IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

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

This responds to the Office Action dated June 19, 2006. Please amend the above-identified patent application as follows.

IN THE CLAIMS

Please amend the claims as follows:

1 – 31. (Cancelled)

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

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

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

checking the credentials of the doctor;

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

checking the exclusive central database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive central database;

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking the credentials of the doctor;

checking the exclusive central database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive central database;

confirming receipt by the patient of the sensitive drug; and

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

34. (Currently Amended) 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).

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

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

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

checking of the credentials of the authorized prescriber;

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

requiring checking of the exclusive central computer database for potential abuse associated with the patient and/or the authorized prescriber;

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

confirming receipt by the patient of the sensitive drug; and

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

39. (New) A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

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

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

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

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

confirming receipt by the patient of the GHB; and

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

40. (New) A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

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

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

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

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

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

41. (New) A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

manufacturing GHB;

only providing manufactured GHB to the exclusive central pharmacy;

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

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

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

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

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

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

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

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

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

checking of the credentials of the authorized prescriber;

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

requiring checking of the exclusive central computer database for potential abuse associated with the patient and/or the authorized prescriber;

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

confirming receipt by the patient of the sensitive drug.

REMARKS

This responds to the Office Action dated June 19, 2006, and the references cited therewith.

Claims 32-34 are amended. Claims 1-10 are canceled. Claims 38-42 are added. As a result, claims 32-42 are now pending in this application.

Interview Summary

Applicant wishes to thank Examiner Najarian and Supervisor Thomas for the courtesies extended to Bradley Forrest and Felissa Cagan during an in-person interview on August 2, 2006. We discussed possible amendments to the claims. Some of the discussed amendments are reflected in amended claims 32 and 33, as well as in new independent claims 38-42. No exhibits were presented.

Double Patenting Rejection

Claims 1-10 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10 of copending Application No. 10/979,665. Applicant has cancelled claims 1-10 without prejudice.

§112 Rejection of the Claims

Claim 34 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 34 has been amended to resolve the rejection.

§103 Rejection of the Claims

Claims 1-2, 4-8, 10, and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) and further in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1). Claims 1-10 have been cancelled, and claim 32 has been amended consistent with amendments discussed.

Claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) as applied to claim 1 above, and further in view of Andreasson et al. (U.S. Patent Publication No. 2003/0160698 A1). Claim 3 was cancelled as described above.

Claim 9 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) as applied to claim 1 above, and further in view of Mayaud (U.S. Patent No. 5,845,255). Claim 9 was cancelled as described above.

Claims 33-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1). Claim 33 was amended consistent with amendments discussed.

Claim 37 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1), and further in view of Melker et al. (U.S. Patent Publication No. 2002/0177232).

New claims 38-42 have been added and are consistent with amendments discussed. In particular, none of the references describe a required checking of an exclusive database for potential abuse, and then not shipping or distributing the sensitive drug if the required check uncovers potential abuse. Some of the claims expressly recite mailing of the sensitive drug only if the check is ok, and a further claim recites that the sensitive drug is GHB extensively throughout the elements of the claim.

CONCLUSION

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

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

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

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

Date 8-8-2006

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

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8 day of ~~July~~ Aug. 2006.

Name

Signature

Electronic Patent Application Fee Transmittal

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

Filed as Small Entity

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Independent claims in excess of 3	2201	1	100	100
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
		Total in USD ($)		**100**

Electronic Acknowledgement Receipt

EFS ID:	1146223
Application Number:	10322348
Confirmation Number:	5446
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor:	Dayton T. Reardan
Customer Number:	21186
Filer:	Gregg Alan Peacock/John Gustav-Wrathall
Filer Authorized By:	Gregg Alan Peacock
Attorney Docket Number:	101.031US1
Receipt Date:	08-AUG-2006
Filing Date:	17-DEC-2002
Time Stamp:	17:06:15
Application Type:	Utility
International Application Number:	

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	$100
RAM confirmation Number	358
Deposit Account	190743
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 and 1.17	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part	Pages
1		101031us1_response.pdf	529480	yes	10

	Multipart Description		
	Doc Desc	Start	End
	Transmittal letter	1	1
	Amendment - After Non-Final Rejection	2	2
	Claims	3	7
	Applicant Arguments/Remarks Made in an Amendment	8	10

Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	8153	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	537633		

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

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

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

Serial No.: 10/322,348
Due Date: September 19, 2006
Group Art Unit: 3626

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

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

X Amendment and Response (9 pgs.).
X Authorization to charge Deposit Account 19-0743 in the amount of $100.00 to cover the fee for additional claims as calculated below.

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

CLAIMS AS AMENDED						
	(1) Claims Remaining After Amendment		(2) Highest Number Previously Paid For	(3) Present Extra	Rate	Fee
TOTAL CLAIMS	11	-	31	0	x 25 =	$0.00
INDEPENDENT CLAIMS	7	-	6	1	x 100 =	$100.00
[]MULTIPLE DEPENDENT CLAIMS PRESENTED						$0.00
TOTAL						$100.00

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

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

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

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8 day of August, 2006.

John D. Gustav-Wrathall
Name

_____
Signature

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

PTO/SB/06 (08-03)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and 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 displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

Application or Docket Number: 10/322,348

CLAIMS AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE	SMALL ENTITY FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY FEE
BASIC FEE (37 CFR 1.16(a))				$____	OR		$____
TOTAL CLAIMS (37 CFR 1.16(c))	minus 20 =	*	X $____ =		OR	X $____ =	
INDEPENDENT CLAIMS (37 CFR 1.16(b))	minus 3 =	*	X $____ =		OR	X $____ =	
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(d))			+ $____ =		OR	+ $____ =	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL		OR	TOTAL	

CLAIMS AS AMENDED – PART II

8/8/06

AMENDMENT A	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
Total (37 CFR 1.16(c))	* 71	Minus	** 31	=	X $25 =		OR	X $____ =	
Independent (37 CFR 1.16(b))	* 7	Minus	*** 6	= 1	X $100 =	100	OR	X $____ =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =	PJ	OR	+ $____ =	
					TOTAL ADD'L FEE	100.00	OR	TOTAL ADD'L FEE	

AMENDMENT B	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
Total (37 CFR 1.16(c))	*	Minus	**	=	X $____ =		OR	X $____ =	
Independent (37 CFR 1.16(b))	*	Minus	***	=	X $____ =		OR	X $____ =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =		OR	+ $____ =	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT C	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
Total (37 CFR 1.16(c))	*	Minus	**	=	X $____ =		OR	X $____ =	
Independent (37 CFR 1.16(b))	*	Minus	***	=	X $____ =		OR	X $____ =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =		OR	+ $____ =	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

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

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

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

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	10/13/06
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Search Notes	Application/Control No.	Applicant(s)/Patent under Reexamination
	10/322,348	REARDAN ET AL.
	Examiner	Art Unit
	Lena Najarian	3626

SEARCHED			
Class	Subclass	Date	Examiner
	updated previous searches	10/4/2006	LN

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
EIC search	10/6/2006	LN

UNITED STATES PATENT AND TRADEMARK OFFICE

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

21186 7590 10/18/2006

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

EXAMINER	
NAJARIAN, LENA	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 10/18/2006

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

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 *08 August 2006*.

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

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

Disposition of Claims

4)☒ Claim(s) *32-42* is/are pending in the application.

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

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-42* is/are rejected.

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

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

Application Papers

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

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

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

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

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

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

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 8/8/06. Claims 32-42 are pending. Claims 1-31 are cancelled. Claims 32, 33, and 34 have been amended. Claims 38-42 are newly added.

Double Patenting

2. The rejection of claims 1-10 under 35 U.S.C. 101 is hereby withdrawn due to the amendment filed 8/8/06.

Claim Rejections - 35 USC § 112

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

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

4. Claims 32-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claim 32 recites "only" receiving prescription requests "at the exclusive central pharmacy." It is unclear to the Examiner whether the exclusive central pharmacy *only* receives prescription requests (i.e., limiting what the central pharmacy can receive to prescription requests) or whether receiving prescription requests *only* happens at the exclusive central pharmacy (i.e, excluding other pharmacies from receiving the prescription requests). Clarification is required.

5. Claims 32-42 recite the limitations for which there is no antecedent basis in the claims. In particular, the following passages lack or have vague antecedent basis:

(i) "the exclusive central database": claim 32, lines 11 and 13

claim 33, lines 8 and 10

(ii) "the exclusive database": claim 34, line 2

(iii) "the exclusive central computer database": claim 38, line 12

claim 39, line 12

claim 40, line 12

claim 41, line 14

claim 42, line 12.

(iv) Claims 35-37 incorporate the deficiencies of claim 33, through dependency, and are also rejected.

Claim Rejections - 35 USC § 103

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

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

7. Claims 32, 38, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US

2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1), and further in view of Ukens ("Specialty Pharmacy").

(A) Claim 32 has been amended to now recite only receiving prescription requests at the exclusive central pharmacy and requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy.

As per these features, Ukens discloses restricting distribution of a specialty medication to only one pharmacy (see page 3, paragraphs 3-5 of Ukens).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Ukens within Moradi, Lilly, and Califano. The motivation for doing so would have been to limit access to dangerous drugs (page 3, paragraph 5 of Ukens).

Claim 32 has also been amended to now recite "checking the exclusive central database for potential abuse of the sensitive drug; only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive central database."

Moradi discloses checking the exclusive central database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive central database (para. 43, para. 45, para. 6, and Fig. 3, items 318 & 322 of Moradi).

The remainder of claim 32 is rejected for the same reasons given in the previous Office Action, and incorporated herein.

(B) Referring to claim 38, Moradi discloses a method of distributing a drug under control of an exclusive central pharmacy, the method comprising (para. 3 and para. 24 of Moradi):

receiving prescription requests at the central pharmacy from an authorized prescriber containing information identifying a patient, the drug, and various credentials of the authorized prescriber (para. 35, para. 116, and para. 117 of Moradi);

checking of the credentials of the authorized prescriber (para. 118 of Moradi);

requiring checking of the exclusive central computer database for potential abuse associated with the patient and/or the authorized prescriber (para. 43, para. 45, and Fig. 3, items 318 & 322 of Moradi);

only providing the drug to the patient provided information in the exclusive computer database is not indicative of potential abuse (para. 43, para. 45, and Fig. 3, items 318 & 322 of Moradi);

and

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

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

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

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Lilly within Moradi. The motivation for doing so would have been to immediately detect problems related to abuse, fraud, and misuse of medications (para. 57 of Lilly).

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

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

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

Moradi, Lilly, and Califano do not expressly disclose wherein the use of the exclusive computer database is required for distribution of the sensitive drug.

However, Ukens discloses restricting distribution of a specialty medication to only one pharmacy (see page 3, paragraphs 3-5 of Ukens).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Ukens within Moradi, Lilly, and Califano. The motivation for doing so would have been to limit access to dangerous drugs (page 3, paragraph 5 of Ukens).

(C) Claim 42 repeats the same limitations as claim 38 and is rejected for the same reasons given for that claim.

8. Claims 33-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1).

(A) Claim 33 has been amended to now recite "checking the exclusive central database for potential abuse of the sensitive drug; only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive central database."

Moradi discloses checking the exclusive central database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive central database (para. 43, para. 45, para. 6, and Fig. 3, items 318 & 322 of Moradi).

The remainder of claim 33 is rejected for the same reasons given in the previous Office Action, and incorporated herein.

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

(C) Claims 35 and 36 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

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

(A) Claim 37 has not been amended and is rejected for the same reasons given in the previous Office Action, and incorporated herein.

10. Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1), and further in view of Talk About Sleep ("An Interview with Orphan Medical about Xyrem").

(A) Referring to claim 39, Moradi discloses a method of distributing a drug under control of an exclusive central pharmacy, the method comprising (para. 3 and para. 24 of Moradi):

receiving prescription requests for the drug at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber (para. 35, para. 116, and para. 117 of Moradi);

checking of the credentials of the authorized prescriber (para. 118 of Moradi);

requiring checking of the exclusive central computer database for potential abuse associated with the patient (para. 43, para. 45, and Fig. 3, items 318 & 322 of Moradi);

only providing the drug to the patient provided information in the exclusive computer database is not indicative of potential abuse (para. 43, para. 45, and Fig. 3, items 318 & 322 of Moradi);

and

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

Moradi does not expressly disclose that the drug is gamma hydroxy butyrate (GHB), entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB, confirming with the patient that GHB educational material has been read prior to providing GHB to the patient for a first time, and generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns.

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

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Lilly within Moradi. The motivation for doing so would have been to immediately detect problems related to abuse, fraud, and misuse of medications (para. 57 of Lilly).

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

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

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

Moradi, Lilly, and Califano do not expressly disclose that the drug is GHB and wherein the use of the exclusive computer database is required for distribution of GHB.

However, Talk About Sleep discloses providing GHB through a specialty distribution system that utilizes a central pharmacy (see "An Interview with Orphan Medical about Xyrem," talkaboutsleep.com).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Talk About Sleep within Moradi, Lilly, and Califano. The motivation for doing so would have been to provide this medicine to patients that need it in a responsible manner (see "An Interview with Orphan Medical about Xyrem," talkaboutsleep.com).

(B) Claim 40 differs from claim 39 by reciting "mailing" GHB as opposed to "providing." As per this feature, the Examiner respectfully submits that Moradi discloses mailing the drugs (see para. 6 of Moradi).

The remainder of claim 40 is rejected for the same reasons given for claim 39 above.

(C) Claim 41 differs from claim 40 by reciting "manufacturing GHB and only providing manufactured GHB to the exclusive central pharmacy."

As per these features, the Examiner respectfully submits that Talk About Sleep discloses manufacturing GHB and only providing manufactured GHB to the exclusive central pharmacy (see "An Interview with Orphan Medical about Xyrem," talkaboutsleep.com).

The remainder of clam 41 is rejected for the same reasons given for claim 40 above.

Response to Arguments

11. Applicant's arguments filed 8/8/06 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 8/8/06.

(1) Applicant argues at page 8 that none of the references describe a required checking of an exclusive database for potential abuse, and then not shipping or distributing the sensitive drug if the required check uncovers potential abuse.

(A) As per the first argument, the Examiner respectfully submits that Moradi discloses at para. 43 a database that keeps track of medicine orders that are delivered to the patients. The Moradi system ensures that patients do not receive medication in excess of their prescription and prevents prescription abuse (see para. 45 of Moradi). As such, it is respectfully submitted that Moradi checks the database for potential abuse and does not ship or distribute the drug if abuse is uncovered (i.e., the medicine has already been delivered).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches tracking the distribution of prescription drugs and other controlled articles (US 6,952,681 B2) and an apparatus and method for processing prescription requests using a remotely located prescription processing system (US 7,058,584 B2).

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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

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

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

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

In
10-13-06

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER

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

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,952,681 B2	10-2005	McQuade et al.	705/28
*	B	US-7,058,584 B2	06-2006	Kosinski et al.	705/2
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Ukens, C. "Specialty Pharmacy," 6/5/00, Drug Topics, v. 144, p. 40.
	V	"An Interview with Orphan Medical about Xyrem," http://www.talkaboutsleep.com/sleep-disorders/archives/Narcolepsy_xyrem_interview.htm, 2/12/01.
	W	
	X	

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

(e.g., B1 for ERIC).
?
Terminal set to DLINK
*** DIALOG HOMEBASE(SM) Main Menu ***

Information:
1. Announcements (new files, reloads, etc.)
2. Database, Rates, & Command Descriptions
3. Help in Choosing Databases for Your Topic
4. Customer Services (telephone assistance, training, seminars, etc.)
5. Product Descriptions

Connections:
6. DIALOG(R) Document Delivery
7. Data Star(R)

/H = Help /L = Logoff /NOMENU = Command Mode

Enter an option number to view information or to connect to an online service. Enter a BEGIN command plus a file number to search a database (e.g., B1 for ERIC).
? b 16

12oct06 13:32:42 User276705 Session D10.1
$0.00 0.209 DialUnits FileHomeBase
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File 16:Gale Group PROMT(R) 1990-2006/Oct 11
(c) 2006 The Gale Group

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(c) 2006 The Gale Group. All rts. reserv.
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DIALOG(R)File 16:Gale Group PROMT(R)
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07443327 Supplier Number: 62598564 (THIS IS THE FULLTEXT)
SPECIALTY PHARMACY.
Ukens, Carol
Drug Topics, v144, n11, p40
June 5, 2000
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The battle for the specialty drug market accelerates as community pharmacists seek a larger market share

Specialty drugs have earned their label. Consider that they're generally used by small patient populations with chronic, often complex, diseases requiring challenging regimens. They're difficult to ship, store, and administer. They demand extra patient care services. They can cost as much as $200,000 a year. And they're a niche that's heating up as community pharmacists try to take an even bigger share of the $24 billion market from specialty pharmacies.

Community pharmacies currently control 89% of the specialty chronic medication market, according to analysts with Warburg Dillon Read in New York City. The remaining 11% belongs to specialty pharmacies, such as Accredo Health, Chronimed Inc., and the Bindley Western spin-off Priority Healthcare, which have sprung up in recent years. However, when it comes to specialty biotech drugs, community pharmacies own only about 18% of that niche. And the makeup of the bigger pie is going to change dramatically in the years ahead, as the specialty pharmacies muscle aside the community pharmacies.

The advantages the specialty pharmacies can muster include contracting with drug manufacturers to deliver their products directly to patients, physicians' offices, and clinics specializing in certain chronic disease states. Some of the therapies are injectables that patients can self-administer at home, but others are administered intravenously in alternate sites, such as physicians' offices or clinics, because hospitalization is too expensive but the treatment is too complicated for patients to use at home. Other drugs require administration by nurses with home health-care agencies.

The services offered by specialty pharmacies go far beyond just delivering the drugs. They also typically handle direct insurance billing and a bank of reimbursement counselors who help patients find alternative payment methods if an insurer denies a claim or the patient is underinsured. They also offer 24-hour free telephone links to a pharmacist trained in the specialty drug and the disease being treated.

Limited distribution of specialty pharmaceuticals has been a thorn in community pharmacy's side at least since Novartis launched Clozaril (clozapine) into a closed network because of the need for close monitoring. Since then, pharmaceutical and biotechnology companies have found that the traditional distribution model of manufacturer-to-wholesaler-to-retail pharmacy does not serve the needs of patients using their more sophisticated products. As a result, some specialty drugs have gotten kid-glove treatment through restricted distribution. For example, the SeroCare Program was created by Serono Laboratories in late 1996 to support Serostim (somatropin (rDNA origin) for injection) prescribed for AIDS wasting. Serostim distribution was limited to select mail-service pharmacies, including American Preferred Pharmacy, Coram Healthcare, Priority Healthcare, and Stadtlanders Pharmacy.

The specialty pharmaceuticals target a wide range of diseases and conditions, but they usually have small patient populations. Consider the menu offered by Gentiva Health Services, Melville, N.Y. The list includes alpha1 antitrypsin deficiency, amyotrophic lateral sclerosis, cancer, Crohn's disease, cystic fibrosis, diabetes, growth hormone deficiency, Guillain-Barre syndrome, hemophilia, HIV/AIDS, multiple sclerosis, myasthenia gravis, and primary immune deficiency. The company also recently reached agreement with United Therapeutics Corp. to distribute Uniprost, a subcutaneous prostacyclin therapy. Currently in phase III clinical trials, the therapy, also known as UT-15, targets late-stage pulmonary hypertension. Getting in on the pre-approval ground floor, Gentiva distributes the therapy to hospitals and patients participating in the clinical trials. If the drug wins Food & Drug Administration approval, the firm will also provide clinical management, distribution, reimbursement, and patient support services for Uniprost.

(2)

To be honest, many community pharmacies don't want to deal with the downside of specialty pharmaceuticals. They don't want to purchase and keep in stock these very expensive drugs prescribed for limited patient populations. Many of these high-tech/high-touch products require a constant temperature during distribution and storage. Dosage monitoring and compliance with drug therapy are also big patient care issues with these drugs. Then there are the hassles of insurance. Some drugs are covered by traditional Rx benefit cards, some are billed under major medical coverage, and some are billed to Medicare if a physician administers them.

"These drugs tend to be more expensive and require special handling," said Doug Long, v.p.-supplier relations for IMS Health, who put the specialty pharmacy market at about $13 billion last year. "I don't think these products are for the faint of heart. But I think the good independent and chain operators can compete in this market. Unless patients can self-medicate, a lot of the activity takes place in the physician's office, so (community pharmacies) are kind of a middleman for the doctor."

Specialty pharmaceuticals and services may not be right for every community pharmacy, agreed Susan Winckler, R.Ph., group director of policy and advocacy, American Pharmaceutical Association. But she added that restricted distribution of such products raises issues of patient access and safety. She pointed out that by restricting distribution of a specialty medication to only one pharmacy, a manufacturer exposes patients to the risk of not receiving their medications in a timely manner if there's a disruption in the delivery system. In addition, shunting one part of therapy away from a patient's regular pharmacist can create the potential for undiscovered drug interactions.

"If you have a product going to only one distributor, you have no safety net for the patient," said Winckler. "It creates problems if there are any issues of drug interactions or coordinating therapy. Using an 800 number for patient care may work for some patients, but if they don't want that, what's their alternative? They have to use whatever the system provides."

A better way to handle specialty pharmaceuticals would be for manufacturers to set the criteria for their specialty products and then open distribution to any pharmacy that measures up, suggested Winckler. "What it boils down to is the ability of the professional and the facility to handle these unique products," she said. "That's a question of what skills do you have and what requirements are you willing to meet, rather than a manufacturer arbitrarily going with one pharmacy provider. We need to look at those drugs that might need to be cared for differently, what are the criteria for participation, and then let people compete. This would be the thalidomide model where pharmacies have to meet certain criteria (before being able to stock and dispense the drug). That makes more sense than saying it's such a dangerous drug we're going to let only one pharmacy have access to it."

Getting in the game

Some drugstore chains also have jumped into specialty pharmaceuticals and services. CVS Corp., for example, created the ProCare subsidiary, which is the most ambitious response to the niche marketplace. Based on combined mail-service and community pharmacies, ProCare focuses on providing support to patients requiring complex, expensive drug regimens. ProCare caters to patients with HIV/AIDS, cancer, and transplantation, as well as those requiring biotech injectables for conditions such as multiple sclerosis and human growth hormone deficiency.

Wrapped inside a larger, long-term alliance CVS forged with Merck-Medco Managed Care last fall, the chain's ProCare became the exclusive provider of specialty pharmacy mail-order services to the pharmacy benefit manager's 51 million plan members. The deal also gave Merck-Medco a 10% equity stake in ProCare.

Sensing that the market is going to grow, Walgreen Co. is looking into options for a move into specialty pharmacy, said Michael Polzin,

spokesman for the Deerfield, Ill., chain that just opened drugstore number 3,000 (see story, page 53). Walgreens does have one specialty pharmacy in Chicago. Operating inside the Howard Brown Health Clinic, which specializes in HIV/ AIDS, the pharmacy "is doing very well," Polzin said. In addition, the chain has a few drugstores with extended abilities to work with HIV/AIDS patients in San Francisco. "We are looking at some possibilities for the future, but nothing I can talk about at this time," he added.

Walgreens Health Initiatives was the chain's entry into specialty pharmacy with a mail-service component. Health Initiatives currently runs a growth hormone program, which delivers medications, offers patient counseling, handles reimbursement issues, and periodically informs the physician of the patient's compliance status. Future specialty pharmacy programs in the works include hemophilia, transplantation, and HIV/AIDS, according to the firm's Web site.

Declaration of independents

Not content to just sit on the sidelines and watch patients and business shunted to their old nemesis, mail-service pharmacies, the National Community Pharmacists Association is attempting to build a national network of independent pharmacies willing to stock specialty products and care for the patients who need them. Teaming up with the specialty pharmacy TheraCom, NCPA launched the Specialty Drugs Network in January. So far, about 4,000 independents have agreed to be part of a primary distribution channel for specialty pharmaceutical manufacturers and payer programs. The free network is designed to give independents access to new products, increased revenue streams, and strategic alliances with manufacturers, insurers, and PBMs.

"Our conception of the Specialty Drugs Network was to gain access to products primarily not available through retail today," said Todd Dankmyer, NCPA executive v.p.-communications. "There's a wide range of these products, primarily injectables, that are extremely expensive and usually for very limited patient populations where reimbursement and insurance coverage are the major challenges."

Independent members of the Specialty Drugs Network can pick and choose which drugs they want to stock and provide patient support for. There's also a just-in-time inventory system. "The members don't have to order anything until they know they have a patient coming in who needs this medication," said Dankmyer. "Second, all major medical claims are handled by TheraCom, so the members don't get into any battling to get the reimbursement, and they don't obligate themselves to accept certain levels of reimbursement."

The Specialty Drugs Network's trump card is members providing high-touch, face-to-face counseling of patients who are often battling life-threatening diseases. That's something mail-service specialty pharmacies cannot provide.

"TheraCom's view is that most retailers are not positioned to handle a lot of these products," Dankmyer said. "They think independents are much more likely to be suited to handle them. Independent pharmacies do compliance monitoring and follow-ups. We were targeting a way to mainstream some of these products going almost exclusively through mail order or directly to the physicians' offices. TheraCom is convinced there's a huge opportunity downstream, with lots of products coming out with these kinds of compliance, price, and reimbursement concerns."

As a specialty pharmacy, TheraCom is well aware that it may not be the patient's preferred provider, said Mark Hansan, president/CEO. That's where the independent pharmacy network comes in. "The big advantage for independents is high touch at the community level," he said. "The independents are truly a jewel in our health-care system, but they've never been in a position to harness their value in a unified way to meet the needs of the manufacturers. Where they've always been outstanding is in the patient care time to counsel, time to instruct, that these products require. They are a great resource. We think that within a very short time,

independent pharmacy will be viewed as the specialty pharmaceuticals provider of choice."

The Specialty Drugs Network sounds like a winner to Tom Lamb, R.Ph., who signed up his Sand Run Pharmacy in Akron, Ohio. "As independents, we want to find a niche that enables us to stay ahead of the competition," he told Drug Topics. "These patients need more than a mail-order pharmacy's toll-free phone call. We feel that independents can provide the necessary services compared with the chains and go the extra mile that you need to take care of claims, counsel patients, or get prior authorization. Along with TheraCom's expertise, the network is kind of a perfect fit for a lot of us, and we anticipate getting more of the specialty drug market share."

Enter the Internet

Some of the specialty pharmacy companies have taken their market share battles to cyberspace. They have erected Web sites that allow patients to directly fill their prescriptions, access information about their conditions and medications, and get answers to their questions from specially trained pharmacists. Some of the companies target a specific disease, such as the Hepatitis Neighborhood maintained by Priority Healthcare Corp., a specialty pharmacy and alternate site specialty drug distributor based in Lake Mary, Fla., or SangStat Medical Corp., which hosts the Transplant Pharmacy Web site for patients on transplantation therapy.

Infu-Tech has taken its Smartmeds. com specialty drug and disease management Web site to another level. The Carlstadt, N.J., specialty pharmaceutical provider will use a wireless Internet platform to deliver medications and drug compliance programs to patients with asthma, diabetes, hypertension, cystic fibrosis, and respiratory syncytial virus. The firm recently reached agreement with CarePlus Health Plan to deliver its wireless services to 1,500 beneficiaries of the New York-based HMO. CarePlus will pay Smartmeds.com a monthly service fee per enrollee. Patients will be able to order their medications directly from the Web via a wireless device. They will also be notified through the wireless device to take their medications and to verify their compliance. The resulting outcomes data will be given to CarePlus.

"We'll provide a wireless device, such as a cell phone, beeper, or palm top, for drug compliance," said Jack Rosen, Infu-Tech CEO. "When it's time to take their medications, we contact (patients) as a reminder and ask them to respond. By using these tools to reinforce drug compliance, this system will benefit the patient as well as lower medical service costs. And if we provide a wireless platform, the enrollee has less motivation to move to another provider."

Up, up, and away

There's no place for the specialty pharmaceutical market to go but up, according to analysts and pharmacists. Factors contributing to the niche's growth mode include the ongoing shift of patients with serious chronic conditions from hospitals to alternate site care or their own homes; the accelerating development and introduction of biotechnology drugs with high-cost profiles; and the intensifying focus on disease management as payers try to keep the lid on escalating health-care costs for patients with certain chronic conditions.

Clues to where this market is going can be gleaned from the balance sheets of publicly traded specialty pharmacies. Consider Memphis-based Accredo Health Inc., which handles seven specialty pharmaceutical lines for drug companies. The firm's latest financial report showed a 36% jump in revenues for the previous nine months, up to about $255 million, compared with the $187 million posted for the same period in fiscal 1999. A look at the profit-and-loss statement of Priority Healthcare Corp. showed net sales of $428 million in 1999, compared with $275 million the previous year.

"Retail providers still garner (89%) of product sales within the specialty pharmacy space," said Steven Valiquette. He is a director and analyst in the U.S. equity research department with Warburg Dillon Read,

which has issued strong buy opinions on some of the specialty pharmacies. "A lot of the drugs being approved today are more complicated to administer than those of the past. And it is the inability of the retail operator to efficiently maintain an inventory and sell these products in a compliant manner that has given birth to the specialty pharmacy industry in the first place. Retail pharmacists simply cannot find enough hours in a day to successfully consult patients on these sophisticated, self-injectable biotech products, and the process is being shifted directly to physicians and specialty pharmacies, which are likely to have stronger clinical expertise than the retail pharmacists. Over the next 10 years, we expect the market share pie ... to essentially flip-flop toward the biotech pharmacy companies."

It remains to be seen whether community pharmacy can compete with the specialty pharmacy venue, countered Walgreens' Polzin. "It needs to be determined whether specialty pharmacy can or cannot be translated into community pharmacies. I don't think anyone knows for sure how easily that may be translated. There's a lot of activity, and drugstores are trying a lot of different approaches, just as we will be trying different approaches, but what the ultimate model will be or how successful it may be remains to be seen."

Savvy independents scratching for every opportunity aren't going to let the specialty pharmacies take over without a fight. "We spent years and a lot of energy fighting restrictive distribution, but if you believe the specialty pharmaceutical people, there's going to be more and more of this stuff," said NCPA's Dankmyer. "We think that if we build a strong network of independent pharmacists, it will be better than anything else in the marketplace. Access to products currently beyond our reach is Job One."

TheraCom's Hansan is even more enthusiastic. "We believe this market will explode," he said. "If you look at the drug pipeline, there's an incredible number of products that fit this category. And there are other specialty drugs coming down the line with very large patient populations, and we assume that independent pharmacies would like to be part of that. That's why we believe that Specialty Drugs Network will only become more and more valuable."

GROWTH OF U.S. SPECIALTY DRUG MARKET

Category	1995 dollar total	1999 dollar total 1995-1999
Cytostatics	$2,439,423,000	$4,870,139,000
Antipsychotics	715,397,000	3,124,321,000
HIV-Reverse transcriptase inhibitors	238,778,000	1,564,886,000
Interferons	149,323,000	1,240,994,000
Transplant-immunosuppression	542,607,000	1,119,089,000
HIV-protease inhibitors	5,912,000	945,813,000
Gonadotropins	194,619,000	338,559,000
Neurological disorders	NA(*)	139,864,000
Phenothiazines	186,247,000	93,763,000

Category	Five year %change 1998-1999	One year % change
Cytostatics	+100%	+21%
Antipsychotics	+337%	+33%
HIV-Reverse transcriptase inhibitors	+555%	+33%
Interferons	+731%	+65%
Transplant-immunosuppression	+106%	+13%

HIV-protease inhibitors	+15898%	+1%
Gonadotropins	+74%	4%
Neurological disorders	NA(*)	+90%
Phenothiazines	-50%	-13%

(*) There were no specialty drugs in this category in 1995.

Source: Xponent Specialty Retail, IMS Health, London
SAMPLING OF SPECIALTY PHARMACEUTICALS

Listed below are some drugs distributed by mail-service specialty pharmacies

Source: IMS Health Xponent Specialty Retail audit

Antipsychotics

Clozaril
Moban
Risperdal
Seroquel
Zyprexa

Cytostatics

Casodex
Eulexin
Novaldex
Lupron Depot
Tamoxifen citrate

Gonadotropins

Follistim
Fertinex
Gonal-F
Humegon
Repronex

HIV-AIDS

Agenerase
Combivir
Crixivan
Epivir
Fortovase
Norvir
Sustiva
Viracept
Viramune
Zerit

Interferons

Avonex
Betaseron
Intron-A
Infergen
Rebetron

Neurologicals

Copaxone

Phenothiazines
Thioridazine HCl
Thorazine
Trifluoperazine
Perphenazine
Serentil

Transplantation/
immunosuppressants

Azathioprine
Cellcept
Neoral
Prograf
Sandimmune
RELATED ARTICLE: JUST WHAT IS A SPECIALTY DRUG?
A pharmaceutical or biotechnology product may be classified as a specialty drug if it meets the following criteria:
* It benefits a targeted patient population with a chronic, potentially life-threatening disease.
* It requires infusion, injection, or other unique method of administration that may need to be performed by a health-care professional.
* It may require refrigeration to maintain temperature control throughout the distribution process.
* It is expensive, with an annual cost per patient in excess of $10,000.
* Insurance carriers may require prior authorization, other documentation, and varying billing methods prior to coverage.
* It requires extensive patient education, clinical monitoring, follow up, and support.
Source: Specialty Drugs Network

PUBLISHER NAME: Medical Economics Company, Inc.
EVENT NAMES: *240 (Marketing procedures)
GEOGRAPHIC NAMES: *1USA (United States)
PRODUCT NAMES: *8045000 (Pharmacists); 2830000 (Drugs & Pharmaceuticals)
INDUSTRY NAMES: BUSN (Any type of business); DRUG (Pharmaceuticals and Cosmetics)
SIC CODES: 2830 (Drugs)
NAICS CODES: 44611 (Pharmacies and Drug Stores); 3254 (Pharmaceutical and Medicine Manufacturing)
SPECIAL FEATURES: LOB; INDUSTRY
?

An Interview with Orphan Medical about Xyrem®

Minneapolis, MN - February 12, 2001

Waiting for Xyrem®

Persons with narcolepsy, especially those who experience cataplexy, are anxiously awaiting the decision by the Food and Drug Administration (FDA) on the approval of Xyrem® as a treatment for the symptoms of narcolepsy. A decision is expected later this spring, as the Xyrem® New Drug Application has been given Priority Review Status.

As a result, there are a number of questions being raised by those most interested in Xyrem®. Naturally, many of these have come up in our regularly scheduled Narcolepsy Chats, so TalkAboutSleep contacted Orphan Medical, the company developing Xyrem, to get some answers. Several individuals from the Orphan Medical corporate staff were kind enough to respond, including CEO John Bullion, Chief Operating Officer William Houghton M.D., and Vice President of Marketing Patti Engel.

The interview covered a number of topics, including availability, cost, medical education, and "how it works". We hope you enjoy reading this interview and find the information helpful to you.

Availability of Xyrem®

TalkAboutSleep: Can you summarize the current status of Xyrem and the NDA? When do you expect the FDA to complete its review? With FDA approval, how long will it be before Xyrem will be available for doctors to prescribe?

Orphan Medical, John Bullion, CEO: Orphan Medical filed the New Drug Application (NDA) on October 2, 2000, and the application was granted priority review status on October 10, 2000. There will also be an advisory committee meeting on March 15, to discuss Xyrem. Based on the priority status, the FDA is expected to provide a decision regarding the NDA by April 2 of this year.

The Company expects that Xyrem will be available for patients within a few weeks following the approval with a full launch campaign and education materials for physicians coming a few months after the approval.

TalkAboutSleep: Will Xyrem be available in pharmacies? Can you describe how the distribution of Xyrem will occur? Is this part of the FDA decision process? Or are there other regulatory groups involved in this process?

Orphan Medical, Patti Engel, Vice President: Xyrem will be available through a specialty distribution system that will utilize a central pharmacy that will handle the delivery of medicine to the patients.

To order Xyrem, a physician will write a prescription and fax that to the central pharmacy. That pharmacy will process the prescription request, call the physician to verify the prescription, call the patient to assist them in gaining coverage from their insurance company, and then set up a delivery time directly to the patient so that they may receive their medicine.

This system was designed by Orphan Medical with assistance and input from State Scheduling authorities, experts in specialty distribution, drug diversion investigators, field law enforcement, narcolepsy patient groups, and pharmacists experienced in dealing with Scheduled medicines.

TalkAboutSleep: What progress is being made on the state regulations where GHB is still "outlawed"? Will people who reside in states with stricter regulation than the federal rules simply not be able to use Xyrem?

Orphan Medical, Patti Engel, Vice President: The federal law allows for patients to have Xyrem as prescribed by their doctor. As of this writing, many states have adopted this stance: a few are waiting for formal FDA approval. Once approved, patients can call 1-888-8ORPHAN to determine Xyrem's status in their particular state.

Pricing and Insurance

TalkAboutSleep: What is the estimated cost to Narcolepsy patients? Is it likely that the drug will be covered by health insurers? Will Orphan Medical provide assistance to persons with narcolepsy in getting insurance coverage? Will Xyrem be available free or at a reduced cost to low-income individuals without insurance? How will this be done?

Orphan Medical, Patti Engel, Vice President: Because the handling requirements are not yet finalized by the FDA, there is not yet a price established for Xyrem. That will be determined nearer the time of approval. If approved, Xyrem will likely be covered by many health insurance plans and our Reimbursement Services department will be available to assist patients that are working with their plans to obtain coverage.

For patients who are uninsured or need financial assistance to obtain Xyrem, there will be a patient assistance program administered through the National Organization for Rare Disorders (NORD) and they will determine the eligibility for patients based on their financial status.

How Does Xyrem Work?
TalkAboutSleep: Originally Xyrem was expected to be a drug for the control of cataplexy for people who have Narcolepsy. We know from personal experiences that it can also help alleviate Excessive Daytime Sleepiness (EDS). Does Orphan Medical know exactly how Xyrem alleviates cataplexy? Is it a chemical effect or does it occur purely by improving sleep?

Orphan Medical, William Houghton, MD, COO: The ultimate mechanism of action is not known. Many of the biochemical changes in the brain have been identified in terms of modulation of levels of important chemicals and neurotransmitter functions in the brain. As well, primary effects of improved sleep architecture occur that may contribute to why Xyrem reaches its optimal results after 8 to 12 weeks. It stands to reason that maintained changes in sleep contribute to improve daytime functioning, but further research into the science of narcolepsy is required.

TalkAboutSleep: With the improvement in EDS that many with narcolepsy experience, has Xyrem been tested on those who don't have cataplexy or those with a diagnosis of Idiopathic Hypersomnolence? If so, have these patients also experienced improvement in their EDS?

Orphan Medical, William Houghton, MD, COO: No, we've been entirely focused on narcolepsy and entry into the clinical trials has been designed to include cataplexy as a diagnosis for narcolepsy. We've not investigated Xyrem for the potential use in other sleep disorders.

TalkAboutSleep: Over the years of testing, have any negative side effects of Xyrem been found?

Orphan Medical, William Houghton, MD, COO: The side effects seen in the trials have been generally minor in nature and tend to abate over time and have included headache, nausea, dizziness, enuresis, and sleepwalking.

Medical Education
TalkAboutSleep: Unfortunately, so many of the doctors who treat patients with Narcolepsy around the country do not keep up with current research and are unaware of the success so many with Narcolepsy have had with Xyrem. Will Orphan Medical have information available to doctors? Will there be an education program for those who may be reluctant to prescribe it?

Orphan Medical, Patti Engel, Vice President: Information on Xyrem will be available to physicians through printed material, participation at medical meetings, and through representatives of Orphan Medical that will be able to discuss the details of Xyrem.

There is also a program called the Xyrem Physician Success Program that will ensure that a physician understands the unique nature of Xyrem and how the prescription and distribution process works to provide this medicine to the patients that need it in a responsible manner.

TalkAboutSleep: Thank you, Orphan Medical, for answering these questions about Xyrem® for our audience.

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Electronic Acknowledgement Receipt

EFS ID:	1444001
Application Number:	10322348
International Application Number:	
Confirmation Number:	5446
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Gregg Alan Peacock/John Gustav-Wrathall
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Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
1		101031us1_response.pdf	1010505	yes	17

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Amendment After Final	2	2
	Claims	3	7
	Applicant Arguments/Remarks Made in an Amendment	8	17
Warnings:			
Information:			
	Total Files Size (in bytes):	1010505	

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

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

IN THE CLAIMS

Please amend the claims as follows:

1 – 31. (Cancelled)

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

~~only~~ receiving all prescription requests at the exclusive central pharmacy from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor;

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

checking the credentials of the doctor;

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

checking the exclusive computer~~central~~ database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer~~central~~ database;

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking the credentials of the doctor;

checking the exclusive computer~~central~~ database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer~~central~~ database;

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

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

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

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

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

checking of the credentials of the authorized prescriber;

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

requiring checking of the exclusive ~~central~~ computer database for potential abuse associated with the patient and/or the authorized prescriber;

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

confirming receipt by the patient of the sensitive drug; and

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

39. (Currently Amended) A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

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

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive ~~central~~ computer database for potential GHB abuse associated with the patient;

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

confirming receipt by the patient of the GHB; and

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

40. (Currently Amended) A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

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

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive ~~central~~ computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

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

41. (Currently Amended) A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

manufacturing GHB;

only providing manufactured GHB to the exclusive central pharmacy;

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

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

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive ~~central~~ computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

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

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

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

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

checking of the credentials of the authorized prescriber;

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

requiring checking of the exclusive ~~central~~ computer database for potential abuse associated with the patient and/or the authorized prescriber;

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

confirming receipt by the patient of the sensitive drug.

REMARKS

This responds to the Office Action dated October 18, 2006.

Claims 32-34 and 38-42 are amended. Claims 32-42 are pending in this application.

§112 Rejection of the Claims

Claims 32-42 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims have been amended to clarify the § 112 rejections, and not in response to art. They are not believed to introduce any new issues, and are believed to place the application in better condition for appeal.

§103 Rejection of the Claims

Claims 32, 38 and 42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) and further in view of Ukens ("Specialty Pharmacy"). This rejection is respectfully traversed, as the references do not disclose all the claimed elements. None of the references describe a required checking of an exclusive database for potential abuse, and then not shipping or distributing the sensitive drug if the required check uncovers potential abuse. In addition, the references are not properly combinable at least due to significant teaching away from such combining.

Moradi does not teach an exclusive computer database.

Claims 32, 38 and 42 all refer to an exclusive computer database. The Office Action indicates that "Moradi discloses checking the exclusive central database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive central database (para. 43, para. 45, para. 6 and FIG. 3, items 318 and 322 of Moradi)."

The cited portions of Moradi are repeated below, and it is clear that there is no teaching of an exclusive computer database as claimed.

Paragraph 43:

"If the prescription is verified as OK, the processing continues in the exemplary embodiment by having the pharmacist fill the prescription and enter the prescription data into the pharmacist's existing Pharmacy Management System (PMS). The PMS system assigns the prescription a prescription number, and the pharmacist enters that prescription number and the number of refills into the PODP 216, which then communicates that data back to the CSS 102 with an identification of the prescription. The pharmacist then gives, at step 322, the ordered medicine and a copy of the prescription image to a prescription deliverer, which is a delivery person in the exemplary embodiments, for delivery to the patient. The CSS 102 is notified that the delivery person is in the process of delivering the medication and the status of the prescription is changed to "delivery" within the CSS database 204. The exemplary embodiment further includes providing the delivery person with a "Route Slip" that has printed directions to the patient's address along with the scanned prescription image. The delivery person hand-delivers the medicine to the recipient if and only if the recipient is holding the original copy of the prescription that is identical to the image provided to the delivery person. This ensures that the proper patient gets the medicine and that the medicine is delivered only once. After the medicine is delivered, the delivery person receives, at step 324, the patient's signature to certify a correct delivery. The delivery person can also stamp the original prescription to signify that the medicine specified in that prescription has been delivered and that the prescription has already been filled. The delivery person then returns, also at step 324, to the POD system 106 and the POD operator updates the order status to "Done" in the PODP 212 so that this information is communicated as a confirmation to the CSS 102 and the CSS Database 204. The exemplary embodiment supports status designations of: delivered, no one at the address, prescription mismatch or one of a number of other potential reasons for non-delivery. Embodiments of the present invention provide the delivery person with a wireless communication device that initiates communication of the delivery status immediately upon delivery of the medication to the patient without

requiring the delivery person to first return to the POD 106. These devices also include a written signature digitizer that is able to capture and digitize the patient's signature and transmit that image to along with the delivery status."

Paragraph 43 may mention various electronic systems, such as the pharmacy management system, but makes no mention of an exclusive computer database.

Paragraph 45:

"All checks to make sure that a patient is not allowed to have a prescription filled twice are performed by the exemplary embodiment of the present invention by human operators (e.g., the driver or the POD operator). This further ensures that patients do not receive medication in excess of there prescription and to prevent prescription abuse."

Paragraph 45 also makes no reference to an exclusive computer database.

Paragraph 5:

"Delivery of prescription medication has changed little in recent times. Conventional prescription medication delivery begins by a prescription being first issued by a physician and then the patient is required to present that prescription to a pharmacist. The pharmacist then prepares the prescribed medication and delivers it to the patient. This process requires the patient to visit the pharmacist and to either wait at the pharmacist's facility or to return to the pharmacist's facility when the prescription is ready. This is often inconvenient for the patient."

Paragraph 5 also makes no reference to an exclusive computer database.

