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

Claim Rejections - 35 USC § 112

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

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

8. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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

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

claim 2, line 2

claim 4, line 2

claim 6, line 2

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

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

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

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

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

Claim Rejections - 35 USC § 101

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

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

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

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

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

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

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

Claim Rejections - 35 USC § 103

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

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

12. Claims 1-2, 4-8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) and further in view of Califano et al. (US 2003/0033168 A1).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Andreasson et al. (US 2003/0160698 A1).

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

Andreasson discloses disclose launching an investigation of lost shipments (para. 79 of Andreasson).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Andreasson within Moradi, Lilly, and Califano. The motivation for doing so would have been to reduce the risk of lost or stolen medical products by immediately notifying healthcare workers so that they may take appropriate action (para. 79 of Andreasson).

14. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Mayaud (5,845,255).

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

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

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

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

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

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

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

Conclusion

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

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

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

In
6-21-05

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600

PTO/SB/08A(10-01)
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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 1

Complete if Known	
Applicati n Number	10/322,348
Filing Date	December 17, 2002
First Nam d Invent r	Reardan Ph.D., Dayton
Group Art Unit	~~1743~~ 3626
Examiner Name	Unknown
Attorney Docket No: 101.031US1	

US PATENT DOCUMENTS

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

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T²

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

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

EXAMINER Lena Nafarian DATE CONSIDERED 6-17-05

Substitute Disclosure Statement Form (PTO-1449)

¹ 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. ² Applicant's unique citation designation number (optional). ³ Applicant is to place a check mark here if English language Translation is attached

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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~~ 3626
Examiner Name	Unknown
Attorney Docket No: 101.031US1	

US PATENT DOCUMENTS

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

EXAMINER Lona Nafarian DATE CONSIDERED 6-17-05

Substitute Disclosure Statement Form (PTO-1449)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

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

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

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

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]

EXAMINER Lena Najarian DATE CONSIDERED 6-17-05

Substitute Disclosure Statement Form (PTO-1449)

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

U.S. PATENT DOCUMENTS

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

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

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Bib Data Sheet

CONFIRMATION NO. 5446

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

APPLICANTS

Dayton T. Reardan, Excelsior, MN;

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

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

none LN 6-17-05

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

none LN 6-17-05

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

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

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

TITLE
Sensitive drug distribution system and method

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

		☐ Other _____
		☐ Credit

Index of Claims

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

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

Claim		Date
Final	Original	6/21/05
	1	√
	2	√
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Search Notes

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

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

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

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

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

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

IN THE SPECIFICATION

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

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

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

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

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

If any disciplinary actions are identified, as referenced at block 278, management of the pharmacy is notified and either approves processing of the prescription with continued monitoring of the physician, or processing of the prescription is not performed, and the physician is noted in the database as unapproved at 284. The MD is contacted by a pharmacist at 286, and informed that the patient's Rx cannot be processed. The enrollment form is then mailed back to the physician with a cover letter reiterating that the prescription cannot be processed at 288. The patient is also sent a letter at 290 indicating that the prescription cannot be processed and the patient is instructed to contact their physician.

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

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

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

A refill request process begins at ~~302~~ 402 in FIG.s 4A and 4B. There are two different paths for refills. A first path beginning at 404 involves generating a report from the central database of patients with a predetermined number of days or product remaining. A second path beginning at 406 is followed when a patient calls to request an early refill.

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

The second path, beginning at 406 results in a note code being entered into the database on a patient screen indicating an early refill request at 432. At 434, a sensitive drug problem identification and management risk diversion report may be completed, documented and distributed. The pharmacist evaluates the patient's compliance with therapy or possible product diversion, misuse or over-use at 436. In one embodiment, cash payers are also identified. The pharmacist then contacts the prescribing physician to alert them of the situation and confirm if the physician approves of the early refill at 438. If the physician does not approve as indicated at 440, the patient must wait until the next scheduled refill date to receive additional product as indicated at 442, and the process ends at 444.

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

FIG. 12 is a copy of one example voucher request 1200 for medication for use with the NORD application request form of FIG. 10. In addition to patient and physician information, prescription information and diagnosis information is also provided.

