARK OFFICE

Sheet 1 of 1

Complete if Known	
Application Number	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan, Dayton
Group Art Unit	3626
Examiner Name	Lena Najarian
Attorney Docket No: 101.031US1	

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[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]
LN		Preliminary Amendment Pursuant to 37 CFR 1.115 filed with United States Patent and Trademark Office on June 17, 2005 in Application Serial No. 11/104,013 (3 pages).	

EXAMINER Lena Najarian DATE CONSIDERED 12-9-05

Substitute Disclosure Statement Form (PTO-1449)

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

Index of Claims

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

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

Claim		Date
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Search Notes

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

SEARCHED			
Class	Subclass	Date	Examiner
	updated previous seaches	12/12/2005	LN

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR

REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL Subsection (b) of 35 U.S.C. § 132, effective on May 29, 2000, provides for continued examination of an utility or plant application filed on or after June 8, 1995. See The American Inventors Protection Act of 1999 (AIPA).	*Application Number*	10/322,348
	Filing Date	December 17, 2002
	First Named Inventor	Dayton T. Reardan
	Group Art Unit	3626
	Examiner Name	Lena Najarian
	Attorney Docket Number	101.031US1
	Customer No.	21186

This is a Request for Continued Examination (RCE) under 37 CFR § 1.114 of the above-identified application entitled SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD.
Submission required under 37 C.F.R. § 1.114

1. __ Consider the amendment(s)/reply under 37 C.F.R. § 1.116 previously filed on .

2. __ Consider the arguments in the Appeal Brief or Reply Brief previously filed on .

3. X Amendment Under 37 CFR § 1.116 (11 pages) is enclosed.

4. __ New power of attorney (pages) is enclosed.

5. X Information Disclosure Statement is enclosed (2 pages), with:
   a. Form 1449 (1 pages)
   b. Copies of IDS Citations (1)

6. X Please charge Deposit Account 19-0743 in the amount of $395.00 to pay the RCE filing fee required under C.F.R. § 1.17(e).

7. X **The Commissioner is hereby authorized to credit overpayments or charge any fees set forth in 37 CFR §§ 1.16 through 1.18 to Deposit Account No. 19-0743.**

8. __ Petition for Extension of Time in the prior application (1 page) is enclosed along with authorization to charge Deposit Account 19-0743 in the amount of to pay the extension fee.

9. X Others: Communication Concerning Related Applications (2 pgs.).

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

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: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29 day of March, 2006.

John Gustav-Wrathall
Name

_____
Signature

EXPEDITED PROCEDURE – EXAMINING GROUP 3626

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

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

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

In response to the Final Office Action mailed December 29, 2005, please amend the application as follows:

IN THE CLAIMS

Please amend the claims as follows.

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

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

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

checking the credentials of the doctor;

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

confirming receipt of the sensitive drug; and

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

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

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

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

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

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

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

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

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

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

11. – 31. (Cancelled)

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

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

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

checking the credentials of the doctor;

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

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking the credentials of the doctor;

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

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

REMARKS

This responds to the Office Action mailed on December 29, 2005.

New claims 32 - 37 have been added. Claims 1-10 and 32-37 are now pending in this application.

New claims 32 - 37 distinguish the references for reasons similar to those provided below regarding claim 1. In addition, claim 32 recites the use of an exclusive central pharmacy and an exclusive central database to track distribution and potential diversion of the sensitive drug.

In paragraph E of the Response to Arguments section of the Final Office Action, it is stated that the then pending claims did not recite that a central pharmacy is a pharmacy that exclusively controls distribution of a sensitive drug. New claims 32 - 37 have been written based on claim 1 to include language that expressly addresses exclusivity of distribution. Such claims also address exclusivity of the central database. None of the references cited are believed to address such exclusivities. The original claims are also believed to describe aspects of centralization, as described in the previous response. The submission of new claims 32-37 is not an admission otherwise.

§103 Rejection of the Claims

Claims 1-2, 4-8 and 10 were 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 Califano et al. (US 2003/0033168 A1).

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

potential liabilities (para. 58 of Lilly)." As stated in the response to arguments section A of the Final Office Action, Lilly also describes reducing misused and abused prescriptions and the need for better tracking and management of prescription in Paragraph 12. However, the purpose for such reductions is related to abuse by the patient, and not abuse of a sensitive drug as claimed. The purpose of the presently claimed invention is to track sensitive drugs and reduce the potential for abuse, such as diversion of the sensitive drug.

