PATENT APPLICATION FEE DETERMINATION RECORD
Effective January 1, 2003

Application or Docket Number

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.

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Customer Number 21186

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

"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

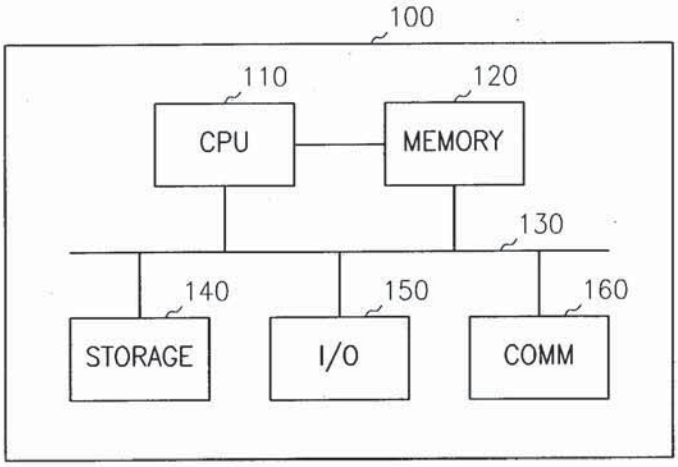

FIG. 1

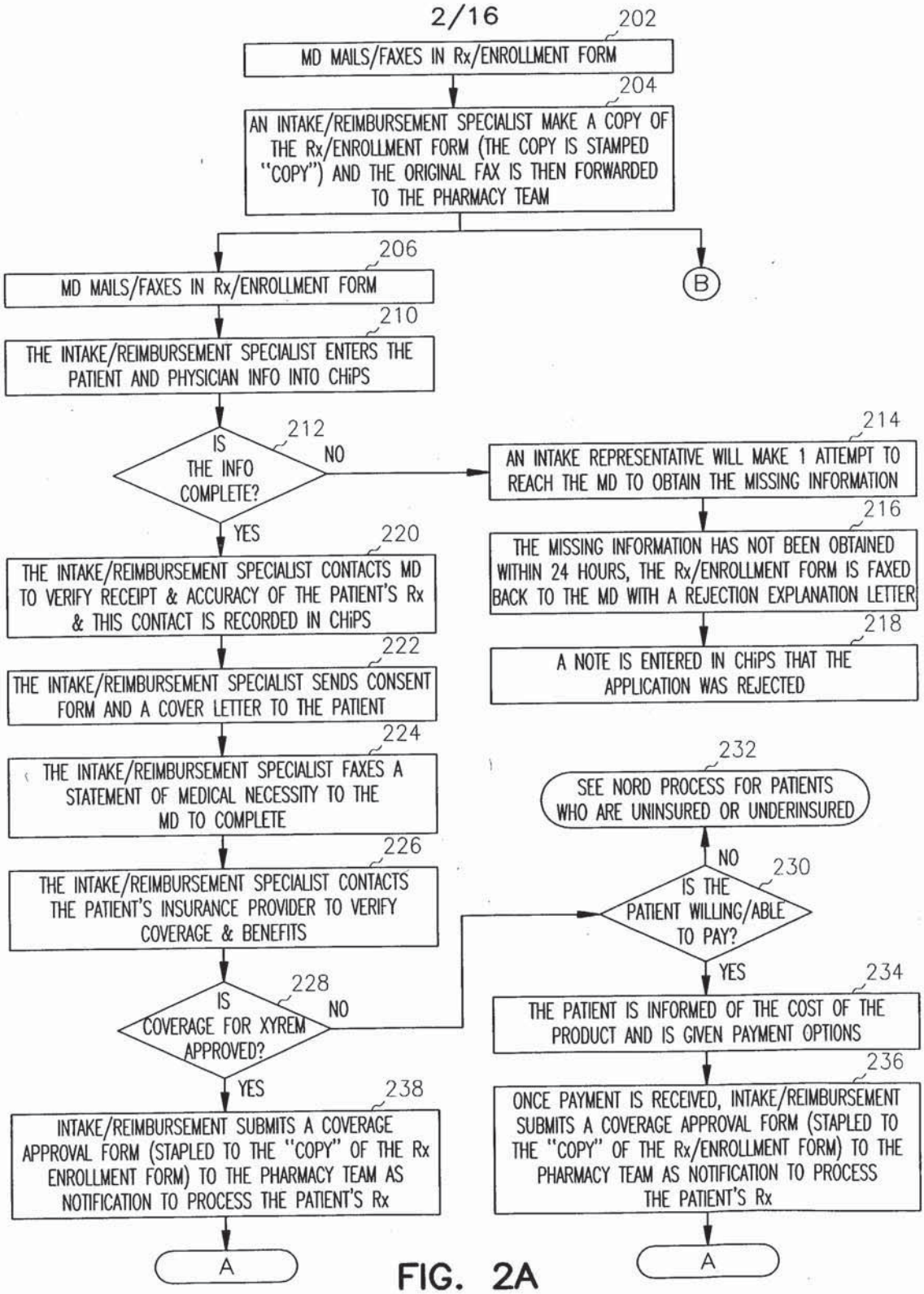
202
MD MAILS/FAXES IN Rx/ENROLLMENT FORM
204
AN INTAKE/REIMBURSEMENT SPECIALIST MAKE A COPY OF THE Rx/ENROLLMENT FORM (THE COPY IS STAMPED "COPY") AND THE ORIGINAL FAX IS THEN FORWARDED TO THE PHARMACY TEAM
206
MD MAILS/FAXES IN Rx/ENROLLMENT FORM
B
210
THE INTAKE/REIMBURSEMENT SPECIALIST ENTERS THE PATIENT AND PHYSICIAN INFO INTO CHiPS
212
IS THE INFO COMPLETE?
NO
214
AN INTAKE REPRESENTATIVE WILL MAKE 1 ATTEMPT TO REACH THE MD TO OBTAIN THE MISSING INFORMATION
216
THE MISSING INFORMATION HAS NOT BEEN OBTAINED WITHIN 24 HOURS, THE Rx/ENROLLMENT FORM IS FAXED BACK TO THE MD WITH A REJECTION EXPLANATION LETTER
218
A NOTE IS ENTERED IN CHiPS THAT THE APPLICATION WAS REJECTED
YES
220
THE INTAKE/REIMBURSEMENT SPECIALIST CONTACTS MD TO VERIFY RECEIPT & ACCURACY OF THE PATIENT'S Rx & THIS CONTACT IS RECORDED IN CHiPS
222
THE INTAKE/REIMBURSEMENT SPECIALIST SENDS CONSENT FORM AND A COVER LETTER TO THE PATIENT
224
THE INTAKE/REIMBURSEMENT SPECIALIST FAXES A STATEMENT OF MEDICAL NECESSITY TO THE MD TO COMPLETE
226
THE INTAKE/REIMBURSEMENT SPECIALIST CONTACTS THE PATIENT'S INSURANCE PROVIDER TO VERIFY COVERAGE & BENEFITS
228
IS COVERAGE FOR XYREM APPROVED?
NO
232
SEE NORD PROCESS FOR PATIENTS WHO ARE UNINSURED OR UNDERINSURED
230
IS THE PATIENT WILLING/ABLE TO PAY?
NO
YES
234
THE PATIENT IS INFORMED OF THE COST OF THE PRODUCT AND IS GIVEN PAYMENT OPTIONS
236
ONCE PAYMENT IS RECEIVED, INTAKE/REIMBURSEMENT SUBMITS A COVERAGE APPROVAL FORM (STAPLED TO THE "COPY" OF THE Rx/ENROLLMENT FORM) TO THE PHARMACY TEAM AS NOTIFICATION TO PROCESS THE PATIENT'S Rx
YES
238
INTAKE/REIMBURSEMENT SUBMITS A COVERAGE APPROVAL FORM (STAPLED TO THE "COPY" OF THE Rx ENROLLMENT FORM) TO THE PHARMACY TEAM AS NOTIFICATION TO PROCESS THE PATIENT'S Rx
A
A

