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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dayton T. Reardan et al.

Title: SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

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

Serial No.: 10/322,348
Due Date: May 21, 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 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

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.

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(GENERAL)

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10/322,348	12/17/2002	Dayton T. Reardan	101.031US1	5446

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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

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

SUBSTITUTE APPEAL BRIEF UNDER 37 CFR § 41.37

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

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,

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

Date July 18 2007 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: 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.

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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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: July 28, 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 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. Zuritis
Reg. No. 36,776

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John D. Gustav Woodruff
Name

John D. Gustav Woodruff
Signature

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(GENERAL)

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

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The time period for reply, if any, is set in the attached communication.

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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.

MAILED

OCT 03 2007

GROUP 3600

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:

C. Luke Gilligan
Primary Examiner
Tech Center 3600

Vincent Millin

Appeals Conference Specialist
Tech Center 3600

DAVID D'ZURILLA
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

C. LUKE GILLIGAN
PRIMARY EXAMINER
TECHNOLOGY CENTER 3600

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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.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

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.

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.

In

10-24-07

C. LUKE GILLIGAN
PRIMARY EXAMINER
TECHNOLOGY CENTER 3600

PTO/SB/08A(10-01)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

OIPE JC105 NOV 0 4 2004 PATENT & TRADEMARK OFFICE

Sheet 1 of 2

Complete if Known	
Application Number	10/322,348
Filing Date	December 17, 2002
First Named Inventor	Reardan, Dayton
Group Art Unit	~~1743~~ 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
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EXAMINER Lena Najarian DATE CONSIDERED 10-24-07

Substitute Disclosure Statement Form (PTO-1449)

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

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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
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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

Substitute Disclosure Statement Form (PTO-1449)

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

REQUEST FOR ORAL HEARING

Mail Stop Appeal Brief - Patents
Commissioner for Patents
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
Minneapolis, MN 55402
(612) 373-6972

Date December 3 2007 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: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 3 day of December 2007.

John D. Gaughan Mitchell
Name

Signature

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

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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.

ROX 1016
CBM of U.S. Patent No. 7,765,107
401 of 560

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.

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[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 Zurilla
Reg. No. 36,776

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John D. Griffin-Wardell
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.

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

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:

Submitted with Payment	yes
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 8784f239bad910502cf76ccd39dc74c2b0736b02	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

Warnings:

Information:

Total Files Size (in bytes):	498492

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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: 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)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

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

EXAMINER	
NAJARIAN, LENA	
ART UNIT	**PAPER NUMBER**
3626	
MAIL DATE	**DELIVERY MODE**
01/08/2008	PAPER

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.

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Alexandria, Virginia 22313-1450

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

EXAMINER	
Lena Najarian	
ART UNIT	**PAPER**
3626	20080104

DATE MAILED:

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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.

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/
ln
1/4/08

~~JOSEPH THOMAS~~
~~SUPERV~~ ~~EXAMINER~~

/Joseph Thomas/
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.
P.O. BOX 2938
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.

The mailing address for the Board is:

BOARD OF PATENT APPEALS AND INTERFERENCES
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VIRGINIA 22313-1450

The facsimile number of the Board is 571-273-0052. Because of the heightened security in the Washington D.C. area, facsimile communications are recommended. Telephone inquiries can be made by calling 571-272-9797 and should be directed to a Program and Resource Administrator.

By order of the Board of Patent Appeals and Interferences

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United States Patent and Trademark Office
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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 12/30/2008

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

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	
MAIL DATE	DELIVERY MODE
12/30/2008	PAPER

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The time period for reply, if any, is set in the attached communication.

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Board of Patent Appeals and Interferences

SCHWEGMAN, LUNDBERG &
WOESSNER, P.A.
P.O. BOX 2938
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

NOTICE OF HEARING
CONFIRMATION REQUIRED WITHIN TWENTY-ONE DAYS

Your attention is directed to 37 CFR § 41.47. The above identified appeal will be heard by the Board of Patent Appeals and Interferences on the date indicated. Hearings will commence at the time set and as soon as the argument in one appeal is concluded, the succeeding appeal will be taken up. The time allowed for argument is twenty minutes unless additional time is requested and permitted before the argument is commenced. If there are any inquires, please contact the Clerk of the Board at 571-272-9797.