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

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

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

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

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

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

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

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

Claims 2, 4-8 and 10 depend from claim 1 and distinguish the references for at least the same reasons as claim 1. In addition, claim 2 recites a central pharmacy. The Office Action states that Moradi discloses confirming receipt by a telephone call from the central pharmacy. Applicant has reviewed the cited sections of Moradi, and cannot find the concept of a central pharmacy. As the term is used in the present application, a central pharmacy is a pharmacy that exclusively controls the distribution of a sensitive drug. While it may have branches and affiliates, it uses the central database to keep track of all distribution of the sensitive drug. This enables a much improved ability to monitor abuse situations. Patients seeking prescriptions from different doctors will be detected, because the drug is tracked in the central database. Each pharmacy that distributes the sensitive drug also uses the central database. Practically, this is accomplished by obtaining FDA approval that requires the use of the central database. Since any entity that distributes the sensitive drug requires the FDA approval, all must use the same central database. The term central database is used to encompass any real or virtual manifestation of a

central database that facilitates evaluation of potential abuse patterns for distribution of the sensitive drug.

Claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Andreasson et al. (US 2003/0160698 A1). Applicant further reserves the right to swear behind each of the references. This rejection is also respectfully traversed. Claim 3 depends from claim 1 and distinguishes from the references at least in the same manner as claim 1. Andreasson et al. describe monitoring distribution of medical products within a facility as indicated by the title. Claim 3 recites launching an investigation of lost shipments, which implies that the shipments have already left a facility. Monitoring within the facility would not address a lost shipment that has left the facility. As such, there is no showing of a reasonable likelihood of success in making the combination. As a proper prima facie case of obviousness has not been established, the rejection should be withdrawn.

In paragraph F of the Response to Arguments section of the Final Office Action, the Examiner indicates that para. 79 of Andreasson discloses tracking the delivery of medical products and immediately notifying healthcare workers of any missing medical product so they can investigate. Note that the start of para. 79 recites "..a closed-loop system for tracking and monitoring medical products within a healthcare facility,..." While Andreasson may describe launching an investigation, it lacks the concept of shipping drugs to a patient, and investigating lost shipments to the patient as claimed.

Claim 9 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Mayaud (U.S. Patent No. 5,845,255). Claim 9 depends from claim 1 and distinguishes from the references at least in the same manner as claim 1. The Office Action cites a motivation to combine the four references as "to reduce the reluctance of physicians to prescribe new drugs by providing them with the latest information about the drugs". This motivation has nothing to do with the problems

addressed by the currently claimed invention as identified above. As a proper prima facie case of obviousness has not been established, the rejection should be withdrawn.

In paragraph G of the Response to Arguments section of the Final Office Action, the Examiner again recites something about recognizing another advantage which would flow naturally from following the suggestion of the prior art, which as stated above, Applicant has not done. It is believed that such an argument incorrectly presupposes that the references are properly combinable, which Applicant believes they are not.

CONCLUSION

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

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

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

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

Date 3-29-2006

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

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29 day of March, 2006.

JOHN D. GUSTAV-WRATHALL
Name

_____
Signature

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

INFORMATION DISCLOSURE STATEMENT

MS RCE
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.

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(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).

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 3-29-2006 By _____
Bradley A. Forrest
Reg. No. 30,837

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29 day of March, 2006.

Name _____ Signature _____

PTO/SB/08A(10-01)
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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	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan, Dayton
Group Art Unit	3626
Examiner Name	Najarian, Lena

Sheet 1 of 1

Attorney Docket No: 101.031US1

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[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]
		"System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) Starter Kit", Celgene Corporation, (2001),103 pgs.	

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

COMMUNICATION CONCERNING RELATED APPLICATION(S)

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

Applicants would like to bring to the Examiner's attention the following related application(s) in the above-identified patent application:

Serial/Patent No.	Filing Date/Issue Date	Attorney Docket	Title
10/979665	November 2, 2004	101.031US2	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
11/097651	April 1, 2005	101.031US3	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
11/097985	April 1, 2005	101.031US4	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Continuations and divisionals may be later filed on the cases listed above, or cited to the Examiner in any previous Communication Concerning Related Applications. Applicants request that the Examiner review all continuations and divisionals of the above-listed or previously-cited patent applications before allowing the claims of the present patent application.