Fig. 3, items 318 and 322: These elements appear to be described in paragraph 43 as discussed above, and do not mention the use of an exclusive computer database. Further, no reference to item 318 was found in the application.

Ukens teaches away from using a central pharmacy

The Office Action indicates that "Ukens discloses restricting distribution of a specialty medication to only one pharmacy (see page 3, paragraphs 3-5 of Ukens)." It goes on to state that

"At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Ukens within Moradi, Lilly, and Califano. The motivation for doing so would have been to limit access to dangerous drugs (page 3, paragraph 5 of Ukens)."

These statements are respectfully traversed. Paragraphs 3-5 of Ukens describes that "...restricted distribution of such products raises issues of patient access and safety." It then goes on to state that "by restricting distribution of a specialty medication to only one pharmacy, a manufacturer exposes patients to the risk of not receiving the medications in a timely manner if there's a disruption in the delivery system. In addition, shunting one part of therapy away from a patient's regular pharmacist can create the potential for undiscovered drug interactions. In paragraph 5, Ukens states: "A better way to handle specialty pharmaceuticals would be for manufacturers to set the criteria for their specialty products and then open distribution to any pharmacy that measures up,..." Thus, while Ukens acknowledges the potential for restricting distribution to a single pharmacy, it describes a better way that does not expose patients to some identified risks. In essence, it advocates away from the use of a single pharmacy. Thus, one of skill in the art would not combine the teachings of Ukens with Moradi, Lilly and Califano to arrive at the current claims.

Ukens does not describe the use of an exclusive computer database. This combination of four references does not provide or suggest a solution to one of skill in the art allowing distribution of a sensitive drug as claimed.

Previous rejections of claim 32 were incorporated.

The Office Action incorporates the same reasons to reject claim 32 as in the previous Office Action. The suggestion to combine the reference in the previous 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.

Rejection of claim 38

The Office Action indicates that Moradi discloses a method of distributing a drug under control of an exclusive central pharmacy in paragraphs 3 and 24. Such paragraphs have been reviewed in detail, and no reference or suggestion of an exclusive central pharmacy for a sensitive drug was found.

Since Moradi does not describe an exclusive central pharmacy, prescription requests are not received at an exclusive central pharmacy as claimed.

As described above, Moradi does not teach or suggest an exclusive computer database for distributing a sensitive drug as claimed.

The Office Action admits that Moradi lacks several further elements, and indicates that "Lilly et al. disclose that the drug is a sensitive drug, entering the information into an exclusive computer database under exclusive control of the central pharmacy..." Applicant respectfully traverses the statement of the teaching of Lilly et al. There is no exclusive computer database for

distribution of a drug. Rather, Lilly et al., as previously pointed out, has a goal of tracking drug use for a patient. This is very different from tracking all the use of a single drug by every patient.

The references are not properly combinable for reasons already discussed above.

Claims 33-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1). Claims 33-36 also include an exclusive computer database used in distributing a sensitive drug. As indicated with respect to claim 32, none of the references, alone or combined teach or suggest the use of an exclusive computer database. Still further, the references are not properly combinable as discussed above.

Claim 37 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) and further in view of Melker et al. (U.S. Patent Publication No. 2002/0177232 A1). This rejection is respectfully traversed. Claim 37 depends from claim 33, which is already believed allowable. The addition of Melker et al., does not provide any of the teaching or suggestion lacking in the other references that are combined.

Claims 39-41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) and further in view of "Talk About Sleep: An Interview with Orphan Medical about Xyrem".

This rejection is respectfully traversed. Claims 39-41 all refer to the use of an exclusive computer database for distribution of a sensitive drug. None of the references alone or combined teach or suggest such an exclusive computer database. "Talk About Sleep: An Interview with Orphan Medical about Xyrem" also does not describe the use of an exclusive computer database for distribution of a sensitive drug such as Xyrem. Further, one or more of the references are not

believed properly combinable as previously described. Thus, these claims are believed in condition for allowance, which is respectfully requested.

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 1-17-2007

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

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 17 day of January 2007.

John D. Gustav Waldron
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 AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In response to the Final Office Action dated October 18, 2006, please amend the application as follows:

IN THE 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: January 18, 2007
Group Art Unit: 3626

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

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

X Amendment and Response (16 pgs.).

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

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

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

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of January, 2007.

John D. Gustav-Wrathall
Name

Signature

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

PTO/SB/06 (08-03)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

Application or Docket Number: 10/322,348

CLAIMS AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE	SMALL ENTITY FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY FEE
BASIC FEE (37 CFR 1.16(a))				$____	OR		$____
TOTAL CLAIMS (37 CFR 1.16(c))	minus 20 =	*	X $____ =		OR	X $____ =	
INDEPENDENT CLAIMS (37 CFR 1.16(b))	minus 3 =	*	X $____ =		OR	X $____ =	
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(d))			+ $____ =		OR	+ $____ =	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL		OR	TOTAL	

CLAIMS AS AMENDED – PART II

8/8/06

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
Total (37 CFR 1.16(c))	* 71	Minus	** 31	=	X $25. =		OR	X $____ =	
Independent (37 CFR 1.16(b))	* 7	Minus	*** 6	= 1	X $100. =	100	OR	X $____ =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =	0	OR	+ $____ =	
					TOTAL ADD'L FEE	100.0	OR	TOTAL ADD'L FEE	

1-17-07

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE	ADDITIONAL FEE	OR	RATE	ADDITIONAL FEE
Total (37 CFR 1.16(c))	* 11	Minus	** 31	=	X $____ =		OR	X $____ =	
Independent (37 CFR 1.16(b))	* 7	Minus	*** 7	=	X $____ =		OR	X $____ =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =		OR	+ $____ =	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE	ADDITIONAL FEE	OR	RATE	ADDITIONAL FEE
Total (37 CFR 1.16(c))	*	Minus	**	=	X $____ =		OR	X $____ =	
Independent (37 CFR 1.16(b))	*	Minus	***	=	X $____ =		OR	X $____ =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $____ =		OR	+ $____ =	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

21186 7590 02/05/2007
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3626	
MAIL DATE	DELIVERY MODE
02/05/2007	PAPER

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

PTOL-90A (Rev. 10/06)

Advisory Action Before the Filing of an Appeal Brief	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 --

THE REPLY FILED 17 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *32-42*.
   Claim(s) withdrawn from consideration: *NONE*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER

Continuation of 11.
Applicant's arguments at pages 7-9 (Moradi does not teach an exclusive computer database) and the arguments at pages 10-14 (the suggestion to combine is not directed to the same or similar problem, hindsight, Lilly teaches away, etc.) have already been addressed in the Final Rejection mailed 10/18/06 (see page 11 of Final Rejection) and the Non-Final Rejection (see pages 14-17 of Non-Final Rejection) mailed 6/19/06, respectively, and are incorporated herein.

Applicant's additional arguments filed 1/17/07 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 1/17/07.

(1) Applicant argues that Ukens teaches away from using a central pharmacy.

In response to applicant's argument that Ukens teaches away from a central pharmacy, 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). The Examiner is relying on the portion of Ukens that discloses that there was at the time of the invention, restricted distribution of pharmaceuticals via one pharmacy. The Examiner acknowledges that the prior art teaches disadvantages concerning the use of a central pharmacy. However, the Examiner also recognizes an advantage, such as limiting distribution of dangerous drugs.

OK to enter
JN 1-31-07

EXPEDITED PROCEDURE – EXAMINING GROUP 3626

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

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

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

In response to the Final Office Action dated October 18, 2006, please amend the application as follows:

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/Applicant Name:	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:				
Notice of appeal	2401	1	250	250
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 2 months with $0 paid	2252	1	225	225
Miscellaneous:				
		Total in USD ($)		**475**

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	

PETITION FOR A TWO-MONTH EXTENSION OF TIME

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

In accordance with the provision of 37 CFR § 1.136(a), it is respectfully requested that a two-month extension of time be granted in which to respond to the Final Office Action mailed October 18, 2006, said period of response being extended from January 18, 2007 to March 19, 2007.

Please charge Deposit Account No. 19-0743 in the amount of $225.00 to cover the required extension fee. 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: 3-19-2007 By: _____
Bradley A. Forrest
Reg. No: 30,837

CERTIFICATE UNDER 37 CFR § 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 19 day of March 2007.

Name: John D. Griffin-Wockhardt 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	

NOTICE OF APPEAL FROM THE DECISION OF THE EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

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

In compliance with 37 C.F.R. § 41.31(a)(1), Applicants hereby appeal to the Board of Patent Appeals and Interferences from the decision dated October 18, 2006, of the Examiner rejecting claims 32-42 of the above-identified patent application.

A request for an extension of time to respond to the Examiner's rejection is submitted herewith along with payment of the required extension fee.

Please charge the amount of $250.00 in payment of the Notice of Appeal fee under 37 C.F.R. § 41.20(b)(1), as well as any additional required fees, to Deposit Account No. 19-0743.

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By Applicants' Attorneys,

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

Date 3-19-2007 By _____
Bradley A. Forrest
Reg. No. 30,837

I hereby certify that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 19 day of March 2007.

John D. Gustafson-Wrobell
Name

_____
Signature

Electronic Acknowledgement Receipt

EFS ID:	1604738
Application Number:	10322348
International Application Number:	
Confirmation Number:	5446
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	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:	19-MAR-2007
Filing Date:	17-DEC-2002
Time Stamp:	17:49:07
Application Type:	Utility

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	$475
RAM confirmation Number	986
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 /.zip	Pages (if appl.)
1		101031us1_noa.pdf	148852	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Extension of Time	2	2
	Notice of Appeal Filed	3	3

Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	8315	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	157167		

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

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

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

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

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

Serial No.: 10/322,348
Due Date: January 18, 2007
Group Art Unit: 3626

MS AF
Commissioner for Patents
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Alexandria, VA 22313-1450

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

X Notice of Appeal (1 pg.).
X Petition for Extension of Time (1 pg.)
X Authorization to charge Deposit Account 19-0743 in the amount of $225.00 to cover the Extension of Time Fee.

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

By: _____
Atty: Bradley A. Forrest
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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
(GENERAL)

Electronic Acknowledgement Receipt

EFS ID:	1796173
Application Number:	10322348
International Application Number:	
Confirmation Number:	5446
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	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:	21-MAY-2007
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Application Type:	Utility

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Payment was successfully received in RAM	$250
RAM confirmation Number	7947
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 /.zip	Pages (if appl.)
1		101031us1_appl.pdf	1731745	yes	33
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Miscellaneous Incoming Letter		1	1	
	Appeal Brief Filed		2	33	
Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	8164	no	2
Warnings:					
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

New International Application Filed with the USPTO as a Receiving Office
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.: 101.031US1 Serial No.: 10/322,348
Filed: December 17, 2002 Due Date: May 21, 2007
Examiner: Lena Najarian Group Art Unit: 3626

MS Appeal Brief - Patents
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 Appeal Brief (32 pgs., including table of contents).
X Authorization to charge Deposit Account No. 19-0743 in the amount of $250 to cover Appeal Brief fee..

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

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

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

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John D. Gustafson-Wroblewski
Name

_____
Signature

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

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Dayton T. Reardan et al. Examiner: Lena Najarian

Serial No.: 10/322,348 Group Art Unit: 3626

Filed: December 17, 2002 Docket: 101.031US1

For: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

APPEAL BRIEF UNDER 37 CFR § 41.37

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P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on March 19, 2007, from the Final Rejection of claims 32-42 of the above-identified application, as set forth in the Final Office Action mailed on October 26, 2006.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of $250.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of pending claims.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, Jazz Pharmaceuticals.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

The present application was filed on December 17, 2002, with claims 1-25. A Preliminary Amendment was filed on September 30, 2004, adding claims 26-31. A non-final Office Action was mailed June 29, 2005. A response was filed September 29, 2005. A Final Office Action was mailed December 29, 2005. A Request for Continued Examination was filed with an Amendment and Response to Final Office Action on March 29, 2006, in which claims 11-31 were cancelled and new claims 32-37 were added. A non-final Office Action was mailed June 19, 2006. A response was filed August 8, 2006, in which claims 1-10 were cancelled and new claims 38-42 were added. A second Final Office Action was mailed October 18, 2006. A response to Final Office Action was filed January 17, 2007. An Advisory Action was mailed February 5, 2007. Claims 32-42 stand finally rejected, remain pending, and are the subject of the present appeal.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Advisory Action dated February 5, 2007.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 32

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

receiving all prescription requests at the exclusive central pharmacy from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor; [*page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking the credentials of the doctor; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that educational material has been read prior to shipping the sensitive drug; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

checking the exclusive computer database for potential abuse of the sensitive drug; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer database; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the sensitive drug; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 33

33. 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; [*page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking the credentials of the doctor; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

checking the exclusive computer database for potential abuse of the sensitive drug; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer database; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the sensitive drug; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 38

38. 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; [*page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

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; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential abuse associated with the patient and/or the authorized prescriber; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the sensitive drug; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 39

39. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber; [page 4, lines 11-18; *page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only providing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the GHB; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 40

40. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber; [page 4, lines 11-18; *page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the GHB; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 41

41. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

manufacturing GHB; [*page 4, line 25-page 5, line 2*]

only providing manufactured GHB to the exclusive central pharmacy; [*page 4, line 25-page 5, line 2*]

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber; [page 4, lines 11-18; *page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the GHB; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 42

42. 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; [page 4, lines 11-18; *page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

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; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential abuse associated with the patient and/or the authorized prescriber; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse; and [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the sensitive drug. [*page 2, line 14*]

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 32-42 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32, 38 and 42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) and further in view of Ukens ("Specialty Pharmacy").

Claims 33-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1).

Claim 37 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) and further in view of Melker et al. (U.S. Patent Publication No. 2002/0177232 A1).

Claims 39-41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) and further in view of "Talk About Sleep: An Interview with Orphan Medical about Xyrem".

7. ARGUMENT

A) The Applicable Law

1) 35 U.S.C. § 112, second paragraph

With regard to 35 U.S.C. § 112, second paragraph, the Board of Patent Appeals and Interferences has stated:

> In rejecting a claim under the second paragraph of 35 U.S.C.§112, it is incumbent on the examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims. *Ex parte* Wu, 10 USPQ 2d 2031, 2033 (B.P.A.I. 1989)(citing *In re* Moore, 439 F.2d 1232, 169 USPQ 236 (C.C.P.A. 1971); *In re* Hammack, 427 F.2d 1378, 166 USPQ 204 (C.C.P.A. 1970)).

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

> The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:
>
> (1) The content of the particular application disclosure;
>
> (2) The teachings of the prior art; and
>
> (3) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. *M.P.E.P.* § 2173.02.

2) 35 U.S.C. §103(a)

The determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on factual evidence. *See Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1336-37 (Fed.Cir. 2005). The legal conclusion, that a claim is obvious within § 103(a), depends on at least four underlying factual issues set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966): (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) evaluation of any relevant secondary considerations.

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 establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested, by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) ; MPEP § 2143.03. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) ; MPEP § 2143.03. As part of establishing a *prima facie* case of obviousness, the Examiner's analysis 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.* To facilitate review, this analysis should be made explicit. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ____ (2007)(slip opinion at 14)(citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)).

The court in *Fine* 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 Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991))." MPEP § 2142.

The test for obviousness under §103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ

543, 551 (Fed. Cir.1985). The Examiner must, as one of the inquiries pertinent to any obviousness inquiry under 35 U.S.C. §103, recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990), *reh'g denied*, 1990 U.S. App. LEXIS 19971 (Fed. Cir.1990). The fact that a reference teaches away from a claimed invention is highly probative that the reference would not have rendered the claimed invention obvious to one of ordinary skill in the art. *Stranco Inc. v. Atlantes Chemical Systems, Inc.*, 15 USPQ2d 1704, 1713 (Tex. 1990). When the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *KSR Int'l Co.*, 550 U.S. ____ (2007)(slip opinion at 12)(citing *United States v. Adams*, 383 U.S. 39, 51-51 (1966)).

Further, the Office Action must provide specific, objective evidence of record for a finding of a suggestion or motivation to combine reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding. *See KSR Int'l Co.*, 550 U.S. ____ (2007)(slip opinion at 14)(citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)); *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). Finally, the Examiner must avoid hindsight. *In re Bond* at 834.

Additionally, there must be a rational underpinning grounded in evidence to support the legal conclusion of obviousness. See *In re Kahn*, 78 USPQ2d 1329 (Fed. Cir. 2006), which states that, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn* citing *In re Lee*, 61 USPQ2d 1430 (Fed. Cir.2002). Additionally, "mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole." *In re Kahn.*

B) Discussion of the rejection of claims 32-42 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.

Claims 32-42 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the response to the Final Office Action, claims 32-42 were amended to clarify the claims in view of the § 112 rejections, and not in response to art. These amendments, as indicated in the Advisory Action mailed February 5, 2007, were entered.

The Advisory Action did not include any direct mention of the status of these Section 112 rejections. Thus, Applicant respectfully submits that the Section 112 rejections have been over come by these amendments. If the Examiner believes otherwise, Applicant reserves the right to submit further argument against the 35 U.S.C. § 112, Second paragraph rejections in a reply to the Examiner's Answer.

C) Discussion of the 35 U.S.C. § 103(a) rejections.

1) Discussion of the rejection of claims 32, 38 and 42 under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1; hereinafter "Moradi") in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1; hereinafter "Lilly") in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1; hereinafter "Califano") and further in view of Ukens ("Specialty Pharmacy;" hereinafter "Ukens").

Applicant respectfully traverses the rejection of claims 32, 38, and 42 because the proposed combination of Moradi, Lilly, Califano, and Ukens fails to teach or suggest each of the claim elements and because Ukens teaches away from the combination.

a. Failure to teach or suggest an exclusive computer database

Each of the claims 32, 38 and 42 all refer to an exclusive computer database. The Final Office Action indicates that "Moradi discloses checking the exclusive central database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive central database (para. 43, para. 45, para. 6, and FIG. 3, items 318 and 322 of Moradi)."

The method of claims 32, 38, and 42 utilize the exclusive computer database to implement strict control over distribution of sensitive drugs. These controls allow for tracking of who is prescribing these drugs and who is receiving them. These controls further ensure proper education about the sensitive drugs is provided to patients and understood. Without this exclusive computer database, such controls are much more difficult to implement.

The cited portions of Moradi are repeated below, and it is clear that there is no teaching of an exclusive computer database as claimed.

Paragraph 43:

> "If the prescription is verified as OK, the processing continues in the exemplary embodiment by having the pharmacist fill the prescription and enter the prescription data into the pharmacist's existing Pharmacy Management System (PMS). The PMS system assigns the prescription a prescription number, and the pharmacist enters that prescription number and the number of refills into the PODP 216, which then communicates that data back to the CSS 102 with an identification of the prescription. The pharmacist then gives, at step 322, the ordered medicine and a copy of the prescription image to a prescription deliverer, which is a delivery person in the exemplary embodiments, for delivery to the patient. The CSS 102 is notified that the delivery person is in the process of delivering the medication and the status of the prescription is changed to "delivery" within the CSS database 204. The exemplary embodiment further includes providing the delivery person with a "Route Slip" that has printed directions to the patient's address along with the scanned prescription image. The delivery person hand-delivers the medicine to the recipient if and only if the recipient is holding the original copy of the prescription that is identical to the image provided to the delivery person. This ensures that the proper patient gets the medicine and that the medicine is delivered only once. After the medicine is delivered, the delivery person receives, at step 324, the patient's signature to certify a correct delivery. The delivery person can also stamp the original prescription to signify that the medicine specified in that prescription has been delivered and that the prescription has already been filled. The delivery person then returns, also at step 324, to the POD system 106 and the POD operator updates the order status to "Done" in the PODP 212 so that this information is communicated as a confirmation to the CSS 102 and the CSS Database 204. The exemplary embodiment supports status designations of: delivered, no one at the address, prescription mismatch or one of a number of other potential reasons for non-delivery. Embodiments of the present invention provide the delivery person with a wireless communication device that initiates communication of the delivery status immediately upon delivery of the medication to the patient without requiring the delivery person to first return to the POD 106. These devices also

include a written signature digitizer that is able to capture and digitize the patient's signature and transmit that image to along with the delivery status."

Paragraph 43 may mention various electronic systems, such as the pharmacy management system, but makes no mention of an exclusive computer database.

Paragraph 45:

"All checks to make sure that a patient is not allowed to have a prescription filled twice are performed by the exemplary embodiment of the present invention by human operators (e.g., the driver or the POD operator). This further ensures that patients do not receive medication in excess of their prescription and to prevent prescription abuse."

Paragraph 45 also makes no reference to an exclusive computer database.

Paragraph 6:

"Delivery of prescription medication by mail is also possible. Current systems require the prescription to be provided to a pharmacy and the pharmacy then mails the medication. This technique has a delay in the initial fulfillment of a new prescription because the prescription is often mailed to the pharmacy, and there is also a delay in mailing the prescription. This technique is better used for prescription refills, including maintenance prescriptions that have routinely refilled prescriptions for medication for which the patient has a recurring therapeutic need. In the case of a refill prescription, there is usually time available to accommodate the delays of this technique. This technique is also open to fraud since the individual patient typically does not personally present his or her prescription to the pharmacy. This technique can also lead to an improper person receiving the prescription, such as when a child that is living with the recipient retrieves mail that contains the mailed prescription."

Paragraph 6 also makes no reference to an exclusive computer database.

Fig. 3, items 318 and 322: These elements appear to be described in paragraph 43 as discussed above, and do not mention the use of an exclusive computer database. Further, no reference to item 318 was found in the application. Applicant therefore submits that Moradi fails to provide any teaching of an exclusive computer database as claimed. Applicant further submits that Lilly, Califano, and Ukens fail to cure this deficiency.

Absent any teaching or suggestion of a central database as claimed, Applicant respectfully submits that Claims 32, 38, and 42 are patentable over the proposed combination of Moradi, Lilly, Califano, and Ukens.

b. Ukens teaches away from the proposed combination of references

Applicant respectfully submits that Ukens teaches away from the proposed combination with Moradi, Lilly, and Califano to produce the presently claimed invention. 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).

The Final Office Action indicates that "Ukens discloses restricting distribution of a specialty medication to only one pharmacy (see page 3, paragraphs 3-5 of Ukens)." The Final Office Action goes on to state that "At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Ukens within Moradi, Lilly, and Califano. The motivation for doing so would have been to limit access to dangerous drugs (page 3, paragraph 5 of Ukens)."

These statements are respectfully traversed. Paragraphs 3-5 of Ukens describes that "...restricted distribution of such products raises issues of patient access and safety." It then goes on to state that "by restricting distribution of a specialty medication to only one pharmacy, a manufacturer exposes patients to the risk of not receiving the medications in a timely manner if there's a disruption in the delivery system. In addition, shunting one part of therapy away from a patient's regular pharmacist can create the potential for undiscovered drug interactions. In paragraph 5, Ukens states: "A better way to handle specialty pharmaceuticals would be for manufacturers to set the criteria for their specialty products and then open distribution to any pharmacy that measures up,..." Thus, while Ukens acknowledges the potential for restricting distribution to a single pharmacy, it describes a "better way" that does not expose patients to

some identified risks. Applicant respectfully submits that one of skill in the art, upon reading Ukens, would be discourage from utilizing an architecture including an exclusive database of a single pharmacy as claimed. As a result, one of skill in the art would be guided in a direction to create a decentralized pharmacy with multiple databases which is a divergent path from that of the present application and claims.

Applicant respectfully submits that when considering the scope and content of the cited references and the differences between these references and claims 32, 38, and 42, one can plainly see the deficiencies of the prior art in failing to teach an exclusive computer database associated with an exclusive central pharmacy as claimed. Further, the differences between the cited references, namely Ukens, and the present claim would lead a person of skill in the art in a divergent direction from the path of the present claims. Applicant therefore requests reversal of the 35 U.S.C. § 103(a) rejection of claims 32, 38, and 42 because the cited references fail to teach or suggest all of the claim elements and because Ukens teaches away from the claims.

2) Discussion of the rejection of claims 33-36 under 35 U.S.C. § 103(a) as being unpatentable over Moradi in view of Lilly.

Applicant respectfully traverses the rejection of claims 33-36 because the combination of Moradi and Lilly fails to teach or suggest all of the claimed elements. For example, the method of independent claim 33 utilizes an exclusive computer database as discussed above.

a. Failure to teach or suggest an exclusive computer database

Claim 33 includes an exclusive computer database. The Final Office Action indicates that "Moradi discloses checking the exclusive central database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive central database (para. 43, para. 45, para. 6, and FIG. 3, items 318 and 322 of Moradi)."

As discussed above, the exclusive computer database is utilized to implement strict control over distribution of sensitive drugs. These controls allow for tracking of who is prescribing these drugs and who is receiving them. These controls further ensure proper

education about the sensitive drugs is provided to patients and understood. Without this exclusive computer database, such controls are much more difficult to implement.

The cited portions of Moradi are repeated below, and it is clear that there is no teaching of an exclusive computer database as claimed.

Paragraph 43:

> "If the prescription is verified as OK, the processing continues in the exemplary embodiment by having the pharmacist fill the prescription and enter the prescription data into the pharmacist's existing Pharmacy Management System (PMS). The PMS system assigns the prescription a prescription number, and the pharmacist enters that prescription number and the number of refills into the PODP 216, which then communicates that data back to the CSS 102 with an identification of the prescription. The pharmacist then gives, at step 322, the ordered medicine and a copy of the prescription image to a prescription deliverer, which is a delivery person in the exemplary embodiments, for delivery to the patient. The CSS 102 is notified that the delivery person is in the process of delivering the medication and the status of the prescription is changed to "delivery" within the CSS database 204. The exemplary embodiment further includes providing the delivery person with a "Route Slip" that has printed directions to the patient's address along with the scanned prescription image. The delivery person hand-delivers the medicine to the recipient if and only if the recipient is holding the original copy of the prescription that is identical to the image provided to the delivery person. This ensures that the proper patient gets the medicine and that the medicine is delivered only once. After the medicine is delivered, the delivery person receives, at step 324, the patient's signature to certify a correct delivery. The delivery person can also stamp the original prescription to signify that the medicine specified in that prescription has been delivered and that the prescription has already been filled. The delivery person then returns, also at step 324, to the POD system 106 and the POD operator updates the order status to "Done" in the PODP 212 so that this information is communicated as a confirmation to the CSS 102 and the CSS Database 204. The exemplary embodiment supports status designations of: delivered, no one at the address, prescription mismatch or one of a number of other potential reasons for non-delivery. Embodiments of the present invention provide the delivery person with a wireless communication device that initiates communication of the delivery status immediately upon delivery of the medication to the patient without requiring the delivery person to first return to the POD 106. These devices also include a written signature digitizer that is able to capture and digitize the patient's signature and transmit that image to along with the delivery status."

Paragraph 43 may mention various electronic systems, such as the pharmacy management system, but makes no mention of an exclusive computer database.

Paragraph 45:

> "All checks to make sure that a patient is not allowed to have a prescription filled twice are performed by the exemplary embodiment of the present invention by human operators (e.g., the driver or the POD operator). This further ensures that patients do not receive medication in excess of there prescription and to prevent prescription abuse."

Paragraph 45 also makes no reference to an exclusive computer database.

Paragraph 6:

> "Delivery of prescription medication by mail is also possible. Current systems require the prescription to be provided to a pharmacy and the pharmacy then mails the medication. This technique has a delay in the initial fulfillment of a new prescription because the prescription is often mailed to the pharmacy, and there is also a delay in mailing the prescription. This technique is better used for prescription refills, including maintenance prescriptions that have routinely refilled prescriptions for medication for which the patient has a recurring therapeutic need. In the case of a refill prescription, there is usually time available to accommodate the delays of this technique. This technique is also open to fraud since the individual patient typically does not personally present his or her prescription to the pharmacy. This technique can also lead to an improper person receiving the prescription, such as when a child that is living with the recipient retrieves mail that contains the mailed prescription."

Paragraph 6 also makes no reference to an exclusive computer database.

Fig. 3, items 318 and 322: These elements appear to be described in paragraph 43 as discussed above, and do not mention the use of an exclusive computer database. Further, no reference to item 318 was found in the application.

Applicant further submits that independent claim 33 must be read as including a sensitive drug under exclusive control of a central pharmacy. This control is through the exclusive computer database of the central pharmacy. This is not to say that all drugs are under exclusive control of the central pharmacy, rather the sensitive drug is under exclusive control of the central pharmacy. This is different from the cited paragraphs [0007] and [00043] of Moradi which merely provides a pharmacy including a central server without any limitation as to the prescriptions which may be filled.

Applicant therefore submits that Moradi fails to provide any teaching of an exclusive computer database as claimed. Applicant further submits that Lilly fails to cure this deficiency. Absent any teaching or suggestion of a central database as claimed, Applicant respectfully submits that claims 33 is patentable over the proposed combination of Moradi and Lilly.

Claims 34-36 depend from patentable independent claim 33 and are patentable for the same reasons, plus the elements of the claims.

Thus, Applicant respectfully requests reversal of the 35 U.S.C. § 103(a) rejections of claims 33-36 because the combination of Moradi and Lilly fails to teach or suggest all of the claim elements.

3) Discussion of the rejection of claim 37 under 35 U.S.C. § 103(a) as being unpatentable over Moradi in view of Lilly and further in view of Melker et al. (U.S. Patent Publication No. 2002/0177232 A1; hereinafter "Melker").

Applicant respectfully submits that claim 37 depends from patentable independent claim 33 and is patentable for the same reasons. Further, Melker fails to cure the deficiencies of Moradi and Lilly as set forth above with regard to claims 33-36. Thus, Applicant respectfully requests reversal of the 35 U.S.C. § 103(a) rejection of claim 37.

4) Discussion of the rejection of claims 39-41 under 35 U.S.C. § 103(a) as being unpatentable over Moradi in view of Lilly in view of Califano and further in view of "Talk About Sleep: An Interview with Orphan Medical about Xyrem."

This rejection is respectfully traversed. Claims 39-41 all refer to the use of an exclusive computer database for distribution of a sensitive drug as discussed above with regard to claims 32-38. None of the references alone or combined teach or suggest such an exclusive computer database. "Talk About Sleep: An Interview with Orphan Medical about Xyrem" also does not describe the use of an exclusive computer database for distribution of a sensitive drug such as Xyrem. Thus, these claims are believed in condition for allowance. Applicant respectfully requests reversal of the 35 U.S.C. § 103(a) rejection of claims 39-41.

8. SUMMARY

For the reasons argued above, claims 32-42 were not properly rejected under 35 U.S.C. §§ 103(a) and 112, second paragraph. Reversal of the rejections and allowance of the pending claim are respectfully requested.

Respectfully submitted,

DAYTON T. REARDAN et al.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402

Date 5-21-2007 By

Bradley A. Forrest
Reg. No. 30,837

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 21 day of May 2007.

John D. Gustav-Wrathall
Name

Signature

CLAIMS APPENDIX

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

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

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

checking the credentials of the doctor;

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

checking the exclusive computer database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer database;

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking the credentials of the doctor;

checking the exclusive computer database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer database;

confirming receipt by the patient of the sensitive drug; and

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

34. The method of claim 33 wherein the exclusive central pharmacy controls the exclusive computer_database.

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

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

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

38. A method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

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

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

checking of the credentials of the authorized prescriber;

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

requiring checking of the exclusive computer database for potential abuse associated with the patient and/or the authorized prescriber;

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

confirming receipt by the patient of the sensitive drug; and

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

39. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

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

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

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

confirming receipt by the patient of the GHB; and

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

40. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

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

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

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

41. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

manufacturing GHB;

only providing manufactured GHB to the exclusive central pharmacy;

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

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

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

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

42. A method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

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

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

checking of the credentials of the authorized prescriber;

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

requiring checking of the exclusive computer database for potential abuse associated with the patient and/or the authorized prescriber;

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

confirming receipt by the patient of the sensitive drug.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.

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/Applicant Name:	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:				
Filing a brief in support of an appeal	2402	1	250	250
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
		Total in USD ($)		**250**

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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 06/28/2007

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

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 06/28/2007

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

PTO-90C (Rev. 10/03)

Notification of Non-Compliant Appeal Brief (37 CFR 41.37)	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--

The Appeal Brief filed on *21 May 2007* is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file anamended brief or other appropriate correction (see MPEP 1205.03) within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.**

1. ☐ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.

2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).

3. ☒ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).

4. ☐ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).

5. ☐ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))

6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).

7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).

8. ☐ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner **and relied upon by appellant in the appeal**, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).

9. ☐ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).

10. ☐ Other (including any explanation in support of the above items):

1.)The brief fails to provide the status of the amendment after final filed 01/17/07.

TIM COLE
PATENT APPEAL CENTER SPECIALIST

Timothy Cole

Timothy Cole

Electronic Acknowledgement Receipt

EFS ID:	1986268
Application Number:	10322348
International Application Number:	
Confirmation Number:	5446
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	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:	18-JUL-2007
Filing Date:	17-DEC-2002
Time Stamp:	17:20:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		101031us1_appl.pdf	1816051 2dc82e4f4524c0af050fecd212a48089c0c0dfbd	yes	33

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Appeal Brief Filed	2	33
Warnings:			
Information:			
	Total Files Size (in bytes):	1816051	

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

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

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

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

Serial No.: 10/322,348
Due Date: July 28, 2007
Group Art Unit: 3626

MS Appeal Brief - Patents
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 Substitute Appeal Brief Under 37 C.F.R. § 41.37 (32 pgs., including 1-page table of contents and 31-page Substitute Appeal Brief).

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

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 18 day of July, 2007.

John D. Gustav Waldron
Name

Signature

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

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

TABLE OF CONTENTS

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Dayton T. Reardan et al. Examiner: Lena Najarian

Serial No.: 10/322,348 Group Art Unit: 3626

Filed: December 17, 2002 Docket: 101.031US1

For: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

SUBSTITUTE APPEAL BRIEF UNDER 37 CFR § 41.37

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Commissioner for Patents
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Sir:

This Substitute Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on March 19, 2007, from the Final Rejection of claims 32-42 of the above-identified application, as set forth in the Final Office Action mailed on October 26, 2006, and further in response to the Notice of Non-Compliant Appeal Brief mailed June 28, 2007.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of $250.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of pending claims.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, Jazz Pharmaceuticals.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

The present application was filed on December 17, 2002, with claims 1-25. A Preliminary Amendment was filed on September 30, 2004, adding claims 26-31. A non-final Office Action was mailed June 29, 2005. A response was filed September 29, 2005. A Final Office Action was mailed December 29, 2005. A Request for Continued Examination was filed with an Amendment and Response to Final Office Action on March 29, 2006, in which claims 11-31 were cancelled and new claims 32-37 were added. A non-final Office Action was mailed June 19, 2006. A response was filed August 8, 2006, in which claims 1-10 were cancelled and new claims 38-42 were added. A second Final Office Action was mailed October 18, 2006. A response to Final Office Action was filed January 17, 2007. An Advisory Action was mailed February 5, 2007. Claims 32-42 stand finally rejected, remain pending, and are the subject of the present appeal.

4. STATUS OF AMENDMENTS

Claims 32-34 and 38-42 were amended in a filing by Appellant on January 17, 2007 following the Final Office Action mailed October 18, 2006. These amendments were entered as indicated in the Advisory Action mailed February 5, 2007. No further amendments have been made subsequent to the Advisory Action dated February 5, 2007.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 32

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

receiving all prescription requests at the exclusive central pharmacy from a medical doctor containing information identifying a patient, the sensitive drug, and various credentials of the doctor; [*page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking the credentials of the doctor; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that educational material has been read prior to shipping the sensitive drug; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

checking the exclusive computer database for potential abuse of the sensitive drug; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer database; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the sensitive drug; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 33

33. 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; [*page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking the credentials of the doctor; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

checking the exclusive computer database for potential abuse of the sensitive drug; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer database; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the sensitive drug; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 38

38. 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; [*page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

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; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential abuse associated with the patient and/or the authorized prescriber; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the sensitive drug; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 39

39. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber; [page 4, lines 11-18; *page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only providing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the GHB; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 40

40. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber; [page 4, lines 11-18; *page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the GHB; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 41

41. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

manufacturing GHB; [*page 4, line 25-page 5, line 2*]

only providing manufactured GHB to the exclusive central pharmacy; [*page 4, line 25-page 5, line 2*]

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber; [page 4, lines 11-18; *page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse; [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the GHB; and [*page 2, line 14*]

generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns. [page 2, lines 24-27; *page 11, lines 10-22; page 9, lines 12-19; FIG. 4 436; FIG. 8, 800, 810, 820, 830, 840]*

Independent Claim 42

42. 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; [page 4, lines 11-18; *page 5, line 22 – page 6, line 11; fig. 2A 202, 204, 206, 210]*

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; [*page 5, lines 11-12, 17-20; page 6, lines 6-9; FIG. 1 140; FIG. 2A 206*]

checking of the credentials of the authorized prescriber; [*page 7, lines 5-22; FIG. 2B 270, 274, 276, 278, 284, 286, 288, 290*]

confirming with the patient that educational material has been read prior to providing the sensitive drug to the patient; [*page 7, lines 1-5; page 7, line 24 – page 8, line 2; FIG. 2A, 208; FIG. 2C 242, 244, 246, 248*]

requiring checking of the exclusive computer database for potential abuse associated with the patient and/or the authorized prescriber; [*page 11, lines 10-22; FIG. 8, 800, 810, 820, 830, 840*]

only providing the sensitive drug to the patient provided information in the exclusive computer database is not indicative of potential abuse; and [*page 9, lines 12-22; FIG. 4B 436, 438, 440, 442*]

confirming receipt by the patient of the sensitive drug. [*page 2, line 14*]

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 32-42 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32, 38 and 42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) and further in view of Ukens ("Specialty Pharmacy").

Claims 33-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1).

Claim 37 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) and further in view of Melker et al. (U.S. Patent Publication No. 2002/0177232 A1).

Claims 39-41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) and further in view of "Talk About Sleep: An Interview with Orphan Medical about Xyrem".

7. ARGUMENT

A) The Applicable Law

1) 35 U.S.C. § 112, second paragraph

With regard to 35 U.S.C. § 112, second paragraph, the Board of Patent Appeals and Interferences has stated:

> In rejecting a claim under the second paragraph of 35 U.S.C.§112, it is incumbent on the examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims. *Ex parte* Wu, 10 USPQ 2d 2031, 2033 (B.P.A.I. 1989)(citing *In re* Moore, 439 F.2d 1232, 169 USPQ 236 (C.C.P.A. 1971); *In re* Hammack, 427 F.2d 1378, 166 USPQ 204 (C.C.P.A. 1970)).

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

> The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:
> (1) The content of the particular application disclosure;
> (2) The teachings of the prior art; and
> (3) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. *M.P.E.P.* § 2173.02.

2) 35 U.S.C. §103(a)

The determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on factual evidence. *See Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1336-37 (Fed.Cir. 2005). The legal conclusion, that a claim is obvious within § 103(a), depends on at least four underlying factual issues set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966): (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) evaluation of any relevant secondary considerations.

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 establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested, by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) ; MPEP § 2143.03. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) ; MPEP § 2143.03. As part of establishing a *prima facie* case of obviousness, the Examiner's analysis 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.* To facilitate review, this analysis should be made explicit. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ____ (2007)(slip opinion at 14)(citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)).

The court in *Fine* 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 Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991))." MPEP § 2142.

The test for obviousness under §103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ

543, 551 (Fed. Cir.1985). The Examiner must, as one of the inquiries pertinent to any obviousness inquiry under 35 U.S.C. §103, recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990), *reh'g denied*, 1990 U.S. App. LEXIS 19971 (Fed. Cir.1990). The fact that a reference teaches away from a claimed invention is highly probative that the reference would not have rendered the claimed invention obvious to one of ordinary skill in the art. *Stranco Inc. v. Atlantes Chemical Systems, Inc.*, 15 USPQ2d 1704, 1713 (Tex. 1990). When the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *KSR Int'l Co.*, 550 U.S. ____ (2007)(slip opinion at 12)(citing *United States v. Adams*, 383 U.S. 39, 51-51 (1966)).

Further, the Office Action must provide specific, objective evidence of record for a finding of a suggestion or motivation to combine reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding. *See KSR Int'l Co.*, 550 U.S. ____ (2007)(slip opinion at 14)(citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)); *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). Finally, the Examiner must avoid hindsight. *In re Bond* at 834.

Additionally, there must be a rational underpinning grounded in evidence to support the legal conclusion of obviousness. See *In re Kahn*, 78 USPQ2d 1329 (Fed. Cir. 2006), which states that, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn* citing *In re Lee*, 61 USPQ2d 1430 (Fed. Cir.2002). Additionally, "mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole." *In re Kahn.*

B) Discussion of the rejection of claims 32-42 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.

Claims 32-42 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the response to the Final Office Action, claims 32-42 were amended to clarify the claims in view of the § 112 rejections, and not in response to art. These amendments, as indicated in the Advisory Action mailed February 5, 2007, were entered.

The Advisory Action did not include any direct mention of the status of these Section 112 rejections. Thus, Applicant respectfully submits that the Section 112 rejections have been over come by these amendments. If the Examiner believes otherwise, Applicant reserves the right to submit further argument against the 35 U.S.C. § 112, Second paragraph rejections in a reply to the Examiner's Answer.

C) Discussion of the 35 U.S.C. § 103(a) rejections.

1) Discussion of the rejection of claims 32, 38 and 42 under 35 U.S.C. § 103(a) as being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1; hereinafter "Moradi") in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1; hereinafter "Lilly") in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1; hereinafter "Califano") and further in view of Ukens ("Specialty Pharmacy;" hereinafter "Ukens").

Applicant respectfully traverses the rejection of claims 32, 38, and 42 because the proposed combination of Moradi, Lilly, Califano, and Ukens fails to teach or suggest each of the claim elements and because Ukens teaches away from the combination.

a. Failure to teach or suggest an exclusive computer database

Each of the claims 32, 38 and 42 all refer to an exclusive computer database. The Final Office Action indicates that "Moradi discloses checking the exclusive central database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive central database (para. 43, para. 45, para. 6, and FIG. 3, items 318 and 322 of Moradi)."

The method of claims 32, 38, and 42 utilize the exclusive computer database to implement strict control over distribution of sensitive drugs. These controls allow for tracking of who is prescribing these drugs and who is receiving them. These controls further ensure proper education about the sensitive drugs is provided to patients and understood. Without this exclusive computer database, such controls are much more difficult to implement.

The cited portions of Moradi are repeated below, and it is clear that there is no teaching of an exclusive computer database as claimed.

Paragraph 43:

> "If the prescription is verified as OK, the processing continues in the exemplary embodiment by having the pharmacist fill the prescription and enter the prescription data into the pharmacist's existing Pharmacy Management System (PMS). The PMS system assigns the prescription a prescription number, and the pharmacist enters that prescription number and the number of refills into the PODP 216, which then communicates that data back to the CSS 102 with an identification of the prescription. The pharmacist then gives, at step 322, the ordered medicine and a copy of the prescription image to a prescription deliverer, which is a delivery person in the exemplary embodiments, for delivery to the patient. The CSS 102 is notified that the delivery person is in the process of delivering the medication and the status of the prescription is changed to "delivery" within the CSS database 204. The exemplary embodiment further includes providing the delivery person with a "Route Slip" that has printed directions to the patient's address along with the scanned prescription image. The delivery person hand-delivers the medicine to the recipient if and only if the recipient is holding the original copy of the prescription that is identical to the image provided to the delivery person. This ensures that the proper patient gets the medicine and that the medicine is delivered only once. After the medicine is delivered, the delivery person receives, at step 324, the patient's signature to certify a correct delivery. The delivery person can also stamp the original prescription to signify that the medicine specified in that prescription has been delivered and that the prescription has already been filled. The delivery person then returns, also at step 324, to the POD system 106 and the POD operator updates the order status to "Done" in the PODP 212 so that this information is communicated as a confirmation to the CSS 102 and the CSS Database 204. The exemplary embodiment supports status designations of: delivered, no one at the address, prescription mismatch or one of a number of other potential reasons for non-delivery. Embodiments of the present invention provide the delivery person with a wireless communication device that initiates communication of the delivery status immediately upon delivery of the medication to the patient without requiring the delivery person to first return to the POD 106. These devices also

include a written signature digitizer that is able to capture and digitize the patient's signature and transmit that image to along with the delivery status."

Paragraph 43 may mention various electronic systems, such as the pharmacy management system, but makes no mention of an exclusive computer database.

Paragraph 45:

"All checks to make sure that a patient is not allowed to have a prescription filled twice are performed by the exemplary embodiment of the present invention by human operators (e.g., the driver or the POD operator). This further ensures that patients do not receive medication in excess of their prescription and to prevent prescription abuse."

Paragraph 45 also makes no reference to an exclusive computer database.

Paragraph 6:

"Delivery of prescription medication by mail is also possible. Current systems require the prescription to be provided to a pharmacy and the pharmacy then mails the medication. This technique has a delay in the initial fulfillment of a new prescription because the prescription is often mailed to the pharmacy, and there is also a delay in mailing the prescription. This technique is better used for prescription refills, including maintenance prescriptions that have routinely refilled prescriptions for medication for which the patient has a recurring therapeutic need. In the case of a refill prescription, there is usually time available to accommodate the delays of this technique. This technique is also open to fraud since the individual patient typically does not personally present his or her prescription to the pharmacy. This technique can also lead to an improper person receiving the prescription, such as when a child that is living with the recipient retrieves mail that contains the mailed prescription."

