No. 2023-1186

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

JAZZ PHARMACEUTICALS, INC.,
Plaintiff-Appellant,

v.

AVADEL CNS PHARMACEUTICALS LLC,
Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware in No. 21-691, Honorable Gregory B. Williams

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BRIEF FOR PLAINTIFF-APPELLANT JAZZ PHARMACEUTICALS, INC.

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December 16, 2022

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PATENT CLAIM

Claim 1 of U.S. Patent No. 8,731,963 reads as follows:

1. A computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, comprising:

one or more computer memories for storing a single computer database having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields;

said prescription fields, contained within the database schema, storing prescriptions for the prescription drug with the potential for abuse, misuse or diversion, wherein the prescription drug is sold or distributed by a company that obtained approval for distribution of the prescription drug;

said patient fields, contained within the database schema, storing information sufficient to identify the narcoleptic patient for whom the company's prescription drug is prescribed;

said prescriber fields, contained within the database schema, storing information sufficient to identify a physician or other prescriber of the company's prescription drug and information to show that the physician or other prescriber is authorized to prescribe the company's prescription drug;

a data processor configured to:

process a database query that operates over all data related to the prescription fields, prescriber fields, and patient fields for the prescription drug; and

reconcile inventory of the prescription drug before the shipments for a day or other time period are sent by using said database query to identify information in the prescription fields and patient fields;

wherein the data processor is configured to process a second database query that identifies that the narcoleptic patient is a cash payer and a physician that is interrelated with the narcoleptic patient through the schema of the single computer database;

said identifying that the narcoleptic patient is a cash payer by said second database query being an indicator of a potential misuse, abuse or diversion by the narcoleptic patient and being used to notify the physician that is interrelated with the narcoleptic patient through the schema of the single computer database.

CERTIFICATE OF INTEREST

Counsel for Jazz Pharmaceuticals, Inc., Steven J. Horowitz,

certifies the following:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

   Jazz Pharmaceuticals, Inc.

2. **Real Party in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

   None

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

   Jazz Pharmaceuticals plc.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

   Quinn Emanuel Urquhart & Sullivan, LLP: Andrew S. Chalson, Quentin Jorgensen, Nicholas LoCastro, Krista M. Rycroft, Evangeline Shih, Eric C. Stops

   Morris, Nichols, Arsht & Tunnell LLP: Jack B. Blumenfeld, Jeremy A. Tigan

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5).

Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, No. 1:22-cv-00941-GBW (D. Del.) (filed July 15, 2022).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not applicable

December 16, 2022

/s/ Steven J. Horowitz

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STATEMENT OF RELATED CASES

There have been no prior appeals in this case.

Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, No. 1:22-cv-00941-GBW (D. Del.) (filed July 15, 2022), which alleges infringement of the patent at issue in this appeal, is currently pending before the United States District Court for the District of Delaware.

JURISDICTIONAL STATEMENT

The district court had jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. This Court has jurisdiction on appeal from the district court's entry of an injunction pursuant to 28 U.S.C. § 1292(c)(1).

INTRODUCTION

This appeal concerns whether a patent that claims an FDA-approved condition of use for a pioneer drug should be listed in the Orange Book. FDA's regulations implementing the statutory listing rules say that patents claiming conditions of use *must* be listed, and there is no serious question that, when the patent in question here was submitted, such patents *could* be listed. Yet the district court in this case found that the listing was improper, issuing an injunction requiring Appellant Jazz Pharmaceuticals, Inc. to request that FDA delist that patent. That injunction rests on an erroneous interpretation of the governing statutes (and one contrary to FDA's own views, reflected in authoritative regulations), as well as an erroneous construction of the patent's claims. The district court's order should be vacated.

In 2002, Jazz's predecessor (Orphan Medical) sought FDA approval for a new drug—Xyrem® (sodium oxybate)—to treat certain symptoms of narcolepsy. The active ingredient in Xyrem is the sodium salt of gamma hydroxybutyrate (GHB), which is a strong central nervous system (CNS) depressant often associated with drug-facilitated

sexual assault and is the only medicine explicitly declared by an act of Congress to be a Schedule I controlled substance. *See* Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, Pub. L. No. 106-172, § 3(b)(1) 114 Stat. 7, 9 (Feb. 18, 2000). Under its regulations, FDA would not (indeed, could not) approve Xyrem absent a means to minimize those risks. *See* 21 C.F.R. § 314.520. Jazz developed such a means through a novel risk management program for Xyrem, which FDA identified as a condition of its approval in both its approval letter and the labeling for Xyrem. Five years later, Congress deemed the risk management program for Xyrem to be a Risk Evaluation and Mitigation Strategy ("REMS"). *See* 21 U.S.C. § 355-1.