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By Applicants' Representatives,

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

Date 3-29-2006 By _____
Bradley A. Forrest
Reg. No. 30,837

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29 day of March, 2006.

John W. Griebe Wrathell
Name

Signature

Electronic Patent Application Fee Transmittal

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

Filed as Small Entity

Utility Filing Fees

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	395	395
		Total in USD ($)		**395**

Electronic Acknowledgement Receipt

EFS ID:	1014264
Application Number:	10322348
Confirmation Number:	5446
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor:	Dayton T. Reardan
Customer Number:	21186
Filer:	Gregg Alan Peacock/John Gustav-Wrathall
Filer Authorized By:	Gregg Alan Peacock
Attorney Docket Number:	101.031US1
Receipt Date:	29-MAR-2006
Filing Date:	17-DEC-2002
Time Stamp:	18:36:53
Application Type:	Utility
International Application Number:	

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	$395.0
RAM confirmation Number	165
Deposit Account	190743
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part	Pages
1		101031us1_rce.pdf	886051	yes	17

Multipart Description

Doc Desc	Start	End
Request for Continued Examination (RCE)	1	1
Amendment After Final	2	12
Information Disclosure Statement (IDS) Filed	13	15
Miscellaneous Incoming Letter	16	17

Warnings:

Information:

2	NPL Documents	steps.pdf	20861586	no	103

Warnings:

Information:

3	Fee Worksheet (PTO-875)	fee-info.pdf	8169	no	2

Warnings:

Information:

Total Files Size (in bytes):	21755806

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.

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S2	18	pharmacy same (controlled or sensitive) adj1 (drug or medicine or medication or substance or agent) same (database or data adj1 base or databank or data adj1 bank)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:12
S3	93	(controlled or sensitive) adj1 (drug or medicine or medication or substance or agent) same (database or data adj1 base or databank or data adj1 bank)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:13
S4	39	(controlled or sensitive) adj1 (drug or medicine or medication or substance or agent) same (database or data adj1 base or databank or data adj1 bank) and (pattern)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:13
S5	5	(controlled or sensitive) adj1 (drug or medicine or medication or substance or agent) same (database or data adj1 base or databank or data adj1 bank) and (gamma adj1 hydroxy adj1 butyrate)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:14
S6	12	(controlled or sensitive) adj1 (drug or medicine or medication or substance or agent) and (gamma adj1 hydroxy adj1 butyrate)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:14
S7	18	(gamma adj1 hydroxy adj1 butyrate) and computer	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:15
S8	67	(gamma adj1 hydroxy adj1 butyrate or gamma adj1 hydroxybutyrate) and computer	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:15
S9	9	(gamma adj1 hydroxy adj1 butyrate or gamma adj1 hydroxybutyrate) and computer and track$3	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:27
S10	379	(block$3 or prevent$3) same (ship$) same (drug or medicine or medication)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:27

EAST Search History

S11	85	(block$3 or prevent$3) same (shipment) same (drug or medicine or medication)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:28
S12	0	(block$3 or prevent$3) same (shipment) same (drug or medicine or medication) same abuse	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:28
S13	135	(block$3 or prevent$3) same (shipment) same (drug or medicine or medication or pharmaceutical)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:28
S14	0	(block$3 or prevent$3) same (shipment) same (drug or medicine or medication or pharmaceutical) same abuse	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:28
S15	17	(block$3 or prevent$3) same (shipment) same (sensitive or controlled) same (substance or drug or medicine or medication or pharmaceutical)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2006/06/01 17:29 title-abstracts

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/322,348	12/17/2002	Dayton T. Reardan	101.031US1	5446

21186 7590 06/19/2006

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

EXAMINER	
NAJARIAN, LENA	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 06/19/2006

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

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

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

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

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

Disposition of Claims

4)☒ Claim(s) *1-10 and 32-37* 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) *1-10 and 32-37* 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-1449 or PTO/SB/08) Paper No(s)/Mail Date *20060329*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the request for continued examination (RCE) filed 3/29/06. Claims 1-10 and 32-37 are pending. Claims 11-31 have been cancelled. Claims 32-37 are newly added.