FIG. 2A

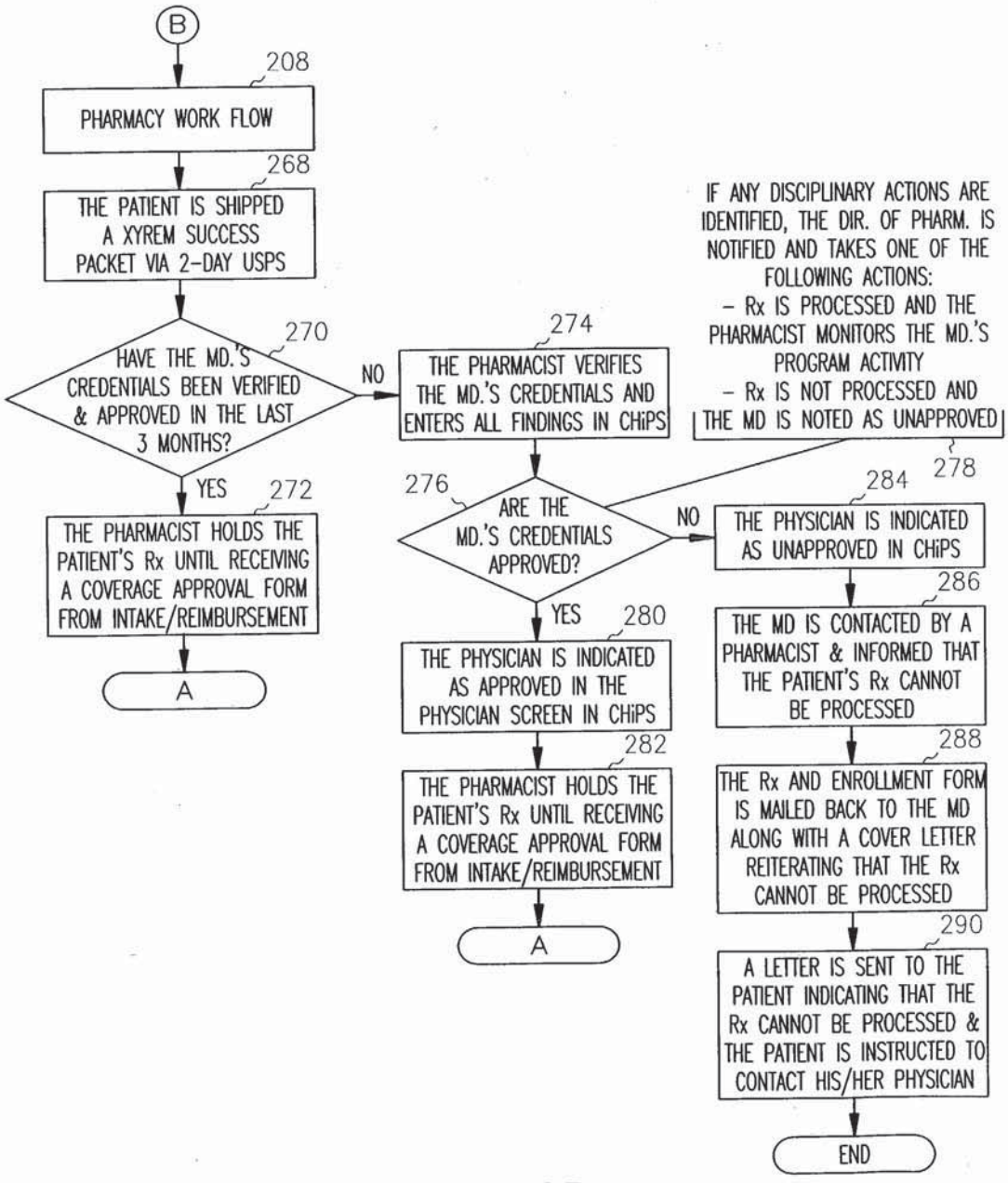
B
208
PHARMACY WORK FLOW
268
THE PATIENT IS SHIPPED A XYREM SUCCESS PACKET VIA 2-DAY USPS
270
HAVE THE MD.'S CREDENTIALS BEEN VERIFIED & APPROVED IN THE LAST 3 MONTHS?
NO
YES
272
THE PHARMACIST HOLDS THE PATIENT'S Rx UNTIL RECEIVING A COVERAGE APPROVAL FORM FROM INTAKE/REIMBURSEMENT
A
274
THE PHARMACIST VERIFIES THE MD.'S CREDENTIALS AND ENTERS ALL FINDINGS IN CHiPS
276
ARE THE MD.'S CREDENTIALS APPROVED?
YES
280
THE PHYSICIAN IS INDICATED AS APPROVED IN THE PHYSICIAN SCREEN IN CHiPS
282
THE PHARMACIST HOLDS THE PATIENT'S Rx UNTIL RECEIVING A COVERAGE APPROVAL FORM FROM INTAKE/REIMBURSEMENT
A
IF ANY DISCIPLINARY ACTIONS ARE IDENTIFIED, THE DIR. OF PHARM. IS NOTIFIED AND TAKES ONE OF THE FOLLOWING ACTIONS:
– Rx IS PROCESSED AND THE PHARMACIST MONITORS THE MD.'S PROGRAM ACTIVITY
– Rx IS NOT PROCESSED AND THE MD IS NOTED AS UNAPPROVED
278
NO
284
THE PHYSICIAN IS INDICATED AS UNAPPROVED IN CHiPS
286
THE MD IS CONTACTED BY A PHARMACIST & INFORMED THAT THE PATIENT'S Rx CANNOT BE PROCESSED
288
THE Rx AND ENROLLMENT FORM IS MAILED BACK TO THE MD ALONG WITH A COVER LETTER REITERATING THAT THE Rx CANNOT BE PROCESSED
290
A LETTER IS SENT TO THE PATIENT INDICATING THAT THE Rx CANNOT BE PROCESSED & THE PATIENT IS INSTRUCTED TO CONTACT HIS/HER PHYSICIAN
END