Because the REMS is an approved condition of use for Xyrem and identified in its approved labeling, Jazz listed the patent covering the REMS in the Orange Book in 2014—U.S. Patent No. 8,731,963 (the "'963 patent"). The '963 patent addresses the problem of how to safely distribute sodium oxybate to treat narcolepsy patients while avoiding abuse, misuse, and diversion of that drug, according to its FDA-approved labeling.

In 2020, Appellee Avadel CNS Pharmaceuticals LLC sought from FDA approval to launch a different version of sodium oxybate to treat narcolepsy. While Avadel's drug, FT218, is not a generic drug, Avadel sought approval via an abbreviated pathway, relying on Xyrem as the "listed drug" for its application. FDA determined that Avadel was "seeking approval of a condition of use that is claimed by the '963 patent, as described [in the Orange Book]," Appx4230–4231, and that Avadel "must provide an appropriate patent certification … to address the '963 patent." Appx4245. Avadel resisted on two fronts. It both sought to overturn FDA's determination through an Administrative Procedure Act challenge in the U.S. District Court for the District of Columbia and brought a counterclaim in this case seeking to require Jazz to delist its '963 patent. While the D.C. court rejected the administrative challenge, the district court in this case granted Avadel's motion for judgment on the pleadings on the delisting counterclaim and issued an injunction requiring Jazz to request that FDA delist the '963 patent. The district court's decision was wrong, and the injunction should be vacated.

At the threshold, the district court erred in its interpretation of the Federal Food, Drug, and Cosmetic Act (FDCA). Under the FDCA, Avadel had the burden to show that the '963 patent "does not claim" an "approved method of using the drug." 21 U.S.C. § 355(c)(3)(D)(ii)(I)(bb). The FDCA does not define "approved method of using the drug," and the district court treated that phrase as effectively presenting a patent-law question: because the court construed the '963 patent to include "system" claims rather than "method" claims, it held that the patent was not properly listed under the FDCA. But the interpretation of the phrase "approved method of using" in the FDCA is a question of FDCA law, not patent law. Congress codified the listing rules in the FDCA—unlike the patent-law provisions from Hatch-Waxman, codified in Title 35—and Congress authorized FDA, rather than the Patent Office, to administer Orange Book listings. FDA's authoritative implementing regulations, which are entitled to deference, provide for the listing of patents that claim "conditions of use for which approval is sought or has been granted," 21 C.F.R. § 314.53(b)(1), and the '963 patent is just such a patent.

Independently, the district court's injunction should be vacated because—even if the '963 patent does not claim a "method using the drug"—it was properly listed in the Orange Book in the first instance and should not now be subject to delisting. The district court declined to analyze whether Jazz was *permitted* to list the patent at the time of listing and, if so, whether permissibly-listed patents are now subject to delisting. The district court's failure to address this question of statutory construction was reversible error because the delisting statute offers no basis to delist patents that were appropriately included in the Orange Book under the law that applied when they were listed. *See* 21 U.S.C. § 355(c)(3)(D)(ii)(I). Because the '963 patent was permissibly listed in 2014, the district court erred in ordering Jazz to delist that patent today.

In any event, even on its own terms, the decision below rests on legal error, because it is based on an erroneous claim construction. The '963 patent, properly construed, claims a method.

STATEMENT OF THE ISSUES

1. Whether the FDCA's references to patents that claim a "method of using [a]" drug should be interpreted to encompass those claiming "conditions of use," as FDA has interpreted that phrase under the FDCA, or instead only to encompass claims construed to cover "methods" as a matter of patent law.

2. Whether 21 U.S.C. § 355(c)(3)(D)(ii)(I) creates a delisting remedy for patents that were properly listed at the time of their original listing.