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1-10 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10 of copending Application No. 10/979,665. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. 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.

5. Claim 34 is 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.

6. Claim 34 recites the limitation "the exclusive central database" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

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

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

8. Claims 1-2, 4-8, 10, and 32 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 Califano et al. (US 2003/0033168 A1).

(A) Referring to claim 1, Moradi discloses a method of distributing a drug, the method comprising (para. 3 of Moradi):

receiving prescription requests from a medical doctor containing information identifying a patient, the drug, and various credentials of the doctor (para. 35, para. 116, and para. 117 of Moradi);

checking the credentials of the doctor (para. 118 of Moradi); and

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

Moradi does not expressly disclose that the drug is a sensitive drug, entering the information into a central computer database for analysis of potential abuse situations, confirming with the patient that educational material has been read prior to shipping the sensitive drug, and generating periodic reports via the central computer database to evaluate potential abuse patterns.

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

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Lilly within Moradi. The motivation for doing so would have been to ensure that prescribers have an accurate view of their patients' use of prescription drugs and to help protect professionals from lawsuits and other potential liabilities (para. 58 of Lilly).

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

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

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Califano within Moradi and Lilly. The motivation

for doing so would have been to ensure that the patient knows about the risks and dangers associated with the drug (para. 43 of Califano).

(B) Referring to claims 2 and 6, Moradi discloses wherein receipt of the drug is confirmed by telephone call from a central pharmacy to the patient (abstract, para. 42, para. 26, and para. 47 of Moradi) and recording a designee identified by the patient to receive the drug (para. 24 of Moradi; the Examiner interprets "recipient's...name" to be a form of "designee").

Moradi does not expressly disclose that the drug is a sensitive drug.

Lilly et al. disclose that the drug is a sensitive drug (para. 33 of Lilly; the Examiner interprets "controlled substance" to be a form of "sensitive drug").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Lilly within Moradi. The motivation for doing so would have been for the distribution method to be used primarily for drugs that are likely to be abused (para. 9 of Lilly).

(C) Referring to claim 4, Moradi and Lilly do not disclose recording the confirmation with the patient that the educational material has been read in the central computer database.

Califano discloses recording the confirmation with the patient that the educational material has been read in the central computer database (para. 120 of Califano).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Califano within Moradi and Lilly. The motivation

for doing so would have been to have documentation confirming that the patient knows about the risks and dangers associated with the drug (para. 43 of Califano).

(D) Referring to claim 5, Moradi discloses verifying the patient's home address (para. 43 of Moradi).

(E) Referring to claim 7, Moradi discloses establishing a delivery date (para. 46 of Moradi).

(F) Referring to claim 8, Moradi discloses wherein prescription refills requested prior to an anticipated date are questioned by a pharmacist (para. 42 of Moradi).

(G) Referring to claim 10, Moradi discloses wherein the credentials of the doctor comprise DEA (Drug Enforcement Agency) and state license numbers (para. 116 and para. 117 of Moradi).

(H) Referring to claim 32, Moradi discloses a method of distributing a drug under exclusive control of an exclusive central pharmacy, the method comprising (para. 3 and para. 24 of Moradi):

receiving prescription requests from a medical doctor containing information identifying a patient, the drug, and various credentials of the doctor (para. 35, para. 116, and para. 117 of Moradi);

checking the credentials of the doctor (para. 118 of Moradi); and

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

Moradi does not expressly disclose that the drug is a sensitive drug, entering the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations, confirming with the patient that

educational material has been read prior to shipping the sensitive drug, and generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

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

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Lilly within Moradi. The motivation for doing so would have been to ensure that prescribers have an accurate view of their patients' use of prescription drugs and to help protect professionals from lawsuits and other potential liabilities (para. 58 of Lilly).

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

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

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

9. Claim 3 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 Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Andreasson et al. (US 2003/0160698 A1).

(A) Referring to claim 3, Moradi, Lilly, and Califano do not disclose launching an investigation of lost shipments.

Andreasson discloses disclose launching an investigation of lost shipments (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 feature of Andreasson within Moradi, Lilly, and Califano. The motivation for doing so would have been to reduce the risk of lost or stolen medical products by immediately notifying healthcare workers so that they may take appropriate action (para. 79 of Andreasson).

10. Claim 9 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 Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Mayaud (5,845,255).