IN THE CLAIMS

Please amend the claims as follows:

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

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

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

checking the credentials of the doctor;

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

confirming receipt of the sensitive drug; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

selecting multiple controls for distribution by an exclusive central pharmacy maintaining a central database, the controls selected from the group consisting of communicating prescriptions from a physician to the central pharmacy, identifying the physicians name, license

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

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

20. (Withdrawn) The method of claim 19 wherein initially selected controls comprise communicating prescriptions from a physician to the central pharmacy, identifying the physicians name, license and DEA registration information, verifying the prescription; obtaining patient information, verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and check on whether any actions are pending against the physician, verifying patient registry information, providing comprehensive education information to the patient, verifying the patient has reviewed the educational materials, verifying the home address of the patient, shipping via US postal service, confirming receipt of an initial shipment of the drug to the patient releasing inventory in a controlled manner to the central pharmacy, flagging

repeat instances of lost, stolen, destroyed or spilled prescriptions, and making the database available to the DEA for checking for abuse patterns in the data.

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

22. (Withdrawn) A method of distributing a sensitive drug, the method comprising:

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

selecting multiple controls for distribution of the sensitive drug; and

adding additional controls to provide sufficient reassurance to a governmental regulatory body that the sensitive drug distribution can be adequately controlled in order to obtain marketing approval by the governmental regulatory body.

23. (Withdrawn) The method of claim 22 wherein the system allows marketing of a drug product pursuant to FDA subpart 4 regulation embodied in Title 21, CFR Part 314.

24. (Withdrawn) The method of claim 22 wherein distribution of the sensitive drug is controlled by a central distribution center sufficient to allow the DEA (Drug Enforcement Agency) to approve the central distribution center.

25. (Withdrawn) The method of claim 22 wherein the governmental regulatory body comprises a state regulatory agency that approves distribution of the sensitive drug in a state.

26. (Withdrawn) A method to control abuse of a sensitive drug by controlling the distribution thereof via an exclusive central pharmacy that maintains a central database that tracks all prescriptions of said sensitive drug and analyzes for potential abuse situations, the method comprising:

determining current and anticipated patterns of potential prescription abuse of said sensitive drug from periodic reports generated by the central database based on prescription

request data from a medical doctor, wherein said request data contain information identifying the patient, the drug prescribed, and credentials of the doctor; and

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

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

communicating prescriptions from a physician to the central pharmacy; identifying the physicians name, license, and DEA registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; verifying patient registry information; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address

of the patient; shipping via US postal service; confirming receipt of an initial shipment of the drug to the patient; releasing inventory in a controlled manner to the central pharmacy; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; and making the database available to the DEA for checking for abuse patterns in the data.

28. (Withdrawn) The method of claim 26 which further comprises consulting a separate database to verify that the medical doctor is eligible to prescribe the drug.

29. (Withdrawn) A method to control abuse of gamma hydroxy butyrate (GHB) by controlling the distribution of GHB via an exclusive central pharmacy that maintains a central database that tracks all prescriptions of GHB and analyzes for potential abuse situations, the method comprising:

determining current and anticipated patterns of potential prescription abuse of GHB from periodic reports generated by the central database based on prescription request data from a medical doctor, wherein said request data contain information identifying the patient, GHB as the drug prescribed, and credentials of the doctor; and

selecting multiple controls for distribution by said exclusive central pharmacy, the controls selected from the group consisting of communicating prescriptions from a physician to the central pharmacy; identifying the physicians name, license, and DEA (Drug Enforcement Agency) registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive printed materials to the physician; contacting the patient's insurance company if any; verifying patient registry information; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address of the patient; shipping via US postal service or similar shipping service; receiving the name of an at least 18 year old designee to receive the drug; confirming receipt of an initial shipment of the drug to the patient returning the drug to the pharmacy after two attempts to deliver; launching an investigation when a shipment is lost; shipping to another pharmacy for delivery; requiring

manufacture at a single location; releasing inventory in a controlled manner to the central pharmacy; questioning early refills; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; limiting the prescription to a one month supply; requiring rewriting of the prescription periodically; and making the database available to the DEA for checking for abuse patterns in the data, for cash payments, and for inappropriate questions.

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

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

31. (Withdrawn) The method of claim 29 which further comprises consulting a separate database to verify that the medical doctor is eligible to prescribe the drug.

REMARKS

This responds to the Office Action mailed on June 29, 2005, and the references cited therewith.

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

Affirmation of Election

Restriction to one of the following claims was required:

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

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

Drawing Objection

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

§112 Rejection of the Claims

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

§101 Rejection of the Claims

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

§103 Rejection of the Claims

Claims 1-2, 4-8 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) and further in view of Califano et al. (US 2003/0033168 A1). Applicant reserves the right to swear behind each of the references at a later date. The rejection is respectfully traversed.