3. Whether—even assuming that patent law provides the correct interpretive framework—the '963 patent claims a method.

STATEMENT OF THE CASE

A. Regulatory Framework

This appeal turns on the interpretation of two provisions of section 505 of the FDCA: 21 U.S.C. § 355(c)(3)(D)(ii)(I) (the "delisting statute"); and 21 U.S.C. § 355(c)(2), as amended by the Orange Book Transparency Act of 2020. These provisions are part of a complex statutory scheme upon which FDA relies to approve applications for new drugs.

When a brand pharmaceutical manufacturer seeks to market a novel drug, the manufacturer submits a new drug application ("NDA") to FDA for approval. There are also two streamlined pathways for drug approval: an abbreviated new drug application ("ANDA") for generic drugs, *see* 21 U.S.C. § 355(j), and a separate process for companies that seek to rely on findings or data that they did not sponsor ("505(b)(2) application"), *see* 21 U.S.C. § 355(b)(2). Both pathways were created by the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, better known as the "Hatch-Waxman Amendments."

The Hatch-Waxman Amendments were designed to strike a balance between encouraging development of innovative new medicines, on the one hand, and ensuring access to affordable generic medicines on the other, and so the timing of when FDA approves an ANDA or 505(b)(2) application depends on the patents covering the brand-name drug. To enable potential applicants to identify the relevant patents, the Hatch-Waxman Amendments and FDA regulations direct brand manufacturers to file certain information about their patents that is ultimately listed in FDA's "Approved Drug Products With Therapeutic Equivalence Evaluations" publication, commonly known as the "Orange

Book." For instance, when the '963 patent was listed in the Orange Book in 2014, section 355(b)(1) (the "listing statute") directed that the "applicant shall file . . . any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug." FDA's implementing regulation identified two categories of patents: those that "must" be listed in the Orange Book and those that "must not" be listed. 21 C.F.R. § 314.53(b)(1). Only "[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates" fell into the category of patents that "must not" be listed. *Id.*

After consulting the Orange Book, a company filing an ANDA or 505(b)(2) application may, among other options, assure FDA that there are no listed patents, that all listed patents have expired, or that the applicant agrees to wait until the listed patents expire. *See* 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)–(III); *id.* §§ 355(b)(2)(A)(i)–(iii). Alternatively, an applicant may file what is commonly referred to in the ANDA context as a "Paragraph IV certification," or, in the 505(b)(2) context, a certification under section 505(b)(2)(A)(iv) ("Paragraph (iv)")—as Avadel eventually did here—which states that a listed patent "is invalid or will

not be infringed by the manufacture, use, or sale of the new drug." 21 U.S.C. § 355(b)(2)(A)(iv). Filing this certification provokes litigation, since the submission of an application under Section 505(b)(2) for a drug claimed in a patent or the use of which is claimed in a patent listed in the Orange Book is a statutory act of infringement, giving the brand an immediate right to sue—as Jazz did here. *See* 35 U.S.C. § 271(e)(2)(A). Once the brand manufacturer brings suit, the ANDA's or 505(b)(2) application's approval is stayed for 30 months, until the patent expires, or until the court finds the patent invalid or not infringed, whichever comes first. *See* 21 U.S.C. § 355(j)(5)(B)(iii); *id.* § 355(c)(3)(C).

On December 8, 2003, Congress amended the FDCA to allow an applicant sued on the basis of a Paragraph (iv) certification to bring a counterclaim seeking to delist the patent (and thereby lift the stay of approval). *See* The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 117 Stat. 2452; 21 U.S.C. § 355(c)(3)(D)(ii)(I) (the "delisting statute"). Under the delisting statute, an applicant sued for patent infringement by "an owner of the patent or the holder of the approved application under [section 355(b)] for the drug that is claimed

by the patent or a use of which is claimed by the patent" can assert a counterclaim seeking an order requiring the plaintiff "to correct or delete the patent information submitted by the holder under [section 355(b)] on the ground that the patent does not claim either": "the drug for which the application was approved" or "an approved method of using the drug." 21 U.S.C. § 355(c)(3)(D)(ii)(I). If the information cannot be corrected, and the plaintiff must instead delete it, the patent is delisted from the Orange Book.

Neither the listing statute nor the regulation, however, prohibited the listing of patents that did not fall into the "must list" category until Congress enacted the Orange Book Transparency Act (the "OBTA"), 134 Stat. 4889, on January 5, 2021. The OBTA, in part, amended the FDCA to provide that "[p]atent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph." 21 U.S.C. § 355(c)(2). Thus, it was not until the OBTA's passing that patents in the "must list" category became the only kind that could be listed in the Orange Book.