Paragraph 6 also makes no reference to an exclusive computer database.

Fig. 3, items 318 and 322: These elements appear to be described in paragraph 43 as discussed above, and do not mention the use of an exclusive computer database. Further, no reference to item 318 was found in the application. Applicant therefore submits that Moradi fails to provide any teaching of an exclusive computer database as claimed. Applicant further submits that Lilly, Califano, and Ukens fail to cure this deficiency.

Absent any teaching or suggestion of a central database as claimed, Applicant respectfully submits that Claims 32, 38, and 42 are patentable over the proposed combination of Moradi, Lilly, Califano, and Ukens.

b. Ukens teaches away from the proposed combination of references

Applicant respectfully submits that Ukens teaches away from the proposed combination with Moradi, Lilly, and Califano to produce the presently claimed invention. 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).

The Final Office Action indicates that "Ukens discloses restricting distribution of a specialty medication to only one pharmacy (see page 3, paragraphs 3-5 of Ukens)." The Final Office Action goes on to state that "At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Ukens within Moradi, Lilly, and Califano. The motivation for doing so would have been to limit access to dangerous drugs (page 3, paragraph 5 of Ukens)."

These statements are respectfully traversed. Paragraphs 3-5 of Ukens describes that "...restricted distribution of such products raises issues of patient access and safety." It then goes on to state that "by restricting distribution of a specialty medication to only one pharmacy, a manufacturer exposes patients to the risk of not receiving the medications in a timely manner if there's a disruption in the delivery system. In addition, shunting one part of therapy away from a patient's regular pharmacist can create the potential for undiscovered drug interactions. In paragraph 5, Ukens states: "A better way to handle specialty pharmaceuticals would be for manufacturers to set the criteria for their specialty products and then open distribution to any pharmacy that measures up,..." Thus, while Ukens acknowledges the potential for restricting distribution to a single pharmacy, it describes a "better way" that does not expose patients to

some identified risks. Applicant respectfully submits that one of skill in the art, upon reading Ukens, would be discourage from utilizing an architecture including an exclusive database of a single pharmacy as claimed. As a result, one of skill in the art would be guided in a direction to create a decentralized pharmacy with multiple databases which is a divergent path from that of the present application and claims.

Applicant respectfully submits that when considering the scope and content of the cited references and the differences between these references and claims 32, 38, and 42, one can plainly see the deficiencies of the prior art in failing to teach an exclusive computer database associated with an exclusive central pharmacy as claimed. Further, the differences between the cited references, namely Ukens, and the present claim would lead a person of skill in the art in a divergent direction from the path of the present claims. Applicant therefore requests reversal of the 35 U.S.C. § 103(a) rejection of claims 32, 38, and 42 because the cited references fail to teach or suggest all of the claim elements and because Ukens teaches away from the claims.

2) Discussion of the rejection of claims 33-36 under 35 U.S.C. § 103(a) as being unpatentable over Moradi in view of Lilly.

Applicant respectfully traverses the rejection of claims 33-36 because the combination of Moradi and Lilly fails to teach or suggest all of the claimed elements. For example, the method of independent claim 33 utilizes an exclusive computer database as discussed above.

a. Failure to teach or suggest an exclusive computer database

Claim 33 includes an exclusive computer database. The Final Office Action indicates that "Moradi discloses checking the exclusive central database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive central database (para. 43, para. 45, para. 6, and FIG. 3, items 318 and 322 of Moradi)."

As discussed above, the exclusive computer database is utilized to implement strict control over distribution of sensitive drugs. These controls allow for tracking of who is prescribing these drugs and who is receiving them. These controls further ensure proper

education about the sensitive drugs is provided to patients and understood. Without this exclusive computer database, such controls are much more difficult to implement.

The cited portions of Moradi are repeated below, and it is clear that there is no teaching of an exclusive computer database as claimed.

Paragraph 43:

> "If the prescription is verified as OK, the processing continues in the exemplary embodiment by having the pharmacist fill the prescription and enter the prescription data into the pharmacist's existing Pharmacy Management System (PMS). The PMS system assigns the prescription a prescription number, and the pharmacist enters that prescription number and the number of refills into the PODP 216, which then communicates that data back to the CSS 102 with an identification of the prescription. The pharmacist then gives, at step 322, the ordered medicine and a copy of the prescription image to a prescription deliverer, which is a delivery person in the exemplary embodiments, for delivery to the patient. The CSS 102 is notified that the delivery person is in the process of delivering the medication and the status of the prescription is changed to "delivery" within the CSS database 204. The exemplary embodiment further includes providing the delivery person with a "Route Slip" that has printed directions to the patient's address along with the scanned prescription image. The delivery person hand-delivers the medicine to the recipient if and only if the recipient is holding the original copy of the prescription that is identical to the image provided to the delivery person. This ensures that the proper patient gets the medicine and that the medicine is delivered only once. After the medicine is delivered, the delivery person receives, at step 324, the patient's signature to certify a correct delivery. The delivery person can also stamp the original prescription to signify that the medicine specified in that prescription has been delivered and that the prescription has already been filled. The delivery person then returns, also at step 324, to the POD system 106 and the POD operator updates the order status to "Done" in the PODP 212 so that this information is communicated as a confirmation to the CSS 102 and the CSS Database 204. The exemplary embodiment supports status designations of: delivered, no one at the address, prescription mismatch or one of a number of other potential reasons for non-delivery. Embodiments of the present invention provide the delivery person with a wireless communication device that initiates communication of the delivery status immediately upon delivery of the medication to the patient without requiring the delivery person to first return to the POD 106. These devices also include a written signature digitizer that is able to capture and digitize the patient's signature and transmit that image to along with the delivery status."

Paragraph 43 may mention various electronic systems, such as the pharmacy management system, but makes no mention of an exclusive computer database.

Paragraph 45:

> "All checks to make sure that a patient is not allowed to have a prescription filled twice are performed by the exemplary embodiment of the present invention by human operators (e.g., the driver or the POD operator). This further ensures that patients do not receive medication in excess of there prescription and to prevent prescription abuse."

Paragraph 45 also makes no reference to an exclusive computer database.

Paragraph 6:

> "Delivery of prescription medication by mail is also possible. Current systems require the prescription to be provided to a pharmacy and the pharmacy then mails the medication. This technique has a delay in the initial fulfillment of a new prescription because the prescription is often mailed to the pharmacy, and there is also a delay in mailing the prescription. This technique is better used for prescription refills, including maintenance prescriptions that have routinely refilled prescriptions for medication for which the patient has a recurring therapeutic need. In the case of a refill prescription, there is usually time available to accommodate the delays of this technique. This technique is also open to fraud since the individual patient typically does not personally present his or her prescription to the pharmacy. This technique can also lead to an improper person receiving the prescription, such as when a child that is living with the recipient retrieves mail that contains the mailed prescription."

Paragraph 6 also makes no reference to an exclusive computer database.

Fig. 3, items 318 and 322: These elements appear to be described in paragraph 43 as discussed above, and do not mention the use of an exclusive computer database. Further, no reference to item 318 was found in the application.

Applicant further submits that independent claim 33 must be read as including a sensitive drug under exclusive control of a central pharmacy. This control is through the exclusive computer database of the central pharmacy. This is not to say that all drugs are under exclusive control of the central pharmacy, rather the sensitive drug is under exclusive control of the central pharmacy. This is different from the cited paragraphs [0007] and [00043] of Moradi which merely provides a pharmacy including a central server without any limitation as to the prescriptions which may be filled.

Applicant therefore submits that Moradi fails to provide any teaching of an exclusive computer database as claimed. Applicant further submits that Lilly fails to cure this deficiency. Absent any teaching or suggestion of a central database as claimed, Applicant respectfully submits that claims 33 is patentable over the proposed combination of Moradi and Lilly.

Claims 34-36 depend from patentable independent claim 33 and are patentable for the same reasons, plus the elements of the claims.

Thus, Applicant respectfully requests reversal of the 35 U.S.C. § 103(a) rejections of claims 33-36 because the combination of Moradi and Lilly fails to teach or suggest all of the claim elements.

3) Discussion of the rejection of claim 37 under 35 U.S.C. § 103(a) as being unpatentable over Moradi in view of Lilly and further in view of Melker et al. (U.S. Patent Publication No. 2002/0177232 A1; hereinafter "Melker").

Applicant respectfully submits that claim 37 depends from patentable independent claim 33 and is patentable for the same reasons. Further, Melker fails to cure the deficiencies of Moradi and Lilly as set forth above with regard to claims 33-36. Thus, Applicant respectfully requests reversal of the 35 U.S.C. § 103(a) rejection of claim 37.

4) Discussion of the rejection of claims 39-41 under 35 U.S.C. § 103(a) as being unpatentable over Moradi in view of Lilly in view of Califano and further in view of "Talk About Sleep: An Interview with Orphan Medical about Xyrem."

This rejection is respectfully traversed. Claims 39-41 all refer to the use of an exclusive computer database for distribution of a sensitive drug as discussed above with regard to claims 32-38. None of the references alone or combined teach or suggest such an exclusive computer database. "Talk About Sleep: An Interview with Orphan Medical about Xyrem" also does not describe the use of an exclusive computer database for distribution of a sensitive drug such as Xyrem. Thus, these claims are believed in condition for allowance. Applicant respectfully requests reversal of the 35 U.S.C. § 103(a) rejection of claims 39-41.

8. SUMMARY

For the reasons argued above, claims 32-42 were not properly rejected under 35 U.S.C. §§ 103(a) and 112, second paragraph. Reversal of the rejections and allowance of the pending claim are respectfully requested.

Respectfully submitted,

DAYTON T. REARDAN et al.

By their Representatives,

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Date July 18, 2007 By

David P. Zurilla
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 18 day of July 2007.

Name John D. Gustafson-Wardell

Signature

CLAIMS APPENDIX

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

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

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

checking the credentials of the doctor;

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

checking the exclusive computer database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer database;

confirming receipt by the patient of the sensitive drug; and

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

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

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

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

checking the credentials of the doctor;

checking the exclusive computer database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer database;

confirming receipt by the patient of the sensitive drug; and

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

34. The method of claim 33 wherein the exclusive central pharmacy controls the exclusive computer database.

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

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

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

38. A method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

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

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

checking of the credentials of the authorized prescriber;

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

requiring checking of the exclusive computer database for potential abuse associated with the patient and/or the authorized prescriber;

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

confirming receipt by the patient of the sensitive drug; and

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

39. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

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

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

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

confirming receipt by the patient of the GHB; and

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

40. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

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

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

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

41. A method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

manufacturing GHB;

only providing manufactured GHB to the exclusive central pharmacy;

receiving prescription requests for GHB at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber;

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

checking of the credentials of the authorized prescriber;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient provided information in the exclusive computer database is not indicative of potential abuse;

confirming receipt by the patient of the GHB; and

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

42. A method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

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

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

checking of the credentials of the authorized prescriber;

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

requiring checking of the exclusive computer database for potential abuse associated with the patient and/or the authorized prescriber;

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

confirming receipt by the patient of the sensitive drug.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/322,348
Filing Date: December 17, 2002
Appellant(s): REARDAN ET AL.

David D'Zurilla
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/18/07 appealing from the Office action mailed 10/18/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 2004/0019794 A1	MORADI et al.	1-2004
US 2004/0176985 A1	LILLY et al.	9-2004
US 2003/0033168 A1	CALIFANO et al.	2-2003

US 2002/0177232 A1 MELKER et al. 11-2002

Ukens, C. "Specialty Pharmacy," 6/5/00, Drug Topics, v. 144, p. 40.

An Interview with Orphan Medical about Xyrem," http://www.talkaboutsleep.com/sleep-disorders/archives/Narcolepsy_xyrem_interview.htm, 2/12/01.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The rejection of claims 32-42 under 35 U.S.C. 112, second paragraph, is withdrawn due to the response filed 1/17/07.

Claim Rejections - 35 USC § 103

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.

Claims 32, 38, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1), and further in view of Ukens ("Specialty Pharmacy").

(A) 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);

checking the exclusive computer database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive computer database (para. 43, para. 45, para. 6, and Fig. 3, items 318 & 322 of Moradi); and

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

Moradi does not expressly disclose that the drug is a sensitive drug, entering the information into an exclusive computer database 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 aforementioned 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 aforementioned feature of Califano within Moradi and Lilly. The motivation for doing so would have been to ensure that the patient knows about the risks and dangers associated with the drug (para. 43 of Califano).

Moradi, Lilly, and Califano do not expressly disclose receiving all prescription requests at the exclusive central pharmacy.

Ukens discloses restricting distribution of a specialty medication to only one pharmacy (see page 3, paragraphs 3-5 of Ukens).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Ukens within Moradi, Lilly, and

Califano. The motivation for doing so would have been to limit access to dangerous drugs (page 3, paragraph 5 of Ukens).

(B) Referring to claim 38, Moradi discloses a method of distributing a drug under control of an exclusive central pharmacy, the method comprising (para. 3 and para. 24 of Moradi):

receiving prescription requests at the central pharmacy from an authorized prescriber containing information identifying a patient, the drug, and various credentials of the authorized prescriber (para. 35, para. 116, and para. 117 of Moradi);

checking of the credentials of the authorized prescriber (para. 118 of Moradi);

requiring checking of the exclusive computer database for potential abuse associated with the patient and/or the authorized prescriber (para. 43, para. 45, and Fig. 3, items 318 & 322 of Moradi);

only providing the drug to the patient provided information in the exclusive computer database is not indicative of potential abuse (para. 43, para. 45, and Fig. 3, items 318 & 322 of Moradi);

and

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

Moradi does not expressly disclose that the drug is a sensitive drug, entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of the sensitive drug, confirming with the patient that educational material has been read prior to providing the sensitive drug to

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

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

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Lilly within Moradi. The motivation for doing so would have been to immediately detect problems related to abuse, fraud, and misuse of medications (para. 57 of Lilly).

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

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

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

Moradi, Lilly, and Califano do not expressly disclose wherein the use of the exclusive computer database is required for distribution of the sensitive drug.

However, Ukens discloses restricting distribution of a specialty medication to only one pharmacy (see page 3, paragraphs 3-5 of Ukens).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Ukens within Moradi, Lilly, and Califano. The motivation for doing so would have been to limit access to dangerous drugs (page 3, paragraph 5 of Ukens).

(C) Claim 42 repeats the same limitations as claim 38 and is rejected for the same reasons given for that claim.

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)

checking the exclusive computer database for potential abuse of the drug and only mailing the drug to the patient if no potential abuse is found by the checking of the exclusive computer database (para. 43, para. 45, para. 6, and Fig. 3, items 318 & 322 of Moradi); and

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

Moradi does not expressly disclose that the drug is a sensitive drug, entering the information into an exclusive computer database 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 computer 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).

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 one of ordinary skill in the art 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).

Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1) in view of Califano et al. (US 2003/0033168 A1), and further in view of Talk About Sleep ("An Interview with Orphan Medical about Xyrem").

(A) Referring to claim 39, Moradi discloses a method of distributing a drug under control of an exclusive central pharmacy, the method comprising (para. 3 and para. 24 of Moradi):

receiving prescription requests for the drug at the central pharmacy from an authorized prescriber containing information identifying a patient and various credentials of the authorized prescriber (para. 35, para. 116, and para. 117 of Moradi);

checking of the credentials of the authorized prescriber (para. 118 of Moradi);

requiring checking of the exclusive computer database for potential abuse associated with the patient (para. 43, para. 45, and Fig. 3, items 318 & 322 of Moradi);

only providing the drug to the patient provided information in the exclusive computer database is not indicative of potential abuse (para. 43, para. 45, and Fig. 3, items 318 & 322 of Moradi);

and

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

Moradi does not expressly disclose that the drug is gamma hydroxy butyrate (GHB), entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB, confirming with the patient that GHB educational material has been read prior to providing GHB to the patient for a first time, and generating periodic reports via the exclusive computer database to evaluate potential GHB diversion patterns.

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

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Lilly within Moradi. The motivation for doing so would have been to immediately detect problems related to abuse, fraud, and misuse of medications (para. 57 of Lilly).

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

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

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

Moradi, Lilly, and Califano do not expressly disclose that the drug is GHB and wherein the use of the exclusive computer database is required for distribution of GHB.

However, Talk About Sleep discloses providing GHB through a specialty distribution system that utilizes a central pharmacy (see "An Interview with Orphan Medical about Xyrem," talkaboutsleep.com).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Talk About Sleep within Moradi, Lilly, and Califano. The motivation for doing so would have been to provide this medicine to patients that need it in a responsible manner (see "An Interview with Orphan Medical about Xyrem," talkaboutsleep.com).

(B) Claim 40 differs from claim 39 by reciting "mailing" GHB as opposed to "providing." As per this feature, the Examiner respectfully submits that Moradi discloses mailing the drugs (see para. 6 of Moradi).

The remainder of claim 40 is rejected for the same reasons given for claim 39 above.

(C) Claim 41 differs from claim 40 by reciting "manufacturing GHB and only providing manufactured GHB to the exclusive central pharmacy."

As per these features, the Examiner respectfully submits that Talk About Sleep discloses manufacturing GHB and only providing manufactured GHB to the exclusive central pharmacy (see "An Interview with Orphan Medical about Xyrem," talkaboutsleep.com).

The remainder of clam 41 is rejected for the same reasons given for claim 40 above.

(10) Response to Argument

In the Appeal Brief filed 18 July 2007, Appellant makes the following arguments:

A) Applicant traverses the rejection of claims 32, 38, and 42 because the proposed combination of Moradi, Lilly, Califano, and Ukens fails to teach or suggest each of the claim elements and because Ukens teaches away from the combination.

B) Moradi fails to provide any teaching of an exclusive computer database as claimed. Applicant further submits that Lilly, Califano, and Ukens fail to cure this deficiency.

Examiner will address Appellant's arguments in sequence as they appear in the brief.

Argument A:

In response to Appellant's first argument, claims 32, 38, and 42 recite combinations which only unite old elements with no change in their respective functions

and which yield predictable results. Thus, the claimed subject matter likely would have been obvious under *KSR*.

In response to Appellant's argument that Ukens teaches away from the proposed combination, 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). The Examiner is relying on the portion of Ukens that discloses that there was at the time of the invention, restricted distribution of pharmaceuticals via one pharmacy. The Examiner acknowledges that the prior art teaches disadvantages concerning the use of a central pharmacy. However, the Examiner also recognizes an advantage, such as limiting distribution of dangerous drugs. In addition, it is respectfully submitted that Appellant's statements are conclusory remarks that fail to provide any rationale or scientific or logical reasoning that would serve to support Appellant's conclusions. In particular, Appellant fails to consider the full teachings of the applied references in the manner set forth by the Examiner.

Argument B:

In response to Appellant's second argument, the Examiner respectfully submits that she gave the "exclusive computer database" the broadest reasonable interpretation in light of Applicant's Specification. The only definition of an exclusive computer database was found at page 2, lines 24-26 of Applicant's Specification, which states "the exclusive central database contains all relevant data related to distribution of the

drug and process of distributing it, including patient, physician and prescription information." Moradi teaches a central service station (CSS) database (para. 22 of Moradi) and Lilly teaches a data storage that includes pharmaceutical transaction information (para. 69 of Lilly). Ukens discloses an exclusive central pharmacy. As such, in light of Applicant's Specification, it is readily apparent that the proper combination of Moradi, Lilly, and Ukens teaches an exclusive computer database.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,
Lena Najarian
Lena Najarian

LN
LN
September 25, 2007

Conferees:

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Primary Examiner
Tech Center 3600

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PRIMARY EXAMINER
TECHNOLOGY CENTER 3600

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan, Dayton
Group Art Unit	~~1743~~ 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/ 0,001,144	05/10/2001	Kapp, Thomas L.			12/22/2000
	US-2001/ 0,042,050	11/15/2001	Fletcher, Robert J., et al.			01/05/2001
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	US-2002/ 0,032,581	03/14/2002	Reitberg, donald P.			06/01/2001
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	US-2003/ 0,144,876	07/31/2003	Kosinski, Diana L., et al.			01/28/2002
	US-2003/ 0,229,519	12/11/2003	Eidex, Brian H., et al.			05/16/2003
	US-2003/ 0,233,256	12/18/2003	Cardenas, Rodolfo , et al.			06/13/2002
	US-2004/ 0,019,567	01/29/2004	Herceg, Michael J., et al.			07/23/2002
	US-2004/ 0,019,794	01/29/2004	Moradi, Ahmad , et al.			07/29/2002
	US-2004/ 0,078,237	04/22/2004	Kaafarani, William , et al.			08/28/2003
LN	US-2004/ 0,107,117	06/03/2004	Denny, Lawrence A.			11/25/2003

EXAMINER Lena Najarian DATE CONSIDERED 10-24-07

Substitute Disclosure Statement Form (PTO-1449)

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Substitute for form 1449A/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*	*Complete if Known*	
	Application Number	10/322,348
	Filing Date	December 17, 2002
	First Named Inventor	Reardan, Dayton
	Group Art Unit	1743 - 3626
	Examiner Name	Unknown
Sheet 2 of 2	Attorney Docket No: 101.031US1	

LN	US-2004/0,117,126	06/17/2004	Fetterman, Jeffrey E., et al.			11/25/2003
	US-2004/0,122,712	06/24/2004	Hill, Sr., Kenneth A., et al.			12/20/2002
	US-2004/0,122,713	06/24/2004	Hill, Sr., Kenneth A., et al.			12/20/2002
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	US-6,021,392	02/01/2000	Lester, Douglas D., et al.			12/08/1997
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LN	US-6,755,784	06/29/2004	Williams, Bruce A., et al.			03/07/2003

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

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

EXAMINER Lena Najarian DATE CONSIDERED 10-24-07

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

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

21186 7590 10/31/2007
SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
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EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3626	
MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

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PTOL-90A (Rev. 04/07)

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 11/4/04 has been considered.

Conclusion

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, 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

10-24-07

C. LUKE GILLIGAN
PRIMARY EXAMINER
TECHNOLOGY CENTER 3600

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.: 101.031US1 Serial No.: 10/322,348
Filed: December 17, 2002 Due Date: December 3, 2007
Examiner: Lena Najarian Group Art Unit: 3626

MS Appeal Brief - Patents
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 Reply Brief Under 37 CFR 41.41 (4 pgs.).
X Request for Oral Hearing (1 pg.).
X Authorization to charge Deposit Account No. 19-0743 in the amount of $515 to cover fee to file a Request for Oral Hearing.

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

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

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

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John O. Gustafson-Wardell
Name

Signature

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.

(GENERAL)

Electronic Acknowledgement Receipt	
EFS ID:	2540191
Application Number:	10322348
International Application Number:	
Confirmation Number:	5446
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	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:	03-DEC-2007
Filing Date:	17-DEC-2002
Time Stamp:	17:26:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

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Payment Type	Deposit Account
Payment was successfully received in RAM	$515
RAM confirmation Number	2806
Deposit Account	190743
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		101031us1_reply_120307.PDF	490327 8784f239bad910502cf76cod39dc74c2b0736b02	yes	6
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Miscellaneous Incoming Letter		1	1	
	Request for Oral Hearing		2	2	
	Reply Brief Filed		3	6	
Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	8165 063e44955eb9f10665c8152988da2465dc66c057	no	2
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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.

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New International Application Filed with the USPTO as a Receiving Office
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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/Applicant Name:	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:				
Request for oral hearing	2403	1	515	515
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
		Total in USD ($)		**515**

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Dayton T. Reardan et al.	Examiner: Lena Najarian
Serial No.: 10/322,348	Group Art Unit: 3626
Filed: December 17, 2002	Docket: 101.031US1

For: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

REPLY BRIEF UNDER 37 CFR § 41.41

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
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The Examiner's Answer admits that the primary reference Moradi fails to disclose entering information into an exclusive computer database that is associated with an exclusive central pharmacy.[1] The Examiner's Answer contends however that Lilly et al. discloses entering information into an exclusive computer database that is associated with an exclusive central pharmacy.[2] The Appellant respectfully disagrees.

The Examiner's Answer contends that an exclusive computer database associated with an exclusive central pharmacy is disclosed in one or more of ¶¶ 11, 33, 54, 57, 58, 61, and 69 of Lilly et al. The Appellant respectfully disagrees, and respectfully submits that ¶ 11 relates to the cost of drug distribution, ¶ 33 relates to controlling information relating to controlled substances and pharmaceutical medications, ¶ 54 relates to government oversight agencies such as the DEA, the FBI, and the CDC, ¶ 57 relates to the ability of pharmacies to verify the drug usage of each purchaser, ¶ 58 relates to physicians' prescribing of prescription drugs, and ¶ 69 relates to the types of transactions that may occur with stored patient, doctor, and pharmaceutical data.

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[1] Examiner's Answer, p. 4.
[2] *Id.*, pp. 4-5.

Paragraph 61 relates to several types of entities that can use the system disclosed therein such as doctors, pharmacies, hospitals, pharmaceutical companies, insurance companies, government agencies, health care informatics companies, health researchers, managed care organizations, and other healthcare providers. It goes on to state that such users may typically maintain their own databases, and that such databases can be accessed by the other entities in the system as needed. The Appellant respectfully submits that such a distributed database system is not an exclusive database associated with an exclusive central pharmacy. Paragraph 61 goes on to state that pharmaceutical data can be stored in a data storage which is external to each entity's database. However, the storage of data in a data storage in addition to the data storage in each entity's database is not an exclusive database that is associated with an exclusive central pharmacy as is recited in the claims.

Consequently, the Appellant respectfully submits that, contrary to the assertions in the Examiner's Answer, Lilly et al. does not disclose entering information into an exclusive computer database that is associated with an exclusive central pharmacy, and for at least this reason, the rejection of the claims should be reversed.

The Examiner's Answer further states that the Examiner gave the claim language "exclusive computer database" the broadest reasonable interpretation.[3] The Appellant respectfully submits however that the broadest reasonable interpretation must be limited by the ordinary meaning of the word at issue. The term "exclusive" means "single" or "sole,"[4] and as pointed out above, Lilly et al. discloses that each entity typically maintains its own database. That is, there is not an exclusive, single, or sole database disclosed in Lilly et al.

The Examiner's Answer further points to paragraph [0022] of Moradi, even though the Examiner's Answer admits earlier that Moradi does not disclose an exclusive computer database. However, while paragraph [0022] discloses a Central Service Station (CSS) 102 that maintains databases, Moradi conspicuously does not state that any of these databases are exclusive.

---

[3] *Id.*, pp. 15-16.
[4] www.merriamwebster.com

Regarding the Ukens reference, the Examiner's Answer contends that it too discloses an exclusive central pharmacy. The Examiner's Answer further takes issue with the Appellant's contention that the Ukens reference teaches away from the claimed subject matter.

The Ukens reference discusses the relationship among community pharmacies, specialty pharmacies, and specialty drugs. The Appellant respectfully submits that a specialty pharmacy is not an exclusive central pharmacy. A specialty pharmacy can be distributed throughout many locations, and an exclusive pharmacy may or may not deal with specialty drugs.[5] Moreover, there is simply no disclosure of an exclusive computer database in Ukens.

In response to the Appellant's pointing out that Ukens teaches away from a specialty pharmacy, the Examiner's Answer states that "the fact that the applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentabilty. . ." The Appellant respectfully submits that it did not recognize, identify, or discuss any advantage that would naturally flow from Ukens or any other cited reference. Rather, the Appellant specifically pointed to the section of Ukens that disparaged a specialty pharmacy, and hence taught away from the claimed subject matter.

The Examiner's Answer admits that Ukens "teaches disadvantages concerning the use of a central pharmacy." The Examiner goes on to state however that she has recognized an advantage, that is, limiting distribution of dangerous drugs. The Examiner further argues that the Appellant's statements are conclusory remarks that fail to provide any rationale or scientific or logical reasoning to support them. In reply, the Appellant respectfully submits that its statements are not at all conclusory. Rather, they are statements and teachings that appear in Ukens, that teach away from the claimed subject matter, and that need no further analysis. The Appellant further respectfully submits that the Examiner's citation of the advantage of limiting the distribution of dangerous drugs comes from the Appellant.[6] Ukens on the other hand relates to the distribution of

---

[5] Specialty drugs, as defined in Ukens, relate to drugs that serve a limited population, such as drugs to treat ALS, and/or drugs that require special care in the distribution system, such as controlled atmospheric conditions. Ukens, p. 2.

[6] Appellant's specification, pp. 1-2.

specialty drugs, not dangerous drugs, and the concerns of distributing such specialty drugs. As noted in Ukens, specialty drugs refer to drugs for a limited patient population and/or that require special handling.[7]

For the foregoing reasons, and the reasons outlined in the Appellant's Brief, the Appellant respectfully submits that the rejection of the claims is in error, and that the rejection of the claims should be reversed.

Respectfully submitted,

DAYTON T. REARDAN et al.

By their Representatives,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402

Date December 3 2007 By _____
David D Zuhlla
Reg. No. 36,776

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John D. Crispin-Wockhardt _____
Name Signature

[7] Such specialty drugs can include pharmaceuticals to treat such diseases as amyotrophic lateral sclerosis, cancer, cystic fibrosis, growth hormone deficiency, hemophilia, HIV/AIDS, and multiple sclerosis.

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	

REQUEST FOR ORAL HEARING

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P.O. Box 1450
Alexandria, VA 22313-1450

In accordance with 37 C.F.R. § 41.47, appellant hereby requests an oral hearing before the Board of Patent Appeals and Interferences with respect to the appeal in the above-identified patent application.

The Examiner's Answer was mailed on October 3, 2007.

Please charge Deposit Account No. 19-0743 in the amount of $515 to cover the fee to file a Request for Oral Hearing. Please charge any required additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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

Date December 3, 2007 By _____
David D'Zurilla
Reg. No. 36,776

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John D. Brush Mitchell
Name

Signature

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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 01/08/2008
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EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3626	
MAIL DATE	DELIVERY MODE
01/08/2008	PAPER

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10322348	12/17/2002	REARDAN ET AL.	101.031US1

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

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Lena Najarian	
ART UNIT	**PAPER**
3626	20080104

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Commissioner for Patents

PTO-90C (Rev.04-03)

Attachment to PTO Form 90C

The reply brief filed 12/3/07 has been entered and considered. The application has been forwarded to the Board of Patent Appeals and Interferences for decision on the appeal.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, 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.

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ln
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JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER

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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 06/11/2008

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

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3626	
MAIL DATE	DELIVERY MODE
06/11/2008	PAPER

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SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
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MINNEAPOLIS, MN 55402

Appeal No: 2008-3962
Application: 10/322,348
Appellant: Dayton T. Reardan et al.

Board of Patent Appeals and Interferences
Docketing Notice

Application 10/322,348 was received from the Technology Center at the Board on May 20, 2008 and has been assigned Appeal No: 2008-3962.

A review of the file indicates that the following documents have been filed by appellant:

Appeal Brief filed on:	July 18, 2007
Reply Brief filed on:	December 03, 2007
Request for Hearing filed on:	December 03, 2007

In all future communications regarding this appeal, please include both the application number and the appeal number.

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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 12/30/2008

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MINNEAPOLIS, MN 55402

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NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
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MINNEAPOLIS, MN 55402

Appeal No:	2008-3962
Appellant:	Dayton T. Reardan, Patti A. Eneel, Bob
Application No:	Gagne et al.
	10/322,348
Hearing Room:	B
	B
Hearing Docket:	Tuesday, February 10, 2009
	01:00 PM
Hearing Date:	Madison Building - East Wing
Hearing Time:	600 Dulany Street, 9th Floor
Location:	Alexandria, Virginia 22313-1450

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January 9, 2009

Time: 12:15 p.m.
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TO: Commissioner for Patents
Board of Patent Appeals and Interferences
P.O. Box 1450
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FROM: Bradley A. Forrest

OUR REF: 101.031US1
TELEPHONE: 571-272-3944

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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.

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Signature of Attorney/Agent/Appellant	1-13-2009 Date	30,837 Registration No.

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21186 7590 09/02/2009

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EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAYTON T. REARDAN, PATTI A. ENEEL, and BOB GAGNE

Appeal 2008-003962
Application 10/322,348
Technology Center 3600

Decided: August 31, 2009

Before HUBERT C. LORIN, LINDA E. HORNER, and
ANTON W. FETTING, *Administrative Patent Judges*.

LORIN, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Dayton T. Reardan, et al. (Appellants) seek our review under 35 U.S.C. § 134 of the final rejection of claims 32-42. We have jurisdiction under 35 U.S.C. § 6(b) (2002).

SUMMARY OF DECISION

We AFFIRM.[1]

THE INVENTION

The invention relates to the distribution of sensitive drugs. Claims 32-42 that are on appeal are process claims (claims 32, 33, 38-42 are the independent claims), and are directed to methods of distributing a sensitive drug (claims 39-41 are directed specifically to distributing gamma hydroxy butyrate (GHB)). All the claimed methods include steps of a "central" pharmacy receiving a prescription request containing information and entering the information into an "exclusive" computer database under "exclusive" control of the central pharmacy for analysis of potential abuse situations." [2]

Claim 32, reproduced below, is illustrative of the subject matter on appeal.

---

[1] Our decision will make reference to the Appellants' Appeal Brief ("App. Br.," filed Jul. 18, 2007) and Reply Brief ("Reply Br.," filed Dec. 3, 2007), and the Examiner's Answer ("Answer," mailed Oct. 3, 2007).

[2] *See* claims 32 and 33: "entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations". *See also* claims 38-42: "entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations".

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

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

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

checking the credentials of the doctor;

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

checking the exclusive computer database for potential abuse of the sensitive drug;

only mailing the sensitive drug to the patient if no potential abuse is found by the checking of the exclusive computer database;

confirming receipt by the patient of the sensitive drug; and

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

THE REJECTIONS

The Examiner relies upon the following as evidence of unpatentability:

Moradi	US 2004/0019794 A1	Jan. 29, 2004
Lilly	US 2004/0176985 A1	Sep. 9, 2004
Califano	US 2003/0033168 A1	Feb. 13, 2003
Melker	US 2002/0177232 A1	Nov. 28, 2002

Ukens, Carol, "*Specialty Pharmacy*," Jun. 5, 2000, Drug Topics, v. 144, n. 11, p. 40. [Ukens]

"*An interview with Orphan Medical about Xyrem*," http://www.talkaboutsleep.com/sleep-disorders/archives/Narcolepsy_xyrem_interview.htm, Feb. 12, 2001. [*Talk About Sleep*]

The following rejections[3] are before us for review:

1. Claims 32, 38, and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi, Lilly, Califano, and Ukens.
2. Claims 33-36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi and Lilly.
3. Claim 37 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi, Lilly, and Melker.
4. Claims 39-41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Moradi, Lilly, Califano, and *Talk About Sleep*.

ISSUES

Would it have been obvious over the cited prior art to use an "exclusive computer database" as claimed given the broadest reasonable construction of the claim term "exclusive" in light of the Specification as it would be interpreted by one of ordinary skill in the art?

With respect to the rejection of claims 32, 38, and 42, does Ukens teach away from the claimed invention?

---

[3] The Examiner withdrew a rejection of claims 32-42 under the second paragraph of 35 U.S.C. §112. Answer 3.

FINDINGS OF FACT

We find that the following enumerated findings of fact (FF) are supported by at least a preponderance of the evidence. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

Claim construction

1. The claims call for an "exclusive computer database."
2. The Specification does not provide an express definition for "exclusive".
3. According to the Specification, an "exclusive central database contains all relevant data related to distribution of the drug and process of distributing it, including patient, physician and prescription information." Specification 2:24-26.
4. One definition for "exclusive" is "excluding or tending to exclude all others." (*See* Webster's New World Dictionary 474 (3rd Ed. 1988.)(Entry 6. for "exclusive.")
5. The Appellants have put forward "single" or "sole" as the definition of "exclusive," relying on www.merriamwebster.com. Reply Br. 2.
6. The term "exclusive" appears to be used only twice in the Specification: (1) at p. 2, ll. 24-26, to describe what the "exclusive computer database" contains (i.e., "contains all relevant data ... .") and (2) at p. 4, l. 30, to indicate that Xyrem "is distributed and dispensed through a primary and exclusive central pharmacy."
7. The Specification describes the computer database only in terms of being a "central" database. *See* Specification 10:30.

8. But for the Examiner's finding, that Moradi and Lilly disclose "exclusive" computer databases, the Examiner's remaining findings characterizing the scope and content of the cited references as well as the differences between the claimed subject matter and the prior art have not been rebutted. Accordingly, as to these findings, they are accepted as being undisputed.
9. Moradi discloses a database in a pharmacy. [0043]
10. Lilly discloses a "[d]ata storage 122 [*See* Fig. 2] [that] provides a scalable, robust data store that maintains all pertinent information about prescriptive medication activities." Lilly [0061].
11. The information stored there may include: the drugs prescribed, the patient, physician, prescription information, and the place the prescription was filled. Lilly [0068]-[0069]
12. Lilly's data storage is a data storage whose singular purpose is to centralize information obtained from various entities, such as hospitals. Lilly [0050].

PRINCIPLES OF LAW

Claim Construction

During examination of a patent application, a pending claim is given the broadest reasonable construction consistent with the specification and should be read in light of the specification as it would be interpreted by one of ordinary skill in the art. *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1369 (Fed. Cir. 2004).

> [W]e look to the specification to see if it provides a definition for claim terms, but otherwise apply a broad interpretation. As this court has discussed, this methodology produces claims with

> only justifiable breadth. *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984). Further, as applicants may amend claims to narrow their scope, a broad construction during prosecution creates no unfairness to the applicant or patentee. *Am. Acad.*, 367 F.3d at 1364.

In re ICON Health and Fitness, Inc., 496 F.3d 1374, 1379 (Fed. Cir. 2007). Limitations appearing in the specification but not recited in the claim are not read into the claim. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed. Cir. 2003).

> *Obviousness*
>
> Section 103 forbids issuance of a patent when '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.'

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, and (3) the level of skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). *See also KSR*, 550 U.S. at 407. ("While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.") The Court in *Graham* further noted that evidence of secondary considerations "might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Graham,* 383 U.S. at 17-18.

ANALYSIS

The rejection of claims 32, 38, and 42 under 35 U.S.C. §103(a) over Moradi, Lilly, Califano, and Ukens.

The Appellants argued claims 32, 38, and 42 as a group. App. Br. 16. We select claim 32 as the representative claim for this group, and the remaining claims 38 and 42 stand or fall with claim 32. 37 C.F.R. § 41.37(c)(1)(vii) (2007).

The Examiner has taken the position that Moradi and Lilly disclose "exclusive" computer databases. *See e.g.*, Final Rejection 5-6 and Answer 4-5.

The Appellants have argued in the Appeal Brief that Moradi does not disclose using an "exclusive" computer database and, moreover, Ukens teaches away from doing so. App. Br. 16-20.

The Examiner responded, in part, that in light of the definition for "exclusive computer database" provided for in the Specification (p. 2, ll. 24-26) it reasonably broadly reads on the prior art databases, *e.g.*, that of Lilly. Answer 15-16.

The Appellants replied that Lilly does not disclose an "exclusive" computer database and with respect to construing the term "exclusive," "the broadest reasonable interpretation must be limited by the ordinary meaning of the word at issue. The term "exclusive" means "single" or "sole," ... Lilly et al. discloses that each entity typically maintains its own database. That is, there is not an exclusive, single, or sole database disclosed in Lilly et al." Reply Br. 2.

Accordingly, the issue is whether, given the broadest reasonable construction of the claim term "exclusive" in light of the Specification as it would be interpreted by one of ordinary skill in the art, would it have been

obvious over the cited prior art to use an "exclusive computer database" as claimed? We find that it would have been.

The Specification provides no express definition for "exclusive." Rather, the Specification uses the term in the context of what the database should contain. FF 3. In fact, the Specification uses term "exclusive" twice and then only once when referring to a computer database. FF 6. Even then the computer database is described only in terms of being a "central" database. FF 7. There is no disclosure which would suggest that the database is rendered structurally different by it being "exclusive" rather than it simply being a "central" database. Furthermore, an ordinary and customary meaning of "exclusive" is "excluding or tending to exclude all others." FF 4. Given its ordinary and customary meaning, an "exclusive computer database" would mean a database exclusive of other databases in "containing all relevant data related to distribution of the drug and process of distributing it, including patient, physician and prescription information." Specification 2:24-26.

Given all this, the broadest reasonable construction of the claim phrase "exclusive computer database" as used in the claims in light of the Specification as it would be interpreted by one of ordinary skill in the art is that it is a central computer database exclusive of other databases that "contains all relevant data related to distribution of the drug and process of distributing it, including patient, physician and prescription information." Specification 2:24-26.

Moradi discloses a database within a pharmacy. FF 9. This is not disputed. Whether Moradi's database is exclusive of other databases in "contain[ing] all relevant data related to distribution of the drug and process

of distributing it, including patient, physician and prescription information" (Specification 2:24-26) is unclear.

Lilly, however, discloses a data storage that maintains all pertinent information about prescriptive medication activities. FF 10. The information stored there may include: the drugs prescribed, the patient, physician, prescription information, and the place the prescription was filled. FF 11. Accordingly, Lilly discloses a data storage "contain[ing] all relevant data related to distribution of the drug and process of distributing it, including patient, physician and prescription information." Specification 2:24-26. Lilly's data storage is a data storage whose singular purpose is to centralize information obtained from various entities, such as hospitals. FF 12. To one of ordinary skill in the art reading Lilly, Lilly's data storage is "exclusive" in that it is the sole data storage that "contains all relevant data related to distribution of the drug and process of distributing it, including patient, physician and prescription information." Specification 2:24-26.

It would have been obvious in light of Lilly to make Moradi's database exclusive of other databases in "contain[ing] all relevant data related to distribution of the drug and process of distributing it, including patient, physician and prescription information" (Specification 2:24-26) because doing so centralizes the information, as expected. "[W]hen a patent "simply arranges old elements with each performing the same function it had been known to perform" and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR* at 417 (quoting *Sakraida v. Ag Pro, Inc.,* 425 U.S. 273, 282 (1976)).

We find that given the broadest reasonable construction of the claim term "exclusive" in light of the Specification as it would be interpreted by

one of ordinary skill in the art, it would have been obvious over the cited prior art to use an "exclusive computer database" as claimed.

The Appellants have also argued that Ukens teaches away from the claimed invention because, though it teaches restricted distribution, it indicates that "[a] better way to handle specialty pharmaceuticals would be for manufacturers to ... open distribution to any pharmacy ... " [0005]. App. Br. 19. We agree Ukens suggests that open distribution is preferable over a restricted distribution. But a restricted distribution is not rendered nonobvious simply because it is disclosed as being less preferable. *Cf. In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) ("A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.")

We have addressed all of the Appellants' arguments. We find them unpersuasive as to error in the rejection of claims 32, 38, and 42.

The rejection of claims 33-36 under 35 U.S.C. §103(a) over Moradi and Lilly.

The Appellants repeat the argument raised against the rejection of claims 32, 38, and 42 in that Moradi and Lilly do not teach or suggest an exclusive computer database. App. Br. 20-23. However, we have found that argument unpersuasive as to the rejection of claims 32, 38, and 42. *See* discussion above. Accordingly, we find it equally unpersuasive as to error in the rejection of claims 33-36.

The rejection of claim 37 under 35 U.S.C. §103(a) over Moradi, Lilly, and Melker.

The Appellants rely on the same argument used to challenge the rejection of claims 33-36. App. Br. 23. We have found that argument unpersuasive. *See* discussion above. And so find it unpersuasive as to error in the rejection of claim 37.

The rejection of claims 39-41 under 35 U.S.C. §103(a) over Moradi, Lilly, Califano, and Talk About Sleep.

The Appellants rely on the same arguments used to challenge the rejections of claims 32-38. App. Br. 23. We have found that argument unpersuasive. *See* discussion above. And so find it unpersuasive as to error in the rejection of claims 39-41.

CONCLUSIONS

We conclude that the Appellants have not shown that the Examiner erred in rejecting claims 32, 38, and 42 under 35 U.S.C. § 103(a) as being unpatentable over Moradi, Lilly, Califano, and Ukens; claims 33-36 under 35 U.S.C. § 103(a) as being unpatentable over Moradi and Lilly; claim 37 under 35 U.S.C. § 103(a) as being unpatentable over Moradi, Lilly, and Melker; and, claims 39-41 under 35 U.S.C. § 103(a) as being unpatentable over Moradi, Lilly, Califano, and *Talk About Sleep*.

DECISION

The decision of the Examiner to reject claims 32-42 is affirmed.

AFFIRMED

mev

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UNITED STATES PATENT AND TRADEMARK OFFICE

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Interview Summary	Application No.	Applicant(s)	
	10/322,348	REARDAN ET AL.	
	Examiner	Art Unit	
	LENA NAJARIAN	3686	

All participants (applicant, applicant's representative, PTO personnel):

(1) *LENA NAJARIAN*. (3)*David D'Zurilla (Reg. No. 36,776)* .

(2) *Bradley Forrest (Reg. No. 30,837)* . (4)_____.

Date of Interview: *15 October 2009*.

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *32, in particular*.

Identification of prior art discussed: *Moradi, Lilly, Ukens*.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Discussed amending the claims to clarify certain elements such as the "exclusive computer database" and "potential abuse." The Examiner will reconsider the applied references in light of any amendments made in an RCE*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/LENA NAJARIAN/ Examiner, Art Unit 3686	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Dayton T. Reardan et al.	Examiner:	Lena Najarian
Serial No.:	10/322,348	Group Art Unit:	3686
Filed:	December 17, 2002	Docket:	101.031US1
Customer No.:	21186	Confirmation No.:	5446
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 PTO 1449 Form be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the PTO 1449 Form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. § 1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement.