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

The *Fine* court stated that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONCLUSION

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

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

Respectfully submitted,
DAYTON T. REARDAN ET AL.
By their Representatives,
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
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Minneapolis, MN 55402
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Date 9-29-2005 By _____
Bradley A. Forrest
Reg. No. 30,837

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29th day of September, 2005.

PATRICIA A. HULTMAN _____

Name Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

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

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

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

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

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

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

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

By: _____
Atty: Bradley A. Forrest
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Signature

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

1P 3626

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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

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

Pursuant to 37 C.F.R. §1.97(c)(2), Applicants have included the fee of $180.00 as set forth in 37 C.F.R. §1.17(p). Please charge any additional fees or credit any overpayment to Deposit Account No. 19-0743.

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

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Pursuant to 37 C.F.R. 1.98(a)(2), Applicant believes that copies of cited U.S. Patents and Published Applications are no longer required to be provided to the Office. Notification of this change was provided in the United States Patent and Trademark Office OG Notices dated October 12, 2004. Thus, Applicant has not included copies of any US Patents or Published Applications cited with this submission. Should the Office require copies to be provided, Applicant respectfully requests that notice of such requirement be directed to Applicant's below-signed representative. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

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Minneapolis, MN 55402
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Date 9-29-2005 By _____
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Reg. No. 30,837

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29th day of September, 2005.

PATRICIA A. HULTMAN
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Signature

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

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

US PATENT DOCUMENTS

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

FOREIGN PATENT DOCUMENTS

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

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		Preliminary Amendment Pursuant to 37 CFR 1.115 filed with United States Patent and Trademark Office on June 17, 2005 in Application Serial No. 11/104,013 (3 pages).	

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Marc Elsayed and Bruce Williams**	Confirmation No.: **Not yet assigned**
Application No.: **11/104,013**	Group Art Unit: **Not yet assigned**
Filing Date: **April 12, 2005**	Examiner: **Not yet assigned**

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

DATE OF DEPOSIT: June 17, 2005

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

Angela Verrecchio

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

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

Sir:

PRELIMINARY AMENDMENT PURSUANT TO 37 CFR § 1.115

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

- ☐ **Amendments to the Specification** begin on page of this paper.
- ☒ **Amendments to the Claims** are reflected in the listing of the claims which begins on page 2 of this paper.
- ☐ **Amendments to the Drawings** begin on page of this paper and include an attached replacement sheet.
- ☒ **Remarks** begin on page 3 of this paper.

DOCKET NO.: CELG-0471 **PATENT**
Application No.: 11/104,013
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REMARKS

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

Date: June 17, 2005

Angela Verrecchio
Registration No. 54,510

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One Liberty Place - 46th Floor
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DOCKET NO.: CELG-0471 **PATENT**
Application No.: 11/104,013
Preliminary Amendment - First Action Not Yet Received

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

Listing of Claims:

Claims 1-10 (Canceled)

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

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

b. entering the data into a computer database;

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

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

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

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

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

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

PATENT APPLICATION FEE DETERMINATION RECORD
Effective January 1, 2003

Application or Docket Number: 10/322348

CLAIMS AS FILED - PART I

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

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

SMALL ENTITY TYPE ☐		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

10/04

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= ~~23~~	86	OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE	140	OR	TOTAL ADDIT. FEE	

DN 10/3/05

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

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

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

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. 1/1)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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

21186 7590 12/29/2005

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

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 12/29/2005

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

PTO-90C (Rev. 10/03)

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

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *03 October 2005*.

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

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

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

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

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

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

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

Application Papers

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

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

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

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

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20051003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 10/3/05.

Claims 1-10 are pending. Claims 1, 2, 4, 8, and 9 have been amended.

Drawings

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

Claim Rejections - 35 USC § 112

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

Claim Rejections - 35 USC § 101

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

Claim Rejections - 35 USC § 103

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

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

6. Claims 1-2, 4-8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) and further in view of Califano et al. (US 2003/0033168 A1).

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

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

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Andreasson et al. (US 2003/0160698 A1).

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

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1)

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

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

Response to Arguments

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Conclusion

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

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

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

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

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

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

In
12-12-05

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER

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

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

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

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OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
LN		Preliminary Amendment Pursuant to 37 CFR 1.115 filed with United States Patent and Trademark Office on June 17, 2005 in Application Serial No. 11/104,013 (3 pages).	