B. Jazz's Xyrem

Jazz markets Xyrem (sodium oxybate) oral solution ("Xyrem"), an

FDA-approved drug product for use in the treatment of both cataplexy and excessive daytime sleepiness, which are devastating symptoms associated with the sleep disorder narcolepsy. Appx59; Appx122 at 2:51–55. The active ingredient in Xyrem is sodium oxybate—a specific salt form of gamma-hydroxybutyrate. Appx122 at 2:51–55. Congress and federal agencies have recognized sodium oxybate as a dangerous substance that has been misused as a "date rape drug" in cases of drug-facilitated sexual assault. Because of its high potential for abuse and misuse involving third parties, Congress classified sodium oxybate as a Schedule I controlled substance under the Controlled Substances Act (a designation reserved for drugs with a high potential for abuse and no accepted medical use). *See* 21 U.S.C. § 812(b)(1); 21 C.F.R. § 1308.11(e)(1).

At the same time, FDA and Congress recognized that studies had established that sodium oxybate might be the basis for a unique treatment for certain symptoms of narcolepsy. Appx122 at 1:41–58. Accordingly, Congress classified FDA-approved forms of sodium oxybate—like Xyrem—as Schedule III controlled substances, thereby acknowledging their legitimate medical uses. *See* 21 U.S.C. § 812(b)(3);

21 C.F.R. § 1308.13(c)(6). In reaching this compromise with respect to FDA-approved forms of sodium oxybate, both Congress and FDA noted that medical use of a sodium oxybate-based drug—like Xyrem—must be strictly controlled to ensure that it cannot be illicitly obtained and misused.

C. FDA's Approval Of Xyrem

In 2002, FDA approved a New Drug Application ("NDA") under Section 505 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a), for sodium oxybate oral solution (NDA No. 21-196), which Jazz now sells under the trade name Xyrem. Appx59. Given the unique status of sodium oxybate as a Schedule III controlled substance in FDA-approved forms, FDA conditioned approval of Xyrem on the development and implementation of a controlled distribution program to ensure proper use of the drug. Appx59–60; Appx362 (approving Xyrem "with a Risk Management Program (RMP) that must include [several specified] components"); *see also* Appx3623 ("Marketing of this drug product and related activities are to be in accordance with the substance and procedure of all FDA regulations *and the specific restrictions on distribution and* <u>*use*</u> *described [in the Xyrem Risk*

Management Program] below." (emphasis added)). Today, to obtain FDA approval of a drug containing sodium oxybate, the agency requires new drug applications to include a Risk Evaluation and Mitigation Strategy ("REMS").[1] *See* 21 U.S.C. § 355-1 (the "REMS statute").

Following FDA approval, the labeling for Xyrem has specified that "Xyrem is available only through a restricted distribution program called the XYWAV and XYREM REMS because of the risks of central nervous system depression and abuse and misuse." Appx862.[2] Consequently, distributing and using Xyrem according to the methods set forth in the FDA-required REMS (which, as explained below, are covered by the '963 patent) are conditions of using the drug.

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[1] A REMS is a form of Risk Management Plan that FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. *See, e.g.*, https://www.fda.gov/files/drugs/published/Risk-Evaluation-and-Mitigation-Strategies--Modifications-and-Revisions-Guidance-for-Industry.pdf at 2. In 2007, Congress deemed Jazz's risk management program to be a REMS when it enacted the REMS statute.

[2] Xywav® is an oxybate product marketed by Jazz that contains 92% less sodium than Xyrem® and is distributed and used according to the methods set forth in the '963 patent. Appx60. For simplicity's sake, the XYWAV and XYREM REMS is referred to hereafter as the "Xyrem REMS."

1. The Orange Book Listing

On May 20, 2014, the United States Patent and Trademark Office issued the '963 patent, Appx59, which covers various elements of the risk-management program (now REMS) for Xyrem. Appx59–60. On May 30, 2014, Jazz listed the '963 patent in the Orange Book under use code 1110 ("U-1110"). That listing, and a related statutory period of pediatric exclusivity, *see* 21 U.S.C. § 355a(b)(1)(B), protect Jazz's exclusive right to market sodium oxybate-based drugs to treat narcolepsy through June 17, 2023.