(A) Referring to claim 9, Moradi, Lilly, and Califano do not disclose shipping comprehensive printed materials to the doctor if the doctor is a first time prescriber of the drug.

Mayaud discloses shipping comprehensive printed materials to the doctor if the doctor is a first time prescriber of the drug (col. 37, lines 6-31 of Mayaud).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Mayaud within Moradi, Lilly, and Califano. The motivation for doing so would have been to reduce the reluctance of physicians to prescribe new drugs by providing them with the latest information about the drugs (col. 37, lines 6-23 of Mayaud).

Mayaud does not expressly disclose that the drug is a sensitive drug.

Lilly et al. disclose that the drug is a sensitive drug (para. 33 of Lilly; the Examiner interprets "controlled substance" to be a form of "sensitive drug").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Lilly within Mayaud, Moradi, and Califano. The motivation for doing so would have been for the distribution method to be used primarily for drugs that are likely to be abused (para. 9 of Lilly).

11. Claims 33-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1).
(A) Referring to claim 33, Moradi discloses a method of distributing a drug under exclusive control of an exclusive central pharmacy, the method comprising (para. 3 and para. 24 of Moradi):

receiving prescription requests from a medical doctor containing information identifying a patient, the drug, and various credentials of the doctor (para. 35, para. 116, and para. 117 of Moradi);

checking the credentials of the doctor (para. 118 of Moradi); and

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

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

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

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Lilly within Moradi. The motivation for doing so would have been to ensure that prescribers have an accurate view of their patients' use of prescription drugs and to help protect professionals from lawsuits and other potential liabilities (para. 58 of Lilly).

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

(C) Referring to claim 35, Moradi discloses selectively blocking shipment of the drug to a patient (para. 45 and para. 46 of Moradi).

Moradi does not expressly disclose that the drug is a sensitive drug.

Lilly discloses that the drug is a sensitive drug (para. 2 of Lilly).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Moradi to include Lilly's sensitive drug with the motivation of tracking and managing controlled substances in order to reduce abuse (para. 2 and para. 12 of Lilly)

(D) Referring to claim 36, Moradi discloses wherein abuse is associated with a patient, and shipment is blocked upon such association (para. 45 and para. 46 of Moradi).

Moradi does not expressly disclose an abuse pattern.

Lilly discloses detecting medication patterns (see para. 58 of Lilly).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Lilly within Moradi. The motivation for doing so would have been to proactively deal with potential abuse problems (para. 58 of Lilly).

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

(A) Referring to claim 37, Moradi and Lilly do not disclose wherein the sensitive drug comprises 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 modify Moradi and Lilly to include gamma hydroxyl butyrate. The motivation for doing so would have been to include drugs of recent concern, such as GHB (para. 3 of Melker).

Response to Arguments

13. Applicant's arguments filed 3/29/06 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 3/29/06.

(1) Applicant argues at pages 5-6 that the suggestion to combine the reference in the Office Action is not directed to the same or similar problem which the claimed invention addresses. Further, there is no teaching in the prior art of application of the combination to solve the same or similar problems which the claimed invention addresses. Lilly describes reducing misused and abused prescriptions and the need for better tracking and management of prescription in Paragraph 12. However, the purpose of such reductions is related to abuse by the patient, and not abuse of a sensitive drug as claimed. The purpose of the presently claimed invention is to track sensitive drugs and reduce the potential for abuse, such as diversion of the sensitive drug.

(2) Applicant argues at page 6 that Califano is directed to obtaining consent for a clinical trial. It is not directed toward preventing abuse. The cited motivation is very different from the purpose of the presently claimed invention of distributing a sensitive drug in a manner that helps prevent abuse, making it very unlikely that one of skill in the art would be motivated to combine the references.

(3) Applicant argues at page 7 that multiple elements from each of Moradi and Lilly were combined to make the rejection. Because multiple elements from each were used, there is no reasonable expectation of success in making the combination. Further, it points toward the improper use of hindsight, using the claims as a roadmap to make the combination.

(4) Applicant argues at page 8 that Lilly describes the cooperative use of a database by multiple different pharmacies, prescribers and patients, to keep track of the prescription history for a patient. It would be an extremely daunting task to get the cooperation of all these parties. The presently claimed invention uses a central database for analysis of potential abuse situations for distribution of a sensitive drug, not to track all prescriptions for a patient. The ambitious path set forth in Lilly would discourage one of skill in the art from considering using it to solve the problems addressed in the presently claimed invention.