EXAMINER Lena Najarian DATE CONSIDERED 12-9-05

Substitute Disclosure Statement Form (PTO-1449)

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

Index of Claims

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

√	Rejected	–	(Through numeral) Cancelled	N	Non-Elected	A	Appeal
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Claim		Date								
Final	Original	12/12/05								
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Search Notes	Application/Control No.	Applicant(s)/Patent under Reexamination
	10/322,348	REARDAN ET AL.
	Examiner	Art Unit
	Lena Najarian	3626

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

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR

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

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

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

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

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

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

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

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

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

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

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

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

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

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 24 day of March, 2006.

John Gustav-Wrathall
Name

_____
Signature

EXPEDITED PROCEDURE – EXAMINING GROUP 3626

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

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

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

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

IN THE CLAIMS

Please amend the claims as follows.

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

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

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

checking the credentials of the doctor;

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

confirming receipt of the sensitive drug; and

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

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

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

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

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

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

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

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

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

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

11. – 31. (Cancelled)

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

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

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

checking the credentials of the doctor;

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

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking the credentials of the doctor;

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

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

REMARKS

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

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

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

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

§103 Rejection of the Claims

Claims 1-2, 4-8 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) and further in view of Califano et al. (US 2003/0033168 A1).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONCLUSION

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

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

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

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

Date 3-29-2006

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

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

JOHN D. GUSTAV-WRATHALL
Name

_____
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

INFORMATION DISCLOSURE STATEMENT

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

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

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

Pursuant to 37 C.F.R. 1.98(a)(2), Applicant believes that copies of cited U.S. Patents and Published Applications are no longer required to be provided to the Office. Notification of this change was provided in the United States Patent and Trademark Office OG Notices dated October 12, 2004. Thus, Applicant has not included copies of any US Patents or Published Applications cited with this submission. Should the Office require copies to be provided, Applicant respectfully requests that notice of such requirement be directed to Applicant's below-signed representative. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

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

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

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

Name _____ Signature _____

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan, Dayton
Group Art Unit	3626
Examiner Name	Najarian, Lena

Sheet 1 of 1

Attorney Docket No: 101.031US1

US PATENT DOCUMENTS

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

FOREIGN PATENT DOCUMENTS

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

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		"System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) Starter Kit", Celgene Corporation, (2001),103 pgs.	

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

COMMUNICATION CONCERNING RELATED APPLICATION(S)

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

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

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

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

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By Applicants' Representatives,

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

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

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

John W. Griebenow
Name

Signature

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

Utility Filing Fees

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

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

Electronic Acknowledgement Receipt

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

Payment information:

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

File Listing:

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

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

Warnings:					
Information:					
2	NPL Documents	steps.pdf	20861586	no	103
Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	8169	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	21755806		

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

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

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

EAST Search History

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

EAST Search History

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

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

21186 7590 06/19/2006

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EXAMINER	
NAJARIAN, LENA	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 06/19/2006

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

PTO-90C (Rev. 10/03)

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

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

Period for Reply

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

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

Status

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

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

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

Disposition of Claims

4)☒ Claim(s) *1-10 and 32-37* is/are pending in the application.

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

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 32-37* is/are rejected.

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

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

Application Papers

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

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

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

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

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20060329*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

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

Double Patenting

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

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

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

Claim Rejections - 35 USC § 112

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

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

5. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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

Claim Rejections - 35 USC § 103

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

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

8. Claims 1-2, 4-8, 10, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) and further in view of Califano et al. (US 2003/0033168 A1).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(H) Referring to claim 32, Moradi discloses a method of distributing a drug under exclusive control of an exclusive central pharmacy, the method comprising (para. 3 and para. 24 of Moradi):

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

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

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

Moradi does not expressly disclose that the drug is a sensitive drug, entering the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations, confirming with the patient that

educational material has been read prior to shipping the sensitive drug, and generating periodic reports via the exclusive computer database to evaluate potential diversion patterns.

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

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

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

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

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

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Andreasson et al. (US 2003/0160698 A1).

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

Andreasson discloses disclose launching an investigation of lost shipments (para. 79 of Andreasson).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Andreasson within Moradi, Lilly, and Califano. The motivation for doing so would have been to reduce the risk of lost or stolen medical products by immediately notifying healthcare workers so that they may take appropriate action (para. 79 of Andreasson).

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1) as applied to claim 1 above, and further in view of Mayaud (5,845,255).

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

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

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Mayaud within Moradi, Lilly, and Califano. The motivation for doing so would have been to reduce the reluctance of physicians to prescribe new drugs by providing them with the latest information about the drugs (col. 37, lines 6-23 of Mayaud).