FIG. 2B

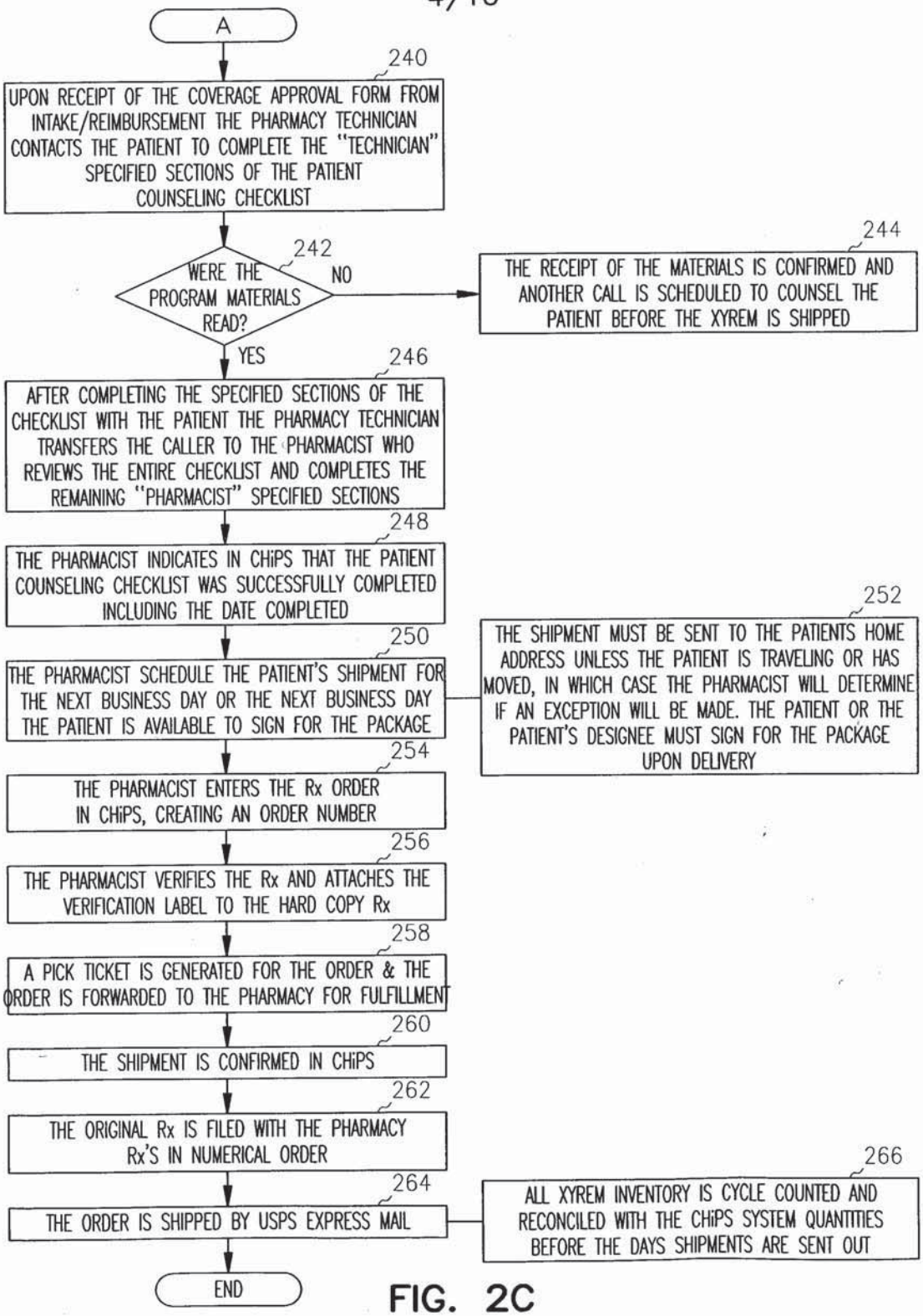
A
240
UPON RECEIPT OF THE COVERAGE APPROVAL FORM FROM INTAKE/REIMBURSEMENT THE PHARMACY TECHNICIAN CONTACTS THE PATIENT TO COMPLETE THE "TECHNICIAN" SPECIFIED SECTIONS OF THE PATIENT COUNSELING CHECKLIST
242
WERE THE PROGRAM MATERIALS READ?
NO
244
THE RECEIPT OF THE MATERIALS IS CONFIRMED AND ANOTHER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