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

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

Respectfully submitted,

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

Date November 2, 2009 By / /
David D'Zurilla
DDZ:jdgw Reg. No. 36,776

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: MS RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 2 day of November, 2009.

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

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
	Confirmation Number	5446
	Group Art Unit	3686
	Examiner Name	Lena Najarian
	Attorney Docket Number	101.031US1
	Customer No.	21186

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

1. Submission required under 37 C.F.R. § 1.114:

   X Amendment Under 37 C.F.R § 1.116 (16 pages) is enclosed.

   X Information Disclosure Statement (2 pages), Form 1449 (1 page), and copies of cited documents (7).

2. Fees

   X Authorization to charge deposit account 19-0743 in the amount of $405.00 to pay the RCE filing fee required under 37 C.F.R. § 1.17(e).

   X **The Commissioner is hereby authorized to charge any additional fees or credit overpayment to Deposit Account No. 19-0743.**

SCHWEGMAN, LUNDBERG & WOESSNER, P.A. By: /David D'Zurilla/
David D'Zurilla
Reg. No. 36,776

CERTIFICATE UNDER 37 C.F.R 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 2 day of November, 2009.

John D. Gustav-Wrathall
Name

/John D. Gustav-Wrathall/
Signature

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	Unknown	Group Art Unit:	Unknown
Filed:	Herewith	Docket No:	101.031US3
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

PRELIMINARY AMENDMENT

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

Prior to taking up this application for examination, please enter the following amendments:

IN THE SPECIFICATION

On page 1, line 4, please insert the following paragraph:

Related Application

This application is a divisional application of U.S. Patent Application Serial No.: 10/322,348, filed December 17, 2002, which application is incorporated herein by reference.

IN THE CLAIMS

Claims 1-18 (Cancelled)

Claim 19 (Currently Amended) 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~~ while maintaining a central database, the controls selected from the group consisting of communicating prescriptions from a physician to ~~the central~~ a 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.

Claim 20. (Currently Amended) The method of claim 19 wherein initially selected controls

comprise communicating prescriptions from a physician to ~~the central~~ a 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.

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

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

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

selecting multiple controls for distribution of the sensitive drug; and

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

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

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

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

Claims 26-31 (Cancelled)

32. (New) The method of claim 22 wherein the distribution of the sensitive drug is monitored by use of a central database that tracks all distribution of the sensitive drug.

33. (New) The method of claim 32 wherein each pharmacy distributing the sensitive drug uses the central database to track distribution of the sensitive drug.

34. (New) The method of claim 32 wherein the sensitive drug is exclusively distributed by a central pharmacy that uses the central database to track distribution of the sensitive drug.

35. (New) The method of claim 34 wherein the central pharmacy may ship the sensitive drug to a second pharmacy for pickup when the second pharmacy's ability to protect against diversion before shipping the drug is confirmed.

36. (New) The method of claim 19 wherein the pharmacy is a central pharmacy.

37. (New) The method of claim 36 wherein the central pharmacy may ship the sensitive drug to a second pharmacy for pickup when the second pharmacy's ability to protect against diversion before shipping the drug is confirmed.

REMARKS

By this amendment, Applicants have amended claims 19 and 20 and have added new claims 32 to 37. No new matter has been added. Support for claim 19 and 20 appears throughout the specification, for example at line 1 of the Summary of the invention, since the term *central pharmacy* is generic to the term *pharmacy*. New claim 36 now recites central pharmacy. Support for new claims 35 and 37 appears in the specification at page 2, lines 15-18. Support for new claims 32 and 33 appears in the specification at page 11, lines 18-22. Support for claim 34 appears throughout the specification, for example at page 4, lines 29 and 30..

Conclusion

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

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

Respectfully Submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

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

Date 4-1-2005 By _____
Bradley A. Forrest
Reg. No. 30,837

"Express Mail" mailing label number: EV 553 984 075 US
Date of Deposit: April 1, 2005
This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	Unknown	Group Art Unit:	Unknown
Filed:	Herewith	Docket No:	101.031US4
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

PRELIMINARY AMENDMENT

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

Prior to taking up this application for examination, please enter the following amendments:

IN THE SPECIFICATION

On page 1, line 4, please insert the following paragraph:

Related Application

This application is a divisional application of U.S. Patent Application Serial No.: 10/322,348, filed December 17, 2002, which application is incorporated herein by reference.

IN THE CLAIMS

Claims 1-25 (Cancelled)

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

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

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

patterns in the data, for cash payments, and for inappropriate questions.

27. (Previously presented) The method of claim 26 wherein initially selected controls comprise

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

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

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

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

selecting multiple controls for distribution by said exclusive central pharmacy, the controls selected from the group consisting of communicating prescriptions from a physician to

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

30. (Previously presented) The method of claim 29 wherein initially selected controls comprise

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

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

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

REMARKS

By this amendment, Applicants have cancelled claims 1-25. Claims 26-31 are now before the Examiner for examination.

Conclusion

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

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

Respectfully Submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

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

Date 4-1-2005 By _____
Bradley A. Forrest
Reg. No. 30,837

"Express Mail" mailing label number: EV 553 984 061 US
Date of Deposit: April 1, 2005
This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to The Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/097,651	04/01/2005	Dayton T. Reardan	101.031US3	6798

21186 7590 05/29/2009
SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
FUELLING, MICHAEL	
ART UNIT	PAPER NUMBER
4135	

NOTIFICATION DATE	DELIVERY MODE
05/29/2009	ELECTRONIC

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

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

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

uspto@slwip.com
scape@slwip.com

Office Action Summary	Application No.	Applicant(s)	
	11/097,651	REARDAN ET AL.	
	Examiner	Art Unit	
	MICHAEL FUELLING	4135	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *01 April 2005*.

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

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

Disposition of Claims

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

4a) Of the above claim(s) *1-18 and 26-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-25 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 *12 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

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

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

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

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

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :01/04/2007; 10/10/2006 and 04/01/2005.

DETAILED ACTION

1. This is a non-final, first office action on the merits for Application Number 11/097,651 filed April 1, 2005.
2. Claims 1-37 are pending.
3. Claims 1-18 and 26-31 have been cancelled.
4. Claims 19-25 and 32-37 currently are pending and have been examined.

Information Disclosure Statement

5. The information disclosure statements (IDS) submitted on 01/04/2007; 10/10/2006 and 04/01/2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Claim Objections

6. Claims 19 and 20 are objected to because of informalities. For example, in line 3 of claim 20, it appears '*physicians'* should be "physician's". Appropriate corrections are required.

Claim Rejections - 35 USC § 112

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

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

8. Claims 19, 20, 21, 36 and 37 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. Claim 19 recites '*the data, cash payments, inappropriate questions*;'. There is insufficient antecedent basis for these limitations. Claims 20, 21, 36 and 37 which depend upon claim 19 have the same defect. Further, claim 20 recites '*the data'*. It is being interpreted the data is any of the drug distribution information recited in claims 19 and 20.

10. Claim 23 recites '*the system*'. There is insufficient antecedent basis for this limitation. It is being interpreted that applicant intended "the method".

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 19-25 and 32-37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

13. Claims 19-25 and 32-37 are not directed to a "process" under 35 U.S.C. §101.

In order for a method to be considered a "process" under 35 U.S.C. §101, a claimed process must either: (1) be tied to a particular machine or apparatus or (2) transform a particular article to a different state or thing. *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584,588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008). If neither of these requirements is met by the claim, the method is not a patent eligible process under 35 U.S.C. §101 and is non-statutory subject matter.

There are two corollaries to these requirements. First, the use of the specific machine or transformation of the article must impose meaningful limits on the claim's scope to impart patent-eligibility. *See Benson*, 409 U.S. at 71-72. Second the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity. *See Flook*, 437 U.S. at 590.

Claims 19-25 and 32-37 are not tied to a particular machine or apparatus, nor do they transform a particular article to a different state or thing.

Claim Rejections - 35 USC § 103

14. 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.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

    1. Determining the scope and contents of the prior art.
    2. Ascertaining the differences between the prior art and the claims at issue.
    3. Resolving the level of ordinary skill in the pertinent art.
    4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. **Examiner's Note**: The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative

of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 19, 21, 22, 23, 24, 25, 32, 33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lilly et al., US Patent Application Publication US 2004/0176985 A1 (Lilly), in view of Reitberg, US Patent Application Publication US 2002/0032581 A1 (Reitberg), in further view of Title 21, Part 314 of the US Code of Federal Regulations (21 CFR 314).

19. Referring to claims 19, 22, 32 and 33, Lilly discloses:

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

- *selecting multiple controls for distribution* (see at least Abstract) *while maintaining a central database* (see at least 0051),
- *the controls selected from the group consisting of*
  - *communicating prescriptions from a physician to a pharmacy* (see at least 0061),
  - *identifying the physicians* [sic] *name, license and DEA (Drug Enforcement Agency) registration information* (see at least 0068),
  - *verifying the prescription* (see at least 0068);
  - *obtaining patient information* (see at least 0068),
  - *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* (see at least 0053),
  - *contacting the patient's insurance company if any* (see at least 0061),
  - *verifying patient registry information* (see at least 0068),
  - *providing comprehensive education information to the patient* (see at least 0053),
  - *verifying the patient has reviewed the educational materials,*
  - *verifying the home address of the patient* (see at least 0068),
  - *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,*
- *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* (see at least Fig. 1 **14**) *for checking for abuse patterns in the data* (see at least 0054)*, cash payments, inappropriate questions;*

While it is part of the regulatory approval process, Lilly does not appear to expressly disclose:

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

Reitberg is in the field of drug trials and teaches predicting drug abuse (0024). It would have been obvious to one of ordinary skill in the art at the time of the

invention to include the predicting abuse feature of Reitberg in the method of Lilly. One would have been motivated to do so because it furthers ensuring the safety of the drug.

Lilly and Reitberg also do not appear to expressly disclose or teach:

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

21 CFR 314 expressly contemplates parties negotiating with the FDA during the drug regulatory approval process (see at least 21 CFR § 314.103(a) [4-1-02 Edition] FDA committed to amicable dispute resolution). It would have been obvious to one of ordinary skill in the art at the time of the invention to include a negotiating feature in the method of Lilly, as modified by Reitberg. One would have been motivated to do so because it furthers a cooperative regulatory approval process.

20. Referring to claim 21, Lilly, Reitberg and 21 CFR 314 disclose or teach all of the limitations of claim 19, and Lilly further discloses their method is for prescription drugs and/or controlled substances (see at least 0032).

21. Referring to claims 23 and 24, Lilly, Reitberg and 21 CFR 314 disclose or teach all of the limitations of claim 22, and Lilly further discloses their method is for

working with the DEA and obtaining regulatory approvals (see at least 0054-0055).

22. Referring to claim 25, Lilly, Reitberg and 21 CFR 314 disclose or teach all of the limitations of claim 22, however, Lilly does not appear to disclose obtaining drug distribution approval from a state regulatory agency. Reitberg's teachings on obtaining drug approvals are not limited to Federal agencies and clearly extend to state agencies (see at least Example 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Lilly, as modified by Reitberg and 21 CFR 314, to include obtaining drug distribution approval from a state regulatory agency. One would have been motivated to do so to obtain full regulatory approval for the given drug in the United States.

23. Referring to claim 36, Lilly, Reitberg and 21 CFR 314 disclose or teach all of the limitations of claim 19, and Lilly further discloses their method is for a central pharmacy (see at least 0061 affiliated or unaffiliated pharmacies).

24. Claims 20, 34, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lilly, in view of Reitberg and 21 CFR 314, as applied to claims 19 and 32 above, and further in view of OFFICIAL NOTICE.

25. Referring to claim 20, Lilly, Reitberg and 21 CFR 314 disclose or teach all of the limitations of claim 19, however, Lilly, Reitberg and 21 CFR 314 do not appear to expressly disclose or teach:

- *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 the patient has reviewed the educational materials*
- *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 pharmacy*
- *flagging repeat instances of lost, stolen, destroyed or spilled prescriptions*

The examiner takes OFFICIAL NOTICE that it is old and well known in the pharmacy business and the pharmaceutical industry to take all of the above-listed controls when shipping drugs. It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the method of Lilly, as modified by Reitberg and 21 CFR 314, to include all of the above-listed controls. One would have been motivated to do so because the controls help to ensure against unauthorized use of prescription drugs.

26. Referring to claim 34, Lilly, Reitberg and 21 CFR 314 disclose or teach all of the limitations of claim 32, and while Lilly discloses a centralized database, Lilly, Reitberg and 21 CFR 314 do not disclose or teach '*the sensitive drug is exclusively distributed by a central pharmacy that uses the central database to track distribution of the sensitive drug*' (emphasis added). The examiner takes OFFICIAL NOTICE that it is old and well known in the pharmaceutical industry to

establish exclusive relationships. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the method of Lilly, as modified by Reitberg and 21 CFR 314, to include an exclusive distribution relationship. One would have been motivated to do so because it simplifies the drug manufacturer's tracking of the distribution of its product.

27. Referring to claims 35 and 37, Lilly, Reitberg and 21 CFR 314 disclose or teach all of the limitations of claims 19 and 34, and while Lilly discloses a central pharmacy, Lilly, Reitberg and 21 CFR 314 do not disclose or teach '*the central pharmacy may ship the sensitive drug to a second pharmacy for pickup when the second pharmacy's ability to protect against diversion before shipping the drug is confirmed'.* The examiner takes OFFICIAL NOTICE that it is old and well known in the pharmacy business to have a central pharmacy serving and monitoring satellite pharmacies. It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the method of Lilly, as modified by Reitberg and 21 CFR 314, to include a central pharmacy serving and monitoring satellite pharmacies. One would have been motivated to do so because it improves the efficiency and integrity of the distribution process.

Conclusion

28. Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Michael Fuelling** whose telephone number is

571.270.1367. The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JAMES A. REAGAN** can be reached at **571.272.6710**.

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://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks

Washington, D.C. 20231

or faxed to **571-273-8300**.

Hand delivered responses should be brought to the **United States Patent and Trademark Office Customer Service Window**:

Randolph Building

401 Dulany Street

Alexandria, VA 22314

/Michael Fuelling/

Examiner

May 22, 2009

Art Unit 4135

/Lynda Jasmin/

Supervisory Patent Examiner, Art Unit 4127

Notice of References Cited	Application/Control No. 11/097,651	Applicant(s)/Patent Under Reexamination REARDAN ET AL.	
	Examiner MICHAEL FUELLING	Art Unit 4135	Page 1 of 1

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	C	US-			
	D	US-			
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	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	21 CFR 314.103
	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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	11/097,651
Filing Date	April 1, 2005
First Named Inventor	Reardan, Dayton
Group Art Unit	3626
Examiner Name	Unknown

Sheet 1 of 1

Attorney Docket No: 101.031US3

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Examiner Initial *	**USP Document Number**	**Publication Date**	**Name of Patentee or Applicant of cited Document**	**Filing Date If Appropriate**
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Examiner Initials*	**Cite No [1]**	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T[2]**
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EXAMINER /Michael Fuelling/ **DATE CONSIDERED** 05/20/2009

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Sheet 1 of 1

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Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T [2]
		"Preliminary Amendment Pursuant to 37 CFR Sec. 1.115", U.S. Application Ser. No. 11/104,013, filed April 12, 2005, (June 17, 2005), 3 pgs.	
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EXAMINER /Michael Fuelling/ **DATE CONSIDERED** 05/20/2009

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

Sheet 1 of 2

Attorney Docket No: 101.031US3

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

Sheet 2 of 2

Attorney Docket No: 101.031US3

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OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
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EXAMINER	/Michael Fuelling/	**DATE CONSIDERED**	05/20/2009

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner:	Unknown
Serial No.:	Unknown	Group Art Unit:	Unknown
Filed:	Herewith	Docket No:	101.031US2
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD		

PRELIMINARY AMENDMENT

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

Prior to taking up this application for examination, please enter the following amendments:

IN THE CLAIMS

Please cancel claims 1-25.

Conclusion

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

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

Respectfully Submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
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Date 11/2/2004 By _____
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Reg. No. 30,837

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

21186 7590 09/14/2009

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

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
09/14/2009	ELECTRONIC

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

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

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

uspto@slwip.com
request@slwip.com

Office Action Summary	Application No.	Applicant(s)	
	11/097,985	REARDAN ET AL.	
	Examiner	Art Unit	
	LENA NAJARIAN	3686	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *01 April 2005*.

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

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

Disposition of Claims

4)☒ Claim(s) *26-31* is/are pending in the application.

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

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-31* is/are rejected.

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

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

Application Papers

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

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

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

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

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20050401; 20061010; 20070104*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 26-31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Under the statute, the claimed invention must fall into one of the four recognized statutory classes of invention, namely, a process (or method); a machine (or system); an article of manufacture; or a composition of matter.

In the present case, claims 26-31 only recite mental steps. In order to qualify as a statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state. The recited steps of independent claim 26 of merely determining current and anticipated patterns of potential prescription abuse of a drug from periodic reports and selecting multiple controls for distribution by an exclusive central pharmacy are not tied to another statutory class (such as a particular apparatus) and do not transform underlying subject matter (such as an article or materials) to a different state or thing. Similar analysis applies for independent claim 29. Therefore, claims 26-31 are deemed to be directed to non-statutory subject matter.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 26-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19, 20, 22, 32-34, and 36 of copending Application No. 11/097651. Although the conflicting claims are not identical, they are not patentably distinct from each other because "GHB" is a form of "sensitive drug" and "selecting multiple controls for distribution by said exclusive central pharmacy" is a form of "selecting multiple controls for distribution while maintaining a central database."

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 26-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-36 of copending Application No. 10/979665. Although the conflicting claims are not identical, they are not patentably distinct from each other because "selecting multiple controls for distribution by said exclusive central pharmacy" is a form of "controlling the distribution of said sensitive drug via an exclusive central pharmacy."

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

6. Claims 26, 27, 29, and 30 are objected to because of the following informalities: "the physicians name" should be changed to "the physician's name" (note line 11 of claims 26 & 29, line 3 of claim 27, and lines 3-4 of claim 30). Appropriate correction is required.

Claim Rejections - 35 USC § 112

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

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

8. Claims 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Regarding claims 26 and 29, the phrase "or similar shipping service" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or similar shipping service"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

10. Claims 26 and 29 recite the limitation "the patient" in lines 7-8, 17-19, and 21 of claim 26 and lines 7, 17-19, and 21 of claim 29. There is insufficient antecedent basis for this limitation in the claims.

11. Claims 27 and 30 recite the limitation "the patient" in lines 8-11 of each claim. There is insufficient antecedent basis for this limitation in the claims.

12. Claims 26 and 29 recite the limitation "the patient's" in line 16 of each claim. There is insufficient antecedent basis for this limitation in the claims.

13. Claims 29 and 30 recite the limitation "the sensitive drug" in line 13 of claim 29 and line 5 of claim 30. There is insufficient antecedent basis for this limitation in the claims.

14. Claims 28 and 31 incorporate the deficiencies of claims 26 and 31, through dependency, and are also rejected.

Claim Rejections - 35 USC § 103

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

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

16. Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1), and further in view of Ukens ("Specialty Pharmacy").

(A) Referring to claim 26, Moradi discloses a method to control abuse of a drug by controlling the distribution thereof via a central pharmacy that maintains a central database that tracks all prescriptions of said drug and analyzes for potential abuse situations, the method comprising (para. 22-24, para. 43, and para. 99 of Moradi):

receiving prescription request data from a medical doctor, wherein said request data contain information identifying the patient, the drug prescribed, and credentials of the doctor (para. 35-36 and para. 116-118 of Moradi); and

selecting multiple controls for distribution by said central pharmacy, controls including verifying the prescription and obtaining patient information (para. 24 and para. 35 of Moradi).

Moradi does not disclose an exclusive central pharmacy, that the drug is a sensitive drug, and determining current and anticipated patterns of potential prescription abuse of said sensitive drug from periodic reports generated by the central database based on prescription request data.

Lilly discloses that the drug is a sensitive drug (para. 2 of Lilly; the Examiner interprets "controlled substance" to be a form of "sensitive drug") and determining current and anticipated patterns of potential prescription abuse of said sensitive drug from periodic reports generated by the central database based on prescription request data (para. 54, para. 57-58, para. 61, para. 69, para. 71, and Fig. 2 of Lilly).

Moradi and Lilly do not expressly disclose an *exclusive* central pharmacy.

Ukens discloses restricting distribution of a specialty medication to only one pharmacy (see page 3, paragraphs 3-5 of Ukens).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Lilly and Ukens within Moradi. The motivation for doing so would have been to provide an accurate view of patient use of prescription drugs, to help protect professionals from lawsuits and other potential liabilities (para. 58 of Lilly) and to limit access to dangerous drugs (page 3, paragraph 5 of Ukens).

Insofar as the claim recites "selected from the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(B) Referring to claim 28, Moradi discloses consulting a separate database to verify that the medical doctor is eligible to prescribe the drug (para. 118 of Moradi).

17. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1), in view of Ukens ("Specialty Pharmacy"), in view of Califano et al. (US 2003/0033168 A1), in view of Wallace et al. (US 6,564,121 B1), in view of Andreasson et al. (US 2003/0160698 A1), and further in view of *Official Notice*.

(A) Referring to claim 27, Moradi discloses wherein initially selected controls comprise communicating prescriptions from a physician to the central pharmacy (para. 23-24 of Moradi); identifying the physicians name, license, and DEA registration information (para. 116-118 of Moradi); verifying the prescription (para. 24 of Moradi); obtaining patient information (para. 35 of Moradi); verifying patient registry information (para. 27 and para. 31 of Moradi); verifying the home address of the patient (para. 40 of Moradi); shipping the drug (para. 6 of Moradi); confirming receipt of an initial shipment of the drug to the patient (abstract of Moradi);

Moradi does not disclose verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; shipping via US postal service; releasing inventory in a controlled manner to the central pharmacy; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; and making the database available to the DEA for checking for abuse patterns in the data.

Lilly discloses making the database available to the DEA for checking for abuse patterns in the data (para. 54 of Lilly).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the aforementioned feature of Lilly within Moradi. The motivation for doing so would have been to determine areas where violations may be occurring (para. 54 of Lilly).

Moradi, Lilly, and Ukens do not disclose verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; shipping via US postal service; releasing inventory in a controlled manner to the central pharmacy; and flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions.

Califano discloses providing comprehensive education information to the patient and verifying the patient has reviewed the educational materials (para. 84 of Califano).

Wallace discloses releasing inventory in a controlled manner to the central pharmacy (col. 26, lines 36-60 of Wallace).

Andreasson discloses flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions (para. 79 of Andreasson).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Califano,

Wallace, and Andreasson within Moradi, Lilly, and Ukens. The motivation for doing so would have been to ensure that the patient knows about the risks and dangers associated with the drug (para. 43 of Califano), so that unauthorized individuals do not have access to the drugs (col. 26, lines 36-55 of Wallace), and to reduce the risk of lost or stolen medical products (para. 79 of Andreasson).

The Examiner takes *Official Notice* that it is old and well-known to ship via the US postal service and to verify the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician.

It would have been obvious to one of ordinary skill in the art at the time of the invention, to ship via US postal service with the motivation of using a reliable shipping service and to consult the National Technical Information Services with the motivation of protecting patients from unethical physicians.

18. Claims 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1), in view of Ukens ("Specialty Pharmacy"), and further in view of Melker et al. (US 2002/017732 A1).

(A) Referring to claim 29, Moradi discloses a method to control abuse of a drug by controlling the distribution thereof via a central pharmacy that maintains a central database that tracks all prescriptions of said drug and analyzes for

potential abuse situations, the method comprising (para. 22-24, para. 43, and para. 99 of Moradi):

receiving prescription request data from a medical doctor, wherein said request data contain information identifying the patient, the drug prescribed, and credentials of the doctor (para. 35-36 and para. 116-118 of Moradi); and

selecting multiple controls for distribution by said central pharmacy, controls including verifying the prescription and obtaining patient information (para. 24 and para. 35 of Moradi).

Moradi does not disclose an exclusive central pharmacy, that the drug is a sensitive drug, and determining current and anticipated patterns of potential prescription abuse of said sensitive drug from periodic reports generated by the central database based on prescription request data.

Lilly discloses that the drug is a sensitive drug (para. 2 of Lilly; the Examiner interprets “controlled substance” to be a form of “sensitive drug”) and determining current and anticipated patterns of potential prescription abuse of said sensitive drug from periodic reports generated by the central database based on prescription request data (para. 54, para. 57-58, para. 61, para. 69, para. 71, and Fig. 2 of Lilly).

Moradi and Lilly do not expressly disclose an *exclusive* central pharmacy.

Ukens discloses restricting distribution of a specialty medication to only one pharmacy (see page 3, paragraphs 3-5 of Ukens).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Lilly and Ukens

within Moradi. The motivation for doing so would have been to ensure that prescribers have an accurate view of their patients' use of prescription drugs, to help protect professionals from lawsuits and other potential liabilities (para. 58 of Lilly) and to limit access to dangerous drugs (page 3, paragraph 5 of Ukens).

Moradi, Lilly, and Ukens do not disclose that the sensitive drug is gamma hydroxy butyrate (GHB).

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

At the time of the invention, it would have been obvious to one of ordinary skill in the art to include the aforementioned feature of Melker within Moradi, Lilly, and Ukens. The motivation for doing so would have been to include drugs of recent concern, such as GHB (para. 3 of Melker).

Insofar as the claim recites "selected from the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(B) Referring to claim 31, Moradi discloses consulting a separate database to verify that the medical doctor is eligible to prescribe the drug (para. 118 of Moradi).

19. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moradi et al. (US 2004/0019794 A1) in view of Lilly et al. (US 2004/0176985 A1), in view of Ukens ("Specialty Pharmacy"), in view of Melker et al. (US 2002/017732 A1), in view of Califano et al. (US 2003/0033168 A1), in view of

Wallace et al. (US 6,564,121 B1), in view of Andreasson et al. (US 2003/0160698 A1), and further in view of *Official Notice*.

(A) Referring to claim 30, Moradi discloses wherein initially selected controls comprise communicating prescriptions from a physician to the central pharmacy (para. 23-24 of Moradi); identifying the physicians name, license, and DEA registration information (para. 116-118 of Moradi); verifying the prescription (para. 24 of Moradi); obtaining patient information (para. 35 of Moradi); verifying patient registry information (para. 27 and para. 31 of Moradi); verifying the home address of the patient (para. 40 of Moradi); shipping the drug (para. 6 of Moradi); confirming receipt of an initial shipment of the drug to the patient (abstract of Moradi);

Moradi does not disclose verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; shipping via US postal service; releasing inventory in a controlled manner to the central pharmacy; flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions; and making the database available to the DEA for checking for abuse patterns in the data.

Lilly discloses making the database available to the DEA for checking for abuse patterns in the data (para. 54 of Lilly).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the aforementioned feature of Lilly within Moradi. The motivation for doing so would have been to determine areas where violations may be occurring (para. 54 of Lilly).

Moradi, Lilly, Ukens, and Melker do not disclose verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; shipping via US postal service; releasing inventory in a controlled manner to the central pharmacy; and flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions.

Califano discloses providing comprehensive education information to the patient and verifying the patient has reviewed the educational materials (para. 84 of Califano).

Wallace discloses releasing inventory in a controlled manner to the central pharmacy (col. 26, lines 36-60 of Wallace).

Andreasson discloses flagging repeat instances of lost, stolen, destroyed, or spilled prescriptions (para. 79 of Andreasson).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Califano, Wallace, and Andreasson within Moradi, Lilly, Ukens, and Melker. The motivation for doing so would have been to ensure that the patient knows about

the risks and dangers associated with the drug (para. 43 of Califano), so that unauthorized individuals do not have access to the drugs (col. 26, lines 36-55 of Wallace), and to reduce the risk of lost or stolen medical products (para. 79 of Andreasson).

The Examiner takes *Official Notice* that it is old and well-known to ship via the US postal service and to verify the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician.

It would have been obvious to one of ordinary skill in the art at the time of the invention, to ship via US postal service with the motivation of using a reliable shipping service and to consult the National Technical Information Services with the motivation of protecting patients from unethical physicians.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a kit for distributing pharmaceutical products (4,976,351).

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is

(571) 272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/LENA NAJARIAN/
Examiner, Art Unit 3686
9/9/09

Notice of References Cited	Application/Control No. 11/097,985	Applicant(s)/Patent Under Reexamination REARDAN ET AL.	
	Examiner LENA NAJARIAN	Art Unit 3686	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,564,121	05-2003	Wallace et al.	700/231
*	B	US-4,976,351	12-1990	Mangini et al.	206/232
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

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	Unknown
Filing Date	Even Date Herewith
First Named Inventor	Reardan, Dayton
Group Art Unit	Unknown
Examiner Name	Unknown

Sheet 1 of 2

Attorney Docket No: 101.031US4

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Filing Date If Appropriate
	US-2001/ 0,001,144	05/10/2001	Kapp, Thomas L.	12/22/2000
	US-2001/ 0,042,050	11/15/2001	Fletcher, Robert J., et al.	01/05/2001
	US-2001/ 0,047,281	11/29/2001	Keresman, III, Michael A., et al.	03/06/2001
	US-2002/ 0,032,581	03/14/2002	Reitberg, donald P.	06/01/2001
	US-2002/ 0,032,582	03/14/2002	Feeney, Jr., Robert J., et al.	08/15/2001
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	US-2003/ 0,046,110	03/06/2003	Gogolak, Victor	08/28/2002
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	US-2003/ 0,093,295	05/15/2003	Lilly, Ralph B., et al.	01/31/2002
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	US-2003/ 0,127,508	07/10/2003	Jones, William N.	01/21/2003
	US-2003/ 0,144,876	07/31/2003	Kosinski, Diana L., et al.	01/28/2002
	US-2003/ 0,229,519	12/11/2003	Eidex, Brian H., et al.	05/16/2003
	US-2003/ 0,233,256	12/18/2003	Cardenas, Rodolfo , et al.	06/13/2002
	US-2004/ 0,019,567	01/29/2004	Herceg, Michael J., et al.	07/23/2002
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	US-2004/ 0,078,237	04/22/2004	Kaafarani, William , et al.	08/28/2003

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

Substitute Disclosure Statement Form (PTO-1449)

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

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

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 0651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*	*Complete if Known*	
	Application Number	Unknown
	Filing Date	Even Date Herewith
	First Named Inventor	Reardan, Dayton
	Group Art Unit	Unknown
	Examiner Name	Unknown
Sheet 2 of 2	Attorney Docket No: 101.031US4	

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

Substitute Disclosure Statement Form (PTO-1449)

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

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

PTO/SB/08A(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	11/097,985
Filing Date	April 1, 2005
First Named Inventor	Reardan, Dayton
Group Art Unit	3626
Examiner Name	Unknown

Sheet 1 of 1

Attorney Docket No: 101.031US4

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

Substitute Disclosure Statement Form (PTO-1449)
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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Application Number	11/097,985
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First Named Inventor	Reardan, Dayton
Group Art Unit	3626
Examiner Name	Unknown

Sheet 1 of 1

Attorney Docket No: 101.031US4

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Examiner Initials*	**Cite No [1]**	**Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.**	**T[2]**
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EXAMINER	/Lena Najarian/	**DATE CONSIDERED**	08/06/2009

Substitute Disclosure Statement Form (PTO-1449)

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	William S. Woods	Examiner: Corey P. Chau
Serial No.:	10/731,915	Group Art Unit: 2644
Filed:	December 10, 2003	Docket No.: 899.009US2
Title:	AUDIO SIGNAL PROCESSING	

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

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

This responds to the Office Action dated October 5, 2004. Please amend the above-identified patent application as follows.

This response is accompanied by a Petition, as well as the appropriate fee, to obtain a one-month extension of the period for responding to the Office action, thereby moving the deadline for response from 5 January 2005 to 5 February 2005.

IN THE CLAIMS

Please amend the claims as follows:

1. (Original) A method of processing audio signals comprising:

processing an input audio signal having one or more feedback components associated with an acoustic feedback path to provide a processed signal;

detecting a feedback component of the one or more feedback components in the input audio signal;

generating a narrowband subaudible probe signal using the processed signal and the detected feedback component;

feeding forward the generated narrowband subaudible probe signal to an output for the processed signal to probe the acoustic feedback path with an acoustic subaudible probe signal; and

adjusting a feedback-inhibiting filter using the narrowband subaudible probe signal to inhibit the feedback component in the input audio signal.

2. (Original) The method of claim 1, wherein the method further includes selectively delaying the processed signal to compensate for a delay in generating the narrowband subaudible probe signal to allow for the use of a high amplitude level in the narrowband subaudible probe signal.

3. (Original) The method of claim 1, wherein the method further includes forming the narrowband subaudible probe signal by:

filtering the processed signal with a notch filter having a bandwidth to form a filtered signal, the notch filter configured to center its bandwidth on a bandwidth of the detected feedback component; and

sending a subaudible narrowband signal having a first bandwidth into the filtered signal to form the narrowband subaudible probe signal having a second bandwidth to probe the feedback path.

4. (Original) The method of claim 3, wherein the method further includes:

comparing the narrowband subaudible probe signal to the input audio signal; and

adjusting the inhibiting filter in response to the comparison to inhibit the feedback component.

5. (Currently Amended) The method of claim 3, wherein the method further includes selectively turning off filtering the processed signal with ~~the operation of~~ the notch filter when the inhibiting filter is adjusted.

6. (Original) The method of claim 3, wherein the method further includes sending the narrowband subaudible probe signal at a level determined using an audibility model.

7. (Original) The method of claim 6, wherein sending the narrowband subaudible probe signal at a level determined using an audibility model includes sending the narrowband subaudible probe signal at a level about equal to a criterion level of the audibility model.

8. (Original) The method of claim 6, wherein sending the narrowband subaudible probe signal at a level determined using an audibility model includes sending the narrowband subaudible probe signal at a level below a criterion level of the audibility model.

9. (Currently Amended) ~~The method of claim 1~~ A method of processing audio signals comprising:

processing an input audio signal having one or more feedback components associated with an acoustic feedback path to provide a processed signal;

detecting a feedback component of the one or more feedback components in the input audio signal;

generating a narrowband subaudible probe signal using the processed signal and the detected feedback component;

feeding forward the generated narrowband subaudible probe signal to an output for the processed signal to probe the acoustic feedback path with an acoustic subaudible probe signal; and

adjusting a feedback-inhibiting filter using the narrowband subaudible probe signal to inhibit the feedback component in the input audio signal, wherein the method further includes forming the narrowband subaudible probe signal by:

generating an amplitude signal that is indicative of an amplitude level for the probe signal;

generating a frequency signal that is indicative of a frequency for the probe signal; and

generating a sinusoidal signal that is based on the amplitude signal and the frequency signal.

10. (Original) The method of claim 9, wherein generating an amplitude signal includes:

filtering the processed signal with a bandpass filter to form a filtered signal;

rectifying the filtered signal to form a rectified signal; and

multiplying the rectified signal with an empirical constant to provide the amplitude signal.

11. (Original) The method of claim 9, wherein generating a frequency signal includes:

dividing a feedback indicator parameter by two to provide a first divided signal;

taking the arccosine of the first divided signal to provide an arccosine signal;

multiplying the arccosine signal with a sampling rate to provide a multiplied signal; and

dividing the multiplied signal by 2 times pi to provide the frequency signal.

12. (Currently Amended) ~~The method of claim 1~~ A method of processing audio signals comprising:

processing an input audio signal having one or more feedback components associated with an acoustic feedback path to provide a processed signal;

detecting a feedback component of the one or more feedback components in the input audio signal;

generating a narrowband subaudible probe signal using the processed signal and the detected feedback component;

feeding forward the generated narrowband subaudible probe signal to an output for the processed signal to probe the acoustic feedback path with an acoustic subaudible probe signal; and

adjusting a feedback-inhibiting filter using the narrowband subaudible probe signal to inhibit the feedback component in the input audio signal, wherein adjusting a feedback-inhibiting filter includes:

modeling a response of the acoustic feedback path to provide a sample that is indicative of the response of the feedback path;

transforming selectively the sample by using a discrete-Fourier-transform to obtain a filter coefficient; and

providing one ore more filter coefficients to the feedback-inhibiting filter.

13. (Original) The method of claim 12, wherein modeling a response includes:

transforming a feedback indicator parameter and the audio input signal to provide a first complex signal having a first phase and a first amplitude; and

transforming the feedback indicator parameter and an output signal to provide a second complex signal having a second phase and second amplitude.

14. (Original) The method of claim 13, wherein modeling further comprises:

determining a difference between the first and the second phase by subtraction to provide a difference signal; and

determining a ratio between the first amplitude and the second amplitude by division to provide a ratio signal.

15. (Original) The method of claim 14, wherein modeling further comprises forming the sample from the difference signal and the ratio signal.

16. (Currently Amended) The method of claim ~~17~~ 15, wherein modeling further comprises averaging the sample.

17. (Original) A system for enhancing audio signals comprising:

a signal processor for processing an input audio signal to provide a processed signal, the input audio signal having a feedback component, the feedback component associated with an acoustic feedback path;

a detector to detect the feedback component in the input audio signal;

a probe generator to generate a probe signal using the processed signal and a signal provided by the detector in response to the detector detecting the feedback component;

an inhibiting filter to inhibit the feedback component in the input audio signal; and

an output to output a narrowband subaudible probe signal formed from the probe signal fed forward from the probe generator, the narrowband subaudible probe signal used to probe the acoustic feedback path with an acoustic subaudible probe signal.

18. (Original) The system of claim 17, wherein the system further includes a switch to selectively provide the output with the processed signal or the narrowband subaudible probe signal.

19. (Original) The system of claim 17, wherein the signal processor includes a compressive amplifier.

20. (Original) The system of claim 17, wherein the system further includes a combiner to subtract a derived signal from the input audio signal, the derived signal representing a version of the feedback component, the derived signal provided by the inhibiting filter approximating a response of the acoustic feedback path.

21. (Original) The system of claim 17, wherein the detector is adapted to determine when the acoustic feedback path will be probed.

22. (Original) The system of claim 17, wherein the detector is adapted to determine a range of frequencies at which the acoustic feedback path will be probed.

23. (Original) The system of claim 17, wherein the system further includes:

a notch filter to filter the processed signal to provide a filtered signal, the notch filter responsive to a feedback parameter from the detector; and

a combiner to combine the filtered signal and the probe signal to feed forward the narrowband subaudible probe signal to the output.

24. (Original) The system of claim 23, wherein the detector is configured to provide a plurality of feedback parameters, and the notch filter is responsive to the plurality of feedback parameters.

25. (Original) The system of claim 23, wherein the system further includes a delay coupled to the signal processor to provide the processed signal to the notch filter.

26. (Original) The system of claim 23, wherein the notch filter has a bandwidth, the notch filter configured to center its bandwidth on a bandwidth of the detected feedback component.

27. (Original) The system of claim 17, wherein the probe generator is configured to generate the probe signal with a bandwidth centered on a bandwidth of the feedback component in the input audio signal.

28. (Original) The system of claim 17, wherein the probe generator is configured to generate a plurality of signals that are combined to form a probe signal used to probe the acoustic feedback path.

29. (Currently Amended) ~~The system of claim 17~~ A system for enhancing audio signals comprising:

a signal processor for processing an input audio signal to provide a processed signal, the input audio signal having a feedback component, the feedback component associated with an acoustic feedback path;

a detector to detect the feedback component in the input audio signal;

a probe generator to generate a probe signal using the processed signal and a signal provided by the detector in response to the detector detecting the feedback component;

an inhibiting filter to inhibit the feedback component in the input audio signal; and

an output to output a narrowband subaudible probe signal formed from the probe signal fed forward from the probe generator, the narrowband subaudible probe signal used to probe the acoustic feedback path with an acoustic subaudible probe signal, wherein the probe generator includes:

an input to receive a feedback indicator parameter from the detector;

an amplitude indicator to indicate an amplitude level of the probe signal, wherein the amplitude indicator provides an amplitude signal;

a frequency indicator to indicate a frequency of the probe signal, wherein the frequency indicator provides a frequency signal; and

a signal generator receptive to the amplitude signal and the frequency signal to generate the probe signal.

30. (Original) The system of claim 29, wherein the amplitude indicator includes:

a bandpass filter receptive to the processed signal to provide a filtered signal;

a full-wave rectifier receptive to the filtered signal to provide a rectified signal; and

a multiplier receptive to the rectified signal and an empirical constant to provide the amplitude signal.

31. (Original) The system of claim 30, wherein the bandpass filter has a bandpass about 150 Hertz wide.

32. (Original) The system of claim 30, wherein the amplitude signal is about 0 to about –3 dB relative to a level of the filtered signal of the bandpass filter.

33. (Original) The system of claim 30, wherein the empirical constant ranges from about 0.71 to about 1.0.

34. (Original) The system of claim 30, wherein the bandpass filter is configured with a predetermined response to attenuate an amplitude level of the probe signal.

35. (Original) The system of claim 29, wherein the frequency indicator includes:

a first divider to divide the feedback indicator parameter by two to provide a first divided signal;

an arccosine function to take the arccosine of the first divided signal to provide an arccosine signal;

a multiplier receptive to the arccosine signal and a system sampling rate to provide a multiplied signal; and

a second divider to divide the multiplied signal by 2 times pi to provide the frequency signal.

36. (Original) The system of claim 29, wherein the frequency signal is a constant value.

37. (Original) The system of claim 29, wherein the signal generator is a sinusoidal generator.

38. (Original) The system of claim 29, wherein the signal generator is a narrowband noise generator.

39. (Original) The system of claim 17, wherein the system further includes a filter adjuster responsive to the detector to adjust the inhibiting filter.

40. (Original) The system of claim 39, wherein the filter adjuster is configured to compare the input audio signal and an output signal delayed from the output to determine amplitude and phase responses of the acoustic feedback path at a selected probe frequency.

41. (Original) The system of claim 39, wherein the filter adjuster is configured to provide the inhibiting filter with a set of filter coefficients from the filter adjuster.

42. (Currently Amended) ~~The system of claim 39~~ A system for enhancing audio signals comprising:

a signal processor for processing an input audio signal to provide a processed signal, the input audio signal having a feedback component, the feedback component associated with an acoustic feedback path;

a detector to detect the feedback component in the input audio signal;

a probe generator to generate a probe signal using the processed signal and a signal provided by the detector in response to the detector detecting the feedback component;

an inhibiting filter to inhibit the feedback component in the input audio signal; and

an output to output a narrowband subaudible probe signal formed from the probe signal fed forward from the probe generator, the narrowband subaudible probe signal used to probe the acoustic feedback path with an acoustic subaudible probe signal, wherein the system further includes a filter adjuster responsive to the detector to adjust the inhibiting filter, wherein the filter adjuster is configured to provide the inhibiting filter with a set of discrete-Fourier-transformed filter coefficients.

43. (Original) The system of claim 39, wherein the filter adjuster includes a modeler receptive to the narrowband subaudible probe signal from the output, a feedback indicator parameter, and the input audio signal to model a response of the acoustic feedback path when the acoustic feedback path is probed with the acoustic subaudible probe signal at a predetermined frequency.

44. (Currently Amended) The system of claim 43 A system for enhancing audio signals comprising:

a signal processor for processing an input audio signal to provide a processed signal, the input audio signal having a feedback component, the feedback component associated with an acoustic feedback path;

a detector to detect the feedback component in the input audio signal;

a probe generator to generate a probe signal using the processed signal and a signal provided by the detector in response to the detector detecting the feedback component;

an inhibiting filter to inhibit the feedback component in the input audio signal; and

an output to output a narrowband subaudible probe signal formed from the probe signal fed forward from the probe generator, the narrowband subaudible probe signal used to probe the acoustic feedback path with an acoustic subaudible probe signal, wherein the system further includes a filter adjuster responsive to the detector to adjust the inhibiting filter, wherein the filter adjuster includes a modeler receptive to the narrowband subaudible probe signal from the output, a feedback indicator parameter, and the input audio signal to model a response of the acoustic feedback path when the acoustic feedback path is probed with the acoustic subaudible probe signal at a predetermined frequency, wherein the modeler includes:

a first Goertzel transformer receptive to the feedback indicator parameter and the input audio signal to provide a first complex signal having a first phase and a first amplitude; and

a second Goertzel transformer receptive to the feedback indicator parameter and the narrowband subaudible probe signal to provide a second complex signal having a second phase and a second amplitude.

45. (Original) The system of claim 44, wherein the modeler further includes:

a combiner to subtract the first phase and the second phase to provide a difference signal; and

a divider to divide the first amplitude and the second amplitude to provide a ratio signal.

46. (Original) The system of claim 45, wherein the difference signal and the ratio signal form a sample representing the response of the acoustic feedback path to the acoustic subaudible probe signal.

47. (Original) The system of claim 46, wherein the sample is averaged.

48. (Original) The system of claim 47, wherein the filter adjuster further includes a discrete-Fourier-transformer to transform the sample to obtain a filter coefficient.

49. (Original) The system of claim 17, the processed signal includes an environmental context of a listener.

REMARKS

This is in response to the Office Action dated October 5, 2004.

Claims 5, 9, 12, 16, 29, 42, and 44 are amended, no claims are canceled, and no claims are added; as a result, claims 1-49 are now pending in this application. The amendments to the claims are fully supported by the specification as originally filed. No new matter is introduced. The amendments are made to clarify the claims. Applicant respectfully requests reconsideration of the above-identified application in view of the amendments above and the remarks that follow.