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

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

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

11. Claims 33-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1).
(A) Referring to claim 33, Moradi discloses a method of distributing a drug under exclusive control of an exclusive central pharmacy, the method comprising (para. 3 and para. 24 of Moradi):

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

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

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

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

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

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

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

(C) Referring to claim 35, Moradi discloses selectively blocking shipment of the drug to a patient (para. 45 and para. 46 of Moradi).

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

Lilly discloses that the drug is a sensitive drug (para. 2 of Lilly).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Moradi to include Lilly's sensitive drug with the motivation of tracking and managing controlled substances in order to reduce abuse (para. 2 and para. 12 of Lilly)

(D) Referring to claim 36, Moradi discloses wherein abuse is associated with a patient, and shipment is blocked upon such association (para. 45 and para. 46 of Moradi).

Moradi does not expressly disclose an abuse pattern.

Lilly discloses detecting medication patterns (see para. 58 of Lilly).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Lilly within Moradi. The motivation for doing so would have been to proactively deal with potential abuse problems (para. 58 of Lilly).

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

(A) Referring to claim 37, Moradi and Lilly do not disclose wherein the sensitive drug comprises gamma hydroxy butyrate (GHB).

Melker teaches that gamma hydroxy butyrate (GHB) is an illicit substance (para. 3 of Melker).

At the time of the invention, it would have been obvious to modify Moradi and Lilly to include gamma hydroxyl butyrate. The motivation for doing so would have been to include drugs of recent concern, such as GHB (para. 3 of Melker).

Response to Arguments

13. Applicant's arguments filed 3/29/06 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 3/29/06.

(1) Applicant argues at pages 5-6 that the suggestion to combine the reference in the Office Action is not directed to the same or similar problem which the claimed invention addresses. Further, there is no teaching in the prior art of application of the combination to solve the same or similar problems which the claimed invention addresses. Lilly describes reducing misused and abused prescriptions and the need for better tracking and management of prescription in Paragraph 12. However, the purpose of such reductions is related to abuse by the patient, and not abuse of a sensitive drug as claimed. The purpose of the presently claimed invention is to track sensitive drugs and reduce the potential for abuse, such as diversion of the sensitive drug.

(2) Applicant argues at page 6 that Califano is directed to obtaining consent for a clinical trial. It is not directed toward preventing abuse. The cited motivation is very different from the purpose of the presently claimed invention of distributing a sensitive drug in a manner that helps prevent abuse, making it very unlikely that one of skill in the art would be motivated to combine the references.

(3) Applicant argues at page 7 that multiple elements from each of Moradi and Lilly were combined to make the rejection. Because multiple elements from each were used, there is no reasonable expectation of success in making the combination. Further, it points toward the improper use of hindsight, using the claims as a roadmap to make the combination.

(4) Applicant argues at page 8 that Lilly describes the cooperative use of a database by multiple different pharmacies, prescribers and patients, to keep track of the prescription history for a patient. It would be an extremely daunting task to get the cooperation of all these parties. The presently claimed invention uses a central database for analysis of potential abuse situations for distribution of a sensitive drug, not to track all prescriptions for a patient. The ambitious path set forth in Lilly would discourage one of skill in the art from considering using it to solve the problems addressed in the presently claimed invention.

(5) Applicant argues at page 8 that Applicant has reviewed the cited sections of Moradi, and cannot find the concept of a central pharmacy. As the term is used in the present application, a central pharmacy is a pharmacy that exclusively controls the distribution of a sensitive drug.

(6) Applicant argues at page 9 that while Andreasson may describe launching an investigation, it lacks the concept of shipping drugs to a patient, and investigating lost shipments to the patient as claimed.

(7) Applicant argues at pages 9-10 that the Office Action cites a motivation to combine the four references as "to reduce the reluctance of physicians to prescribe new drugs by providing them with the latest information about the drugs." This motivation has nothing to do with the problems addressed by the currently claimed invention as identified above. As a proper prima facie case of obviousness has not been established, the rejection should be withdrawn.

(A) As per the first argument, the Examiner fails to understand the distinction between the tracking and management of drugs to reduce misused and abused prescriptions, as taught by Lilly and "potential abuse," as claimed by Applicant. At para. 11, Lilly discloses that "abuse" includes reselling drugs on the street. As such, it is respectfully submitted that both Lilly and Applicant's invention are directed to the same or similar problem of diversion of sensitive drugs.