FIG. 2C

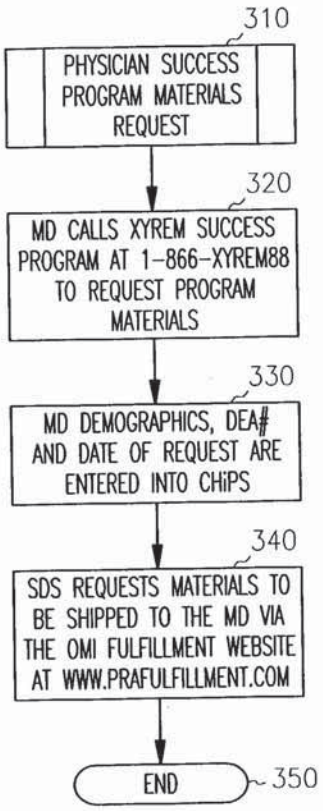
310
PHYSICIAN SUCCESS PROGRAM MATERIALS REQUEST
320
MD CALLS XYREM SUCCESS PROGRAM AT 1-866-XYREM88 TO REQUEST PROGRAM MATERIALS
330
MD DEMOGRAPHICS, DEA# AND DATE OF REQUEST ARE ENTERED INTO CHiPS
340
SDS REQUESTS MATERIALS TO BE SHIPPED TO THE MD VIA THE OMI FULFILLMENT WEBSITE AT WWW.PRAFULFILLMENT.COM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