Objection to the Claims

Claim 16 was objected to due to an informality. Claim 16 is amended to overcome this objection. Applicant respectfully requests withdrawn of this objection to claim 16, and reconsideration and allowance of this claim.

Double Patenting Rejection

Claims 1 and 3-8 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-7 of co-pending Application No. 09/393,463 in view of "Feedback Cancellation in Hearing Aids: Results from a Computer Stimulation", by Kates and in further view of Kuo (U.S. Patent No. 6,097,823).

Claims 1, 2 and 9-16 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 36-39 and 46-50 of co-pending Application No. 09/393,463 in view of "Feedback Cancellation in Hearing Aids: Results from a Computer Stimulation", by Kates and in further view of Kuo (U.S. Patent No. 6,097,823).

Claims 17-49 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-15, 18-21, 23-35 and 40-45 of co-pending Application No. 09/393,463.

Applicant will address these rejections when the claims are otherwise indicated as allowable.

§112 Rejection of the Claims

Claim 5 was rejected under 35 USC § 112, second paragraph, as being indefinite.

Claim 5 is amended. Applicant submits that claim 5 satisfies 35 USC § 112 and respectfully requests withdrawn of this rejection to claim 5, and reconsideration and allowance of this claim.

§103 Rejection of the Claims

Claims 1, 3, 4, 5, 17, 18, 20-22, 41 and 43 were rejected under 35 USC § 103(a) as being unpatentable over "Feedback Cancellation in Hearing Aids: Results from a Computer Stimulation", by Kates in view of Kuo (U.S. Patent No. 6,097,823).

Claims 1-4, 6-8, 17, 19-20, 23, 25, 27-28, 39-41 and 49 were rejected under 35 USC § 103(a) as being unpatentable over Goodings et al. (U.S. Patent No. 5,259,033) in view of Kuo (U.S. Patent No. 6,097,823).

Claims 1, 17, 23, 24, 26 and 28 were rejected under 35 USC § 103(a) as being unpatentable over Finn et al. (U.S. Patent No. 6,496,581) in view of Goodings et al. (U.S. Patent No. 5,259,033), and further in view of Kuo (U.S. Patent No. 6,097,823).

Applicant traverses these grounds of rejection of these claims. Further, Applicant reserves the right to swear behind Kuo and Finn et al. (hereafter Finn) at a later date.

With respect to claim 19, in the Office Action, it is stated that "Thurmond for example, discloses a compressor." Applicant cannot find in the Office Action a citation for Thurmond with respect to a U.S. patent number, an international patent number, or other citation of publication. Applicant respectfully requests that a reference citation identifying the Thurmond reference be provided.

In the Office Action, Kuo is cited in all rejections with respect to a narrowband probe. In the Office Action, it is stated, with respect to Kuo, that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a generator that generates a chirp signal (i.e. a chirp signal is an equivalent probe signal wherein at an instantaneous moment it is a narrow band signal) to inject into the system as a probe signal." Applicant respectfully disagrees. Applicant submits that a narrowband signal is different from an instantaneous moment of a chirp signal. Additional features must be applied to the chirp

signal to use the instantaneous moment of a chirp signal as a narrowband signal, such as processing the chirp signal to obtain the instantaneous moment as a narrowband signal for use as a probe signal. Applicant cannot find a teaching or a suggestion of such additional features in the cited references. Further, no reference or objective evidence has been provided in the Office Action to support the statement quoted above. Applicant submits that the only teaching, suggestion, and motivation of record regarding a narrowband signal for use as recited in independent claims 1and 17 is provided in the Applicant's disclosure. Therefore, Applicant submits that the cited combinations of references do not teach or suggest all the elements of claims 1 or 17. Thus, Applicant submits that claims 1 and 17 are patentable over the cited references for at least the reasons stated above. Further, the claims dependent on independent claims 1 and 17 are patentable over the cited references for at least the reasons stated above.

Applicant respectfully requests withdrawal of these rejections of claims 1-8, 17-28, 39-41, 43, and 49 and reconsideration and allowance of these claims.

Allowable Subject Matter

Claims 9-16, 29-38, 42, and 44-48 were objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 9, 12, 29, 42, and 44 are amended into independent form including all of the limitations of the base claim and any intervening claims. Claims 10 and 11, claims 13-16, claims 30-38, and claims 45-48 depend on claims 9, 12, 29, and 44, respectively. Thus, Applicant submits that claims 10, 11, 13-16, 30-38, and 45-48 are patentable.

Applicant respectfully requests withdrawal of these objections to claims 9-16, 29-38, 42, and 44-48, and reconsideration and allowance of these claims.

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) 371-2157 to facilitate prosecution of this application.

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

Respectfully submitted,

WILLIAM S. WOODS

By his Representatives,

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Date 2 February 2005 By David R. Cochran
David R. Cochran
Reg. No. 46,632

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 of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 2 day of February, 2005.

Paula Suchy
Name

Paula Suchy
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner: Michael Fuelling
Serial No.:	11/097,651	Group Art Unit: 4135
Filed:	April 1, 2005	Docket No.: 101.031US3
Customer No.: 21186		Confirmation No.: 6798
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD	

AMENDMENT & RESPONSE UNDER 37 C.F.R. § 1.111

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

In response to the Office Action dated May 29, 2009, please amend the application as follows.

This response is accompanied by a Petition, as well as the appropriate fee, to obtain a one-month extension of the period for responding to the Office action, thereby moving the deadline for response from August 29, 2009 to September 29, 2009.

IN THE CLAIMS

Please amend the claims as follows:

Claims 1-18 (Cancelled)

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

using a computer processor for determining current and anticipated patterns of potential abuse of the sensitive drug;

using the computer processor for selecting multiple controls for distribution while maintaining a central database, the controls comprising controls beyond the controls for traditional drugs based on the sensitivity of the drug, the controls selected from the group consisting of communicating prescriptions from a physician to a pharmacy, identifying the ~~physicians~~ physician's name, license and DEA (Drug Enforcement Agency) registration information, verifying the prescription; obtaining patient information, verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and 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, 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 in the database, cash payments stored in the database, inappropriate questions stored in the database;

displaying the selected controls to an output device; and

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

20. (Currently Amended) The method of claim 19 wherein initially selected controls comprise communicating prescriptions from a physician a pharmacy, identifying the ~~physicians~~ physician's name, license and DEA registration information, verifying the prescription; obtaining patient information, verifying the physician is eligible to prescribe the sensitive drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and 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 pharmacy, flagging repeat instances of lost, stolen, destroyed or spilled prescriptions, and making the database available to the DEA for checking for abuse patterns in the data.

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

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

using a computer processor for determining current and anticipated patterns of potential abuse of the sensitive drug;

using the computer processor for selecting multiple controls for distribution of the sensitive drug, the controls comprising controls beyond the controls for traditional drugs based on the sensitivity of the drug;

displaying the selected controls to an output device; and

using the computer processor for 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. (Currently Amended) The method of claim 22 wherein the method ~~system~~ allows marketing of a drug product pursuant to FDA subpart 4 regulation embodied in Title 21, CFR Part 314.

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

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

Claims 26-31 (Cancelled)

32. (Previously Presented) The method of claim 22 wherein the distribution of the sensitive drug is monitored by use of a central database that tracks all distribution of the sensitive drug.

33. (Previously Presented) The method of claim 32 wherein each pharmacy distributing the sensitive drug uses the central database to track distribution of the sensitive drug.

34. (Previously Presented) The method of claim 32 wherein the sensitive drug is exclusively distributed by a central pharmacy that uses the central database to track distribution of the sensitive drug.

35. (Previously Presented) The method of claim 34 wherein the central pharmacy may ship the sensitive drug to a second pharmacy for pickup when the second pharmacy's ability to protect against diversion before shipping the drug is confirmed.

36. (Previously Presented) The method of claim 19 wherein the pharmacy is a central pharmacy.

37. (Previously Presented) The method of claim 36 wherein the central pharmacy may ship the sensitive drug to a second pharmacy for pickup when the second pharmacy's ability to protect against diversion before shipping the drug is confirmed.

REMARKS

This responds to the Office Action dated May 29, 2009.

Claims 19, 20, 22, and 23 are currently amended, no claims are currently canceled, claims 1-18 and 26-31 have previously been canceled, and no claims are currently added; as a result, claims 19-25 and 32-37 are now pending and subject to examination in this application.

Claim Objections

Claims 19 and 20 were objected to as allegedly being informal. Appropriate correction has been made. The Applicant respectfully requests the withdrawal of the objection to claims 19 and 20.

§ 101 Rejection of the Claims

Claims 19-25 and 32-37 were rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter.

The Applicant has amended claim 19. Support for the amendments to claim 19 can be found in the specification at p. 5, lines 3-21, p. 12, lines 4-9, in FIG. 1, Nos. 110, 150, and in FIGS. 13A and 13B.

Claim 19 has been amended in the body of the claim to recite "using a computer processor for determining current and anticipated patterns of potential abuse of the sensitive drug; and using the computer processor for selecting multiple controls for distribution while maintaining a central database." Claim 19 has further been amended to recite "displaying the selected controls to an output device." The Applicant respectfully submits that these amendments tie the recited process to a particular machine, and recite a concrete, tangible, and useful result. The Applicant respectfully requests the withdrawal of the rejection of claim 19 under 35 U.S.C. § 101.

Claim 22 has been amended in a fashion similar to claim 19 to recite "using a computer processor for determining current and anticipated patterns of potential abuse of the sensitive drug; using the computer processor for selecting multiple controls for distribution of the sensitive drug; displaying the selected controls to an output device; and using the computer processor for

adding additional controls . . ." The Applicant respectfully submits that for the same and/or similar reasons as for claim 19, the amendments to claim 22 overcome the rejection of claim 22 under 35 U.S.C. § 101, and respectfully requests the withdrawal of the rejection of claim 22.

§ 112 Rejection of the Claims

Claims 19-21, 23, 36 and 37 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

The Applicant has amended claim 19 to overcome the rejection under 35 U.S.C. § 112, second paragraph. The Applicant respectfully requests the withdrawal of the rejection.

The Applicant has amended claim 23 to overcome the rejection under 35 U.S.C. § 112, second paragraph. The Applicant respectfully requests the withdrawal of the rejection.

§ *103 Rejection of the Claims*

Claims 19, 21, 22-25, 32, 33 and 36 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Lilly et al. (U.S. Patent Application Publication No. 2004/0176985 A1) in view of Reitberg (U.S. Patent Application Publication No. 2002/0032581 A1), in further view of Title 21, Part 314 of the U.S. Code of Federal Regulations (21 CFR 314). The Applicant respectfully traverses this rejection.

The Applicant respectfully submits that a *prima facie* case of obvious has not been established for at least three reasons.

First, the claimed invention, the Lilly reference, and the Reitberg reference are all directed to different subject matter. Specifically, the claimed invention is directed to a method for obtaining FDA approval for a sensitive drug as recited in the preamble of claim 19. This method is implemented by "negotiating with the FDA and adding further controls from the group [of specifically recited controls]" as recited in the body of the claim. In contrast, the Lilly reference is directed to a controlled substance tracking system, and the Reitberg reference is directed to a single patient drug trial. The Applicant respectfully submits that the differences between both a controlled substance tracking system as in Lilly, and a single patient drug trial as in Reitberg, are too great to establish a *prima facie* case of obviousness for the claimed system of obtaining FDA approval for a sensitive drug.

Second, it would not have been obvious to combine the Lilly reference with the Reitberg reference because the two references themselves are directed to two different areas. The Lilly reference is directed to a controlled substance tracking system, while the Reitberg reference is directed to single patient drug trials. The Applicant respectfully submits that it would not have been obvious for one of skill in the art, at the time that the invention was made, to combine the Reitberg reference relating to predicting abuse potential in a single patient drug trial with the Lilly reference that relates to a controlled substance tracking system. While one of skill in the art may understand from Reitberg the need to anticipate patterns of potential abuse in a trial of a new drug, it would not be apparent to one of skill in the art to anticipate such patterns for the distribution of approved prescriptions in Lilly.

Third, the Applicant respectfully submits that a *prima facie* case of obviousness is not established via the citation of 21 CFR 314.103(a), which provides that the FDA should be committed to amicable dispute resolution. The Applicant respectfully submits that a general statement that the FDA is or should be committed to amicable dispute resolution is not a disclosure of the specifically claimed "negotiating with the FDA by adding further controls from the group," wherein the group includes such things as "receiving the name of an at least 18 year old designee to receive the drug" and "returning the drug to the pharmacy after two attempts to deliver."

Additionally, the Applicant has amended the claims to more particularly point out and distinctly claim the subject matter that the Applicant regards as his invention. Specifically, the Applicant has amended the claims to recite "the controls comprising controls beyond the controls for traditional drugs based on the sensitivity of the drug."[1] The Applicant respectfully submits that neither Lilly nor Reitberg discloses this feature, and for this additional reason, the Applicant respectfully submits that the claims are not unpatentable over Lilly and Reitberg under 35 U.S.C. § 103.

For at least these reasons, the Applicant respectfully submits that a *prima facie* case of obviousness has not been established, and the Applicant respectfully requests the withdrawal of the rejection of the claims.

[1] Support for this amendment can be found in the specification at page 2, lines 4-5.

Claims 20, 34, 35 and 37 were rejected under 35 U.S.C. § 103(a) as being obvious over Lilly et al. (U.S. Patent Application Publication No. 2004/0176985 A1) in view of Reitberg (U.S. Patent Application Publication No. 2002/0032581 A1) as applied to claims 19 and 32, and further in view of official notice. The Applicant respectfully traverses this rejection.

Claims 20, 34, 35, and 37 depend either on independent claim 19 or independent claim 22, which as indicated above, are believed allowable. The Applicant therefore respectfully submits that for at least this reason, claims 20, 34, 35, and 37 are also allowable, and the Applicant respectfully requests a notice to that effect.

CONCLUSION

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

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

Respectfully submitted,

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Date September 17, 2009 By / /
David D'Zurilla
Reg. No. 36,776

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 17 day of September, 2009.

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

REMARKS

This responds to the Office Action dated October 18, 2006, the Advisory Action dated February 5, 2007, and the decision of the Board of Patent Appeals and Interferences dated August 31, 2009.

Claims 32, 33, and 38-42 are currently amended; no claims are currently canceled; and no claims are currently added; as a result, claims 32-42 are pending and subject to examination in this application.

Interview Summary

The Applicant expresses its gratitude to Examiner Najarian for the courtesies extended to the Applicant's representatives Mr. Bradley Forrest and Mr. David D'Zurilla during an in-person interview at the United States Patent Office on October 15, 2009.

The Applicant's representatives discussed with Examiner Najarian the Board decision of August 31, 2009, and in particular the Board's holding that the Lilly reference disclosed an exclusive data storage because in the Board's view the database in Lilly contains all relevant data related to the distribution of a drug and the process of distributing it. The Applicant's representatives discussed with Examiner Najarian the amendment to the claims in response to this holding by the Board. Specifically, the Applicant has amended the claims so that the prescriptions are received only at the central pharmacy and that all prescriptions are processed only by the exclusive pharmacy and using only the exclusive computer database.

The Applicant's representatives discussed with Examiner Najarian a further amendment to the claims in which the computer system determines that the sensitive drug is mailed to patients only if no potential abuse is found. The Applicant's representatives note that no potential abuse is found when no abuse has been found by both the patient and the doctor.

The Applicant's representatives further discussed the extensive approval process that the Applicant and the Food and Drug Administration (FDA) were involved in relating to a new indication for the drug gamma hydroxyl butyrate (GHB), and how the patent application was borne out of this FDA approval process.

Examiner Najarian expressed her concerns that the Ukens reference disclosed a single pharmacy, that the claims did not specifically recite that the computer system executed the steps of the claimed method, that the claims did not identify the potential abuse, and that the Lilly reference discloses in paragraph [0054] multi-source interstate prescriptive medication abuse.

No agreement on the claims or the claim amendments was reached.

§103 Rejection of the Claims

Claims 32, 38 and 42 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) and further in view of Ukens ("Specialty Pharmacy").

The Applicant has amended claim 32 to recite the additional features of:

> "receiving in a computer processor all prescription requests, for any and all patients being prescribed the sensitive drug, only at the exclusive central pharmacy from any and all medical doctors allowed to prescribe the sensitive drug . . . ;
>
> requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations, such that all prescriptions for the sensitive drug are processed only by the exclusive central pharmacy using only the exclusive computer database;
>
> . . . checking with the computer processor the credentials of the any and all doctors;
>
> . . . ~~only~~ mailing the sensitive drug to the patient only if no potential abuse is found by the patient to whom the sensitive drug is prescribed and the doctor prescribing the sensitive drug".

Support for the amendment that recites "receiving in a computer processor all prescription requests, for any and all patients being prescribed the prescription drug, only at the exclusive central pharmacy from any and all medical doctors allowed to prescribe the sensitive drug" can be found in the specification at page 1, lines 27-29.

Support for the amendment that recites ". . . such that all prescriptions for the sensitive drug are processed only by the exclusive central pharmacy using only the exclusive computer database" can be found in the specification at page 1, lines 27-28 and page 4, line 29 – page 5, line 1.

Support for the amendment that recites "mailing the sensitive drug to the patient only if no potential abuse is found by the patient to whom the sensitive drug is prescribed and the doctor prescribing the sensitive drug" can be found in the specification at page 1, lines 27-31.

The Applicant respectfully submits that these amendments differentiate the claimed subject matter over the references of record at least because none of the references of record, either alone or in combination, discloses "that all prescriptions for [a] sensitive drug are processed only by [an] exclusive central pharmacy using only [an] exclusive computer database" and "mailing the sensitive drug to the patient only if no potential abuse is found by the patient to whom the sensitive drug is prescribed and the doctor prescribing the sensitive drug."

The Moradi reference does not disclose these features. While the Moradi reference discloses a central service station that is used in an automated prescription delivery system,[1] Moradi does not disclose that all prescriptions for a sensitive drug, or all prescriptions for any other drug for that matter, are processed ***only*** by the central service station. That is, Moradi does not disclose, teach, or suggest requiring that a drug be distributed only through its disclosed system. Moradi also does not disclose that a drug is mailed to a patient only if no potential abuse is found by both the patient and the doctor.

The Lilly reference does not disclose these features. The Lilly reference discloses a data storage 122, and even states that it relates to a centralized method for tracking and managing prescriptive medication information.[2] However, Lilly does not disclose that all drugs are processed by its system or method using its data storage 122. Rather, as disclosed by Lilly, each user (such as a doctor, hospital, or pharmacy) may maintain its own database, and the data storage 122 can maintain a copy of this data which is used by the system, or the system can obtain the data by accessing a user's database.[3] In other words, Lilly discloses that each user maintains its own database, and while a user can access the data storage 122 to try to find out

[1] Moradi, ¶ [0006].
[2] Lilly, ¶¶ [0050] and [0061].
[3] Lilly, ¶ [0061].

information about a patient, there is no disclosure in Lilly that all prescriptions for a particular drug must use ***only*** the database 122. Rather, a user could simply use its own database, without any concern for abuse or liability, or use its own database and the database 122. In contrast, the claimed subject matter recites that all prescriptions are processed ***only*** by a central pharmacy using ***only*** an exclusive database. Further, Lilly does not disclose that a drug is mailed to a patient only if no potential abuse is found by both the patient and the doctor.

The Califano reference does not disclose these features. The Califano reference relates to managing informed consent processes in clinical trials or medical procedures. The Applicant respectfully submits that it does not disclose a system or method wherein "all prescriptions for [a] sensitive drug are processed only by [an] exclusive central pharmacy using only [an] exclusive computer database" or "mailing the drug to the patients only if no potential abuse is found by the patient to whom the drug is prescribed and the doctor prescribing the sensitive drug" as is recited in claim 32.

The Ukens reference does not disclose the feature that a drug is mailed to a patient only if no potential abuse is found by both the patient and the doctor.

Moreover, even if all the elements of the claimed subject matter were disclosed in the cited references, and the Applicant respectfully reiterates that none of the references, either alone or in combination, discloses "all prescriptions for [a] sensitive drug are processed only by [an] exclusive central pharmacy using only [an] exclusive computer database" and "mailing the sensitive drug to the patients only if no potential abuse is found by the patient to whom the sensitive drug is prescribed and the doctor prescribing the sensitive drug," the Applicant respectfully submits that a *prima facie* case of obviousness still does not exist. The cited references, taken as a whole, simply would not have lead one of skill in the art to come up with the claimed subject matter.

Specifically, the Moradi reference relates to the distribution of a plurality of prescription medicines, and in particular, after validating the prescription and selecting a delivery location based on the location of the patient, the prescribed medicine is delivered to the patient.[4] And while there is a check in Moradi to prevent prescription abuse, the check is only of an individual

[4] Moradi, Abstract.

patient to determine if that patient is permitted to have a prescription filled twice.[5] This is much different than a system in which "all prescriptions for [a] sensitive drug are processed only by [an] exclusive central pharmacy using only [an] exclusive computer database" and wherein the sensitive drug is mailed to the patient only if no potential abuse is found by "the patient to whom the sensitive drug is prescribed and the doctor prescribing the sensitive drug" as is recited in claim 32.

Similarly, the Lilly reference relates to tracking prescriptions only on a per patient basis. Specifically, the Lilly system and method allows a determination of a "complete prescriptive medication history of ***the*** patient"[6] by "obtaining a medication history of ***a selected prescription medication purchaser*** for all prescriptive medicines purchased by ***the selected prescriptive medication purchaser*** from all of the plurality of unaffiliated pharmacies based on the transferred pharmaceutical computer data."[7] So, like in Moradi, Lilly focuses on a single patient. This is much different than a system in which "all prescriptions for [a] sensitive drug are processed only by [an] exclusive central pharmacy using only [an] exclusive computer database" as is recited in claim 32.

The Califano reference does not even relate to tracking prescriptions, either on a per patient or per drug basis. Ukens does not disclose providing a sensitive drug to a patient only if no potential abuse is found by the patient prescribed the sensitive drug and the doctor prescribing the sensitive drug.

In summary, these references simply do not relate to the tracking of a particular sensitive drug using an exclusive central pharmacy and an exclusive central database to determine potential abuse by the doctors who are permitted to prescribe such sensitive drugs and the patients to whom prescriptions are written. Consequently, a *prima facie* case of obviousness does not exist, and the Applicant respectfully requests a withdrawal of the rejection of the claims.

In response to the concerns expressed by Examiner Najarian during the Interview of October 15, 2009, the Applicant offers the following.

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[5] Moradi, ¶ [0045].
[6] Lilly, Abstract (*Emphasis Added*).
[7] Lilly, ¶ [0037] (*Emphasis Added*).

Examiner Najarian stated that the Ukens reference discloses a single pharmacy. The Applicant respectfully replies that Ukens does not disclose mailing a sensitive, prescriptive, or other drug to a patient only if no potential abuse is found by the patient to whom the drug is prescribed and the doctor prescribing the sensitive drug, as is recited in the claims. The Applicant further respectfully submits that no other reference of record discloses this feature.

Examiner Najarian stated that the claims recited that the computer system was used to perform the steps, not that the computer system performed the steps. The Applicant has amended the claims, and respectfully submits that the amendments address and overcome the concerns of Examiner Najarian.

Examiner Najarian stated that the claim phrase that recites that the drug is mailed only if no potential abuse is found recites patients "or" doctors. The Applicant has amended the claims to recite patients "and" doctors.

Examiner Najarian stated that the claims did not identify the potential abuse. The Applicant respectfully submits that the particular type of abuse is not what the Applicant considers its invention to be, and therefore respectfully submits that the claims should not be limited by any particular type of abuse. The specification provides examples of abuse such as reselling drugs for profit,[8] and the Applicant respectfully submits that one of skill in the art would realize that the claimed subject matter could be applied to other abuse situations.

In response to the Applicant's amendment that the sensitive drug is mailed to a patient only if no potential abuse is found by the patient and the doctor, Examiner Najarian brought to the attention of the Applicant's representatives paragraph [0054] of Lilly that discusses "multi-source interstate prescriptive medication abuse." The Applicant respectfully submits that this is not a disclosure of the claimed feature of mailing a sensitive drug to a patient only if no abuse is found by the patient and the doctor. Indeed, the Applicant respectfully submits that Lilly is directed to obtaining a medication history of a selected prescriptive medication purchaser,[9] and that any multi-source interstate feature of Lilly is only for that selected purchaser, not that selected purchaser ***and*** the doctor prescribing the drug as recited in the claims.

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[8] Applicant's specification, page 1, lines 9-21.
[9] Lilly, paragraph [0037].

Independent claims 38 and 42 have been amended in a manner substantially similar to the amendments to claim 32. As indicated above, it is believed that claim 32 is allowable over the cited references, and the Applicant respectfully submits that for substantially similar reasons, claims 38 and 42 are also allowable over the cited references.

Claims 33-36 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1).

Claim 37 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) and further in view of Melker et al. (U.S. Patent Publication No. 2002/0177232 A1).

Independent claim 33 has been amended in a manner substantially similar to the amendments to claim 32. As indicated above, it is believed that claim 32 is allowable over the cited references, and the Applicant respectfully submits that for substantially similar reasons, claims 33-37 are also allowable over the cited references.

Claims 39-41 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Moradi et al. (U.S. Patent Publication No. 2004/0019794 A1) in view of Lilly et al. (U.S. Patent Publication No. 2004/0176985 A1) in view of Califano et al. (U.S. Patent Publication No. 2003/0033168 A1) and further in view of "Talk About Sleep: An Interview with Orphan Medical about Xyrem".

Independent claims 39, 40, and 41 have been amended in a manner substantially similar to the amendments to claim 32. As indicated above, it is believed that claim 32 is allowable over the cited references, and the Applicant respectfully submits that for substantially similar reasons, claims 39, 40, and 41 are also allowable over the cited references.

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) 371-2140 to facilitate prosecution of this application.

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

Respectfully submitted,

DAYTON T. REARDAN ET AL.

By their Representatives,

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Date November 2, 2009

By /David D'Zurilla/
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Reg. No. 36,776

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John D. Gustav-Wrathall
Name

/John D. Gustav-Wrathall/
Signature

Electronic Acknowledgement Receipt	
EFS ID:	6377668
Application Number:	10322348
International Application Number:	
Confirmation Number:	5446
Title of Invention:	Sensitive drug distribution system and method
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Gregory M. Stark/John Gustav-Wrathall
Filer Authorized By:	Gregory M. Stark
Attorney Docket Number:	101.031US1
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Application Type:	Utility under 35 USC 111(a)

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Payment Type	Deposit Account
Payment was successfully received in RAM	$405
RAM confirmation Number	4650
Deposit Account	190743
Authorized User	
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		101031us1_rcef_110209.pdf	403579 3ee1f076760a56f03603cd4bed6f7d79157cb851	yes	20

Multipart Description/PDF files in .zip description

Document Description	Start	End
Request for Continued Examination (RCE)	1	1
Transmittal Letter	2	3
Information Disclosure Statement (IDS) Filed (SB/08)	4	4
Amendment After Final	5	5
Claims	6	12
Applicant Arguments/Remarks Made in an Amendment	13	20

Warnings:					
Information:					
2	NPL Documents	101031US4PAMD04-01-05.pdf	274175 e5889267a31113c39697c3412d7945026019d92a	no	7
Warnings:					
Information:					
3	NPL Documents	101-031US42.pdf	878785 1d8812144d014505680a469fe54dd5a6d17b9d4c	no	22
Warnings:					
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4	NPL Documents	899009US2_AARN_02-02-05.pdf	859394 1baf1b5eaca7de48e613235ad48efed91f429a0f	no	17
Warnings:					
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5	NPL Documents	101031US2PAMD11-02-04.pdf	59199 ca16c29ae38c7adfece7253af3bf691680315cf5	no	3

Warnings:					
Information:					
6	NPL Documents	101031US3PAMD04-01-05.pdf	231951 8af010e62dfdc14bcc023852022c703a0512 8fe3	no	6
Warnings:					
Information:					
7	NPL Documents	101031US3-NF.pdf	731364 19e58ba578e5c22b79ead1c02873a08c3e2 74d7a	no	21
Warnings:					
Information:					
8	NPL Documents	101031US3_AARN_09-17-09.pdf	135890 c1c0078430ca62e2c0be1ebe06aed7d0f33 1a6f0	no	10
Warnings:					
Information:					
9	Fee Worksheet (PTO-875)	fee-info.pdf	29941 1d1d042b0ded5ba5c0dab35d69c080941f 31aff8	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	3604278		

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

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

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

EXPEDITED PROCEDURE – EXAMINING GROUP 3626

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

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

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

In response to the Final Office Action dated October 18, 2006 and the Advisory Action dated February 5, 2007, and further in light of the decision of the Board of Patent Appeals and Interferences dated August 31, 2009, please amend the application as follows.

This response is accompanied by a Request for Continued Examination.

PTO/SB/08A(04-07)
Modified form approved for use through 09/30/2007. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** (Use as many sheets as necessary)	*Complete if Known*	
	Application Number	10/322,348
	Filing Date	December 17, 2002
	First Named Inventor	Dayton T. Reardan
	Group Art Unit	3686
	Examiner Name	Lena Najarian
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
	US-20020032581A1	03/14/2002	Reitberg, D P	06/01/2001
	US-4,976,351	12/11/1990	Mangini, R. J, et al.	06/01/1989
	US-6,564,121	05/13/2003	Wallace, R. L, et al.	12/03/1999

FOREIGN PATENT DOCUMENTS

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

OTHER DOCUMENTS – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T [1]
	"Aplication Serial No. 11/097,985 (Atty Ref 101.031US4), Preliminary Amendment mailed 04-01-05", 7 pgs	
	"Application Serial No 11/097,985 Non Final Office Action Mailed 09/14/2009", 22	
	"Application Serial No. 10/731,915 (Atty Ref 101.031US1), Non Final Office Action Response mailed 02-02-05", 17 pgs	
	"Application Serial No. 10/979,665 (Atty Ref 101.031US2), Preliminary Amendment mailed 11-02-04", 3 pgs	
	"Application Serial No. 11/097,651 (Atty Ref 101.031US3), Preliminary Amendment mailed 04-01-05", 6 pgs	
	"Application Serial No. 11/097,651, Non-Final Office Action mailed 05-29-09", 21 pgs	
	"Application Serial No. 11/097,651, Response filed 09-17-09 to Non Final Office Action mailed 05-29-09", 10 pgs	

EXAMINER **DATE CONSIDERED**

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

IN THE CLAIMS

Please amend the claims as follows:

1 – 31. (Cancelled)

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

receiving in a computer processor all prescription requests, for any and all patients being prescribed the sensitive drug, only at the exclusive central pharmacy from [[a]] any and all medical doctors allowed to prescribe the sensitive drug, the prescription requests containing information identifying [[a]] patients, the sensitive drug, and various credentials of the any and all medical doctors;

requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations, such that all prescriptions for the sensitive drug are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor the credentials of the any and all doctors;

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

checking the exclusive computer database for potential abuse of the sensitive drug;

~~only~~ mailing the sensitive drug to the patient only if no potential abuse is found by ~~the checking of the exclusive computer database~~ the patient to whom the sensitive drug is prescribed and the doctor prescribing the sensitive drug;

confirming receipt by the patient of the sensitive drug; and

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

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

receiving in a computer processor all prescription requests, for any and all patients being prescribed the sensitive drug, only at the exclusive central pharmacy from [[a]] any and all medical doctors allowed to prescribe the sensitive drug, the prescription requests containing information identifying [[a]] patients, the sensitive drug, and various credentials of the any and all medical doctors;

entering the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations, such that all prescriptions for the sensitive drug are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor the credentials of the any and all doctors;

checking the exclusive computer database for potential abuse of the sensitive drug;

~~only~~ mailing the sensitive drug to a [[[the]]] patient only if no potential abuse is found by ~~the checking of the exclusive computer database~~ the patient to whom the sensitive drug is prescribed and the doctor prescribing the sensitive drug;

confirming receipt by the patient of the sensitive drug; and

generating with the computer processor 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 computer database.

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

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

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

38. (Currently Amended) A computerized method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

receiving in a computer processor prescription requests, for any and all patients being prescribed the sensitive drug, only at the central pharmacy from [[an]] any and all authorized prescribers allowed to prescribed the sensitive drug, the prescription requests containing information identifying [[a]] patients, the sensitive drug, and various credentials of the any and all authorized prescribers;

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, such that all prescriptions for the sensitive drug are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor ~~of~~ the credentials of the any and all authorized prescribers;

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

requiring checking of the exclusive computer database for potential abuse associated with the patient and[[/or]] the authorized prescriber;

~~only~~ providing the sensitive drug to the patient only provided information in the exclusive computer database is not indicative of potential abuse by the patient to whom the sensitive drug is prescribed and the authorized prescriber of the sensitive drug;

confirming receipt by the patient of the sensitive drug; and

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

39. (Currently Amended) A computerized method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving in a computer processor prescription requests for GHB, for any and all patients being prescribed GHB, only at the central pharmacy from [[an]] any and all authorized prescribers allowed to prescribe GHB, the prescription requests for GHB containing information identifying [[a]] patients and various credentials of the any and all authorized prescribers;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB, such that all prescriptions for GHB are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor ~~of~~ the credentials of the any and all authorized prescribers;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

~~only~~ providing GHB to the patient only provided information in the exclusive computer database is not indicative of potential abuse by the patient to whom GHB is prescribed and the authorized prescriber of the GHB;

confirming receipt by the patient of the GHB; and

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

40. (Currently Amended) A computerized method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving in a computer processor prescription requests for GHB, for any and all patients being prescribed GHB, only at the central pharmacy from [[an]] any and all authorized prescribers allowed to prescribe GHB, the prescription requests containing information identifying [[a]] patients and various credentials of the any and all authorized prescribers;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB, such that all prescriptions for the

sensitive drug are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor [[of]] the credentials of the any and all authorized prescribers;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient only provided information in the exclusive computer database is not indicative of potential abuse by the patient to whom GHB is prescribed and the authorized prescriber of the GHB;

confirming receipt by the patient of the GHB; and

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

41. (Currently Amended) A computerized method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

manufacturing GHB;

~~only~~ providing manufactured GHB only to the exclusive central pharmacy;

receiving in a computer processor all prescription requests for GHB, for any and all patients being prescribed GHB, only at the central pharmacy from [[an]] any and all authorized prescribers allowed to prescribe GHB, the prescription requests containing information identifying [[a]] patients and various credentials of the any and all authorized prescribers;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB, such that all prescriptions for GHB are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor ~~of~~ the credentials of the any and all authorized prescribers;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient only provided information in the exclusive computer database is not indicative of potential abuse by the patient to whom GHB is prescribed and the doctor prescribing the GHB;

confirming receipt by the patient of the GHB; and

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

42. (Currently Amended) A computerized method of distributing a sensitive drug under control of an exclusive central pharmacy, the method comprising:

receiving in a computer processor all prescription requests, for any and all patients being prescribed the sensitive drug, only at the central pharmacy from [[an]] any and all authorized prescribers allowed to prescribed the sensitive drug, the prescription requests containing information identifying [[a]] patients, the sensitive drug, and various credentials of the any and all authorized prescribers;

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, such that all prescriptions for the sensitive drug are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor ~~of~~ the credentials of the any and all authorized prescribers;

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

requiring checking of the exclusive computer database for potential abuse by the patient to whom the sensitive drug is prescribed and the authorized prescriber allowed to prescribe the sensitive drug ~~associated with the patient and/or the authorized prescriber~~;

~~only~~ providing the sensitive drug to the patient only provided information in the exclusive computer database is not indicative of potential abuse by the patient to whom the sensitive drug is prescribed and the authorized prescriber allowed to prescribe the sensitive drug; and

confirming receipt by the patient of the sensitive drug.

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/Applicant Name:	Dayton T. Reardan
Filer:	Gregory M. Stark/John Gustav-Wrathall
Attorney Docket Number:	101.031US1
Filed as Small Entity	

Utility under 35 USC 111(a) Filing Fees

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	405	405
		Total in USD ($)		**405**

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 10/322,348	Filing Date 12/17/2002	☐ To be Mailed

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
	11/02/2009	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	* 20	Minus	** 31	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 7	Minus	***7	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

		(Column 1)		(Column 2)	(Column 3)					
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

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

Legal Instrument Examiner:
/WANDA ANTHONY/

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

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

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L12	109	("4674652" | "4695954" | "4766542" | "4847764" | "4860899" | "4991877" | "5065315" | "5072383" | "5084828" | "5208762" | "5292029" | "5347453" | "5347477" | "5390238" | "5502944" | "5528021").PN. OR ("5737539").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/12/16 18:13
L14	4121	((705/3) or (600/300)).CCLS.	US-PGPUB	OR	OFF	2009/12/16 18:17
L15	6	((data adj1 base or database or repository or databank or data adj1 bank or storage) AND (prescription or drug or medication or pharmaceutical or medicine) AND (request) AND (patient) AND (exclusive or sole or single or main or one or specialty) AND (pharmacy) AND (abuse or misuse)).CLM.	US-PGPUB	OR	ON	2009/12/16 18:26

S2	10	(prescription or medication or pharmaceutical or medicine or drug) same (abus$ or misus $) same (doctor or prescriber or nurse or physician or professional) same (patient) same (database or data adj1 base or databank or data adj1 bank or repository) same (single or exclusive or central)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/12/08 15:20
S3	39	(prescription or medication or pharmaceutical or medicine or drug) same (abus$ or misus $) same (doctor or prescriber or nurse or physician or professional) same (patient) same (database or data adj1 base or databank or data adj1 bank or repository)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/12/08 15:21
S4	286	(prescription or medication or pharmaceutical or medicine or drug) with (abus$ or misus $) with (doctor or prescriber or nurse or physician or professional)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/12/08 15:24
S5	6	(prescription or medication or pharmaceutical or medicine or drug) with (abus$ or misus $) with (doctor or prescriber or nurse or physician or professional) with credential	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/12/08 15:24

S10	97	specialty same distribut$ same (drug or prescription or pharmaceutical or substance)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/12/09 16:42
S11	26	specialty same distribut$ same (drug or prescription or pharmaceutical or substance) same pharmacy	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/12/09 16:42
S13	17	specialty same distribut$ same (drug or prescription or pharmaceutical or substance) same (exclusive or single or sole)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/12/09 16:43
S14	4	specialty same distribut$ same FDA	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/12/09 16:43
S15	9	(specialty or exclusive) same distribut$ same FDA	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/12/09 16:43

EAST Search History (Interference)

<This search history is empty>

12/16/2009 6:28:59 PM
C:\Documents and Settings\lnajarian2\My Documents\EAST\Workspaces\10322348.wsp

PTO/SB/08A(04-07)
Modified form approved for use through 09/30/2007. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** (Use as many sheets as necessary)	*Complete if Known*	
	Application Number	10/322,348
	Filing Date	December 17, 2002
	First Named Inventor	Dayton T. Reardan
	Group Art Unit	3686
	Examiner Name	Lena Najarian
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
	US-20020032581A1	03/14/2002	Reitberg, D P	06/01/2001
	US-4,976,351	12/11/1990	Mangini, R. J, et al.	06/01/1989
	US-6,564,121	05/13/2003	Wallace, R. L, et al.	12/03/1999

FOREIGN PATENT DOCUMENTS

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

OTHER DOCUMENTS – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T [1]
	"Aplication Serial No. 11/097,985 (Atty Ref 101.031US4), Preliminary Amendment mailed 04-01-05", 7 pgs	
	"Application Serial No 11/097,985 Non Final Office Action Mailed 09/14/2009", 22	
	"Application Serial No. 10/731,915 (Atty Ref 101.031US1), Non Final Office Action Response mailed 02-02-05", 17 pgs	
	"Application Serial No. 10/979,665 (Atty Ref 101.031US2), Preliminary Amendment mailed 11-02-04", 3 pgs	
	"Application Serial No. 11/097,651 (Atty Ref 101.031US3), Preliminary Amendment mailed 04-01-05", 6 pgs	
	"Application Serial No. 11/097,651, Non-Final Office Action mailed 05-29-09", 21 pgs	
	"Application Serial No. 11/097,651, Response filed 09-17-09 to Non Final Office Action mailed 05-29-09", 10 pgs	

EXAMINER	/Lena Najarian/	DATE CONSIDERED	12/16/2009

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

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

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	10322348	REARDAN ET AL.
	Examiner	**Art Unit**
	LENA NAJARIAN	3686

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

CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
705	3				
600	300				

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		17	2	33										
	2		18	3	34										
	3		19	4	35										
	4		20	5	36										
	5		21	6	37										
	6		22	7	38										
	7		23	8	39										
	8		24	9	40										
	9		25	10	41										
	10		26	11	42										
	11		27												
	12		28												
	13		29												
	14		30												
	15		31												
	16	1	32												

/LENA NAJARIAN/ Examiner.Art Unit 3686	12/16/09	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	11	
/Gerald J. O'Connor/ SPE, GAU 3686	12/18/2009	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	2C

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	10322348	REARDAN ET AL.
	Examiner	Art Unit
	LENA NAJARIAN	3686

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	12/8/09	LN
East (see attached printout) USPAT;US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	12/9/09	LN
forward/backward search	12/16/09	LN
considered 705 template EIC search results	12/15/09	LN

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
705	3	12/16/09	LN
600	300	12/16/09	LN
	PGPUB text search (see interference search printout)	12/16/09	LN

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	10322348	REARDAN ET AL.
	Examiner	Art Unit
	LENA NAJARIAN	3686

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

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

CLAIM		DATE								
Final	Original	12/16/2009								
	1	-								
	2	-								
	3	-								
	4	-								
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	29	-								
	30	-								
	31	-								
1	32	=								
2	33	=								
3	34	=								
4	35	=								
5	36	=								

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	10322348	REARDAN ET AL.
	Examiner	Art Unit
	LENA NAJARIAN	3686

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

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

CLAIM		DATE								
Final	Original	12/16/2009								
6	37	=								
7	38	=								
8	39	=								
9	40	=								
10	41	=								
11	42	=								

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BIB DATA SHEET

CONFIRMATION NO. 5446

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
10/322,348	12/17/2002 **RULE**	436	3686	101.031US1

APPLICANTS

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

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

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

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

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /LENA NAJARIAN/ Examiner's Signature	☐ Met after Allowance LN Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		MN	16	25	4

ADDRESS

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

TITLE

Sensitive drug distribution system and method

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

BIB (Rev. 05/07).

STIC Search Report
EIC 3600

Scientific and Technical Information Center

STIC Database Tracking Number: 317266

To:	From:
Lena Najarian Location: KNX 5A59 Art Unit: 3686 Date: 12/15/09 Case Serial Number:10/322348	Eileen Patton Location: EIC3600 KNX 2D08A Phone: (571) 272-3413 eileen.patton@uspto.gov

Search Notes

Dear Examiner Najarian:

Please find attached the results of your search for the above-referenced case. The search was conducted in Dialog, ProQuest, EBSCOhost and the internet.

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

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

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

**EIC-Searcher identified "potential references of interest" are selected based upon their apparent relevance to the terms/concepts provided in the examiner's search request.*

I. Potential References of Interest

A. Dialog

21/3,K/3 (Item 1 from file: 73)
DIALOG(R)File 73: EMBASE

0074963062 **EMBASE No:** 1992114735
Policy and medical-legal issues in the prescribing of controlled substances
Clark H.W.
Journal of Psychoactive Drugs (J. PSYCHOACT. DRUGS) (United States) December 1, 1991 , 23/4 (321-328)
CODEN: JPDRD **ISSN:** 0279-1072
Document Type: Journal **;** Article **Record Type:** Abstract
Language: English **Summary language:** English
Policy and medical-legal issues in the prescribing of controlled substances
The physician who **prescribes controlled substances** is faced with an array of laws, regulatory policies, and professional attitudes about their use. **Prescriptions** for these scheduled **drugs** are furthermore **monitored** by the pharmacists who dispense them. Certain drugs, such as the opioids and the benzodiazepines, are considered so potentially abusive that special programs have been... ...to track the behavior of physician prescribers. Multiple copy programs have been implemented in some states. More recent proposals recommend electronic data transfer (EDT) of **pharmacy** information to **centralized processing points** so that **misprescribing physicians and doctor- shopping patients can be identified**. Regulators concerned about physician behavior and confronted by demands of nonphysicians to **prescribe controlled substances** may find EDT a good solution. Physicians should be concerned about being censured for misprescribing, because such actions may lead to inclusion in the National Practitioner Data Bank. With all of the regulatory concerns about controlled substances, those physicians who would employ long-term opioid therapy for their chronic pain patients must follow certain basic guidelines to be able to defend themselves against allegations of deviant professional behavior. Such procedures as conducting a history and physical examination, maintaining a written treatment plan, consulting with knowledgeable colleagues, and assessing for addictive behavior can provide the practitioner with safeguards....

22/3,K/4 (Item 4 from file: 636)
DIALOG(R)File 636: Gale Group Newsletter DB(TM)

01055345 **Supplier Number:** 40582007 **(USE FORMAT 7 FOR FULLTEXT)**
LINKS
Health Daily , v 1 , n 108 , p N/A
Nov 23 , 1988
Language: English **Record Type:** Fulltext
Document Type: Magazine/Journal ; Trade
Word Count: 962
-
...cover.