(B) In response to applicant's argument that Califano is directed to obtaining consent for a clinical trial and not directed toward preventing abuse, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined

teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In addition, it is respectfully submitted that all of the applied references relate to health care management. As such, the references are combinable to a person of ordinary skill in the art.

(C) As per the third argument, the issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

(i) obviousness does not require absolute predictability;

(ii) non-preferred embodiments of prior art must also be considered; and

(iii) the question is not express teaching of references, but what they would suggest.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

(D) As per the fourth argument, in response to applicant's argument that Lilly is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the Examiner respectfully submits that Lilly is directed to the tracking and management of prescriptions to reduce misuse and abuse (para. 12 of Lilly). As such, Lilly is in the field of applicant's endeavor and is pertinent to the particular problem with which the applicant was concerned.

(E) As per the fifth argument, the Examiner respectfully submits that throughout Moradi reference is made to a pharmacy (note para. 24 and item 106 of Fig. 1). As such, it is respectfully submitted that the broadest reasonable interpretation of the term "central pharmacy" would include the pharmacy that is disclosed in Moradi. In addition, it is noted that the features upon which applicant relies (i.e., exclusively controls the distribution of a sensitive drug) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(F) As per the sixth argument, the Examiner respectfully submits that para. 79 of Andreasson discloses tracking the delivery of medical products and immediately

notifying healthcare workers and/or administrators of any missing medical products so that they make take appropriate action to recover and/or investigate the missing medical products. Para. 43 discloses comparing the information of the medical products shipped to the healthcare facility with the information received from the pharmacy terminal to verify that all of the medical products shipped to the healthcare facility were received by the pharmacy. As such, it is readily apparent that Andreasson teaches launching an investigation of lost shipments.

(G) As per the seventh argument, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a system for dispensing drugs in health care institutions (4,847,764); a medicine dispensing apparatus (3,556,342); a system and method for tracking medical devices (US 2004/0008123 A1); a method and system for prescription distribution security (US 2003/0197366 A1); and a distribution system (US 2002/0010661 A1).

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

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

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

LN
In
6-2-06

C. LUKE GILLIGAN
PATENT EXAMINER

PTO/SB/08A(10-01)
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan, Dayton
Group Art Unit	3626
Examiner Name	Najarian, Lena

Sheet 1 of 1

Attorney Docket No: 101.031US1

US PATENT DOCUMENTS

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

FOREIGN PATENT DOCUMENTS

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

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
LN		"System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) Starter Kit", Celgene Corporation, (2001),103 pgs.	

EXAMINER Lena Najarian DATE CONSIDERED 5-30-06

Substitute Disclosure Statement Form (PTO-1449)

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

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

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2002/0177232 A1	11-2002	Melker et al.	436/151
*	B	US-4,847,764	07-1989	Halvorson, Jerry L.	700/231
*	C	US-3,556,342	01-1971	Joseph S. Guarr	221/2
*	D	US-2004/0008123 A1	01-2004	Carrender et al.	340/825.49
*	E	US-2003/0197366 A1	10-2003	Kusterbeck, Shawn	283/69
*	F	US-2002/0010661 A1	01-2002	Waddington et al.	705/28
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
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NON-PATENT DOCUMENTS

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

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

Index of Claims

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

√	Rejected	–	(Through numeral) Cancelled	N	Non-Elected	A	Appeal
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Search Notes

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

SEARCHED			
Class	Subclass	Date	Examiner
	updated previous searches	6/1/2006	LN

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	6/1/2006	LN

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

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

TELEPHONE: 571-272-7072

FAX NUMBER (571) 273-8300

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

Document(s) Transmitted: **Proposed Claims for Examiner Interview (9 pages).**

Total pages of this transmission, including cover letter: 10 pgs.
If you do NOT receive all of the pages described above, please telephone us at 612-373-6900 or fax us at 612-339-3061.

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

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

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

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

John Gustav-Wrathall

7-28-06
Date of Transmission

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

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

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

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

checking the credentials of the doctor;

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

confirming receipt of the sensitive drug; and

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

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

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

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

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

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

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

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

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

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

11. – 31. (Cancelled)

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

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

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

checking the credentials of the doctor;

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

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking the credentials of the doctor;

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

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

Additional limitations:

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

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

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

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

A progression of claims based off claim 32 and 33.

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

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

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

checking the credentials of the authorized prescriber;

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

confirming receipt by the patient of the sensitive drug; and

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

Last element optional?

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

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

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

checking the credentials of the authorized prescriber;

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

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking the credentials of the authorized prescriber;

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

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

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

confirming receipt by the patient of the sensitive drug; and

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