(5) Applicant argues at page 8 that Applicant has reviewed the cited sections of Moradi, and cannot find the concept of a central pharmacy. As the term is used in the present application, a central pharmacy is a pharmacy that exclusively controls the distribution of a sensitive drug.

(6) Applicant argues at page 9 that while Andreasson may describe launching an investigation, it lacks the concept of shipping drugs to a patient, and investigating lost shipments to the patient as claimed.

(7) Applicant argues at pages 9-10 that the Office Action cites a motivation to combine the four references as "to reduce the reluctance of physicians to prescribe new drugs by providing them with the latest information about the drugs." This motivation has nothing to do with the problems addressed by the currently claimed invention as identified above. As a proper prima facie case of obviousness has not been established, the rejection should be withdrawn.

(A) As per the first argument, the Examiner fails to understand the distinction between the tracking and management of drugs to reduce misused and abused prescriptions, as taught by Lilly and "potential abuse," as claimed by Applicant. At para. 11, Lilly discloses that "abuse" includes reselling drugs on the street. As such, it is respectfully submitted that both Lilly and Applicant's invention are directed to the same or similar problem of diversion of sensitive drugs.

(B) In response to applicant's argument that Califano is directed to obtaining consent for a clinical trial and not directed toward preventing abuse, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined

teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In addition, it is respectfully submitted that all of the applied references relate to health care management. As such, the references are combinable to a person of ordinary skill in the art.

(C) As per the third argument, the issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

(i) obviousness does not require absolute predictability;

(ii) non-preferred embodiments of prior art must also be considered; and

(iii) the question is not express teaching of references, but what they would suggest.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

(D) As per the fourth argument, in response to applicant's argument that Lilly is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the Examiner respectfully submits that Lilly is directed to the tracking and management of prescriptions to reduce misuse and abuse (para. 12 of Lilly). As such, Lilly is in the field of applicant's endeavor and is pertinent to the particular problem with which the applicant was concerned.

(E) As per the fifth argument, the Examiner respectfully submits that throughout Moradi reference is made to a pharmacy (note para. 24 and item 106 of Fig. 1). As such, it is respectfully submitted that the broadest reasonable interpretation of the term "central pharmacy" would include the pharmacy that is disclosed in Moradi. In addition, it is noted that the features upon which applicant relies (i.e., exclusively controls the distribution of a sensitive drug) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(F) As per the sixth argument, the Examiner respectfully submits that para. 79 of Andreasson discloses tracking the delivery of medical products and immediately

notifying healthcare workers and/or administrators of any missing medical products so that they make take appropriate action to recover and/or investigate the missing medical products. Para. 43 discloses comparing the information of the medical products shipped to the healthcare facility with the information received from the pharmacy terminal to verify that all of the medical products shipped to the healthcare facility were received by the pharmacy. As such, it is readily apparent that Andreasson teaches launching an investigation of lost shipments.

(G) As per the seventh argument, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

Conclusion

14. 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 system for dispensing drugs in health care institutions (4,847,764); a medicine dispensing apparatus (3,556,342); a system and method for tracking medical devices (US 2004/0008123 A1); a method and system for prescription distribution security (US 2003/0197366 A1); and a distribution system (US 2002/0010661 A1).

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

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

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

ln
6-2-06

C. LUKE GILLIGAN
PATENT EXAMINER

PTO/SB/08A(10-01)
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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	10/322,348
	Filing Date	December 17, 2002
	First Named Inventor	Reardan, Dayton
	Group Art Unit	3626
	Examiner Name	Najarian, Lena
Sheet 1 of 1	Attorney Docket No: 101.031US1	

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[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]
LN		"System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) Starter Kit", Celgene Corporation, (2001),103 pgs.	