FIG. 3

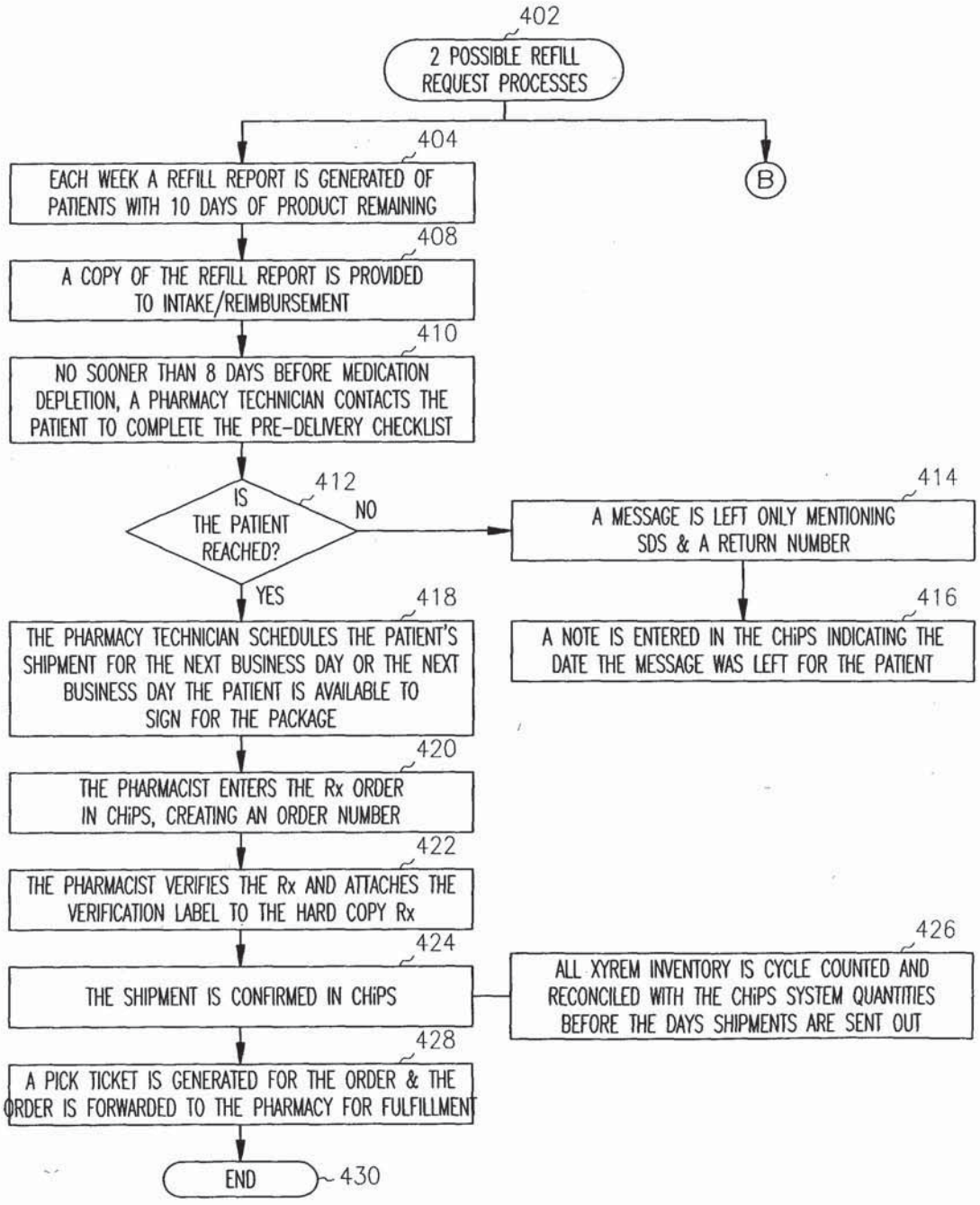
402
2 POSSIBLE REFILL REQUEST PROCESSES
404
EACH WEEK A REFILL REPORT IS GENERATED OF PATIENTS WITH 10 DAYS OF PRODUCT REMAINING
B
408
A COPY OF THE REFILL REPORT IS PROVIDED TO INTAKE/REIMBURSEMENT
410
NO SOONER THAN 8 DAYS BEFORE MEDICATION DEPLETION, A PHARMACY TECHNICIAN CONTACTS THE PATIENT TO COMPLETE THE PRE-DELIVERY CHECKLIST
412
IS THE PATIENT REACHED?
NO
414
A MESSAGE IS LEFT ONLY MENTIONING SDS & A RETURN NUMBER
YES
418
THE PHARMACY TECHNICIAN SCHEDULES THE PATIENT'S SHIPMENT FOR THE NEXT BUSINESS DAY OR THE NEXT BUSINESS DAY THE PATIENT IS AVAILABLE TO SIGN FOR THE PACKAGE
416
A NOTE IS ENTERED IN THE CHiPS INDICATING THE DATE THE MESSAGE WAS LEFT FOR THE PATIENT
420
THE PHARMACIST ENTERS THE Rx ORDER IN CHiPS, CREATING AN ORDER NUMBER
422
THE PHARMACIST VERIFIES THE Rx AND ATTACHES THE VERIFICATION LABEL TO THE HARD COPY Rx
424
THE SHIPMENT IS CONFIRMED IN CHiPS
426
ALL XYREM INVENTORY IS CYCLE COUNTED AND RECONCILED WITH THE CHiPS SYSTEM QUANTITIES BEFORE THE DAYS SHIPMENTS ARE SENT OUT
428
A PICK TICKET IS GENERATED FOR THE ORDER & THE ORDER IS FORWARDED TO THE PHARMACY FOR FULFILLMENT
END
430