The application involved in this appeal has been published. Accordingly, the hearing in this appeal is open to the public.

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BPAI HEARINGS FAX No: (571) 273-0299 USPTO Central Fax No: (571) 273-8300

BPAI Mailing Address: Board of Patent Appeals and Interferences
United States Patent and Trademark Office
P.O. BOX 1450
Alexandria, Virginia 22313-1450

In all communications relating to this appeal, please identify the appeal by its number.

CHECK ONE: ( ) HEARING ATTENDANCE CONFIRMED ( ) HEARING ATTENDANCE WAIVED

_____ _____ _____
Signature of Attorney/Agent/Appellant Date Registration No.

Names of other visitors expected to accompany counsel: _____
For information on visitor access to hearing rooms and security procedures at the USPTO Alexandria Campus, see http://www.uspto.gov/web/offices/dcom/gcounsel/contact.htm#bpai_contacts

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PATENT, TRADEMARK & COPYRIGHT ATTORNEYS
P.O. Box 2938
Minneapolis, MN 55402
Telephone (612) 373-6900 Facsimile (612) 339-3061

January 9, 2009

Time: 12:15 p.m.
(Minneapolis, Minn.)

TO: Commissioner for Patents
Board of Patent Appeals and Interferences
P.O. Box 1450
Alexandria, VA 22313-1450

FROM: Bradley A. Forrest

OUR REF: 101.031US1
TELEPHONE: 571-272-3944

FAX NUMBER (571) 273-8300

COURTESY COPY TO BPAI HEARINGS FAX NO: (571) 273-0299

*** Please deliver to the Board of Patent Appeals and Interferences. ***

Document(s) Transmitted: **Signed Waiver of Attendance at Hearing (1 pg.).**

Total pages of this transmission, including cover letter: 2 pgs.
If you do NOT receive all of the pages described above, please telephone us at 612-373-6900 or fax us at 612-339-3061.

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

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

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

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

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John D. Gustav-Wrathall

1-13-2009
Date of Transmission

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SCHWEGMAN, LUNDBERG &
WOESSNER, P.A.
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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

NOTICE OF HEARING
CONFIRMATION REQUIRED WITHIN TWENTY-ONE DAYS

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The application involved in this appeal has been published. Accordingly, the hearing in this appeal is open to the public.

CONFIRMATION OR WAIVER OF THE HEARING IS REQUIRED. This form must be completed below and facsimile transmitted to both: (1) the USPTO Central fax number (official copy), and (2) the Board of Patent Appeals and Interferences fax number (courtesy copy) within TWENTY-ONE (21) DAYS from the mailing date of this notice indicating confirmation or waiver of the hearing. A copy of this notice may be alternately filed by mail if facsimile is not available.

BPAI HEARINGS FAX No: (571) 273-0299 USPTO Central Fax No: (571) 273-8300

BPAI Mailing Address: Board of Patent Appeals and Interferences
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Alexandria, Virginia 22313-1450

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Signature of Attorney/Agent/Appellant	1-13-2009 Date	30,837 Registration No.

Names of other visitors expected to accompany counsel: _____

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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 09/02/2009
SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
09/02/2009	ELECTRONIC

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request@slwip.com

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

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

ROX 1016
CBM of U.S. Patent No. 7,765,107
433 of 560

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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 10/21/2009

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

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
10/21/2009	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

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*.

(2) *Bradley Forrest (Reg. No. 30,837)*.

(3) *David D'Zurilla (Reg. No. 36,776)*.

(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.

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

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/

David D'Zurilla
Reg. No. 36,776

DDZ:jdgw

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: MS 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

PTO/SB/08A(04-07)
Modified form approved for use through 09/30/2007. OMB 651-0031
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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	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

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.

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.