EXAMINER Lena Najarian DATE CONSIDERED 5-30-06

Substitute Disclosure Statement Form (PTO-1449)

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

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

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2002/0177232 A1	11-2002	Melker et al.	436/151
*	B	US-4,847,764	07-1989	Halvorson, Jerry L.	700/231
*	C	US-3,556,342	01-1971	Joseph S. Guarr	221/2
*	D	US-2004/0008123 A1	01-2004	Carrender et al.	340/825.49
*	E	US-2003/0197366 A1	10-2003	Kusterbeck, Shawn	283/69
*	F	US-2002/0010661 A1	01-2002	Waddington et al.	705/28
	G	US-			
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
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	W	
	X	

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

Index of Claims

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

√	Rejected	–	(Through numeral) Cancelled	N	Non-Elected	A	Appeal
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Claim		Date
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Search Notes

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

SEARCHED			
Class	Subclass	Date	Examiner
	updated previous searches	6/1/2006	LN

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	6/1/2006	LN

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July 28, 2006

Time: 5:37 p.m.
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TO: Commissioner for Patents
Attn: Lena Najarian
Patent Examining Corps
Facsimile Center
P.O. Box 1450
Alexandria, VA 22313-1450

FAX NUMBER (571) 273-8300

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

TELEPHONE: 571-272-7072

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

Document(s) Transmitted: **Proposed Claims for Examiner Interview (9 pages).**

Total pages of this transmission, including cover letter: 10 pgs.
If you do NOT receive all of the pages described above, please telephone us at 612-373-6900 or fax us at 612-339-3061.

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

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

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

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

John Gustav-Wrathall

7-28-06
Date of Transmission

07/28/2006 FRI 17:32 FAX 612 339 3061 SLWK
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JUL 2 8 2006

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

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

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

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

checking the credentials of the doctor;

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

confirming receipt of the sensitive drug; and

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

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

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

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

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

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

PAGE 2/10 * RCVD AT 7/28/2006 6:40:41 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-6/39 * DNIS:2738300 * CSID:612 339 3061 * DURATION (mm-ss):07-24

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

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

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

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

11. – 31. (Cancelled)

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

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

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

checking the credentials of the doctor;

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

confirming receipt by the patient of the sensitive drug; and

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

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

PAGE 3/10 * RCVD AT 7/28/2006 6:40:41 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-6/39 * DNIS:2738300 * CSID:612 339 3061 * DURATION (mm-ss):07-24

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

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

checking the credentials of the doctor;

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

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

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Additional limitations:

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

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

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

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

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A progression of claims based off claim 32 and 33.

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

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

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

checking the credentials of the authorized prescriber;

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

confirming receipt by the patient of the sensitive drug; and

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

Last element optional?

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

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

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

checking the credentials of the authorized prescriber;

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

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

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

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

checking the credentials of the authorized prescriber;

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

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

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

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking the credentials of the authorized prescriber;

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

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

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

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking the credentials of the authorized prescriber;

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

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

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July 31, 2006

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

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

FAX NUMBER (571) 273-8300

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

TELEPHONE: 571-272-7072

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

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

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

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

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

Examiner: Lena Najarian
Group Art Unit: 3626
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Application No. 10/322,348

Filed: 12/17/2002

Interview Agenda

2PM August 2, 2006.

Attendees:

For Applicant: Brad Forrest; Felissa Cagan

For USPTO: Examiner Najarian and Supervisor Thomas

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

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

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checking the credentials of the authorized prescriber;

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Last element optional?

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

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

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checking the credentials of the authorized prescriber;

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

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

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

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

checking the credentials of the authorized prescriber;

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

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

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

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

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

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

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

confirming receipt by the patient of the sensitive drug; and

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

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

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

(1) *Lena Najarian*. (3)*Brad Forrest*.

(2) *Joseph Thomas*. (4)*Felissa Cagan*.

Date of Interview: *02 August 2006*.

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

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

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

Identification of prior art discussed: Moradi + Lilly

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

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

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

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

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

Joseph Thomas
JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER

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

Lena Najarian
Examiner's signature, if required

Summary of Record of Interview Requirements

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

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

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

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

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

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

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

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

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

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

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

Examiner to Check for Accuracy

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

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

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

IN THE CLAIMS

Please amend the claims as follows:

1 – 31. (Cancelled)

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

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

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

checking the credentials of the doctor;

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

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

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

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking of the credentials of the authorized prescriber;

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

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

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

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking of the credentials of the authorized prescriber;

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

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

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

confirming receipt by the patient of the GHB; and

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

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

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

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

checking of the credentials of the authorized prescriber;

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

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

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

confirming receipt by the patient of the GHB; and

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

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

manufacturing GHB;

only providing manufactured GHB to the exclusive central pharmacy;

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

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

checking of the credentials of the authorized prescriber;

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

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

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

confirming receipt by the patient of the GHB; and

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

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

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

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

checking of the credentials of the authorized prescriber;

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

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

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

confirming receipt by the patient of the sensitive drug.