FIG. 4A

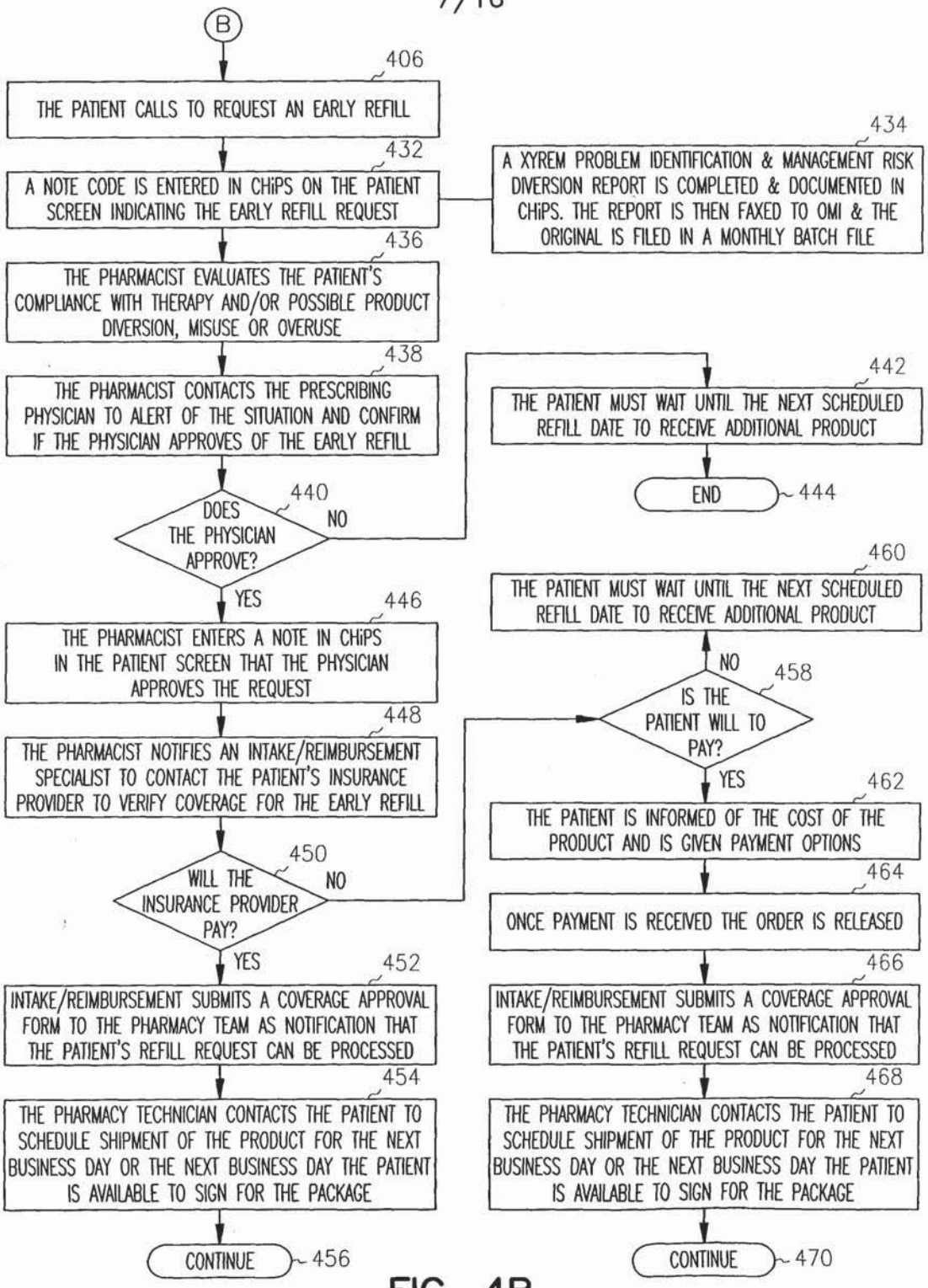
B
406
THE PATIENT CALLS TO REQUEST AN EARLY REFILL
432
A NOTE CODE IS ENTERED IN CHIPS ON THE PATIENT SCREEN INDICATING THE EARLY REFILL REQUEST
434
A XYREM PROBLEM IDENTIFICATION & MANAGEMENT RISK DIVERSION REPORT IS COMPLETED & DOCUMENTED IN CHIPS. THE REPORT IS THEN FAXED TO OMI & THE ORIGINAL IS FILED IN A MONTHLY BATCH FILE
436
THE PHARMACIST EVALUATES THE PATIENT'S COMPLIANCE WITH THERAPY AND/OR POSSIBLE PRODUCT DIVERSION, MISUSE OR OVERUSE
438
THE PHARMACIST CONTACTS THE PRESCRIBING PHYSICIAN TO ALERT OF THE SITUATION AND CONFIRM IF THE PHYSICIAN APPROVES OF THE EARLY REFILL
440
DOES THE PHYSICIAN APPROVE?
NO
442
THE PATIENT MUST WAIT UNTIL THE NEXT SCHEDULED REFILL DATE TO RECEIVE ADDITIONAL PRODUCT
END
444
YES
446
THE PHARMACIST ENTERS A NOTE IN CHIPS IN THE PATIENT SCREEN THAT THE PHYSICIAN APPROVES THE REQUEST
448
THE PHARMACIST NOTIFIES AN INTAKE/REIMBURSEMENT SPECIALIST TO CONTACT THE PATIENT'S INSURANCE PROVIDER TO VERIFY COVERAGE FOR THE EARLY REFILL
450
WILL THE INSURANCE PROVIDER PAY?
NO
YES
452
INTAKE/REIMBURSEMENT SUBMITS A COVERAGE APPROVAL FORM TO THE PHARMACY TEAM AS NOTIFICATION THAT THE PATIENT'S REFILL REQUEST CAN BE PROCESSED
454
THE PHARMACY TECHNICIAN CONTACTS THE PATIENT TO SCHEDULE SHIPMENT OF THE PRODUCT FOR THE NEXT BUSINESS DAY OR THE NEXT BUSINESS DAY THE PATIENT IS AVAILABLE TO SIGN FOR THE PACKAGE
CONTINUE
456
460
THE PATIENT MUST WAIT UNTIL THE NEXT SCHEDULED REFILL DATE TO RECEIVE ADDITIONAL PRODUCT
NO
458
IS THE PATIENT WILL TO PAY?
YES
462
THE PATIENT IS INFORMED OF THE COST OF THE PRODUCT AND IS GIVEN PAYMENT OPTIONS
464
ONCE PAYMENT IS RECEIVED THE ORDER IS RELEASED
466
INTAKE/REIMBURSEMENT SUBMITS A COVERAGE APPROVAL FORM TO THE PHARMACY TEAM AS NOTIFICATION THAT THE PATIENT'S REFILL REQUEST CAN BE PROCESSED
468
THE PHARMACY TECHNICIAN CONTACTS THE PATIENT TO SCHEDULE SHIPMENT OF THE PRODUCT FOR THE NEXT BUSINESS DAY OR THE NEXT BUSINESS DAY THE PATIENT IS AVAILABLE TO SIGN FOR THE PACKAGE
CONTINUE
470