Derville explained that the drug processors or some other entity will have to implement automated drug prepayment and postpayment utilization review of claims to **identify misuse** of drugs. Reviews will address the beneficiary's use of covered drugs, drug interactions and therapies and **physician** prescribing **patterns**. Beneficiary utilization reviews will **identify** potential **abuse** of drugs, such as unusual therapy for age or gender or multiple **prescriptions** for **controlled substances**, while **physician prescribing pattern** reviews will target excessive prescriptions, especially for restrictive drugs, and fragmented patterns of prescribing maintenance-type drugs. Utilization reviews are the "area we know the...

15/3,K/5 (Item 5 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0012649646 *Drawing available*
WPI Acc no: 2002-499029/**200253**
XRAM Acc no: C2002-141338
XRPX Acc No: N2002-395040
Controlled articles distribution tracking method for sample distribution and inventory control, involves confirming authority of sales representative to distribute samples and practitioners to receive samples
Patent Assignee: CHESTER M (CHES-I); DATA REDUCTION SYSTEMS CORP (DATA-N); DEPALMA M J (DEPA-I); MCQUADE R (MCQU-I)
Inventor: CHESTER M; DEPALMA M J; MCQUADE R

Patent Family (2 patents, 1 countries)

Patent Number	Kind	Date	Application Number	Kind	Date	Update	Type
US 20020042762	A1	20020411	US 2000230764	P	20000907	200253	B
			US 2001942803	A	20010830		
US 6952681	B2	20051004	US 2001942803	A	20010830	200565	E

Priority Applications (no., kind, date): US 2000230764 P 20000907; US 2001942803 A 20010830
Original Titles:Tracking the distribution of **prescription drugs** and other **controlled** articles... ...**Tracking** the distribution of **prescription drugs** and other **controlled** articles **Alerting Abstract** ...USE - For real time and automatic **tracking** of distribution of **prescription drug** samples and other **controlled** articles for sample distribution and inventory control... Original Publication Data by AuthorityArgentina**Publication No.** ...**Claims:**comprising a representative identifier, a distributee identifier, and a statement describing the contents of the packet of articles being distributed from the portion of the **central inventory** conveyed to the distributing representative;b) confirming the authority of the distributing representative to distribute the packet;c) confirming the authority of the distributee to... Basic Derwent Week: **200253**

15/3K/10 (Item 6 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT

00521070

METHOD, SYSTEM AND APPARATUS FOR BIOMETRIC IDENTIFICATION
PROCEDE, SYSTEME ET APPAREIL D'IDENTIFICATION BIOMETRIQUE
Patent Applicant/Patent Assignee:

- **BEECHAM James E**

Inventor(s):

- **BEECHAM James E**

	Country	Number	Kind	Date
Patent	WO	9952422	A1	19991021
Application	WO	99US8120		19990414
Priorities	US	9881891		19980415

...the
autofocus iris scanner of LG Technologies of Korea. The iris scan measurement is encoded and filed in a computerized database optionally within a single **database** of a **central computer**. The **prescribing** physician when **prescribing** a **controlled substance** for a patient will have in his office an iris scanner and will instruct the patient to enter iris data, typically from the right eye, into the scanner. This scanner is linked to the **central database**. The patient encoded iris scan data and the physician encoded iris scan data are thus linked in a data file which optionally includes further specifications... ...When a match
of encoded iris data occurs,, the data is displayed to the pharmacist. In the circumstance where a patient has recently filled another **controlled substance prescription** in the same region, the data of the prior prescription is displayed, and alerts the pharmacist that the **patient** may have a controlled substance **abuse** problem.

In another embodiment of the instant invention the computer at the physician office is a stand alone computer linked to a two dimensional bar...prescription and avoids name mix-ups or pseudonym. The data retrieved may alert authorities such as the state Board of Pharmacy to a problem in **patient** substance **abuse**.

Similarly the database search criteria may be set to identify all physicians who prescribe more than a set number of **controlled substance prescriptions** within a 12-month period. The data retrieved may alert authorities such as the state Board of Pharmacy to a problem with a physician prescribing...is monitored for indication that a person is picking up. medication from multiple pharmacies and for multiple individuals as

might indicate a pattern of substance **abuse** in the case of fraudulent **controlled substance prescriptions**.

It is envisioned that the step of a physician ordering a medication prescription in the instant invention can be a surrogate carrying out the order...circumstance verify via telephone input of physician biometric to the pharmacy computer the fact that physician 412 has decided to authorize a refill of the **prescription** of the **controlled substance** for patient 414. Alternatively where the match of patient 414 biometric data in the database includes information the pharmacist interprets as a pattern of controlled substance **abuse** the **pharmacist** may decline to fill the prescription or alternatively alert **physician** 412 to the possible **abuse** of controlled substance medication by **patient** 414.

Turning now to Fig. 6, illustrated is a patient 601 in a hospital bed who has previously received a prescription order from his physician...

II. Inventor Search Results from Dialog

9/3,K/1 (Item 1 from file: 5)
DIALOG(R)File 5: Biosis Previews(R)

0020219855 **Biosis No.:** 200800266794
Microbiologically sound and stable solutions of gamma-hydroxybutyrate salt for the treatment of narcolepsy
Author: Anonymous; Cook Harry; Hamilton Martha; Danielson Douglas; Goderstad Colette; **Reardan Dayton**
Author Address: Eden Prairie, MN USA**USA
Journal: Official Gazette of the United States Patent and Trademark Office Patents AUG 28 2007 2007
Patent Number: US 07262219 **Patent Date Granted:** August 28, 2007 20070828 **Patent Classification:** 514-557 **Patent Assignee:** Orphan Medical Inc **Patent Country:** USA
ISSN: 0098-1133
Document Type: Patent
Record Type: Abstract
Language: English
Author: ...**Reardan Dayton**

9/3,K/2 (Item 2 from file: 5)
DIALOG(R)File 5: Biosis Previews(R)

18017375 **Biosis No.:** 200400388164
Microbiologically sound and stable solutions of gamma-hydroxybutyrate salt for the treatment of narcolepsy
Author: Cook Harry (Reprint); Hamilton Martha; Danielson Douglas; Goderstad Colette ; **Reardan Dayton**
Author Address: Eden Prairie, MN, USA**USA
Journal: Official Gazette of the United States Patent and Trademark Office Patents 1285 (4): Aug. 24, 2004 2004
Medium: e-file
Patent Number: US 6780889 **Patent Date Granted:** August 24, 2004 20040824 **Patent Classification:** 514-557 **Patent Assignee:** Orphan Medical, Inc., Minnetonka, MN, USA **Patent Country:** USA
ISSN: 0098-1133 _(ISSN print)
Document Type: Patent
Record Type: Abstract
Language: English
Author: ...**Reardan Dayton**

9/3,K/3 (Item 1 from file: 73)
DIALOG(R)File 73: EMBASE

0079522002 **EMBASE No:** 2003228233
Effects of estradiol, phytoestrogens, and Ginkgo biloba extracts against 1-methyl-4-phenyl-pyridine-induced oxidative stress
Gagne B.; Gelinas S.; Bureau G.; Lagace B.; Ramassamy C.; Chiasson K.; Valastro B.; Martinoli M.-G.
Department of Biochemistry, Research Group in Neuroscience, Univ. du Que. a Trois-Rivieres, Trois-Rivieres, Que., Canada
Author email: martinol@uqtr.uquebec.ca

Corresp. Author/Affil: Martinoli M.-G.: Department of Biochemistry, Universite du Quebec, C.P. 500, Trois-Rivieres, Que. G9A 5H7, Canada
Corresp. Author Email: martinol@uqtr.uquebec.ca
Endocrine (Endocrine) (United States) June 1, 2003 , 21/1 (89-95)
CODEN: EOCRE **ISSN:** 0969-711X
Item Identifier (DOI): 10.1385/ENDO:21:1:89
Document Type: Journal ; Article **Record Type:** Abstract
Language: English **Summary language:** English
Number of References: 56
Gagne B...

26/3,K/1 (Item 1 from file: 350)
DIALOG(R)File 350: Derwent WPIX

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

Patent Family (1 patents, 1 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**
US 20050222874	A1	20051006	US 2002322348	A	20021217	200572	B
			US 200597651	A	20050401		

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

...Inventor: **GAGNE B**... ...**REARDAN D T** Original Publication Data by AuthorityArgentina**Publication No.** Inventor name & address:**Reardan, Dayton T**... ...**Gagne, Bob**

26/3,K/2 (Item 2 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0015350954 *Drawing available*
WPI Acc no: 2005-701214/200572
Related WPI Acc No: 2004-516067; 2005-354186; 2005-701943
XRPX Acc No: N2005-575389
Abuse control method of sensitive drug e.g. cocaine, involves providing database for drug enforcement agency for checking abuse patterns of drug, with respect to each cash payment and inappropriate questions
Patent Assignee: ORPHAN MEDICAL INC (ORPH-N)
Inventor: ENGEL P A; **GAGNE B**; **REARDAN D T**

Patent Family (1 patents, 1 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**

US 20050216309	A1	20050929	US 2002322348	A	20021217	200572	B
			US 200597985	A	20050401		

Priority Applications (no., kind, date): US 2002322348 A 20021217; US 200597985 A 20050401
...Inventor: **GAGNE B**... ...**REARDAN D T** Original Publication Data by AuthorityArgentina**Publication No.** Inventor name & address:**Reardan, Dayton T**... ...**Gagne, Bob**

26/3,K/3 (Item 3 from file: 350)
DIALOG(R)File 350: Derwent WPIX

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

Patent Family (1 patents, 1 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**
US 20050090425	A1	20050428	US 2002322348	A	20021217	200536	B
			US 2004979665	A	20041102		

Priority Applications (no., kind, date): US 2002322348 A 20021217; US 2004979665 A 20041102
Inventor: **ENEEL P A**... ...**GAGNE B**... ...**REARDAN D T** Original Publication Data by AuthorityArgentina**Publication No.** Inventor name & address:**Reardan, Dayton T**... ...**Eneel, Patti A**... ...**Gagne, Bob**

26/3,K/4 (Item 4 from file: 350)
DIALOG(R)File 350: Derwent WPIX

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

Patent Family (1 patents, 1 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**
US 20040117205	A1	20040617	US 2002322348	A	20021217	200449	B

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

Inventor: **ENEEL P A**... ...**GAGNE B**... ...**REARDAN D T** Original Publication Data by AuthorityArgentina**Publication No.** Inventor name & address:**Reardan, Dayton T**... ...**Eneel, Patti A**... ...**Gagne, Bob**

26/3,K/5 (Item 5 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0012745923
WPI Acc no: 2002-598783/200264
Related WPI Acc No: 2000-465620
XRAM Acc no: C2002-168978
Stable composition of gamma-hydroxybutryate in aqueous medium, rendered chemically stable and resistant to microbial growth, useful for treating e.g. sleep disorders
Patent Assignee: COOK H N (COOK-I); DANIELSON D (DANI-I); GODERSTAD C (GODE-I); HAMILTON M (HAMI-I); REARDAN D (REAR-I)
Inventor: COOK H N; DANIELSON D; GODERSTAD C; HAMILTON M; **REARDAN D**

Patent Family (1 patents, 1 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**
US 20020077334	A1	20020620	US 1999470570	A	19991222	200264	B

Priority Applications (no., kind, date): US 1999470570 A 19991222
...Inventor: **REARDAN D** Original Publication Data by AuthorityArgentina**Publication No.** ...Inventor name & address:**REARDAN, DAYTON**

26/3,K/6 (Item 6 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0010395368
WPI Acc no: 2000-465620/200040
Related WPI Acc No: 2002-598783
XRAM Acc no: C2000-140186
Aqueous compositions of gamma-hydroxybutyric acid are chemically stable and resistant to microbial growth and include a pH adjusting agent and a preservative
Patent Assignee: ORPHAN MEDICAL INC (ORPH-N)
Inventor: COOK H; COOK H N; DANIELSON D; GODERSTAD C; HAMILTON M; **REARDAN D**; **REARDAN D T**; DOUGLAS D

Patent Family (20 patents, 87 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**
WO 2000038672	A2	20000706	WO 1999US30740	A	19991222	200040	B
AU 200020590	A	20000731	AU 200020590	A	19991222	200050	E
EP 1140061	A2	20011010	EP 1999964320	A	19991222	200167	E
			WO 1999US30740	A	19991222		
US 6472431	B2	20021029	US 1998113745	P	19981223	200274	E
			US 1999470570	A	19991222		

JP 2002533388	W	20021008	WO 1999US30740	A	19991222	200281	E
			JP 2000590626	A	19991222		
EP 1140061	B1	20030502	EP 1999964320	A	19991222	200330	E
			WO 1999US30740	A	19991222		
			EP 200375658	A	19991222		
EP 1316309	A1	20030604	EP 1999964320	A	19991222	200337	E
			EP 200375658	A	19991222		
DE 69907508	E	20030605	DE 69907508	A	19991222	200345	E
			EP 1999964320	A	19991222		
			WO 1999US30740	A	19991222		
US 20030125385	A1	20030703	US 1998113745	P	19981223	200345	E
			US 1999470570	A	19991222		
			US 2002194021	A	20020711		
ES 2193777	T3	20031101	EP 1999964320	A	19991222	200382	E
US 6780889	B2	20040824	US 1998113745	P	19981223	200457	E
			US 1999470570	A	19991222		
			US 2002194021	A	20020711		
US 20040209955	A1	20041021	US 1998113745	P	19981223	200470	E
			US 1999470570	A	19991222		
			US 2002194021	A	20020711		
			US 2004841709	A	20040507		
AU 779354	B2	20050120	AU 200020590	A	19991222	200512	E
CA 2355293	C	20050816	CA 2355293	A	19991222	200557	E
			WO 1999US30740	A	19991222		
IL 143733	A	20061031	IL 143733	A	19991222	200680	E
US 7262219	B2	20070828	US 1998113745	P	19981223	200757	E
			US 1999470570	A	19991222		
			US 2002194021	A	20020711		
			US 2004841709	A	20040507		
US 20070270491	A1	20071122	US 1998113745	P	19981223	200779	E
			US 1999470570	A	19991222		
			US 2002194021	A	20020711		
			US 2004841709	A	20040507		
			US 2007777877	A	20070713		
IN 200702633	P2	20080801	WO 1999US30740	A	19991222	200929	E
			IN 2001KN688	A	20010629		
			IN 2007KN2633	A	20070713		

JP 2009167189	A	20090730	JP 2000590626	A	19991222	200950	E
			JP 200928694	A	20090210		
IN 225248	B	20081107	WO 1999US30740	A	19991222	200967	E
			IN 2001KN688	A	20010629		
			IN 2007KN2633	A	20070713		

Priority Applications (no., kind, date): US 1998113745 P 19981223; US 1999470570 A 19991222; US 2002194021 A 20020711; US 2004841709 A 20040507; US 2007777877 A 20070713
...Inventor: **REARDAN D**... ...**REARDAN D T** Original Publication Data by AuthorityArgentina**Publication No.**
...Inventor name & address:**REARDAN D**... ...**REARDAN D**... ...**REARDAN, Dayton**... ...**REARDAN, Dayton**... ...**Reardan, Dayton T**... ...**REARDAN D T**... ...**Reardan, Dayton**... ...**Reardan, Dayton**... ...**Reardan, Dayton**... ...**Reardan, Dayton**... ...**Reardan, Dayton**... ...**Reardan, Dayton**... ...**REARDAN, Dayton**

DIALOG(R)File 348: EUROPEAN PATENTS

31/3K/1 (Item 1 from file: 348)
01589939
Microbiologically sound and stable solutions of gamma-hydroxybutyrate salt for the treatment of narcolepsy
Mikrobenbestandige und stabilisierte Losungen die gamma-Hydroxybuttersauresalze zur Behandlung von Narkolepsie enthalten
Solutions de sels d'hydroxybutyrate stables et saines au plan microbiologique,pour le traitement de la narcolepsie
Patent Assignee:

- **Orphan Medical Inc.** (2715280)
  Suite 475, 13911 Ridgedale Drive; Minnetonka, MN 55305 (US)
  (Applicant designated States: all)

Inventor:

- **Goderstad, Colette**
  469 Hills Courte North; St. Paul, Minnesota 55113; (US)
- **Hamilton, Martha**
  306 South Exchange Street; St. Paul, Minnesota 55102; (US)
- **Cook, Harry N.**
  15441 Village Woods Drive; Eden Prairie, Minnesota 55437; (US)
- **Reardan, Dayton T.**
  22345 Bracketts Road; Excelsior, Minnesota 55331; (US)
- **Danielson, Douglas**
  1594 Wood Lea Drive; Otsego, Michigan 49078-9755; (US)
- **...US)**
  ; ;
- **Reardan, Dayton T...**
  ; ;

Legal Representative:

- **Lucas, Brian Ronald (33295)**
  Lucas & Co. 135 Westhall Road; Warlingham, Surrey CR6 9HJ; (GB)

	Country	Number	Kind	Date	
Patent	EP	1316309	A1	20030604	(Basic)
Application	EP	2003075658		19991222	
Priorities	US	113745	P	19981223	

31/3K/3 (Item 1 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT

00890823
GAMMA-HYDROXYBUTYRATE COMPOSITIONS CONTAINING CARBOHYDRATE, LIPID OR AMINO ACID CARRIERS
COMPOSITIONS DE GAMMA-HYDROXYBUTYRATE CONTENANT DES EXCIPIENTS GLUCIDES, LIPIDES, OU ACIDES AMINES
Patent Applicant/Patent Assignee:

- **ORPHAN MEDICAL INC**
  Suite 475, 13911 Ridgedale Drive, Minnetonka, MN 55305; US; US(Residence); US(Nationality); (For all designated states except: US)

Patent Applicant/Inventor:

- **MILLER Brian L**
  21508 Maple Avenue, Rogers, MN 55374; US; US(Residence); US(Nationality)
- **MAMELAK Mortimer**
  19 Tumbleweed Road, Toronto, M2J 2N2; CA; CA(Residence); CA(Nationality); (Designated only for: US)
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- **...Designated only for: US)**
- **REARDAN Dayton T...**

Legal Representative:

- **VIKSNINS Ann S (agent)**
  Schwegman, Lunberg, Woessner & Kluth, P.O. Box 2938, Minneapolis, MN 55402; US

	Country	Number	Kind	Date
Patent	WO	200224715	A2-A3	20020328
Application	WO	2001US29569		20010921
Priorities	US	2000234720		20000922

III. Text Search Results from Dialog

A. Patent Files, Abstract

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  File 347:JAPIO Dec 1976-2009/May(Updated 090903)
         (c) 2009 JPO & JAPIO
  File 350:Derwent WPIX 1963-2009/UD=200956
         (c) 2009 Thomson Reuters

Set     Items   Description
S1      29177   ((SENSITIVE OR DANGEROUS OR MONITORED OR REGULATED OR RISKY
             OR CONTROLLED OR ADDICTIVE OR MOOD()ALTERING OR ILLEGAL OR H-
             ARD OR (HABIT OR ADDICTION)(1N)FORMING OR NARCOTI?ING OR HAZA-
             RDOUS)(3N)(PHARMACEUTIC? OR PHARMAECEUTIC? OR PHARMACO? OR PH-
             ARMAECO? OR DRUG OR DRUGS OR SUBSTANCE OR SUBSTANCES OR MEDIC-
             ATION? ? OR MEDICINE? ? OR PILLS OR MEDICAMENT? ? OR ANAESTHE-
             TIC OR PAINKILLER? ? OR PAIN()KILLER? ? OR STIMULANT? ?) OR N-
             ARCOTIC? ? OR OPIATE OR OPIATES OR OPIOID? ? OR BENZODIAZEPIN-
             ES OR HYDROCODONE)
S2         99   S1(4N)(PRESCRIPTION? ? OR PRESCRIBE? ? OR PRESCRIBING OR W-
             RITTEN()(ORDER? ? OR INSTRUCTION? ? OR DIRECTION? ?) OR REQUE-
             ST? ? OR SCRIPT? ?)
S3         44   S2(5N)(TRACK? OR MONITOR? OR CONTROL? OR RESTRICT? OR SURV-
             EIL? OR MANAG? OR REGULAT? OR ENFORC? OR INHIBIT? OR LIMIT? OR
              RESTRAIN? OR CONSTRAIN? OR PROHIBIT? OR SUPERVIS? OR CHECKIN-
             G)
S4        159   (ABUSE? ? OR ABUSIVE? OR ABUSING OR ILLEGAL? OR MISUSE OR -
             MIS()(USE OR USED OR USING) OR MISUSED OR MISUSING OR UNSCRUP-
             ULOUS?? OR UNETHICAL OR DRUG()(DEALER? ? OR DEALING) OR DISCI-
             PLINARY()ACTION? ? OR  MALTREATMENT? ? OR IMPROPER?? OR DISRE-
             PUTABLE OR MISTREATMENT? ? OR MISPRESCRIBING)(4N)(IDENTIF? OR
             MONITOR? OR ANALY?E? ? OR ANALYSIS OR ANALY?ING OR WARN? ? OR
             WARNING? ? OR RED()FLAG OR ALERT? OR DETECT? OR REVEAL? OR DI-
             SCOVER? OR EXPOSE? ? OR EXPOSING OR UNCOVER? OR RECOGNI?E? ? -
             OR RECOGNI?ING OR RECOGNITION)
S5        161   (PATTERN? ? OR HABIT? ? OR RECORD? ? OR HISTORY OR HISTORI-
             ES OR BEHAVIOR? ? OR BEHAVIOUR? ? OR PROFILE OR PROFILES OR R-
             EPORT? ? OR DOCUMENTATION OR FILE OR FILES OR HISTORIC?? OR B-
             ACKGROUND? ?)(3N)(PATIENT? ? OR OUTPATIENT? ? OR INPATIENT? ?
             OR REQUESTER? ? OR PRESCRIPTION()HOLDER? ? OR CONSUMER? ? OR -
             INDIVIDUAL? ? OR PERSON? ? OR CLIENT? ? OR PATRON? ? OR CUSTO-
             MER? ? OR BENEFICIARY? ? OR BENEFICIARIES)
S6         16   (PATTERN? ? OR HABIT? ? OR RECORD? ? OR HISTORY OR HISTORI-
             ES OR BEHAVIOR? ? OR BEHAVIOUR? ? OR PROFILE OR PROFILES OR R-
             EPORT? ? OR DOCUMENTATION OR FILE OR FILES OR HISTORIC?? OR B-
             ACKGROUND? ? OR PRECENDENT? ? OR CREDENTIAL? ?)(3N)(PHARMACIS-
             T? ? OR PHARMAECIST? ? OR PHARMACOLOGIST? ? OR PHARMAECOLOGIS-
             T? ? OR DRUGGIST? ? OR CHEMIST? ? OR APOTHECAR? OR PHARMACOPO-
             LIST? ? OR  PHYSICIAN? ? OR DOCTOR? ? OR  CLINICIAN? ? OR SUR-
             GEON? ? OR PROVID?R? ? OR PRACTITIONER? ? OR PROFESSIONAL? ? -
             OR SPECIALIST? ?)
S7        157   (CENTRAL OR EXCLUSIVE OR MAIN OR MASTER OR PRIMARY OR BASE
             OR HOMEBASE OR CENTRALI?ED OR  CONTROLLING OR SOLO OR RESTRIC-
             TED)(3N)(PHARMACY OR PHARMACIES OR FACILITY OR FACILITIES OR -
             DRUGGIST? ? OR CHEMIST? ? OR STATION? ? OR BUILDING? ? OR LOC-
             ATION? ? OR CENTER? ? OR CENTRE? ? OR CLINIC? ? OR HOSPITAL? ?
              OR OFFICE OR OFFICES OR ESTABLISHMENT? ? OR SITE OR HEAD()QU-
             ARTER? ? OR HEADQUARTER? ? OR HQ OR APOTHECAR? OR DRUGSTORE OR
              STORE)
S8        129   (CENTRAL OR EXCLUSIVE OR MAIN OR MASTER OR PRIMARY OR BASE
             OR HOMEBASE OR CENTRALI?ED OR  CONTROLLING OR MAINFRAME)(3N)(-
             DATABASE OR DATABASES OR DATABANK? ? OR DATAFILE? ?  OR DATA(-
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             )(BASE OR BASES OR BANK OR BANKS) OR REPOSITOR? OR DB OR D()B
             OR DBMS OR RDBMS OR D()B()M()S OR PORTAL OR PORTALS OR COMPUT-
             ER? ? OR CPU OR SERVER OR SERVERS OR PROCESSOR? ?)
S9          5   S3 AND S4
S10         8   S3 AND (S5 OR S6)
S11         6   S3 AND (S7 OR S8)
S12        10   S9 OR S10 OR S11
S13         3   S12 AND PY=1963:2002
S14         7   S12 AND AY=1963:2002 AND AC=US
S15         7   S13 OR S14
S16         5   S2 AND S4 AND (S5 OR S6)
S17         8   S1 AND S4 AND (S5 OR S6)
S18         4   S17 AND (S7 OR S8)
S19         4   (S16 OR S17 OR S18) NOT S15
S20        11   S2 AND (S5 OR S6)
S21         4   S20 AND (S7 OR S8)
S22         4   (S20 OR S21) NOT (S15 OR S19)
S23         4   S4 AND S5 AND S6
S24         4   S4 AND S7 AND S8
S25         0   (S23 OR S24) NOT (S15 OR S19 OR S22)
S26         6   AU=((REARDAN, D? OR REARDAN D? OR REARDAN(2N)D?) OR (ENEEL,
              P? OR ENEEL P? OR ENEEL(2N)P?) OR (GAGNE, B? OR GAGNE B? OR -
             GAGNE(2N)B?))
```

15/3,K/1 (Item 1 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0015351683 *Drawing available*
WPI Acc no: 2005-701943/200572
Related WPI Acc No: 2004-516067; 2005-354186; 2005-701214
XRPX Acc No: N2005-576014
Food and drug administration approval acquisition method of e.g. narcotics, involves selecting controls from group containing identifying physician name and license, and verifying whether physician is eligible to prescribe drug
Patent Assignee: ORPHAN MEDICAL INC (ORPH-N)
Inventor: ENGEL P A; GAGNE B; REARDAN D T ***Inventor's Publication***

Patent Family (1 patents, 1 countries)

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

Priority Applications (no., kind, date): US 2002322348 A 20021217; US 200597651 A 20050401
Alerting Abstract ...ADVANTAGE - **Abuses** of drug are **identified**, and education is provided to both physician and patient... Original Publication Data by AuthorityArgentina**Publication No. Original Abstracts:**A drug distribution system and method utilizes a **central** pharmacy and **database to track** all **prescriptions** for **a sensitive drug**. Information is **kept in** the database regarding all physicians allowed to **prescribe** the sensitive **drug**, **and** all **patients receiving** the drug. Abuses are **identified** by **monitoring** data **in** the **database** for prescription **patterns** by physicians and **prescriptions** obtained **by patients**. Further verification is made that the physician is eligible to prescribe the drug by consulting a separate database, and optionally whether any actions are taken... Basic Derwent Week: 200572

15/3,K/2 (Item 2 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0015350954 *Drawing available*
WPI Acc no: 2005-701214/200572
Related WPI Acc No: 2004-516067; 2005-354186; 2005-701943
XRPX Acc No: N2005-575389
Abuse control method of sensitive drug e.g. cocaine, involves providing database for drug enforcement agency for checking abuse patterns of drug, with respect to each cash payment and inappropriate questions
Patent Assignee: ORPHAN MEDICAL INC (ORPH-N)
Inventor: ENGEL P A; GAGNE B; REARDAN D T ***Inventor's Publication***

Patent Family (1 patents, 1 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**
US 20050216309	A1	20050929	US 2002322348	A	20021217	200572	B
			US 200597985	A	20050401		

Priority Applications (no., kind, date): US 2002322348 A 20021217; US 200597985 A 20050401
Alerting Abstract ...potential prescription abuse of sensitive drug are determined from periodic reports generated by database, based on prescription request data with information identifying patient, prescribed drug, **credential** of **doctor**. The database is made available for drug enforcement agency (DEA) for checking abuse patterns of drug, with respect to cash payment and inappropriate questions. Original Publication Data by AuthorityArgentina**Publication No. Original Abstracts:**A drug distribution system and method utilizes a **central** pharmacy and **database to track** all **prescriptions** for **a sensitive drug**. Information is **kept in** the database regarding all physicians allowed to **prescribe** the sensitive **drug**, **and** all **patients receiving** the drug. Abuses are **identified** by **monitoring** data **in** the **database** for prescription **patterns** by physicians and **prescriptions** obtained **by patients**. Further verification is made that the physician is eligible to prescribe the drug by consulting a separate database, and optionally whether any actions are taken... Basic Derwent Week: 200572

15/3,K/3 (Item 3 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0015006281 *Drawing available*
WPI Acc no: 2005-354186/200536
Related WPI Acc No: 2004-516067; 2005-701214; 2005-701943
XRPX Acc No: N2005-289217
Sensitive drug e.g. Xyrem, distributing method for treating cataplexy, involves making periodic reports via database to evaluate potential abuse patterns, where database has information identifying patient, drug and credentials
Patent Assignee: ORPHAN MEDICAL INC (ORPH-N)
Inventor: ENEEL P A; GAGNE B; REARDAN D T ***Inventor's Publication***

Patent Family (1 patents, 1 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**
US 20050090425	A1	20050428	US 2002322348	A	20021217	200536	B
			US 2004979665	A	20041102		

Priority Applications (no., kind, date): US 2002322348 A 20021217; US 2004979665 A 20041102
Alerting Abstract ...NOVELTY - The method involves entering information identifying a patient, sensitive drug and various **credentials** of a **doctor** into a database to **analyze** potential **abuse** situations, and checking the credentials. A confirmation is made with the patient that educational material has been read prior to shipping the drug. The receipt ... ... a method of **monitoring** potential **abuse** of **a** sensitive **drug** by use of an **exclusive central database** a **method of obtaining** Food and Drug Administration approval for a sensitive drug a therapeutic

method for treating a narcoleptic patient in need of treatment with gamma hydroxy butyrate... ... support via ongoing contact with patients and a toll free helpline. The method maintains and monitors the patient and prescribing physician registries to ensure proper **distribution** of the **sensitive drug**.Original Publication Data by AuthorityArgentina**Publication No. Original Abstracts:**A drug distribution system and method utilizes a **central** pharmacy and **database to track** all **prescriptions** for **a sensitive drug**. Information is **kept in** the database regarding all physicians allowed to **prescribe** the sensitive **drug**, **and** all **patients receiving** the drug. Abuses are **identified** by **monitoring** data **in** the **database** for prescription **patterns** by physicians and **prescriptions** obtained **by patients**. Further verification is made that the physician is eligible to prescribe the drug by consulting a separate database, and optionally whether any actions are taken... ...**Claims:**of distributing a sensitive drug, the method comprising:receiving prescription requests from a medical doctor containing information identifying the patient, the sensitive drug, and various **credentials** of the doctor;entering the **information** into a **central database** for **analysis** of potential **abuse** situations;**checking the credentials of** the **doctor**;**confirming** with the patient that educational **material** has been **read** prior to shipping the sensitive drug;confirming receipt of the sensitive drug; andgenerating periodic reports via the **central database** to evaluate potential abuse patterns.Basic Derwent Week: 200536

15/3,K/4 (Item 4 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0014328324 *Drawing available*
WPI Acc no: 2004-516067/200449
Related WPI Acc No: 2005-354186; 2005-701214; 2005-701943
XRPX Acc No: N2004-408813
Sensitive drug e.g. cocaine, distributing method, involves confirming with patient that educational material has been read prior to shipping, confirming receipt of drug, and generating periodic reports via central database
Patent Assignee: ENEEL P A (ENEE-I); GAGNE B (GAGN-I); REARDAN D T (REAR-I)
Inventor: ENEEL P A; GAGNE B; REARDAN D T ***Inventor's Publication***

Patent Family (1 patents, 1 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**
US 20040117205	A1	20040617	US 2002322348	A	20021217	200449	B

Priority Applications (no., kind, date): US 2002322348 A 20021217
.cocaine, distributing method, involves confirming with patient that educational material has been read prior to shipping, confirming receipt of drug, and generating periodic reports via central database Alerting Abstract ...NOVELTY - The method involves receiving prescription requests from a doctor and entering information into a **central database** for **analysis** of potential **abuse** situations. **Credentials** of the **doctor** are checked and the patient is queried to confirm that educational material has been read prior to shipping. The receipt of the drug is confirmed... DESCRIPTION - The **central database** contains all relevant data related to the distribution of the drug and process of distribution, including patient, physician and prescription information... ... a method of **monitoring** potential **abuse** of **a** sensitive **drug** by use of an **exclusive central database** a **method of obtaining** food and drug administration (FDA) approval for a sensitive drug... ... ADVANTAGE - The **central database** ensures that all prescriptions, prescribers, and patients are **tracked and** subject to investigations, thereby minimizing risk and ensuring that the drugs are not abused. The method provides an education and limits a potential for the abuse. Several queries and reports are run against the database **to** provide information which **reveal** potential **abuse** of the sensitive drug.Original Publication Data by AuthorityArgentina**Publication No. Original Abstracts:**A drug distribution system and method utilizes a **central** pharmacy and **database to track** all **prescriptions** for **a sensitive drug**. Information is **kept in** the database regarding all physicians allowed to **prescribe** the sensitive **drug**, **and** all **patients receiving** the drug. Abuses are **identified** by **monitoring** data **in** the **database** for prescription **patterns** by physicians and **prescriptions** obtained **by patients**. Further verification

is made that the physician is eligible to prescribe the drug by consulting a separate database, and optionally whether any actions are taken... ...**Claims:**of distributing a sensitive drug, the method comprising:receiving prescription requests from a medical doctor containing information identifying the patient, the sensitive drug, and various **credentials** of the doctor;entering the **information** into a **central database** for **analysis** of potential **abuse** situations;**checking the credentials of** the **doctor**;**confirming** with the patient that educational **material** has been **read** prior to shipping the sensitive drug;confirming receipt of the sensitive drug; andgenerating periodic reports via the **central database** to evaluate potential abuse patterns.Basic Derwent Week: 200449

15/3,K/6 (Item 6 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0012649557 *Drawing available*
WPI Acc no: 2002-498938/**200253**
Related WPI Acc No: 2005-675101
XRAM Acc no: C2002-141317
XRPX Acc No: N2002-394958
Pharmaceutical parenteral mixture-compounder comprises computer containing memory for storing process operation and control instructions
Patent Assignee: BAXTER INT INC (BAXT); CZARNY R W (CZAR-I); KIRCHER J J (KIRC-I); LEWIS R E (LEWI-I); MILLER J E (MILL-I); NITZKI-GEORGE D M (NITZ-I)
Inventor: CZARNY R W; KIRCHER J J; LEWIS R E; MILLER J A; MILLER J E; NITZKI-GEORGE D M

Patent Family (2 patents, 1 countries)

Patent Number	Kind	Date	Application Number	Kind	Date	Update	Type
US 20020035412	A1	20020321	US 1999168695	P	19991203	200253	B
			US 2000729498	A	20001204		
US 6975924	B2	20051213	US 2000729498	A	20001204	200581	E

Priority Applications (no., kind, date): US 1999168695 P 19991203; US 2000729498 A 20001204
Technology Focus ...prescription mixtures in the queue to group together the mixtures which have such commonality of predetermined components. The computer also retrieves data relating to a **patient profile**, such as, **patient**'s name, age and weight, or retrieves data relating to categories of patients, such as, adult, pediatric, neo-natal or premature patients. The computer compares... ...a patient in a category and provides a signal when a component is outside of the predetermined limits for the component in the mixture. The **patient**'s **profile** data further includes a **history** of the **patient**'s weight and mixture prescriptions over a period of time. The processing device is provided to prepare a **report** concerning the **patient**, including a projection of the patient's weight at some time in the future. The memory device includes data relating to the amount of fluid... **Extension Abstract** Original Publication Data by AuthorityArgentina**Publication No.** ...**Claims:**least one communication port for establishing a communication link with each compounder that is to be controlled;said computing means being adapted to receive a **prescription** admixture, identify the **pharmaceutical** components thereof, determine the compatibility of the pharmaceutical components relative to one another, determine the order in which the components are transferred in preparing the... Basic Derwent Week: **200253**

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

0016082131 *Drawing available*
WPI Acc no: 2006-613762/200663 ***Bad Date***
XRAM Acc no: C2006-189501
New isotopically labeled diazepine derivative useful for preventing or stopping prescription drug abuse
Patent Assignee: DR PHARMA NOVA LLC (DRPH-N); REIS A J (REIS-I); SCHAFMEISTER C (SCHA-I)
Inventor: REIS A J; SCHAFMEISTER C

Patent Family (3 patents, 111 countries)

Patent Number	Kind	Date	Application Number	Kind	Date	Update	Type
WO 2006091885	A2	20060831	WO 2006US6730	A	20060223	200663	B
CA 2614223	A1	20060831	CA 2614223	A	20060223	200882	E
			WO 2006US6730	A	20060223		
			CA 2614223	A	20080103		
US 20090208413	A1	20090820	US 2005656232	P	20050224	200955	E
			WO 2006US6730	A	20060223		
			US 2008922794	A	20080905		

Priority Applications (no., kind, date): US 2005656232 P 20050224; US 2005656232 P 20050224; US 2008922794 A 20080905

Alerting Abstract ... composition comprising a mixture of a drug having different labels in a specified ratio and a carrier; a method (M1) of preventing or stopping drug **abuse**; a method (M2) of **monitoring** patient compliance with a **prescription** for a **controlled pharmaceutical** agent; a method (M3) of monitoring patient compliance with a prescription for a drug enforcement agency (DEA) schedule II - V drug; a method (M4) of facilitating replacement drug prescription by a provider; a method (M5) of safely tapering a drug; a method (M6) of **prescribing** a labeled **controlled drug** to a patient; and a method (M7) of identifying a non-compliant patient who does not comply with a prescription for medication. R 5 , R... ... USE - For preventing or stopping prescription drug **abuse**, and for **monitoring** patient compliance with a **prescription** for a **controlled pharmaceutical** agent (claimed...

19/3,K/2 (Item 2 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0014443481 *Drawing available*
WPI Acc no: 2004-634162/200461 ***Bad Date***
XRPX Acc No: N2004-501320
Prescription dispensing system for identifying medication abuse, has electronic database associated with computer unit to search database by data item and to perform preset data processing on records to produce data packet
Patent Assignee: ERICSSON A D (ERIC-I); HALL T E (HALL-I)
Inventor: ERICSSON A D; HALL T E

Patent Family (1 patents, 1 countries)

Patent Number	Kind	Date	Application Number	Kind	Date	Update	Type
US 20040162740	A1	20040819	US 2003367411	A	20030214	200461	B

Priority Applications (no., kind, date): US 2003367411 A 20030214
Prescription dispensing system for identifying medication abuse, has electronic database associated with computer unit to search database by data item and to perform preset data processing on records to

produce data packet Alerting Abstract ... a method for transmitting transaction records to the prescription system from remote sources for addition to the electronic database a method for obtaining a **patient**`s medication **history** a method **for** determining whether **a** proposed transaction will violate prescription fill limitations for a medicinal substance a method for determining whether prescription activity in a given geographic area is indicative... ... 24 Federal **controlled substance** act classification database Original Publication Data by AuthorityArgentina**Publication No.** ...**Original Abstracts:**operably associated with the computer means for communicating the processed data packet to a user. The database can be used to identify prescription fraud, medication **overuse** and **abuse**, and to provide **an** early **warning** for bioterror attacks

19/3,K/4 (Item 4 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0009500628 *Drawing available*
WPI Acc no: 1999-443146/199937
Related WPI Acc No: 1999-346451; 1999-394209; 2000-246158; 2000-524447
XRAM Acc no: C1999-130543
XRPX Acc No: N1999-330421
On-site assaying system for detecting use of illegal drugs etc.
Patent Assignee: ESCREEN INC (ESCR-N); NAT MEDICAL REVIEW OFFICE INC (NAME-N)
Inventor: LAPPE M

Patent Family (2 patents, 1 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**
US 5929422	A	19990727	US 1997832957	A	19970404	199937	B
US RE38509	E	20040504	US 1997832957	A	19970404	200430	E
			US 2001916905	A	20010726		

Priority Applications (no., kind, date): US 1997832957 A 19970404; US 2001916905 A 20010726
On-site assaying system for detecting use of illegal drugs etc. Alerting Abstract ...USE - Assaying system for **detecting** use of **illegal drugs** etc... Original Publication Data by AuthorityArgentina**Publication No.** ...**Claims:**substances within human physiological fluid, at least one fixed strip and at least one blank region also located upon the test card, organized in a **pattern** with the **individual** analysis strips **to** produce an **encoded** machine readable source of data, wherein the analysis strips, upon detecting a proscribed substance, will change from a first color to a second darker color...

22/3,K/1 (Item 1 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0015350955 *Drawing available*
WPI Acc no: 2005-701215/200572
Related WPI Acc No: 2005-701213 ***Bad Date***
XRPX Acc No: N2005-575390
Pharmaceutical inventory computerized monitoring method for inmates in e.g. medication dispensation workstation, involves forming records based on dispensing of unit packet of medication to inmate and consumption of medication by inmate
Patent Assignee: CLEMENTS L M (CLEM-I); HAMMACK G G (HAMM-I); JACKSON K M (JACK-I); MITCHEM S C (MITC-I); UNIV TEXAS SYSTEM (TEXA)
Inventor: CLEMENTS L M; HAMMACK G G; JACKSON K M; MITCHEM S C

Patent Family (2 patents, 107 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**
US 20050216310	A1	20050929	US 2004806878	A	20040323	200572	B
WO 2005096209	A2	20051013	WO 2005US9765	A	20050323	200572	E

Priority Applications (no., kind, date): US 2004806878 A 20040323

.**Original Abstracts:**of medicines and pharmaceuticals from a pharmacy and medicinal administration facility for use in correctional facilities, such as in prisons. Information related to past medical **history** of a **patient may** be reviewed **while** simultaneously reviewing a prescription written for the same patient. Prescription filling tasks can also be controlled, such as printing labels for medication in batches to... ... of medicines and pharmaceuticals from a pharmacy and medicinal administration facility for use in correctional facilities, such as in prisons. Information related to past medical **history** of a **patient** may be reviewed (20) while **simultaneously** reviewing a **prescription** written for the same patient. Prescription filling tasks can also be controlled, such as **printing** labels for **medication** in batches **to** assist with the shipment of medication to prison units. Compliance records associated with medicinal administration of prescribed medications to **patients** can also be maintained...

22/3,K/2 (Item 2 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0013669459 *Drawing available*
WPI Acc no: 2003-765859/200372
XRPX Acc No: N2003-613418

Pharmaceuticals interactions analyzing method for patients, involves issuing warning when specified pharmaceutical contains active substance that is incompatible with profile diagnosed information

Patent Assignee: FAGERHOLM M (FAGE-I); KVARNSTROM N (KVAR-I)
Inventor: FAGERHOLM M; KVARNSTROM N

Patent Family (1 patents, 1 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**
US 20030144883	A1	20030731	US 2002353495	P	20020130	200372	B
			US 2002283772	A	20021029		

Priority Applications (no., kind, date): US 2002353495 P 20020130; US 2002283772 A 20021029

.**Original Abstracts:**is a computer program for analyzing interactions between pharmaceuticals used by a patient by analyzing the prescribed pharmaceutical with a pharmaceutical profile section showing pharmaceuticals **used** by the **patient**, a diagnose **profile section** showing diagnose **information** about the **patient**, and an over-**sensitivity profile** section showing pharmaceuticals and medical substances to which the patient is sensitive. The program automatically issues warnings if the prescribed drug is incompatible with any... **Claims:** We claim: **1**. A method of analyzing interactions between pharmaceuticals used by a patient, comprising: providing a computer program having patient data information of a **patient**, a pharmaceutical **profile** section showing **pharmaceuticals** used by the **patient**, **a** diagnose **profile section** showing diagnose information about the **patient and** an over-**sensitivity profile** section showing pharmaceuticals and medical substances to which the **patient is** sensitive; analyzing a medical database linked to the computer program to **determine** if a **prescribed pharmaceutical** is incompatible with the diagnose information in the diagnose profile section and issuing a warning when the prescribed pharmaceutical is incompatible with the diagnose information...

22/3,K/3 (Item 3 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0012808978 *Drawing available*
WPI Acc no: 2002-666060/200271
XRPX Acc No: N2002-526997
Handheld printing unified medical prescription transcriber for medical practitioners, retrieves digital data from database by matching digital voice signal with stored data and converts it into transcription format during printing
Patent Assignee: HEGARTY D D (HEGA-I); RODAN ENTERPRISES LLC (RODA-N)
Inventor: HEGARTY D D

Patent Family (2 patents, 1 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**
US 20020099534	A1	20020725	US 2001770087	A	20010125	200271	B
US 6889190	B2	20050503	US 2001770087	A	20010125	200531	E

Priority Applications (no., kind, date): US 2001770087 A 20010125
.**Original Abstracts:**a unitary hand held medical prescription transcriber and printing unit. More specifically, a small, portable electronic device is provided which can record words spoken by **a physician** and from those words generate a printed medical prescription that is delivered directly from the device itself. The unit digitizes words spoken by the user... ... unitary hand held medical prescription transcriber and printing unit. More specifically, a small, portable electronic device is provided which can record words spoken by a **physician** and from those **words** generate a printed medical prescription that is delivered directly from the device itself. The unit digitizes words spoken by the user, processes the speech to... ... may display the prescription on a liquid crystal display screen and the user may edit the prescription before printing a hard copy. The unit assists **in** accurate dispensing of **medicines** by providing a legible **prescription** printout, while at the same time being neither time consuming nor difficult to operate.

22/3,K/4 (Item 4 from file: 350)
DIALOG(R)File 350: Derwent WPIX

0012283770
WPI Acc no: 2002-224672/200228
Related WPI Acc No: 2002-507329; 2004-106525; 2004-592623; 2005-581344; 2006-779010
Delivering drug, particularly teratogenic or other hazardous drug to patient involves generating prescription approval code to be retrieved by pharmacy before prescription is filled
Patent Assignee: CELGENE CORP (CGEN)
Inventor: KAMINSHI J K; KAMINSKI J K; WILLIAMS B A; KAMINSKI J; WILLIAMS B

Patent Family (26 patents, 25 countries)							
Patent Number	**Kind**	**Date**	**Application Number**	**Kind**	**Date**	**Update**	**Type**
US 20040122703	A1	20040624	US 2000742703	A	20001220	200428	B
WO 2002035440	A1	20020502	WO 2001US29303	A	20001024	200236	E
AU 2001014372	A	20020506	AU 200114372	A	20001024	200237	E
BR 0115075	A	20030826	BR 2001015075	A	20001024	200369	E
MX 2002006176	A1	20021001	WO 2001US29303	A	20001024	200377	E
US 20040172617	A1	20040902	US 2000742703	A	20001220	200458	E
WO 2002035440	A1	20020502	WO 2001US29303	A	20001024	200236	E
AU 2001014372	A	20020506	AU 200114372	A	20001024	200237	E
BR 0115075	A	20030826	BR 2001015075	A	20001024	200369	E
JP 2006209801	A	20060810	WO 2001US29303	A	20001024	200654	E
EP 1330765	A1	20030730	EP 2001978627	A	20001024	200350	E
NZ 541736	A	20061222	WO 2001US29303	A	20001024	200703	E
CN 1425167	A	20030618	CN 2001807530	A	20001024	200358	E

AU 2005201675	B2	20080313	AU 2005201675	A	20050421	200857	NCE
EP 1970827	A1	20080917	EP 2000976627	A	20001024	200862	E
			EP 200810221	A	20001024		
JP 2009233326	A	20091015	JP 2006108968	A	20001024	200969	E
			JP 200963647	A	20090316		

Priority Applications (no., kind, date): US 2000694217 A 20001023; AU 2005201675 A 20050421

Delivering drug, particularly teratogenic or other hazardous drug to patient involves generating prescription approval code to be retrieved by pharmacy before prescription is filled Technology Focus ...is probative of the onset of the adverse side effect. It also comprises genetic testing. The second set of information comprises a survey regarding the **patients behavior** and compliance with the risk avoidance measures. The survey is effected telephonically using an integrated voice response system. The patient has childbearing potential and the... **Extension Abstract**

B. Patent Files, Full-Text