REMARKS

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

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

Interview Summary

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

Double Patenting Rejection

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

§112 Rejection of the Claims

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

§103 Rejection of the Claims

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

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

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

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

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

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

CONCLUSION

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

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

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

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

Date 8-8-2006

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

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

Name

Signature

Electronic Patent Application Fee Transmittal

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

Filed as Small Entity

Utility Filing Fees

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

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

Electronic Acknowledgement Receipt

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

Payment information:

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

File Listing:

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

Multipart Description

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

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	8153	no	2

Warnings:

Information:

Total Files Size (in bytes):	537633

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

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

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

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

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

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

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

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

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

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

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

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

John D. Gustav-Wrathall
Name

Signature

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

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

Application or Docket Number: 10/322,348

CLAIMS AS FILED – PART I

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

CLAIMS AS AMENDED – PART II

8/8/06

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
AMENDMENT A	Total (37 CFR 1.16(c))	* 11	Minus	** 31	=	X $25 =		OR	X $____ =	
	Independent (37 CFR 1.16(b))	* 7	Minus	*** 6	= 1	X $100 =	100	OR	X $____ =	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =	0	OR	+ $____ =	
						TOTAL ADD'L FEE	100.00	OR	TOTAL ADD'L FEE	
AMENDMENT B	Total (37 CFR 1.16(c))	*	Minus	**	=	X $____ =		OR	X $____ =	
	Independent (37 CFR 1.16(b))	*	Minus	***	=	X $____ =		OR	X $____ =	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =		OR	+ $____ =	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
AMENDMENT C	Total (37 CFR 1.16(c))	*	Minus	**	=	X $____ =		OR	X $____ =	
	Independent (37 CFR 1.16(b))	*	Minus	***	=	X $____ =		OR	X $____ =	
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =		OR	+ $____ =	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

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

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

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

21186 7590 10/18/2006

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

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 10/18/2006

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

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

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

Period for Reply

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

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

Status

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

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

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

Disposition of Claims

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

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

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-42* is/are rejected.

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

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

Application Papers

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

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

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

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

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

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

DETAILED ACTION

Notice to Applicant

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

Double Patenting

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

Claim Rejections - 35 USC § 112

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

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

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

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

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

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

claim 33, lines 8 and 10

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

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

claim 39, line 12

claim 40, line 12

claim 41, line 14

claim 42, line 12.

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

Claim Rejections - 35 USC § 103

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Response to Arguments

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

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

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

Conclusion

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

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

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

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

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

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

In
10-13-06

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER

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

U.S. PATENT DOCUMENTS

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

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

Index of Claims

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

√	Rejected	–	(Through numeral) Cancelled	N	Non-Elected	A	Appeal
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Search Notes

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

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

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

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

EXPEDITED PROCEDURE – EXAMINING GROUP 3626

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

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

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

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

IN THE CLAIMS

Please amend the claims as follows:

1 – 31. (Cancelled)

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

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

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

checking the credentials of the doctor;

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

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

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

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking the credentials of the doctor;

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

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

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

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

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

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

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

checking of the credentials of the authorized prescriber;

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

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

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

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking of the credentials of the authorized prescriber;

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

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

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

confirming receipt by the patient of the GHB; and

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

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

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

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

checking of the credentials of the authorized prescriber;

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

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

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

confirming receipt by the patient of the GHB; and

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

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

manufacturing GHB;

only providing manufactured GHB to the exclusive central pharmacy;

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

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

checking of the credentials of the authorized prescriber;

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

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

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

confirming receipt by the patient of the GHB; and

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

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

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

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

checking of the credentials of the authorized prescriber;

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

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

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

confirming receipt by the patient of the sensitive drug.

REMARKS

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

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

§112 Rejection of the Claims

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

§103 Rejection of the Claims

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

Moradi does not teach an exclusive computer database.

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

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

Paragraph 43:

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

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

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

Paragraph 45:

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

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

Paragraph 5:

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

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

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

Ukens teaches away from using a central pharmacy

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