FIG. 4B

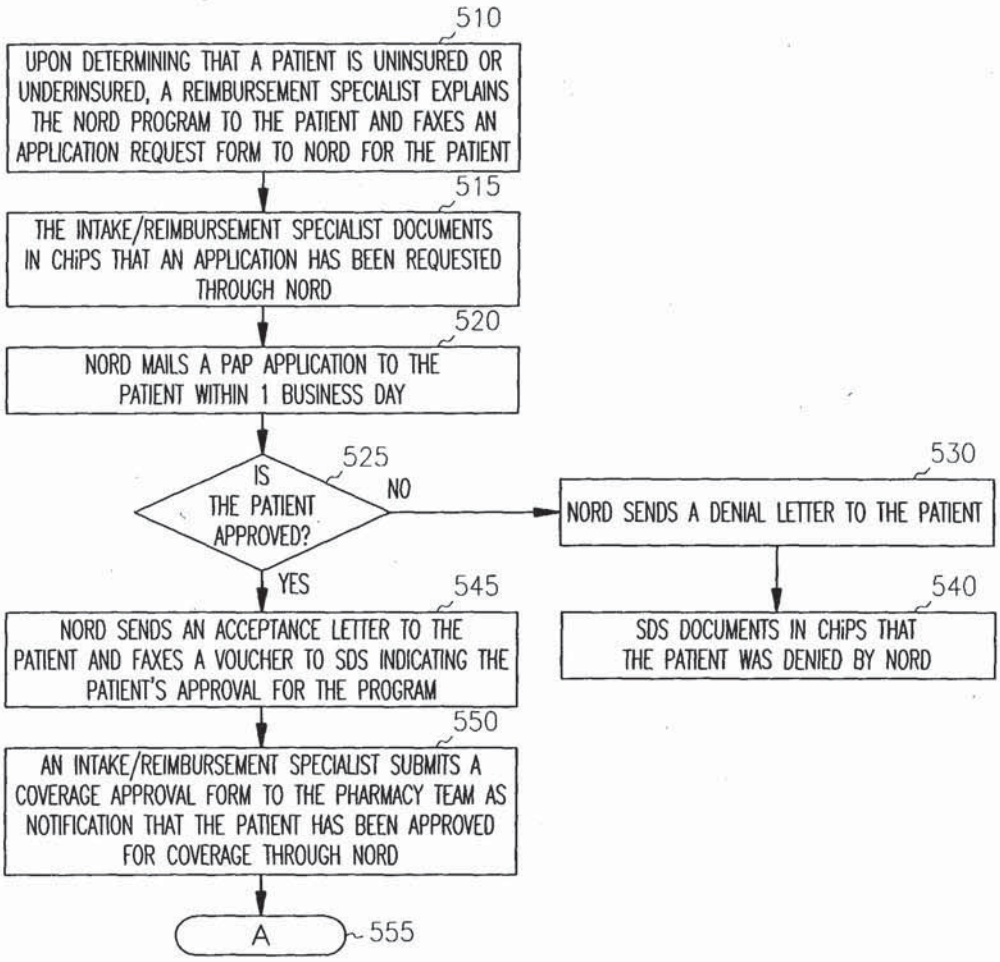
510
UPON DETERMINING THAT A PATIENT IS UNINSURED OR UNDERINSURED, A REIMBURSEMENT SPECIALIST EXPLAINS THE NORD PROGRAM TO THE PATIENT AND FAXES AN APPLICATION REQUEST FORM TO NORD FOR THE PATIENT
515
THE INTAKE/REIMBURSEMENT SPECIALIST DOCUMENTS IN CHiPS THAT AN APPLICATION HAS BEEN REQUESTED THROUGH NORD
520
NORD MAILS A PAP APPLICATION TO THE PATIENT WITHIN 1 BUSINESS DAY
525
IS THE PATIENT APPROVED?
NO
530
NORD SENDS A DENIAL LETTER TO THE PATIENT
540
SDS DOCUMENTS IN CHiPS THAT THE PATIENT WAS DENIED BY NORD
YES
545
NORD SENDS AN ACCEPTANCE LETTER TO THE PATIENT AND FAXES A VOUCHER TO SDS INDICATING THE PATIENT'S APPROVAL FOR THE PROGRAM
550
AN INTAKE/REIMBURSEMENT SPECIALIST SUBMITS A COVERAGE APPROVAL FORM TO THE PHARMACY TEAM AS NOTIFICATION THAT THE PATIENT HAS BEEN APPROVED FOR COVERAGE THROUGH NORD
A
555

FIG. 5

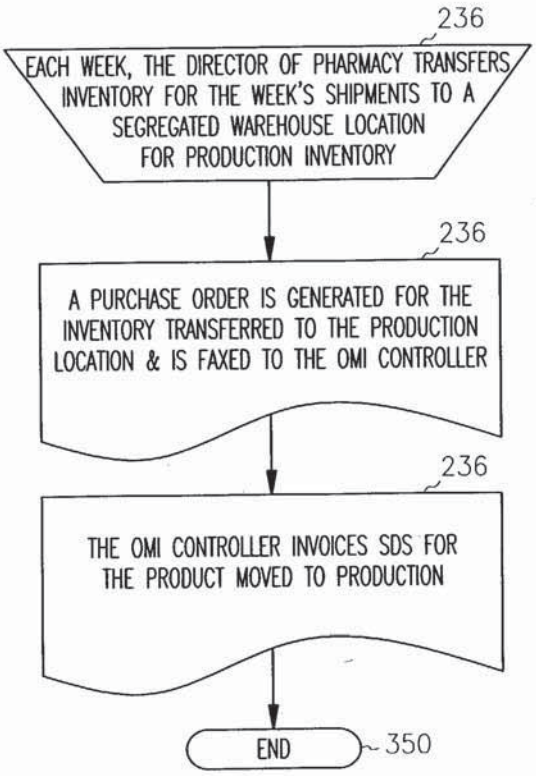

FIG. 6

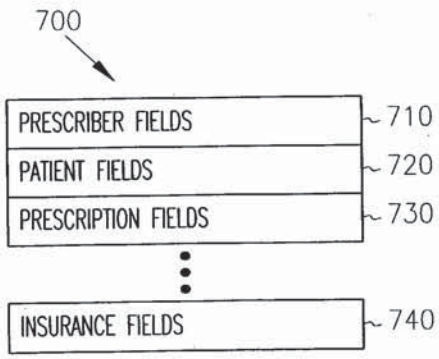

FIG. 7

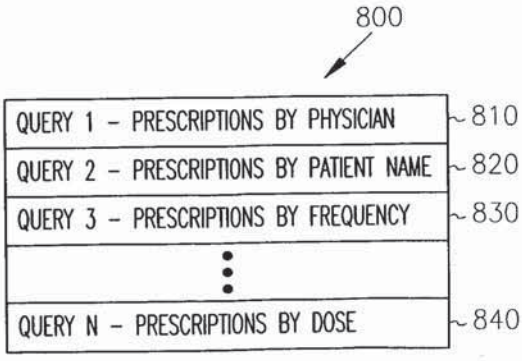

FIG. 8

900

PRESCRIPTION AND ENROLLMENT FORM

PRESCRIBER INFORMATION

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

PRESCRIPTION FORM

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

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

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

PATIENT INFORMATION

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

PLEASE ATTACH COPIES OF PATIENT'S INSURANCE CARDS

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

FIG. 9

1000

PATIENT ASSISTANCE APPLICATION REQUEST FORM

DATE:

TO: PATIENT ASSISTANCE ORGANIZATION
FROM: SDS

FAX #: 203-798-2291

PLEASE SEND A XYREM PATIENT ASSISTANCE PROGRAM APPLICATION TO:

PATIENT NAME _____

ADDRESS _____

_____

_____

TELEPHONE: ( ) _____

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

_____ BOTTLES (THREE MONTHS SUPPLY)

BACKGROUND INFORMATION:

_____

_____

_____

_____

_____

_____

FIG. 10

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

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

PHONE: <123-456-7890

CASE CODE: ********

FIRST SHIPMENT THIS YEAR

DRUG	QUANTITY
XYREEM 180ml btl	1

VALIDATION DATE:	03/01/2001
EXPIRATION DATE:	05/31/2001
ISSUE DATE:	03/15/2001

APPROVED _____

PHARMACY USE

NORD COPY

****

(DETACH HERE)

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

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

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

PHONE: <123-456-7890

CASE CODE: ********

FIRST SHIPMENT THIS YEAR

DRUG	QUANTITY
XYREM 180ml btl	1

VALIDATION DATE:	03/01/2001
EXPIRATION DATE:	05/31/2001
ISSUE DATE:	03/15/2001

APPROVED _____

PHARMACY USE

FIG. 11

1200

SENSITIVE DRUG PHYSICIAN'S CERTIFICATE OF MEDICAL NEED

PATIENT INFORMATION

DATE: _____

NAME: _____
LAST FIRST M

DATE OF BIRTH: _____

DRUG BEING PRESCRIBED: XYREM

DIAGNOSIS/CONDITION FOR WHICH DRUG IS BEING PRESCRIBED: _____

ICD-9: _____

PHYSICIAN INFORMATION

PHYSICIAN'S NAME (PLEASE PRINT): _____

PHYSICIAN'S SIGNATURE: _____ DATE: _____

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

FIG. 12

ACTIVITY REPORTS

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

FIG. 13A

ACTIVITY REPORTS

PHARMACY			
# OF PHYSICIAN SUCCESS PACKETS SHIPPED			X
# OF COMPLETED SHIPMENTS			X
# OF INCOMPLETE SHIPMENTS AND REASON			X
# OF SHIPPING ERRORS			X
# OF P&P 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

ACTIVITY REPORTS

PATIENT CARE		X	
# OF ADVERSE EVENTS REPORTED AND TYPE		X	
# OF ADVERSE EVENTS SENT TO OMI		X	
# OF DOSING PROBLEMS AND TYPE		X	
# OF NONCOMPLIANCE EPISODES AND REASON		X	
# OF PATIENT COUNSELED AND REASON		X	
# OF PATIENTS DISCONTINUED AND REASON		X	
PATIENT CARE		X	
# OF PATIENTS REFERRED TO PHYSICIAN AND REASON		X	
# OF ACTIVE PATIENTS		X	
# OF NEW PATIENTS		X	
# OF RESTART PATIENTS		X	
# OF DISCONTINUED PATIENTS AND REASON		X	
DRUG INFORMATION		X	
# OF DRUG INFORMATION REQUESTS AND TYPE		X	
# OF CALLS TRIAGED TO OMI		X	

FIG. 13C

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.

[redacted]

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.

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: _____

§ 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.

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)

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:	101.031US
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

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)

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	

Sheet 1 of 1

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

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:

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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:

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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
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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
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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		

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

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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.

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(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.

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

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

(ii) Asserting an argument of patentability.

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

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

(1) Each inventor named in the application:

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

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	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:

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. Kirle Signature _____

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,

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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

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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 30, 2004**.

Dawn M. Poole
Name:

_____
Signature

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	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)

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
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	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 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	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

	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
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	US-2004/ 0162740	08/19/2004	Ericsson, Arthur D., et al.			02/14/2003
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	US-5,845,255	12/01/1998	Mayaud, C.	705	3	10/02/1997
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	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=~~ 43	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.

FORM PTO-875 (Rev. 1/03) Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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
Filed: December 17, 2002
Examiner: Unknown

Serial No.: 10/322,348
Due Date: N/A
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. Poole
Name

Dawn M. Poole
Signature

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	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.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Supplemental Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 19-0743 in order to have this Supplemental Information Disclosure Statement considered.

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

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 2nd day of November, 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
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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
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	US-2002/ 0,161,607	10/31/2002	Subich, David C.			02/23/2001
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	US-2004/ 0,107,117	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 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	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

	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
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	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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looked at titles/abstracts

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

looked at titles/abstracts

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

looked at titles/abstracts

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
S28	5	(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 (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 (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	2005/06/21 12:59 looked at titles/abstracts

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

looked at titles/abstracts

looked at titles/abstracts

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
S41	97	(((sensitive 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 11:45
S42	9	(((sensitive 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) same (abuse or abusive or fraud) 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 11:44

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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

pulled 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
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
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
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

looked at titles/abstracts

looked at titles/abstracts

considered 1

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.

PTO-90C (Rev. 10/03)

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

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) 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*, 15/4/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

C.O.D

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