```
  File 348:EUROPEAN PATENTS 1978-200936
         (c) 2009 European Patent Office
  File 349:PCT FULLTEXT 1979-2009/UB=20090827|UT=20090709
         (c) 2009 WIPO/Thomson

Set     Items   Description
S1      59929   ((SENSITIVE OR DANGEROUS OR MONITORED OR REGULATED OR RISKY
              OR CONTROLLED OR ADDICTIVE OR MOOD()ALTERING OR ILLEGAL OR H-
             ARD OR (HABIT OR ADDICTION)(1N)FORMING OR NARCOTI?ING OR HAZA-
             RDOUS)(3N)(PHARMACEUTIC? OR PHARMAECEUTIC? OR PHARMACO? OR PH-
             ARMAECO? OR DRUG OR DRUGS OR SUBSTANCE OR SUBSTANCES OR MEDIC-
             ATION? ? OR MEDICINE? ? OR PILLS OR MEDICAMENT? ? OR ANAESTHE-
             TIC OR PAINKILLER? ? OR PAIN()KILLER? ? OR STIMULANT? ?) OR N-
             ARCOTIC? ? OR OPIATE OR OPIATES OR OPIOID? ? OR BENZODIAZEPIN-
             ES OR HYDROCODONE)
S2      26066   S1 AND PY=1978:2002
S3      22051   S1 AND ((AC=US OR AC=US/PR) AND AY=1978:2002)
S4      31553   S2 OR S3
S5        221   S1(4N)(PRESCRIPTION? ? OR PRESCRIBE? ? OR PRESCRIBING OR W-
             RITTEN()(ORDER? ? OR INSTRUCTION? ? OR DIRECTION? ?) OR REQUE-
             ST? ? OR SCRIPT? ?)
S6         65   S5(5N)(TRACK? OR MONITOR? OR CONTROL? OR RESTRICT? OR SURV-
             EIL? OR MANAG? OR REGULAT? OR ENFORC? OR INHIBIT? OR LIMIT? OR
              RESTRAIN? OR CONSTRAIN? OR PROHIBIT? OR SUPERVIS? OR CHECKIN-
             G)
S7       4036   (ABUSE? ? OR ABUSIVE? OR ABUSING OR ILLEGAL? OR MISUSE OR -
             MIS()(USE OR USED OR USING) OR MISUSED OR MISUSING OR UNSCRUP-
             ULOUS?? OR UNETHICAL OR DRUG()(DEALER? ? OR DEALING) OR DISCI-
             PLINARY()ACTION? ? OR  MALTREATMENT? ? OR IMPROPER?? OR DISRE-
             PUTABLE OR MISTREATMENT? ? OR MISPRESCRIBING)
S8        348   S7(5N)(PATIENT? ? OR OUTPATIENT? ? OR INPATIENT? ? OR REQU-
             ESTER? ? OR PRESCRIPTION()HOLDER? ? OR CONSUMER? ? OR INDIVID-
             UAL? ? OR PERSON? ? OR CLIENT? ? OR PATRON? ? OR CUSTOMER? ? -
             OR BENEFICIARY? ? OR BENEFICIARIES)
S9         32   S7(5N)(PHARMACIST? ? OR PHARMAECIST? ? OR PHARMACOLOGIST? ?
              OR PHARMAECOLOGIST? ? OR DRUGGIST? ? OR CHEMIST? ? OR APOTHE-
```

```
             CAR? OR PHARMACOPOLIST? ? OR  PHYSICIAN? ? OR DOCTOR? ? OR  C-
             LINICIAN? ? OR SURGEON? ? OR PROVID?R? ? OR PRACTITIONER? ? OR
              PROFESSIONAL? ? OR SPECIALIST? ?)
S10      2090   (CENTRAL OR EXCLUSIVE OR MAIN OR MASTER OR PRIMARY OR BASE
             OR HOMEBASE OR CENTRALI?ED OR  CONTROLLING OR SOLO OR RESTRIC-
             TED)(3N)(PHARMACY OR PHARMACIES OR FACILITY OR FACILITIES OR -
             DRUGGIST? ? OR CHEMIST? ? OR STATION? ? OR BUILDING? ? OR LOC-
             ATION? ? OR CENTER? ? OR CENTRE? ? OR CLINIC? ? OR HOSPITAL? ?
              OR OFFICE OR OFFICES OR ESTABLISHMENT? ? OR SITE OR HEAD()QU-
             ARTER? ? OR HEADQUARTER? ? OR HQ OR APOTHECAR? OR DRUGSTORE OR
              STORE)
S11      2465   (CENTRAL OR EXCLUSIVE OR MAIN OR MASTER OR PRIMARY OR BASE
             OR HOMEBASE OR CENTRALI?ED OR  CONTROLLING OR MAINFRAME)(3N)(-
             DATABASE OR DATABASES OR DATABANK? ? OR DATAFILE? ?  OR DATA(-
             )(BASE OR BASES OR BANK OR BANKS) OR REPOSITOR? OR DB OR D()B
             OR DBMS OR RDBMS OR D()B()M()S OR PORTAL OR PORTALS OR COMPUT-
             ER? ? OR CPU OR SERVER OR SERVERS OR PROCESSOR? ?)
S12        4   S6 (20N) S7
S13        2   S6 (50N) (S8 OR S9)
S14        8   S6 (50N) (S10 OR S11)
S15       11   S12 OR S13 OR S14
S16       42   S5 (20N) S7
S17       11   S16 (30N) (S8 OR S9)
S18        0   S17 (30N) (S10 OR S11)
S19        0   S16 (30N) (S10 OR S11)
S20        0   S16 (60N) (S10 OR S11)
S21        6   S5 (10N) (S10 OR S11)
S22        0   S5 (10N) (S8 AND S9)
S23     1057   S4 (5N) S7
S24       36   S23 (20N) S5
S25        9   S24 (50N) (S8 OR S9)
S26        0   S24 (50N) (S10 OR S11)
S27       29   S4 ( 10N) S10
S28        0   S27 (40N) S7
S29        1   S27 (40N) S11
S30       10   (S17 OR S21 OR S25 OR S29) NOT S15
S31        4   AU=((REARDAN, D? OR REARDAN D? OR REARDAN(2N)D?) OR (ENEEL,
              P? OR ENEEL P? OR ENEEL(2N)P?) OR (GAGNE, B? OR GAGNE B? OR -
             GAGNE(2N)B?))
```

DIALOG(R)File 348: EUROPEAN PATENTS

15/3K/1 (Item 1 from file: 348)
00731437

PATIENT CARE AND COMMUNICATION SYSTEM

PATIENTENGESUNDHEITSVORSORGE- UND KOMMUNIKATIONSSYSTEM

SYSTEME D'ADMINISTRATION DE SOINS ET DE COMMUNICATION

Patent Assignee:

- **EXECUTONE INFORMATION SYSTEMS, INC.** (1852490)
  6 Thorndal Circle; Darien, CT 06820 (US)
  (applicant designated states: AT;BE;CH;DE;DK;ES;FR;GB;GR;IE;IT;LI;LU;MC;NL;PT;SE)

Inventor:

- **CHACO, John**
  1 Great Meadow Road; Seymour, CT 06483; (US)
- **HERSH, Israel**
  175 Sairmont Terrace; Fairfield, CT 06432; (US)

- **ORLOVSKY, Dmitry**
  26 Tamanny Trail; Danbury, CT 06811; (US)
- **VINCENS, Joe**
  15 Roy Mountain Road; Prospect, CT 06712; (US)

Legal Representative:
- **Read, Matthew Charles et al (47911)**
  Venner Shipley & Co. 20 Little Britain; London EC1A 7DH; (GB)

	Country	Number	Kind	Date	
Patent	EP	689699	A1	19960103	(Basic)
	EP	689699	B1	19990428	
	WO	9422098		19940929	
Application	EP	94911420		19940228	
	WO	94US2114		19940228	
Priorities	US	33287		19930316	

If the individual is authorized to access the locker, step 2064 records the identifying information and the authorization information on the **central computer** 432. As each medicine container is removed from the locker, it is scanned by the bar-code reader. When the bar-code information has been scanned, the process changes a value in a memory location to indicate that the container may be removed.
The actual use of the **prescription medicines** may also be **monitored** from the information provided to the **central computer** 432. This information indicates the individuals who had access to the drug locker, the time they removed and returned the medicines, the patients to whom...

DIALOG(R)File 348: EUROPEAN PATENTS

15/3K/2 (Item 2 from file: 348)
00598239
A dispenser for use with a drug dispensing apparatus
Spender zur Anwendung in einer Vorrichtung zur Abgabe von Arzneimitteln
Distributeur pour usage dans un systeme de distribution de medicaments
Patent Assignee:
- **BAXTER INTERNATIONAL INC.** (318505)
  One Baxter Parkway; Deerfield, Illinois 60015 (US)
  (applicant designated states: DE;FR;GB;SE)

Inventor:
- **Blechl, Joseph**
  26036 West Lakeview; Ingleside, Illinois; (US)
- **Hadjimitsos, Panos**
  11 Amherst Court; Buffalo Grove, Illinois; (US)
- **Kurts, James R.**
  128 North Garfield; Mundelein, Illinois; (US)
- **Shimizu, Hiroyasu**
  517-37, Higashi Bessho; Ota-shi, Gunma 373; (JP)

- **Haraguchi, Manabu**
  50-8, Hinode, Oizumi-machi; Ora-gun, Gunma 370-05; (JP)

Legal Representative:
- **Lerwill, John et al (33011)**
  A.A. Thornton & Co. Northumberland House 303-306 High Holborn; London, WC1V 7LE; (GB)

	Country	Number	Kind	Date	
Patent	EP	597558	A2	19940518	(Basic)
	EP	597558	A3	19940608	
	EP	597558	B1	19980114	
Application	EP	93203615		19900525	
Priorities	JP	89132059		19890525	
	JP	90107295		19900423	

Specification: ...Initially, the controlled substances were shipped to medical facilities packaged in containers, such as bottles, jars, and the like. These containers were stored at a **central pharmacy location**. When a doctor required administration of a dose of a **controlled substance** to a patient, a **prescription** was written and a nurse was responsible for obtaining the dosage from the pharmacy and administering it to the patient.

15/3K/8 (Item 4 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT

01033947
APPARATUS AND METHOD FOR CONSTRUCTING FORMULARIES
APPAREIL ET PROCEDE POUR ETABLIR DES NOMENCLATURES DE MEDICAMENTS
Patent Applicant/Patent Assignee:
- **MEDCO HEALTH SOLUTIONS INC**
  100 Parsons Pond Drive, Mailstop F3-19, Franklin Lakes, NJ 07417; US; US(Residence); US(Nationality)

Inventor(s):
- **BROWN Kenneth J**
  100 Parsons Pond Drive, Mailstop F3-19, Franklin Lakes, NJ 07417; US
- **TOBIN William D**
  100 Parsons Pond Drive, Mailstop F3-19, Franklin Lakes, NJ 07417; US
- **STETTIN Glen D**
  100 Parsons Pond Drive, Mailstop E2-04, Franklin Lakes, NJ 07417; US
- **DANIEL Roselin**
  100 Parsons Pond Drive, Mailstop E2-04, Franklin Lakes, NJ 07417; US

Legal Representative:
- **DONNER Irah H(et al)(agent)**
  Hale & Dorr LLP, 1455 Pennsylvania Avenue, N.W., Washington, DC 20004; US

	Country	Number	Kind	Date
Patent	WO	200362954	A2-A3	20030731
Application	WO	2003US1650		20030122
Priorities	US	2002349407		20020122
	US	2003337366		20030107

Detailed Description:
...etc. It is also possible for the CAE 112 to meet directly, or in person, with the user 124 (e.g., healthcare provider representative).

The **central computer** 1 18 of the prescription coverage provider 1 10 stores information pertaining to prescription products that can used in the formulary. The **prescription** products are typically **drugs** and/or **controlled substances** that are useable for medicinal purposes and/or treatments.
Such products are assigned specific identifiers known as a National Drug Code (NDQ identifier. New products...

15/3K/9 (Item 5 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT

00561819
PRESCRIPTION-CONTROLLED DATA COLLECTION SYSTEM AND METHOD
SYSTEME ET PROCEDE DE RECUEIL DE DONNEES COMMANDES PAR UNE ORDONNANCE
Patent Applicant/Patent Assignee:
- **VISIONARY MEDICAL INC**

Inventor(s):
- **SHEEHAN David M**
- **NITZBERG Mark J**
- **FITZGERALD Patrick J**

	Country	Number	Kind	Date
Patent	WO	200025192	A2	20000504
Application	WO	99US24965		19991022
Priorities	US	98105692		19981026

Detailed Description:
...a patient. In this implementation, a doctor at a remote location authorizes the patient to collect and transfer the data in a fashion analogous to **prescribing drugs**.
A **prescription controlled** data collection system 100 according to the present invention is illustrated in Figure 1. In overview, a prescribing party 104 writes a prescription 112 that authorizes a collecting party 122 to collect data and transfer the data to a **central server** II 0. The status of the prescription and data collected (block II 6) are available to the prescribing party 104 having access to server II...

15/3K/11 (Item 7 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT

00273922
PATIENT CARE AND COMMUNICATION SYSTEM
SYSTEME D'ADMINISTRATION DE SOINS ET DE COMMUNICATION
Patent Applicant/Patent Assignee:

- **EXECUTONE INFORMATION SYSTEMS INC**

Inventor(s):

- **CHACO John**
- **HERSH Israel**
- **ORLOVSKY Dmitry**
- **VINCENS Joe**

	Country	Number	Kind	Date
Patent	WO	9422098	A1	19940929
Application	WO	94US2114		19940228
Priorities	US	9333287		19930316

.on door 2011,
If the individual is authorized to access the
15 locker, step 2064 records the identifying information and
the authorization information on the **central computer**
432, As each medicine container is removed from the
locker, it is scanned by the bar-code reader, When the
bar-code information has been scanned, the process
20 changes a value in a memory location to indicate that the
container may be removed,
The actual use of the **prescription medicines**
may also be **monitored** from the information provided to
25 the **central computer** 432, This information indicates the
individuals who had access to the drug locker, the time
they removed and returned the medicines, the patients to
whom...

30/3K/1 (Item 1 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT

01004829
METHODS FOR TREATING SUBSTANCE ABUSE WITH CHOLINESTERASE INHIBITORS
PROCEDES DE TRAITEMENT DE LA CONSOMMATION ABUSIVE DE SUBSTANCES PSYCHOACTIVES A L'AIDE D'INHIBITEURS DE LA CHOLINESTERASE
Patent Applicant/Patent Assignee:

- **EISAI CO LTD**
  Koishikawa 4-6-10, Bunkyo-Ku, Tokyo 112-8088; JP; JP(Residence); JP(Nationality); (For all designated states except: US)

Patent Applicant/Inventor:

- **PRATT Raymond**
  38 Meadow View Court, Leonia, NJ 07605; US; US(Residence); US(Nationality); (Designated only for: US)
- **IENI John**
  253 Ridgewood Avenue, Glen Ridge, NJ 07028; US; US(Residence); US(Nationality); (Designated only for: US)

Legal Representative:

- **GRIEFF Edward D(et al)(agent)**
  The Willard Office Building, 1455 Pennsylvania Avenue NW, Washington, DC 20004; US

	Country	Number	Kind	Date
Patent	WO	200332914	A2-A3	20030424
Application	WO	2002US32998		20021017
Priorities	US	2001329529		20011017

The invention provides methods for treating substance **abuse** in a **patient** by administering an effective amount of at least one cholinesterase inhibitor. The methods of the invention are applicable to any substances that are **abused** by **patients** or that may cause physical and/or psychological dependence (i.e., addiction). **Addictive substances** may be **prescription drugs** or street **drugs**. **Addictive substances** include, for example, alcohol, opioids, anxiolytic drugs, hypnotic drugs, cocaine, psychedelic agents, marijuana, amphetamines, hallucinogens, phencyclidine, benzodiazepines, and the like. Addictive substances include club drugs...

30/3K/9 (Item 9 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT

00563715
REMOTE PHYSICIAN AUTHENTICATION SERVICE
SERVICE D'AUTHENTIFICATION DE MEDECINS A DISTANCE
Patent Applicant/Patent Assignee:

- **PHYSICIAN VERIFICATION SERVICES INC**
- **MCCORMICK Douglas K**
- **DUBNER Robert J**

Inventor(s):

- **MCCORMICK Douglas K**
- **DUBNER Robert J**

	Country	Number	Kind	Date
Patent	WO	200027088	A2	20000511
Application	WO	99US22253		19990924

	Country	Number	Kind	Date
Priorities	US	98106838		19981103
	US	99248308		19990211

.S. regulations, other non-U.S.
national regulatory agencies currently maintain bans on direct-to-consumer advertising.
According to the World Health Organization (WHO), direct **consumer** promotion of **prescription drugs** is **illegal** except in the United States and Morocco.
Backimound: Marketiqg
The pharmaceutical industry spends more than $15 billion annually marketing to physicians in the United States...

30/3K/10 (Item 10 from file: 349)
DIALOG(R)File 349: PCT FULLTEXT

00438212
SYSTEM FOR DRUG AND HEALTH CARE SUPPLY DISTRIBUTION AND REPLENISHMENT
SYSTEME DE DISTRIBUTION ET DE RECHARGE POUR MEDICAMENTS ET FOURNITURES MEDICALES
Patent Applicant/Patent Assignee:

- **PYXIS CORPORATION**

Inventor(s):

- **LESTER Douglas D**
- **COLELLA Salvatore**
- **SWENSON David D**
- **BROADFIELD Laird**
- **DAFT H Thomas**
- **LAWRENCE Stephen M**
- **WIDENHOFER Gerald J**

	Country	Number	Kind	Date
Patent	WO	9828676	A2	19980702
Application	WO	97US22396		19971209
Priorities	US	96762041		19961209
	US	97867605		19970602

Detailed Description:
...program. The communication between the DDMs IS and
9
the health care provider's pharmacy software program of the present invention, may be accomplished through **hard** wiring the **drug** dispensing machines throughout the **facility** to a **central computer** 20 operatin(the pharmacy second software prograrn. Other suitable means, such as RF communication, to provide a cornmunications link between the drug dispensing machines and...

IV. Text Search Results from Dialog

A. NPL Files, Abstract

```
  File  35:Dissertation Abs Online 1861-2009/Aug
        (c) 2009 ProQuest Info&Learning
  File 583:Gale Group Globalbase(TM) 1986-2002/Dec 13
        (c) 2002 Gale/Cengage
  File  65:Inside Conferences 1993-2009/Sep 08
        (c) 2009 BLDSC all rts. reserv.
  File   2:INSPEC 1898-2009/Aug W4
        (c) 2009 The IET
  File 474:New York Times Abs 1969-2009/Sep 08
        (c) 2009 The New York Times
  File 475:Wall Street Journal Abs 1973-2009/Sep 08
        (c) 2009 The New York Times
  File  99:Wilson Appl. Sci & Tech Abs 1983-2009/Aug
        (c) 2009 The HW Wilson Co.
  File 256:TecTrends 1982-2009/Aug W5
        (c) 2009 Info.Sources Inc. All rights res.
  File   5:Biosis Previews(R) 1926-2009/Dec W1
        (c) 2009 The Thomson Corporation
  File  73:EMBASE 1974-2009/Dec 15
        (c) 2009 Elsevier B.V.
  File 155:MEDLINE(R) 1950-2009/Dec 09
        (c) format only 2009 Dialog
  File  34:SciSearch(R) Cited Ref Sci 1990-2009/Dec W1
        (c) 2009 The Thomson Corp
  File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec
        (c) 2006 The Thomson Corp
  File  74:Int.Pharm.Abs 1970-2009/Sep B1
        (c) 2009 The Thomson Corporation
  File  42:Pharm. News Index 1974-2009/Nov W3
        (c) 2009 ProQuest Info&Learning

Set     Items   Description
S1     786496   ((SENSITIVE OR DANGEROUS OR MONITORED OR REGULATED OR RISKY
              OR CONTROLLED OR ADDICTIVE OR MOOD()ALTERING OR ILLEGAL OR H-
             ARD OR (HABIT OR ADDICTION)(1N)FORMING OR NARCOTI?ING OR HAZA-
             RDOUS)(3N)(PHARMACEUTIC? OR PHARMAECEUTIC? OR PHARMACO? OR PH-
             ARMAECO? OR DRUG OR DRUGS OR SUBSTANCE OR SUBSTANCES OR MEDIC-
             ATION? ? OR MEDICINE? ? OR PILLS OR MEDICAMENT? ? OR ANAESTHE-
             TIC OR PAINKILLER? ? OR PAIN()KILLER? ? OR STIMULANT? ?) OR N-
             ARCOTIC? ? OR OPIATE OR OPIATES)
S2      3859   S1(4N)(PRESCRIPTION? ? OR PRESCRIBE? ? OR PRESCRIBING OR W-
             RITTEN()(ORDER? ? OR INSTRUCTION? ? OR DIRECTION? ?) OR REQUE-
             ST? ? OR SCRIPT? ?)
S3      1747   S2(5N)(TRACK? OR MONITOR? OR CONTROL? OR RESTRICT? OR SURV-
             EIL? OR MANAG? OR REGULAT? OR ENFORC? OR INHIBIT? OR LIMIT? OR
              RESTRAIN? OR CONSTRAIN? OR PROHIBIT? OR SUPERVIS? OR CHECKIN-
             G)
S4      3865   (ABUSE? ? OR ABUSIVE? OR ABUSING OR ILLEGAL? OR MISUSE OR -
             MIS()(USE OR USED OR USING) OR MISUSED OR MISUSING OR UNSCRUP-
             ULOUS?? OR UNETHICAL OR DRUG()(DEALER? ? OR DEALING) OR DISCI-
             PLINARY()ACTION? ? OR  MALTREATMENT? ? OR IMPROPER?? OR DISRE-
             PUTABLE OR MISTREATMENT? ?)(4N)(IDENTIF? OR MONITOR? OR ANALY-
             ?E? ? OR ANALYSIS OR ANALY?ING OR WARN? ? OR WARNING? ? OR RE-
             D()FLAG OR ALERT? OR DETECT? OR REVEAL? OR DISCOVER? OR EXPOS-
             E? ? OR EXPOSING OR UNCOVER? OR RECOGNI?E? ? OR RECOGNI?ING OR
```

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             RECOGNITION)
S5       12330   (PATTERN? ? OR HABIT? ? OR RECORD? ? OR HISTORY OR HISTORI-
             ES OR BEHAVIOR? ? OR BEHAVIOUR? ? OR PROFILE OR PROFILES OR R-
             EPORT? ? OR DOCUMENTATION OR FILE OR FILES OR HISTORIC?? OR B-
             ACKGROUND? ?)(3N)(PATIENT? ? OR OUTPATIENT? ? OR INPATIENT? ?
             OR REQUESTER? ? OR PRESCRIPTION()HOLDER? ? OR CONSUMER? ? OR -
             INDIVIDUAL? ? OR PERSON? ? OR CLIENT? ? OR PATRON? ? OR CUSTO-
             MER? ?)
S6        2064   (PATTERN? ? OR HABIT? ? OR RECORD? ? OR HISTORY OR HISTORI-
             ES OR BEHAVIOR? ? OR BEHAVIOUR? ? OR PROFILE OR PROFILES OR R-
             EPORT? ? OR DOCUMENTATION OR FILE OR FILES OR HISTORIC?? OR B-
             ACKGROUND? ? OR PRECENDENT? ? OR CREDENTIAL? ?)(3N)(PHARMACIS-
             T? ? OR PHARMAECIST? ? OR PHARMACOLOGIST? ? OR PHARMAECOLOGIS-
             T? ? OR DRUGGIST? ? OR CHEMIST? ? OR APOTHECAR? OR PHARMACOPO-
             LIST? ? OR  PHYSICIAN? ? OR DOCTOR? ? OR  CLINICIAN? ? OR SUR-
             GEON? ? OR PROVID?R? ? OR PRACTITIONER? ? OR PROFESSIONAL? ? -
             OR SPECIALIST? ?)
S7        2888   (CENTRAL OR EXCLUSIVE OR MAIN OR MASTER OR PRIMARY OR BASE
             OR HOMEBASE OR CENTRALI?ED OR  CONTROLLING OR SOLO OR RESTRIC-
             TED)(3N)(PHARMACY OR PHARMACIES OR FACILITY OR FACILITIES OR -
             DRUGGIST? ? OR CHEMIST? ? OR STATION? ? OR BUILDING? ? OR LOC-
             ATION? ? OR CENTER? ? OR CENTRE? ? OR CLINIC? ? OR HOSPITAL? ?
              OR OFFICE OR OFFICES OR ESTABLISHMENT? ? OR SITE OR HEAD()QU-
             ARTER? ? OR HEADQUARTER? ? OR HQ OR APOTHECAR? OR DRUGSTORE OR
              STORE)
S8        1712   (CENTRAL OR EXCLUSIVE OR MAIN OR MASTER OR PRIMARY OR BASE
             OR HOMEBASE OR CENTRALI?ED OR  CONTROLLING OR MAINFRAME)(3N)(-
             DATABASE OR DATABASES OR DATABANK? ? OR DATAFILE? ?  OR DATA(-
             )(BASE OR BASES OR BANK OR BANKS) OR REPOSITOR? OR DB OR D()B
             OR DBMS OR RDBMS OR D()B()M()S OR PORTAL OR PORTALS OR COMPUT-
             ER? ? OR CPU OR SERVER OR SERVERS)
S9           3   AU=((REARDAN, D? OR REARDAN D? OR REARDAN(2N)D?) OR (ENEEL,
              P? OR ENEEL P? OR ENEEL(2N)P?) OR (GAGNE, B? OR GAGNE B? OR -
             GAGNE(2N)B?))
S10         64   S3 AND S4
S11         10   S10 AND S5
S12          3   S11 AND S6
S13          0   S10 AND S7
S14          1   S10 AND S8
S15          1   (S11 OR S14) NOT PY>2002
S16         38   S3 AND S7
S17          1   S16 AND (DATABASE? ? OR DATA()BASE? ? OR REPOSITOR? OR DB -
              OR D()B OR DBMS OR D()B()M()S)
S18         26   S2 AND S4 AND (S5 OR S6)
S19          0   S18 AND (S7 OR S8)
S20         22   (S16 OR S18) NOT (S15 OR PY>2002)
S21         19   RD  (unique items)
```

15/3,K/1 (Item 1 from file: 74)
DIALOG(R)File 74: Int.Pharm.Abs

00166057 27-02154
CONTROLLED SUBSTANCES UTILIZATION REVIEW TO DETECT ABUSE POTENTIAL
Strachota, A.; Wilkins, N.; Smith, G.; O'Brien, M.
PARTNERS National Health Plans, 7760 France Avenue South, Minneapolis, MN 55435, USA
ASHP Midyear Clinical Meeting, V24, (Dec), pHMO-3, 1989
Abstract of Meeting Presentation

Language: English **Record Type:** Abstract
CONTROLLED SUBSTANCES UTILIZATION REVIEW TO DETECT ABUSE POTENTIAL
...CSUR) was performed screening prescription claims processed from a network model HMO over a 12 month interval. The goal was to reduce the number of **patients** with **profiles** suggestive of drug abuse potential. Criteria indicating potential patient overuse and used for contacting the prescribing physician were: 1. Multiple physicians visited to obtain controlled... ...in 27% of the responses. In 10% of the responses received, the physician was no longer a plan provider. The review raised the awareness of **controlled substance prescribing** to these physicians, was well received and had a positive impact in one-quarter of the responses returned.
Webster

21/3,K/16 (Item 9 from file: 34)
DIALOG(R)File 34: SciSearch(R) Cited Ref Sci

05096113 **Genuine Article#:** TP781 **No. References:** 34
Title: EFFECTIVENESS OF NOTIFICATION AND GROUP EDUCATION IN MODIFYING PRESCRIBING OF REGULATED ANALGESICS
Author: ANDERSEN JF; MCEWAN EL; HRUDEY WP
Corporate Source: BRITISH COLUMBIA MINIST HLTH & MINIST RESPONSIBLE,ADULT CLIN & ADDICT SERV BRANCH,3RD FLOOR/VICTORIA/BC V8T 4J1/CANADA/; UNIV VICTORIA,DEPT PSYCHOL/VICTORIA/BC/CANADA/; UNIV BRITISH COLUMBIA,FAC MED,DEPT HLTH CARE & EPIDEMIOL/VANCOUVER/BC/CANADA/
Journal: CANADIAN MEDICAL ASSOCIATION JOURNAL , 1996 , V 154 , N1 (JAN 1) , P 31-39
ISSN: 0820-3946
Language: ENGLISH **Document Type:** ARTICLE (Abstract Available)
Abstract: ...Nonacademic primary care practices in British Columbia.

Participants: Fifty-four physicians randomly selected from a group of 100 physicians who had written a number of **prescriptions** for **regulated drugs** more than than two standard deviations above the mean number of prescriptions written for such drugs in 1992. Any physician who was unable to participate...
Descriptors:
Identifiers: ...CONTROLLED TRIAL; **PRIMARY** CARE; **OFFICE** PRACTICE; POLYPHARMACY; OUTREACH; BEHAVIOR; FEEDBACK
Research Fronts:

21/3,K/17 (Item 1 from file: 74)
DIALOG(R)File 74: Int.Pharm.Abs

00292283 35-13192
DRUG DIVERSION BY HEALTH PROFESSIONALS
Burke, J. J.; Fitzgerald, M. E.
Cincinnati PD Pharmaceutical Unit, 801 B West 8th Street, Suite 319, Cincinnati, OH 45203, USA
Internet: Burke@choice.net

ASHP Midyear Clinical Meeting, V33, (Dec), pPI-73, 1998
Abstract of Meeting Presentation
Language: English **Record Type:** Abstract

The **illegal** diversion of **prescription drugs** in the health care facility is a national problem that, at one time or another, affects all institutions. Being familiar with the top pharmaceutical drugs of abuse, and how they are used, is the first step in reducing these incidents. Knowing the **profile** of the health **professional** diverting the drugs, and their methods, can offer assistance in identifying the drug dependent person. Utilizing several methods of prevention can make diverting pharmaceuticals in... ...toward rehabilitation of the offender.

Learning objectives: 1. Identify the top prescription drugs of abuse, including how they are used, and their values in the **illegal** market. 2. **Identify** the profile of the prescription drug dependent health professional and methods of drug diversion. 3. Identify specific avenues to enhance the prevention of drug diversion in the health facility.

Self-assessment questions: True or False: 1. Hydrocodone is the most abused pharmaceutical drug. 2. Absenteeism is part of the typical **profile** of the health **professional** diverting prescription drugs. 3. Drug diversion education for the health facility staff assists in reducing incidents of the theft of pharmaceuticals.

Answers: 1. T; 2...

Descriptors: ...diversion, health professionals; Health professions -- drug diversion, overview; Drug diversion -- health professions, overview; Crime -- drug diversion, health professionals; Prescriptions -- drug diversion, health professionals; Drug abuse -- **prescriptions**, **drug diversion**; **Controlled substances** -- abuse, **drug** diversion

21/3,K/19 (Item 3 from file: 74)
DIALOG(R)File 74: Int.Pharm.Abs

00193099 29-00022

ACCEPTANCE BY PHYSICIANS OF RECOMMENDED DRUG REGIMEN MODIFICATIONS

Poole, T. A.; Petry, M. L.
Department of Pharmacy, Manatee Memorial Hospital, 206 Second Street East, Bradenton, FL 34208, USA
ASHP Midyear Clinical Meeting, V26, (Dec), pP-179D, 1991
Abstract of Meeting Presentation
Language: English **Record Type:** Abstract

...attached to the outside of the patient's chart are in use for ranitidine, cefotaxime, ceftazidime, tobramycin, cefoxitin, and ceftriaxone. On a daily basis, the **Pharmacy** computer data **base** is queried to identify patients with orders for the monitored drugs. Using these data, the patient's pharmacy profile and chart are reviewed and a determination is made whether to sticker the chart.

Inappropriate **prescribing** of the **monitored drugs** has decreased significantly since the inception of the program; physician acceptance of the program has been excellent. Through our passive method of intervention using recommended..

```
  File  15:ABI/Inform(R) 1971-2009/Sep 07
        (c) 2009 ProQuest Info&Learning
  File   9:Business & Industry(R) Jul/1994-2009/Sep 05
        (c) 2009 Gale/Cengage
  File 610:Business Wire 1999-2009/Sep 08
        (c) 2009 Business Wire.
  File 810:Business Wire 1986-1999/Feb 28
        (c) 1999 Business Wire
  File 275:Gale Group Computer DB(TM) 1983-2009/Aug 07
        (c) 2009 Gale/Cengage
  File 624:McGraw-Hill Publications 1985-2009/Sep 08
        (c) 2009 McGraw-Hill Co. Inc
  File 621:Gale Group New Prod.Annou.(R) 1985-2009/Jul 30
        (c) 2009 Gale/Cengage
  File 636:Gale Group Newsletter DB(TM) 1987-2009/Aug 13
        (c) 2009 Gale/Cengage
  File 613:PR Newswire 1999-2009/Sep 08
        (c) 2009 PR Newswire Association Inc
  File 813:PR Newswire 1987-1999/Apr 30
        (c) 1999 PR Newswire Association Inc
  File  16:Gale Group PROMT(R) 1990-2009/Aug 13
        (c) 2009 Gale/Cengage
  File 160:Gale Group PROMT(R) 1972-1989
        (c) 1999 The Gale Group
  File 634:San Jose Mercury  Jun 1985-2009/Sep 01
        (c) 2009 San Jose Mercury News
  File 148:Gale Group Trade & Industry DB 1976-2009/Aug 20
        (c) 2009 Gale/Cengage
  File  20:Dialog Global Reporter 1997-2009/Sep 08
        (c) 2009 Dialog
  File 149:TGG Health&Wellness DB(SM) 1976-2009/Nov W2
        (c) 2009 Gale/Cengage
  File 444:New England Journal of Med. 1985-2009/Dec W1
        (c) 2009 Mass. Med. Soc.
  File 129:PHIND(Archival) 1980-2009/Dec W2
        (c) 2009 Informa UK Ltd
  File 130:PHIND(Daily & Current) 2009/Dec 14
        (c) 2009 Informa UK Ltd
  File 455:Drug News & Perspectives 1992-2005/Aug
        (c) 2005 Prous Science

Set     Items   Description
S1     481561   ((SENSITIVE OR DANGEROUS OR MONITORED OR REGULATED OR RISKY
              OR CONTROLLED OR ADDICTIVE OR MOOD()ALTERING OR ILLEGAL OR H-
             ARD OR (HABIT OR ADDICTION)(1N)FORMING OR NARCOTI?ING OR HAZA-
             RDOUS)(3N)(PHARMACEUTIC? OR PHARMAECEUTIC? OR PHARMACO? OR PH-
             ARMAECO? OR DRUG OR DRUGS OR SUBSTANCE OR SUBSTANCES OR MEDIC-
             ATION? ? OR MEDICINE? ? OR PILLS OR MEDICAMENT? ? OR ANAESTHE-
             TIC OR PAINKILLER? ? OR PAIN()KILLER? ? OR STIMULANT? ?) OR N-
             ARCOTIC? ? OR OPIATE OR OPIATES OR OPIOID? ? OR BENZODIAZEPIN-
             ES OR HYDROCODONE)
S2     188468   S1 NOT PY>2002
S3       4840   S2(4N)(PRESCRIPTION? ? OR PRESCRIBE? ? OR PRESCRIBING OR W-
             RITTEN()(ORDER? ? OR INSTRUCTION? ? OR DIRECTION? ?) OR REQUE-
             ST? ? OR SCRIPT? ?)
S4      70239   (ABUSE? ? OR ABUSIVE? OR ABUSING OR ILLEGAL? OR MISUSE OR -
             MIS()(USE OR USED OR USING) OR MISUSED OR MISUSING OR UNSCRUP-
             ULOUS?? OR UNETHICAL OR DRUG()(DEALER? ? OR DEALING) OR DISCI-
```

```
            PLINARY()ACTION? ? OR  MALTREATMENT? ? OR IMPROPER?? OR DISRE-
            PUTABLE OR MISTREATMENT? ? OR MISPRESCRIBING)
S5       7738   (PATTERN? ? OR HABIT? ? OR RECORD? ? OR HISTORY OR HISTORI-
            ES OR BEHAVIOR? ? OR BEHAVIOUR? ? OR PROFILE OR PROFILES OR R-
            EPORT? ? OR DOCUMENTATION OR FILE OR FILES OR HISTORIC?? OR B-
            ACKGROUND? ?)(3N)(PATIENT? ? OR OUTPATIENT? ? OR INPATIENT? ?
            OR REQUESTER? ? OR PRESCRIPTION()HOLDER? ? OR CONSUMER? ? OR -
            INDIVIDUAL? ? OR PERSON? ? OR CLIENT? ? OR PATRON? ? OR CUSTO-
            MER? ?)
S6       3092   (PATTERN? ? OR HABIT? ? OR RECORD? ? OR HISTORY OR HISTORI-
            ES OR BEHAVIOR? ? OR BEHAVIOUR? ? OR PROFILE OR PROFILES OR R-
            EPORT? ? OR DOCUMENTATION OR FILE OR FILES OR HISTORIC?? OR B-
            ACKGROUND? ? OR PRECENDENT? ? OR CREDENTIAL? ?)(3N)(PHARMACIS-
            T? ? OR PHARMAECIST? ? OR PHARMACOLOGIST? ? OR PHARMAECOLOGIS-
            T? ? OR DRUGGIST? ? OR CHEMIST? ? OR APOTHECAR? OR PHARMACOPO-
            LIST? ? OR  PHYSICIAN? ? OR DOCTOR? ? OR  CLINICIAN? ? OR SUR-
            GEON? ? OR PROVID?R? ? OR PRACTITIONER? ? OR PROFESSIONAL? ? -
            OR SPECIALIST? ?)
S7       4055   (CENTRAL OR EXCLUSIVE OR MAIN OR MASTER OR PRIMARY OR BASE
            OR HOMEBASE OR CENTRALI?ED OR  CONTROLLING OR SOLO OR RESTRIC-
            TED)(3N)(PHARMACY OR PHARMACIES OR FACILITY OR FACILITIES OR -
            DRUGGIST? ? OR CHEMIST? ? OR STATION? ? OR BUILDING? ? OR LOC-
            ATION? ? OR CENTER? ? OR CENTRE? ? OR CLINIC? ? OR HOSPITAL? ?
             OR OFFICE OR OFFICES OR ESTABLISHMENT? ? OR SITE OR HEAD()QU-
            ARTER? ? OR HEADQUARTER? ? OR HQ OR APOTHECAR? OR DRUGSTORE OR
             STORE)
S8         96   S7(5N)(DATABASE OR DATABASES OR DATABANK? ? OR DATAFILE? ?
            OR DATA()(BASE OR BASES OR BANK OR BANKS) OR REPOSITOR? OR DB
            OR D()B OR DBMS OR RDBMS OR D()B()M()S OR PORTAL OR PORTALS -
            OR COMPUTER? ? OR CPU OR SERVER OR SERVERS OR PROCESSOR? ?)
S9       1185   S3 (15N) S4
S10        29   S9 (20N) S5
S11         1   S10 (20N) S6
S12         3   S9 (20N) S6
S13         0   (S10 OR S12) (20N) S8
S14         0   (S10 OR S12) (S)S8
S15         0   (S10 OR S12)(S) S7
S16      1631   S3(5N)(TRACK? OR MONITOR? OR CONTROL? OR RESTRICT? OR SURV-
            EIL? OR MANAG? OR REGULAT? OR ENFORC? OR INHIBIT? OR LIMIT? OR
             RESTRAIN? OR CONSTRAIN? OR PROHIBIT? OR SUPERVIS? OR CHECKIN-
            G)
S17      5935   S4(4N)(IDENTIF? OR MONITOR? OR ANALY?E? ? OR ANALYSIS OR A-
            NALY?ING OR WARN? ? OR WARNING? ? OR RED()FLAG OR ALERT? OR D-
            ETECT? OR REVEAL? OR DISCOVER? OR EXPOSE? ? OR EXPOSING OR UN-
            COVER? OR RECOGNI?E? ? OR RECOGNI?ING OR RECOGNITION)
S18        37   S16 (S) S17
S19         9   S18 (S)(S5 OR S6)
S20         1   S18 (S)S7
S21        11   S11 OR S12 OR S19 OR S20
S22        10   RD  (unique items)
S23         0   AU=((REARDAN, D? OR REARDAN D? OR REARDAN(2N)D?) OR (ENEEL,
             P? OR ENEEL P? OR ENEEL(2N)P?) OR (GAGNE, B? OR GAGNE B? OR -
            GAGNE(2N)B?))
```

22/3,K/1 (Item 1 from file: 636)
DIALOG(R)File 636: Gale Group Newsletter DB(TM)

01825163 **Supplier Number:** 43098337 **(USE FORMAT 7 FOR FULLTEXT)**
HOUSE BILLS
Health Legislation & Regulation , p N/A

June 24 , 1992
Language: English **Record Type:** Fulltext
Document Type: Newsletter ; Trade
Word Count: 275

-

H.R.5051. To prevent and **detect illegal** and inappropriate drug distribution leading to increased health costs and drug abuse by allowing information on **prescription** of **drugs** that are **controlled substances** in schedules II, III, and IV, to be electronically transmitted to and collected by **central repositories** of designated state health agencies to improve the confidentiality of **patient records**, and to ensure improved treatment of pain, mental health-related needs and other patient prescribing needs. (Stark) Commerce.

H.R.5052. To provide for the...

22/3,K/2 (Item 2 from file: 636)
DIALOG(R)File 636: Gale Group Newsletter DB(TM)

01808643 **Supplier Number:** 43051875 **(USE FORMAT 7 FOR FULLTEXT)**
New Bills in Congress: SENATE BILLS AND HOUSE BILLS
Health Manager's Update , p N/A
June 3 , 1992
Language: English **Record Type:** Fulltext
Document Type: Magazine/Journal ; Trade
Word Count: 596

-

...affordable health insurance is available to all citizens through a Unimed Program. (Ford) Ways & Means, Commerce, and Education & Labor.

H.R.5051. To prevent and **detect illegal** and inappropriate drug distribution leading to increased health costs and drug abuse by allowing information on **prescription** of **drugs** that are **controlled substances** in schedules II, III, and IV, to be electronically transmitted to and collected by **central repositories** of designated state health agencies to improve the confidentiality of **patient records**, and to ensure improved treatment of pain, mental health-related needs and other patient prescribing needs. (Stark) Commerce.

H.R.5052. To provide for the...

22/3,K/3 (Item 3 from file: 636)
DIALOG(R)File 636: Gale Group Newsletter DB(TM)

01790574 **Supplier Number:** 43001457 **(USE FORMAT 7 FOR FULLTEXT)**

HEARING FOR US FDA BILL THIS MONTH?
Marketletter , p N/A

May 18 , 1992
Language: English **Record Type:** Fulltext
Document Type: Magazine/Journal; Newsletter ; Trade
Word Count: 329
-
...Stark has introduced his Prescription Accountability & Patient Care Improve-ment Act (HR 5051) into the House.
The aim of this legislation is to prevent and **detect illegal** and inappropriate drug distribution leading to increased health costs and drug abuse, by allowing information on **prescriptions** of **controlled substances** in Schedules II, III and IV to be electronically collected by "central repositories of designated state health agencies." This will improve the confidentiality of **patient records**, and ensure improved treatment of pain and other patient needs, says the bill.

22/3,K/5 (Item 1 from file: 20)
DIALOG(R)File 20: Dialog Global Reporter

09622045 **(USE FORMAT 7 OR 9 FOR FULLTEXT)**
(Editorial) Doctors take to the streets
KOREA HERALD
February 18, 2000
Journal Code: FKHD **Language:** English **Record Type:** FULLTEXT
Word Count: 747
(USE FORMAT 7 OR 9 FOR FULLTEXT)
...monitored. Otherwise, the misuse or even alteration of prescriptions at drugstores can occur. Such malpractice may have tragic effects. Pharmacists, for instance, are required to **report** to **patients** ' clinics or hospitals in the event they substitute some of the prescribed medicines, but whether they will comply with the requirement is a matter that...

22/3,K/6 (Item 1 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)

01313805 **Supplier Number:** 11666494 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Responsible prescribing of controlled substances.
Voth, Eric A.; Dupont, Robert L.; Voth, Harold M.
American Family Physician , v44 , n5 , p1673(6)
Nov ,
1991
Publication Format: Magazine/Journal
ISSN: 0002-838X
Language: English

Record Type: Fulltext; Abstract **Target Audience:** Professional
Word Count: 2141 **Line Count:** 00254
Abstract: Physicians' prescribing habits are carefully **regulated** when **controlled substances** are involved. **Disciplinary actions** for **improper** prescribing can range from loss of prescribing privileges to loss of one's medical license. Data from the Drug **Abuse Warning** Network **reveal** that, in 1987, 14 of the 20 most common causes of drug overdose, dependence or adverse effects were caused either by prescription or over-the...
Abstract:
...have two incentives for obtaining drugs; they may abuse the prescribed controlled substances themselves or sell them to other addicts.
Avoiding Problems in Practice
The **detection** of prescription **abuse** may require an attitude shift on the part of the physician. Physicians tend to trust their patients and therefore may be at risk for manipulation. When a patient **requests** a **controlled substance**, it may be prudent to question the validity of the **patient**'s medical **history** and to "read between the lines."
Identifying the potential overdose victim can be difficult. Patients who are confused or mildly demented may accidentally take medications...

22/3,K/7 (Item 2 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)

01313366 **Supplier Number:** 11198422 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Institution of a 'no narcotics' policy for after-hours telephone calls.
Madlon-Kay, Diane J.
Journal of Family Practice , v33 , n1 , p92(3)
July ,
1991
Publication Format: Magazine/Journal
ISSN: 0094-3509
Language: English
Record Type: Fulltext; Abstract **Target Audience:** Professional
Word Count: 1569 **Line Count:** 00192
...been previously diagnosed as substance abusers by their clinic physicians. Five patients' charts revealed multiple requests for controlled medications but no specific diagnosis of substance **abuse**.
The 28 patients **identified** as substance abusers did not differ significantly from nonabusers in terms of age, sex, **primary clinic**, day of call, symptom, or wether a specific medication was requested.
Eight of the ten residents completed a questionnaire about their experience with the "no...

22/3,K/8 (Item 3 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)

01260740 **Supplier Number:** 10841835
Intravenous methylphenidate abuse: prototype for prescription drug abuse.
Parran, Theodore Vandoren, Jr.; Jasinski, Donald R.
Archives of Internal Medicine , v151 , n4 , p781(3)
April ,
1991
Document Type: evaluation **Publication Format:** Magazine/Journal
ISSN: 0003-9926
Language: English
Record Type: Abstract **Target Audience:** Professional

Abstract: ...of its effects. As methylphenidate has been prescribed more frequently of late for hyperactive children and those with attention-deficit disorder, more cases of its **abuse** have been **recognized**. A series of 22 patients who were known methylphenidate abusers were described. Nine of these had children who were on methylphenidate for hyperactivity. All of these **patients** had long **histories** of drug abuse; 21 of them used the methylphenidate intravenously. All had complications attributable to their use of the drug. Among these were weight loss... ...cause the various types of lung disease seen. Of note is the fact that the methylphenidate abused by these patients was obtained solely through physicians' **prescriptions**. Since this is a **controlled substance**, educating physicians to recognize drug-seeking behavior and requiring such devices as triplicate prescription forms with meticulous record-keeping are among the mechanisms necessary to...
Abstract:

22/3,K/9 (Item 4 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)

01193074 **Supplier Number:** 08134753 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Help for impaired physicians.
McDermott, Robert M.; Samkoff, J.
Physician Executive , v15 , n1 , p26(4)
Jan-Feb ,
1989
Publication Format: Magazine/Journal
ISSN: 0898-2759
Language: English
Record Type: Fulltext **Target Audience:** Professional
Word Count: 2656 **Line Count:** 00224
...so-called geographical cure"). State impaired physician programs are generally in a better position to provide ongoing monitoring than are hospital-based programs, and will **report** on the **physician**'s progress in treatment to the appropriate person at the physician's workplace. Hospitals should consider making loans available to cover any treatment costs not...

...impaired physician program assists in formulating after care plans, monitors compliance with the terms of the plan (including attendance at support group meetings and urine **monitoring** for **abuse** of drugs, in the case of chemical dependence), and maintains communication

with the treating physician, with the therapist, with the person monitoring the recovering physician...Schedule II and III drugs by physicians recovering from chemical dependence should be monitored by the designated clinical supervisor. The recovering physician should refrain from **prescribing** any **controlled drugs** until privileges are fully reinstated. The physician should agree not to use such drugs unless they are prescribed by another physician for a legitimate reason...

22/3,K/10 (Item 5 from file: 149)
DIALOG(R)File 149: TGG Health&Wellness DB(SM)

01118602 **Supplier Number:** 05201437 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Pharmacists say no to prescription forgery. (includes related articles)
Weiss, Barbara
Drug Topics , v131 , p36(7)
Aug 17 ,
1987
Publication Format: Magazine/Journal
ISSN: 0012-6616
Language: English
Record Type: Fulltext **Target Audience:** Trade
Word Count: 3991 **Line Count:** 00369
...clinic is careful about taking too many Rxs from certain doctors in the "nerve' and "pain' categories. Other pharmacists watch out for doctors who overprescribe **narcotics** or otherwise **abuse** their **prescribing** privileges.

Pharmacists also keep an eye out for patients who are likely to be abusers. Many **pharmacists** keep **patient profiles** to help them weed out the "shoppers'--patients who go to many doctors for the same medication. And patients with known reputations as drug abusers...

V. Additional Resources Searched

A. ProQuest

No documents found for: *(((sensitive or monitored or controlled or regulated or addictive or illegal or "habit forming" or narcotizing) w/3 (drug? or pharmaceutical? or pharmaeceutical? or substance? or medication or medicine?)) or narcotic? or opioid? or opiate?) W/3 (prescription? or prescribe? or prescribing) W/3 TEXT((track* or monitor* or control* or restrict* or surveil* or manag* or regulat* or enforc* or inhibit* or limit* or restrain* or constrain* or prohibit* or supervis* or checking)) AND TEXT((abuse? or abuser? or abusive* or abusing or misuse or misused or misusing or unscrupulous* or misprescribing)) AND TEXT((central or exclusive or main or master or primary or base or homebase or centrali?ed or controlling or solo or restricted or mainframe) w/3 (database or databases)) AND PDN(<12/17/2002)*

No documents found for: *((((sensitive or monitored or controlled or regulated or addictive or illegal or "habit forming" or narcotizing) w/3 (drug? or pharmaceutical? or pharmaeceutical? or substance? or medication or medicine?)) or narcotic? or opioid? or opiate?) W/3 (prescription? or prescribe? or prescribing) W/3 TEXT((track* or monitor* or control* or restrict* or surveil* or manag* or regulat* or enforc* or inhibit* or limit* or restrain* or constrain* or prohibit* or supervis* or checking)) AND TEXT((abuse? or abuser? or abusive* or abusing or misuse or misused or misusing or unscrupulous* or misprescribing)) AND TEXT((central or exclusive or main or master or primary or base or homebase or centrali?ed or controlling or solo or restricted) w/3 (pharmacy or pharmacies or facility or facilities or druggist? or chemist? or location? or hospital? or apothecar*)) AND PDN(<12/17/2002)*

No documents found for: *(((sensitive or monitored or controlled or regulated or addictive or illegal or "habit forming" or narcotizing) w/3 (drug? or pharmaceutical? or pharmaeceutical? or substance? or medication or medicine?)) or narcotic? or opioid? or opiate?) W/3 TEXT(prescription? or prescribe? or prescribing) W/3 TEXT((track* or monitor* or control* or restrict* or surveil* or manag* or regulat* or enforc* or inhibit* or limit* or restrain* or constrain* or prohibit* or supervis* or checking)) AND TEXT((abuse? or abuser? or abusive* or abusing or misuse or misused or misusing or unscrupulous* or misprescribing)) AND PDN(<12/17/2002)*

12 documents found for: *(((sensitive or monitored or controlled or regulated or addictive or illegal or "habit forming" or narcotizing) w/3 (drug? or pharmaceutical? or pharmaeceutical? or substance? or medication or medicine?)) or narcotic? or opioid? or opiate?) AND TEXT(prescription? or prescribe? or prescribing) AND TEXT((track* or monitor* or control* or restrict* or surveil* or manag* or regulat* or enforc* or inhibit* or limit* or restrain* or constrain* or prohibit* or supervis* or checking)) AND TEXT((abuse? or abuser? or abusive* or abusing or misuse or misused or misusing or unscrupulous* or misprescribing)) AND TEXT((central or exclusive or main or master or primary or base or homebase or centrali?ed or controlling or solo or restricted or mainframe) w/3 (database or databases or repositor*)) AND PDN(<12/17/2002)*

N.B. looks into program to monitor prescription drugs

BOBBI-JEAN MACKINNON. **New Brunswick Telegraph Journal**. Saint John, N.B.: Jun 1, 2002.

Abstract (Summary)

Health Minister Elvy Robichaud will ask staff already reviewing the prescription drug plan to look at the jury's recommendation as part of their mandate. Some of the other recommendations included: implementing a triplicate prescription program for narcotics, with one copy each for the physician, pharmacist and the College of Physicians and Surgeons; reinstating the position of a federal narcotics inspector who travels from pharmacy to pharmacy gathering information about possible cases of overprescribing by doctors or drug abuse by patients; and making it mandatory for pharmacies not to fill prescriptions for narcotics more than one day early.

The province will consider developing a prescription drug monitoring program, as recommended by a coroner's jury this week.

Health Minister Elvy Robichaud will ask staff already reviewing the prescription drug plan to look at the jury's recommendation as part of their mandate.

He expects a report by September.

The four-day coroner's inquest into the prescription overdose death of Stephen Beshara, 20, of Rothesay, came up with 17 recommendations to prevent similar deaths.

Some of the other recommendations included: implementing a triplicate prescription program for narcotics, with one copy each for the physician, pharmacist and the College of Physicians and Surgeons; reinstating the position of a federal narcotics inspector who travels from pharmacy to pharmacy gathering information about possible cases of overprescribing by doctors or drug abuse by patients; and making it mandatory for pharmacies not to fill prescriptions for narcotics more than one day early.

Mr. Beshara died in his sleep on Dec. 19, 2000. Autopsy results revealed several prescription drugs in his system, including Valium and Dilaudid, a powerful and addictive painkiller. Mr. Beshara had legitimate prescriptions for the drugs - all from Dr. Joe McLaughlin, of Quispamsis.

Asked by reporters whether he thought the idea of a monitoring program made sense, Mr. Robichaud said: Yes, yes. It always makes sense and it's always been something we wanted to do."

But it comes down to funding, he said, with estimates ranging from $50 to $100 million to develop a real-time central computer database of prescription information all pharmacies can access. "Definitely there is an intention to do that, but with the resources we have, it's to do what is more practical at this very moment," said Mr. Robichaud. "But then again, I will ask the staff to have a look at it and see what could be done in the short term."

As it stands, the department only monitors prescriptions the province covers for low-income seniors and people on income assistance, Susan Gamble, project manager of the prescription drug program in Fredericton, testified at the inquest.

The system records all prescriptions purchased through the person's drug card, she said. The government does not have the right to track prescriptions not put through on the cards, she said.

Every month, the system reviews data from the past three months, looking for "red flags," such as the person seeing three or more doctors, visiting three or more pharmacies, receiving nine or more prescriptions for the same drug, or more than 50 prescriptions in total, said Ms. Gamble.

It highlights about 25,000 cases per year, she said. Staff will then take a closer look at the cases. Dilaudid, an increasingly abused drug, is one of the first things they'll look for, she said.

If staff feels the cases warrant further investigation, they usually send letters to the pharmacies involved expressing concern. In many cases, there are legitimate explanations, such as the person being a palliative care patient, said Ms. Gamble.

If there is evidence of a problem, the government can restrict the person to one doctor and one pharmacy of their choice if they want to continue receiving benefits. But Medicare will still pay for the person to see another doctor and the government has no control over the person paying cash for prescriptions at other pharmacies, she said.

Mr. Beshara's file was not one that would have been flagged, said Ms. Gamble. Of the 13 prescriptions the government covered for him in 2000, all of them were from the same doctor and although he did go to a few different pharmacies, it wasn't within a three-month period. "His file is not one I would look into as far as restricting a client," she said.

The inquest heard from other witnesses that Mr. Beshara received at least eight other prescriptions that were not put through on his government card. Most of them were for Valium, which is relatively cheap compared to some other drugs, said Ms. Gamble.

Some people who know the system and don't want the government to know how many drugs they're getting will choose to pay cash for the cheaper drugs and only put the more expensive ones through on their cards, she said.

The government is always looking at improving processes, said Ms. Gamble. "With drug abuses province-wide, we continue to look to see what we can do to safeguard.

"There are a lot of thin lines" to balance, she said, citing the human rights of clients and the rights of doctors to prescribe.

If the province does decide to implement a drug monitoring program, several witnesses suggested using British Columbia's system, introduced in 1995, as a model.

PharmaNet, a partnership between the B.C. Ministry of Health and the College of Pharmacists of B.C., is a secure, real-time computer network that links all community pharmacies as well as many hospital pharmacies to a central database of information, which includes, among other things, patient medication histories and drug information.

Every time a prescription is dispensed, a medication profile for the patient is returned to the pharmacist for review. The profile includes all prescriptions dispensed at any pharmacy in the past 14 months, alerting the pharmacist to potential overprescribing or misuse of prescription drugs.

It also alerts the pharmacist if the dose prescribed or the duration of therapy is outside normal limits, provides warnings of potential harmful medication interactions, and provides, at the pharmacist's request, educational material for the patient.

It may also advise the pharmacist of any adverse reactions, allergies and clinical conditions recorded for the patient.

Response time for the system is usually about five seconds.

Statistics for the first three months of this year show that PharmaNet flagged:

372 cases of potential overuse/abuse

193 cases of suspected multiple-doctoring or polypharmacing

68 cases of falsified or altered prescriptions

more than 128,000 cases of potential drug interactions

The system has also been introduced in hospital emergency departments and, in a recent pilot, in doctors' offices.

PharmaNet operates behind a firewall that prevents unauthorized use. All users are required to sign confidentiality agreements before being granted access and must provide unique identifiers when logging into the system.

Patients can also ask a pharmacist to place a keyword on their patient profile, which further limits access. The patient simply reveals the keyword at the time of the purchase. In cases of emergency, if the patient is unable to provide the keyword, their doctor can contact the PharmaNet 24-hour help desk to request that the keyword be removed from the patient's profile.

The system cost about $20 million to set up and costs about $9 million annually to operate.

Although estimates of how much it would cost to implement a similar system in New Brunswick vary widely, most agree it would cost much less since it is a much smaller province.

The population of B.C. is about four million, up from about 3.8 million in 1995 when the system was established. By comparison, New Brunswick's population is only about 757,000.

New Brunswick also has far fewer pharmacies at 167, compared to B.C's 850.

HOUSE OKS CREATION OF DATABASE ON NARCOTICS IN SOUTHWEST VA.; [FINAL Edition]

KATRICE FRANKLIN THE VIRGINIAN-PILOT. **Virginian - Pilot**. Norfolk, Va.: Mar 8, 2002. pg. B.4

Abstract (Summary)

The House of Delegates voted 59-40 Thursday to begin devising a limited database that lists the names and addresses of Southwest Virginians who buy any of 16 narcotics, including codeine, morphine and opium.

The database, which would be kept confidential and controlled by the state Department of Health director, would take about 18 months to create. The intent is to stop drug abusers from taking prescriptions to several pharmacists to get them filled. To catch abusers, police must now visit pharmacists believed to have filled the addicts' prescriptions.

Graphic THE BILL The House of Delegates voted to begin devising a database of names and addresses of Southwest Virginians who buy any of 16 dangerous narcotics, including codeine, morphine and opium.

Swallowing strong pain medicine won't place most Virginians on a new controversial state database that tracks certain pharmacist- filled prescriptions.

But Southwest Virginians who take addictive narcotics - legally or illegally - will soon be a part of a prescription-monitoring program that some say is destined for the rest of the state.

The House of Delegates voted 59-40 Thursday to begin devising a limited database that lists the names and addresses of Southwest Virginians who buy any of 16 narcotics, including codeine, morphine and opium.

Supporters of the measure said the monitoring program would help the state crack down on drug abuse and save lives. Opponents warned that it could invade the privacy of legal drug users, including cancer patients.

An identical measure for a two-year test program has been approved by the Senate. The bill now goes to Gov. Mark R. Warner, who must decide whether to sign it into law.

The database, which would be kept confidential and controlled by the state Department of Health director, would take about 18 months to create. The intent is to stop drug abusers from taking prescriptions to several pharmacists to get them filled. To catch abusers, police must now visit pharmacists believed to have filled the addicts' prescriptions.

Access to the database would be restricted to state police actively investigating a suspected abuser. Anyone publicly releasing the confidential material would be subject to a maximum $2,500 fine and a year in jail.

Sponsors of the measure originally sought to make the database statewide and monitor a wider variety of drugs, including some cough syrups. But several lawmakers said the program infringed on personal privacy.

Del. S. Chris Jones, R-Suffolk, helped revise the bill. Jones, a pharmacist, admitted the problem isn't limited to Southwest Virginia.

During a lengthy debate on the bill, SB425, supporters said the database is the state's best attempt at stopping the escalating abuse of OxyContin. The drug is a prescribed pain killer that some people crush and inject to get high.

The addictions have resulted in more than 100 deaths nationwide, about half in Virginia and many in the southwest region which borders Kentucky and West Virginia. Both states have set up similar databases to stop the addictions.

Opponents said the program smacked of "Big Brother."

"It will inevitably have a chilling effect on doctors' willingness to prescribe pain medications," said Del. Kristen J. Amundson, D- Fairfax.

Amundson's father died last month of cancer. He took OxyContin.

"This is where the erosion of freedom begins ladies and gentlemen," said Del. Ward L. Armstrong, D-Henry.

Reach Katrice Franklin at (804) 697-1563 or kfrankli(AT)pilotonline.com

Registry may reduce illegal use of drug

THERESE SMITH COX. **Charleston Daily Mail**. Charleston, W.V.: Apr 19, 2001. pg. 6.C

Health and law enforcement officials hope the illicit use of the prescription painkiller OxyContin decreases under a new law awaiting the governor's signature. Legislators agreed to require the state Health Care Authority to create a central repository for information on certain drugs, including the practitioners who prescribed them, the pharmacies that filled the orders and the patients who received them.

The measure modifies the controlled substances monitoring act by targeting Schedule II, III and IV drugs selected by the Health Care Authority.

While Schedule I drugs are highly abused but have no accepted medical use, Schedule II drugs are those prescriptions with high abuse potential, such as oxycodone, amphetamines and morphine. Schedule III have less abuse potential and include acetaminophen with some quantities of narcotics. And Schedule IV drugs, such as benzodiazepines, carry even less abuse potential.

Sallie Hunt, the authority's chief policy officer, said the data will be confidential but will be available to the State Police and authorized state licensing boards, such as medicine, osteopathic medicine and pharmacy.

"It is in reaction to OxyContin problems and the need for the state to get its arms around pharmacy costs in general," Hunt said.

Sgt. Michael Corsaro, spokesman for the State Police, said the measure is another weapon in officers' arsenal against illegal use of narcotic substances.

"The State Police could use this as an excellent tool in the fight against certain narcotic substances," Corsaro said.

While Steve Neddo of the Metro Drug Unit said the registry could be a big help in tracking the illicit use of OxyContin and other addictive prescription drugs, he believes his office also should have access to the data bank.

OxyContin, a powerful drug often a godsend to those with advanced cancer pain, cost the state Medicaid program nearly $4 million last year and also was the most expensive drug group for the state Workers' Compensation Division during the last quarter of 2000.

Reports abound of the illicit use of the addictive narcotic by patients who shop for doctors who will prescribe it and pharmacies that will fill it. Others sell the prescription on the street at $1 a milligram.

Though Medicaid and Workers' Compensation can track OxyContin sales through reimbursement systems, they can't record data when people pay cash for the drug.

But the new law would require all legitimate sales of OxyContin and other targeted drugs to be recorded in a data bank.

Here's how it will work, said William Douglas, executive director and general counsel for the state Board of Pharmacy:

Once the targeted drugs are selected, every prescription filled will be transmitted electronically from the point of sale to the authority. Or, the information will go on a disk and be submitted monthly. The information will be organized by patient, doctor or drug, Douglas said.

"This is the only way to accurately know who is getting drugs from what doctors and pharmacies," Douglas said.

The bill also gives legal immunity to pharmacists for refusing to fill certain prescriptions.

West Virginia lawmakers implemented a similar law in 1996 but did not fund it adequately. After 18 months, it fizzled.

The Health Care Authority asked for $332,464 to implement the law this time and $80,282 a year thereafter, Hunt said. Legislators this week will decide if it's worth it.

Now 17 other states have similar laws, Douglas said.

"This could have great implications in the state in getting a handle on controlled substance abuse going on," he said. "We get anecdotal stories but what is true abuse? This is the only way to have specific data."

Therese Smith Cox can be reached at 348-4874 or by e-mail at therese@dailymail.com.

B. EBSCOhost

(((sensitive or monitored or controlled or regulated or addictive or illegal or "habit forming" or narcotizing) N3 (drug? or pharmaceutical? or pharmaeceutical? or substance? or medication or medicine?)) or narcotic? or opioid? or opiate?) AND (prescription? or prescribe? or prescribing) AND (track or monitor* or control* or restrict* or surveil* or manag* or regulat* or enforc* or inhibit* or limit* or restrain* or constrain* or prohibit* or supervis* or checking) AND (abuse? or abuser? or abusive* or abusing or misuse or misused or misusing or unscrupulous* or misprescribing) AND ((central or exclusive or main or master or primary or base or homebase or centrali?ed or controlling or solo or restricted or mainframe) N3 (database or databases or repositor*)) AND ((central or exclusive or main or master or primary or base or homebase or centrali?ed or controlling or solo or restricted) N3 (pharmacy or pharmacies or facility or facilities or druggist? or chemist? or location? or hospital? or apothecar*))*

Note: Your initial search query did not yield any results.

Notice of References Cited	Application/Control No. 10/322,348	Applicant(s)/Patent Under Reexamination REARDAN ET AL.	
	Examiner LENA NAJARIAN	Art Unit 3686	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,737,539	04-1998	Edelson et al.	705/3
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

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NOTICE OF ALLOWANCE AND FEE(S) DUE

21186 7590 12/31/2009

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

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	

DATE MAILED: 12/31/2009

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

TITLE OF INVENTION: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	03/31/2010

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

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

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

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

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

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

If the SMALL ENTITY is shown as NO:

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

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

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

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

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

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

PART B - FEE(S) TRANSMITTAL

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

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

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

21186 7590 12/31/2009

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

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

Certificate of Mailing or Transmission

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

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

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

TITLE OF INVENTION: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	03/31/2010

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

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

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

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

2. For printing on the patent front page, list

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

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

1 _____

2 _____

3 _____

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

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

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

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

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

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

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

❑ A check is enclosed.

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

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

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

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

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

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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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 12/31/2009

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P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	

DATE MAILED: 12/31/2009

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

The Patent Term Adjustment to date is 446 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 446 day(s).

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

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

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

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

Notice of Allowability	Application No.	Applicant(s)	
	10/322,348	REARDAN ET AL.	
	Examiner	Art Unit	
	LENA NAJARIAN	3686	

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

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

1. ☒ This communication is responsive to *11/2/09*.

2. ☒ The allowed claim(s) is/are *32-42*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

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

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

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

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

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

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 20091102
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Examiner's Amendment

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

Authorization for this examiner's amendment was given in a telephone interview with David D'Zurilla (Reg. No. 36,776) on 12/10/09.

The application has been amended as follows:

32. (Currently Amended) A computerized method of distributing a ~~sensitive~~ prescription drug under exclusive control of an exclusive central pharmacy, the method comprising:

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

requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations, such that all prescriptions for the ~~sensitive~~ prescription drug are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor the credentials of the any and all doctors to determine the eligibility of the doctors to prescribe the prescription drug;

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

checking the exclusive computer database for potential abuse of the ~~sensitive~~ prescription drug;

mailing the ~~sensitive~~ prescription drug to the patient only if no potential abuse is found by the patient to whom the ~~sensitive~~ prescription drug is prescribed and the doctor prescribing the ~~sensitive~~ prescription drug;

confirming receipt by the patient of the ~~sensitive~~ prescription drug; and

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

33. (Currently Amended) A computerized method of distributing a ~~sensitive~~ prescription drug under exclusive control of an exclusive central pharmacy, the method comprising:

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

entering the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations, such that all prescriptions for the ~~sensitive~~ prescription drug are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor the credentials of the any and all doctors to determine the eligibility of the doctors to prescribe the prescription drug;

checking the exclusive computer database for potential abuse of the ~~sensitive~~ prescription drug;

mailing the ~~sensitive~~ prescription drug to a patient only if no potential abuse is found by the patient to whom the ~~sensitive~~ prescription drug is prescribed and the doctor prescribing the ~~sensitive~~ prescription drug;

confirming receipt by the patient of the ~~sensitive~~ prescription drug; and

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

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

37. (Currently Amended) The method of claim 33 wherein the ~~sensitive~~ prescription drug comprises gamma hydroxy butyrate (GHB).

38. (Currently Amended) A computerized method of distributing a ~~sensitive~~ prescription drug under control of an exclusive central pharmacy, the method comprising:

receiving in a computer processor prescription requests, for any and all patients being prescribed the ~~sensitive~~ prescription drug, only at the central pharmacy from any and all authorized prescribers allowed to prescribed the ~~sensitive~~ prescription drug, the prescription requests containing information identifying patients, the ~~sensitive~~ prescription drug, and various credentials of the any and all authorized prescribers;

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~~

prescription drug, such that all prescriptions for the ~~sensitive~~ prescription drug are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor the credentials of the any and all authorized prescribers to determine the eligibility of the prescribers to prescribe the prescription drug;

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

requiring checking of the exclusive computer database for potential abuse associated with the patient and the authorized prescriber;

providing the ~~sensitive~~ prescription drug to the patient only provided information in the exclusive computer database is not indicative of potential abuse by the patient to whom the ~~sensitive~~ prescription drug is prescribed and the authorized prescriber of the ~~sensitive~~ prescription drug;

confirming receipt by the patient of the ~~sensitive~~ prescription drug; and

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

39. (Currently Amended) A computerized method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving in a computer processor prescription requests for GHB, for any and all patients being prescribed GHB, only at the central pharmacy from any and all authorized prescribers allowed to prescribe GHB, the prescription requests for GHB containing information identifying patients and various credentials of the any and all authorized prescribers;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB, such that all

prescriptions for GHB are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor the credentials of the any and all authorized prescribers to determine the eligibility of the prescribers to prescribe GHB;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

providing GHB to the patient only provided information in the exclusive computer database is not indicative of potential abuse by the patient to whom GHB is prescribed and the authorized prescriber of the GHB;

confirming receipt by the patient of the GHB; and

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

40. (Currently Amended) A computerized method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

receiving in a computer processor prescription requests for GHB, for any and all patients being prescribed GHB, only at the central pharmacy from any and all authorized prescribers allowed to prescribe GHB, the prescription requests containing information identifying patients and various credentials of the any and all authorized prescribers;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB, such that all prescriptions for ~~the sensitive drug~~ GHB are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor the credentials of the any and all authorized prescribers to determine the eligibility of the prescribers to prescribe GHB;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient only provided information in the exclusive computer database is not indicative of potential abuse by the patient to whom GHB is prescribed and the authorized prescriber of the GHB;

confirming receipt by the patient of the GHB; and

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

41. (Currently Amended) A computerized method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy, the method comprising:

manufacturing GHB;

providing manufactured GHB only to the exclusive central pharmacy;

receiving in a computer processor all prescription requests for GHB, for any and all patients being prescribed GHB, only at the central pharmacy from any and all authorized prescribers allowed to prescribe GHB, the prescription requests containing information identifying patients and various credentials of the any and all authorized prescribers;

entering the information into an exclusive computer database under exclusive control of the central pharmacy for analysis of potential abuse situations, wherein the use of the exclusive computer database is required for distribution of GHB, such that all prescriptions for GHB are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor the credentials of the any and all authorized prescribers to determine the eligibility of the prescribers to prescribe GHB;

confirming with the patient that GHB educational material has been read prior to providing GHB to the patient a first time;

requiring checking of the exclusive computer database for potential GHB abuse associated with the patient;

mailing GHB to the patient only provided information in the exclusive computer database is not indicative of potential abuse by the patient to whom GHB is prescribed and the doctor prescribing the GHB;

confirming receipt by the patient of the GHB; and

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

42. (Currently Amended) A computerized method of distributing a ~~sensitive~~ prescription drug under control of an exclusive central pharmacy, the method comprising:

receiving in a computer processor all prescription requests, for any and all patients being prescribed the ~~sensitive~~ prescription drug, only at the central pharmacy from any and all authorized prescribers allowed to prescribed the ~~sensitive~~ prescription drug, the prescription requests containing information identifying patients, the ~~sensitive~~ prescription drug, and various credentials of the any and all authorized prescribers;

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~~ prescription drug, such that all prescriptions for the ~~sensitive~~ prescription drug are processed only by the exclusive central pharmacy using only the exclusive computer database;

checking with the computer processor the credentials of the any and all authorized prescribers to determine the eligibility of the prescribers to prescribe the prescription drug;

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

requiring checking of the exclusive computer database for potential abuse by the patient to whom the ~~sensitive~~ prescription drug is prescribed and the authorized prescriber allowed to prescribe the ~~sensitive~~ prescription drug;

providing the ~~sensitive~~ prescription drug to the patient only provided information in the exclusive computer database is not indicative of potential abuse by the patient to whom the ~~sensitive~~ prescription drug is prescribed and the authorized prescriber allowed to prescribe the ~~sensitive~~ prescription drug; and

confirming receipt by the patient of the ~~sensitive~~ prescription drug.

Allowable Subject Matter

2. Claims 32-42 are allowed.

3. The following is an examiner's statement of reasons for allowance: Claims 32, 33, 38, and 42, now renumbered as claims 1, 2, 7, and 11, are directed to a computerized method of distributing a prescription drug under exclusive control of an exclusive central pharmacy.

The closest prior art of record, Moradi (US 2004/0019794 A1), Lilly et al. (US 2004/0176985 A1), Califano et al. (US 20030033168 A1), and Ukens ("Specialty Pharmacy") teach receiving prescription requests, checking the credentials of the doctors, checking a database for potential abuse of the drug, confirming receipt by the patient of the drug, confirming with the patient that educational material has been read prior to shipping the drug, generating reports to evaluate potential diversion patterns, and restricting distribution of a medication to one pharmacy.

However, the closest prior art of record does not teach or fairly suggest that *all* prescriptions for the prescription drug are processed only by the exclusive central pharmacy *using only the exclusive computer database.* The exclusive computer database is checked for potential abuse of the prescription drug and the prescription drug is mailed/provided only if no potential abuse is found by the patient to whom the prescription drug is prescribed *and* the doctor/authorized presciber prescribing the prescription drug.

Dependent claims 34-37 (now renumbered as claims 3-6) incorporate the allowable subject matter of claim 33, through dependency, and are also allowable for the same reasons.

Claims 39, 40, and 41 are directed to a computerized method of distributing gamma hydroxy butyrate (GHB) under control of an exclusive central pharmacy.

The closest prior art of record, Moradi (US 2004/0019794 A1), Lilly et al. (US 2004/0176985 A1), Califano et al. (US 20030033168 A1), and Talk About Sleep ("An Interview with Orphan Medical about Xyrem") teach receiving prescription requests, checking the credentials of the doctors, checking a database for potential abuse of the drug, confirming receipt by the patient of the drug, confirming with the patient that educational material has been read prior to shipping the drug, generating reports to evaluate potential diversion patterns, and providing GHB through a specialty distribution system that utilizes a central pharmacy.

However, the closest prior art of record does not teach or fairly suggest that *all* prescriptions for GHB are processed only by the exclusive central pharmacy *using only the exclusive computer database.* The exclusive computer database is checked for potential GHB abuse and GHB is provided/mailed only if no potential abuse is found by the patient to whom GHB is prescribed *and* the doctor/authorized prescriber of the GHB.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571) 272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

6. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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

/L. N./
Examiner, Art Unit 3686
ln
12/16/09

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

Electronic Acknowledgement Receipt	
EFS ID:	6757671
Application Number:	10322348
International Application Number:	
Confirmation Number:	5446
Title of Invention:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Karen L. Himmel/LeShere Wolfe
Filer Authorized By:	Karen L. Himmel
Attorney Docket Number:	101.031US1
Receipt Date:	06-JAN-2010
Filing Date:	17-DEC-2002
Time Stamp:	12:43:34
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1055
RAM confirmation Number	7625
Deposit Account	190743
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

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

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		101031US1ISSUEXMIT.pdf	404199 f3fe1ec2124e710154d055d8e6ea1e23715e9960	yes	3

Multipart Description/PDF files in .zip description

Document Description	Start	End
Miscellaneous Incoming Letter	1	1
Issue Fee Payment (PTO-85B)	2	2
Change of Address	3	3

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	31811 173b20be1135a947c5a5e4b4f653c95572a62e5f	no	2

Warnings:

Information:

Total Files Size (in bytes):	436010

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

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

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

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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

21186 7590 12/31/2009

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

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

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

LeShere Wolfe (Depositor's name)
/LeShere Wolfe/ (Signature)
January 6, 2010 (Date)

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

TITLE OF INVENTION: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	03/31/2010

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

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

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

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

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

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

(A) NAME OF ASSIGNEE: JPI Commercial, LLC.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Palo Alto, California

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

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

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

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

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

Authorized Signature /David D'Zurilla/ Date January 6, 2010

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

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dayton T. Reardan et al.	Examiner: Lena Najarian
Serial No.:	10/322,348	Group Art Unit: 3686
Filed:	December 17, 2002	Docket No.: 101.031US1
Customer No.: 21186		Confirmation No.: 5446
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD	

COMMUNICATION RE: FEE ADDRESS

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

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

Customer Number 21186

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

Respectfully submitted,

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

Date January 6, 2010 By /David D'Zurilla/
David D'Zurilla
Reg. No. 36,776

DDZ:CMG:lrw

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 6th day of January, 2010.

LeShere Wolfe
Name

/LeShere Wolfe/
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/Applicant Name:	Dayton T. Reardan
Filer:	Karen L. Himmel/LeShere Wolfe
Attorney Docket Number:	101.031US1
Filed as Small Entity	

Utility under 35 USC 111(a) Filing Fees

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.:	101.031US1	Serial No.:	10/322,348
Filed:	December 17, 2002	Due Date:	March 31, 2010
Examiner:	Lena Najarian	Group Art Unit:	3686
Customer No.:	21186	Confirmation No.:	5446

Notice of Allowance Date: December 31, 2009

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

We are transmitting herewith the following:

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

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

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

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 6th day of January, 2010.

LeShere Wolfe /LeShere Wolfe/
Name Signature

IN THE SPECIFICATION

Please amend the paragraph on page 6, starting at line ~~17~~ 15 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~~ 23 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~~ 16 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~~ 9 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~~ 26 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~~ 1 as follows:

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: 3686
Filed:	December 17, 2002	Docket: 101.031US1
Customer No.:	21186	Confirmation No.: 5446
Title:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD	

COMMUNICATION RE: INCORRECT FILING RECEIPT

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

Applicants hereby request correction of the Filing Receipt with respect to the above-identified patent application. In the Filing Receipt mailed August 13, 2003 (copy enclosed), The Full Name of Joint Inventor number 2 should read **Patti A. Engel** this is evidenced by a copy of the Combined Declaration and Power of Attorney as filed May 21, 2003(copy attached).

Applicants respectfully request that the above-identified printing error(s) be corrected and that a Corrected Filing Receipt be sent to Applicants' representatives at the address given below.

Respectfully submitted,

Schwegman, Lundberg & Woessner, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 371-2140

Date January 21, 2010 By /David D'Zurilla/

David D'Zurilla
Reg. No. 36,776

DDZ:CMG:lrw

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 21st day of January, 2010.

LeShere Wolfe
Name

/LeShere Wolfe/
Signature

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/322,348	12/17/2002	1743	527	101.031US1	16	25	4

CONFIRMATION NO. 5446

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

UPDATED FILING RECEIPT

OC000000010690004

Date Mailed: 08/13/2003

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

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

Domestic Priority data as claimed by applicant

Foreign Applications

If Required, Foreign Filing License Granted: 03/21/2003

Projected Publication Date: 06/17/2004

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Sensitive drug distribution system and method

Preliminary Class

PRCT-3

436

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SCHWEGMAN ■ LUNDBERG ■ WOESSNER ■ KLUTH

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Signature: Bob Gagne Date: 1 May 2003
Bob Gagne

§ 1.56 Duty to disclose information material to patentability.

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

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

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

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

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

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

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

(ii) Asserting an argument of patentability.

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

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

(1) Each inventor named in the application:

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	6853196
Application Number:	10322348
International Application Number:	
Confirmation Number:	5446
Title of Invention:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Karen L. Himmel/LeShere Wolfe
Filer Authorized By:	Karen L. Himmel
Attorney Docket Number:	101.031US1
Receipt Date:	21-JAN-2010
Filing Date:	17-DEC-2002
Time Stamp:	13:24:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		101031US1XMITFRCT.pdf	483112 b701123ebfa35d0c43d6fb57ef1eb73b7d1e0f62	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	1
	Request for Corrected Filing Receipt	2	2
	Miscellaneous Incoming Letter	3	4
	Oath or Declaration filed	5	8
Warnings:			
Information:			
	Total Files Size (in bytes):	483112	

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

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

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

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

Docket No.:	101.031US1	Serial No.:	10/322,348
Filed:	December 17, 2002	Due Date:	N/A
Examiner:	Lena Najarian	Group Art Unit:	3686
Customer No.:	21186	Confirmation No.:	5446

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

We are transmitting herewith the attached:

X Communication Re: Incorrect Filing Receipt (1 pg..)
X Copy of Filing Receipt (3 pgs.)
X Copy of Executed Combined Declaration and Power of Attorney(4 pgs.)

It is believed that no additional fee is required. However, if necessary, please charge any additional required fees or credit overpayment to Deposit Account No. 19-0743.

Schwegman, Lundberg & Woessner, P.A.
Customer No.: 21186
DDZ:CMG:lrw

By /David D'Zurilla/
David D'Zurilla
Reg. No. 36,776

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 21st day of January, 2010.

/LeShere Wolfe/

LeShere Wolfe
Name

Signature

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/322,348	02/23/2010	7668730	101.031US1	5446

21186 7590 02/03/2010

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

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 446 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

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

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

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

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

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

IR103 (Rev. 10/09)

MODIFIED PTO/SB/131 (01-10)
Approved for use through 02/28/2011. OMB 0651-0020
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR RECALCULATION OF PATENT TERM ADJUSTMENT IN VIEW OF *WYETH**

Attorney Docket Number: 101.031US1	Patent Number: 7,668,730
Filing date (or 371(b) or (f) Date): December 17, 2002	Issue Date: February 23, 2010
First Named Inventor: Dayton T. Reardan et al.	
Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD	

PATENTEE HEREBY REQUESTS RECALCULATION OF THE PATENT TERM ADJUSTMENT (PTA) UNDER 35 USC 154(b) INDICATED ON THE ABOVE-IDENTIFIED PATENT. THE PATENTEE'S SOLE BASIS FOR REQUESTING THE RECALCULATION IS THE USPTO'S PRE-WYETH INTERPRETATION OF 35 U.S.C. 154(b)(2)(A).

Note: This form is only for requesting a recalculation of PTA for patents issued before March 2, 2010, if the sole basis for requesting the recalculation is the USPTO's pre-*Wyeth* interpretation of 35 U.S.C. 154(b)(2)(A). See Instruction Sheet on page 2 for more information.

Patentees are reminded that to preserve the right to review in the United States District Court for the District of Columbia of the USPTO's patent term adjustment determination, a patentee must ensure that he or she also takes the steps required under 35 U.S.C. 154(b)(3) and (b)(4) and 37 CFR 1.705 in a timely manner.

**Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir., Jan. 7, 2010).

Signature / Monique M. Perdok Shonka /	Date Feb. 23, 2010
Name: Monique M. Perdok Shonka	Registration Number: 42,989

Note: *Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below**.

☒ *Total of 1 forms are submitted.

The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Electronic Acknowledgement Receipt

EFS ID:	7065280
Application Number:	10322348
International Application Number:	
Confirmation Number:	5446
Title of Invention:	SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD
First Named Inventor/Applicant Name:	Dayton T. Reardan
Customer Number:	21186
Filer:	Barbara Jean Clark/Peter Rebuffoni
Filer Authorized By:	Barbara Jean Clark
Attorney Docket Number:	101.031US1
Receipt Date:	23-FEB-2010
Filing Date:	17-DEC-2002
Time Stamp:	11:53:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for PTA recalculation in view of Wyeth	101_031US1_PTA.pdf	57837 5cf8f9b917fe17384f05dfa7300530cb35c081ba	no	1
Warnings:					
Information:					

Total Files Size (in bytes):	57837

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

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

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

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

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

Mail Date: 04/20/2010

Applicant	: Dayton T. Reardan	: DECISION ON REQUEST FOR
Patent Number	: 7668730	: RECALCULATION of PATENT
Issue Date	: 02/23/2010	: TERM ADJUSTMENT IN VIEW
Appliction No	: 10/322,348	: OF WYETH AND NOTICE OF INTENT TO
Filed	: 12/17/2002	: ISSUE CERTIFICATE OF CORRECTION
		:

The Request for Recalculation is **GRANTED** to the extent indicated.

The patent term adjustment has been determined to be **547** days. The USPTO will *sua sponte* issue a certificate of correction reflecting the amount of PTA days determined by the recalculation.

Prior to the issuance of the certificate of correction, the USPTO will afford patentee an opportunity to be heard and request reconsideration. Accordingly, patentee has **one month or thirty (30) days**, whichever is longer, to file a request for reconsideration of this patent term adjustment calculation. See 35 U.S.C. 154(b)(3)(B)(ii) and 37 CFR 1.322(a)(4). No extensions of time will be granted under 37 CFR 1.136.

Patentee should use document code PET.OP if electronically filing a request for reconsideration of this patent term adjustment calculation. The patentee must also include the information required by 37 CFR 1.705(b)(2) and the fee required by 37 CFR 1.18(e). If patentee does not file a timely request for reconsideration of this patent term adjustment calculation including the information required by 37 CFR 1.705(b)(2) and the fee required by 37 CFR 1.18(e), the USPTO will issue a certificate of correction reflecting the PTA determination noted above.

Patentee should be aware that in order to preserve the right to review in the United States District Court for the District of Columbia of the USPTO patent term adjustment determination, patentee must ensure that he or she also take the steps required under 35 U.S.C. 154(b)(4)(A) in a timely manner. Nothing in the request for recalculation should be construed as providing an alternative time frame for commencing a civil action under 35 U.S.C. 154(b)(4)(A).

Any questions concerning this decision should be directed to the Office of Patent Legal Administration at 571-272-7702.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,668,730 B2
APPLICATION NO. : 10/322348
DATED : February 23, 2010
INVENTOR(S) : Reardan et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page:

The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 547 days.

Signed and Sealed this

Seventh Day of December, 2010

David J. Kappos

David J. Kappos
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NUMBER	PATENT NUMBER	GROUP ART UNIT	FILE WRAPPER LOCATION
10/322,348	7668730	3686	9200

Correspondence Address/Fee Address Change

The following fields have been set to Customer Number 107632 on 06/25/2013

- **Correspondence Address**
- **Maintenance Fee Address**

The address of record for Customer Number 107632 is:

107632
Schwegman Lundberg & Woessner/Jazz Pharmaceutical
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