2. The '963 Patent's Claimed REMS

The claims of the '963 patent address the unique problem that the Xyrem REMS was invented to solve: using sodium oxybate for legitimate medical purposes while avoiding the potential for misuse, abuse, or diversion of sodium oxybate by or against others. Appx95 at 1:32–45. The claims relate to using a computer-implemented system to safely distribute sodium oxybate for treatment of a narcoleptic patient. Specifically, the independent claims recite a "computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion . . . ." Appx98 at 8:39–41.

D. Avadel's Application For FDA Approval Of FT218

In December 2020, Avadel asked FDA to approve its proposed sodium oxybate product, FT218,[3] via an abbreviated regulatory pathway, submitting a section 505(b)(2) application, and relying on Xyrem as the "listed drug" for that application. That strategy allowed Avadel to rely on FDA's prior finding that Jazz's product is safe and effective. At the same time, it required Avadel to file a patent certification regarding each patent listed in the Orange Book for Xyrem, including the '963 patent. 21 U.S.C. § 355(b)(2)(A); 21 C.F.R. § 314.54(a)(1)(vi).

Rather than file a patent *certification*, Avadel filed a patent *statement*—telling FDA that its application did not seek approval for any protected use. *See* 21 U.S.C. § 355(b)(2)(B). FDA rejected Avadel's filing strategy, concluding that Avadel's patent statement was not accurate. On May 24, 2022, the agency issued a decision stating that Avadel sought "approval of a condition of use that is claimed by the '963

[3] FT218's proposed brand name is "Lumryz." But because an unapproved new drug product like FT218 cannot be marketed in the United States, *see* 21 U.S.C. §§ 331(a), 355(d), it is more appropriate to refer to the drug by its investigational moniker.

patent, as described by the U-1110 use code." Appx5568–5569. As a result, FDA explained that it would not approve Avadel's application unless Avadel replaced its inaccurate statement with a patent certification. *Id.*; *see* 21 U.S.C. § 355(d)(6); 21 C.F.R. § 314.125(b)(7). Avadel submitted the missing patent certification to FDA "under protest" and, as the statute requires, notified Jazz, Xyrem's listed patentholder. FDA tentatively approved FT218 on July 18, 2022.[4] Appx55.

Avadel also responded to the denial in part by filing claims in the U.S. District Court for the District of Columbia against multiple federal agencies and agency heads, including FDA, seeking equitable relief. *See Avadel CNS Pharms., LLC v. Becerra*, No. 22-cv-02159, Doc. 1 (Complaint) (D.D.C. July 21, 2022). According to Avadel, FDA violated the Administrative Procedure Act by (1) "second-guess[ing] Avadel's decision to file a patent statement" and "compelling Avadel to submit a patent certification instead," *id.* at 24, and (2) unreasonably delaying

[4] *See* Tentative Approval Letter from Teresa Buracchio, Director, Division of Neurology 1, FDA Office of New Drugs, to Marla E. Scarola, Vice President, Regulatory Program Management (Jul. 18, 2022) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/214755Orig1s000TA_ltr.pdf.

approval of FT218, *id.* at 25–26. Jazz intervened. The D.C. district court ultimately entered judgment against Avadel because of the "availability of adequate alternative relief" in the ongoing patent suit, *Avadel CNS Pharms., LLC v. Becerra*, No. 22-cv-02159, 2022 WL 16650467, at *2 (D.D.C. Nov. 3, 2022)—*i.e.*, the proceedings in the district court in Delaware, from which this appeal arises.

E. Procedural History

Upon receiving notice of Avadel's patent certification, the FDCA gave Jazz two choices: either allow the tentative approval to be "made effective immediately" if certain other regulatory exclusivities were adjudicated, or else sue Avadel for patent infringement. 21 U.S.C. § 355(c)(3)(C). Jazz sued. *See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, No. 1:22-cv-00941-GBW, Doc. 1 (Complaint) (D. Del. July 15, 2022). That lawsuit triggered a statutory stay of approval, precluding FDA from approving FT218 until Jazz's pediatric exclusivity ends in June 2023. *See* 21 U.S.C. § 355(c)(3)(C).

Prior to the July 2022 patent infringement suit, however, Jazz sued Avadel on the '963 patent in this case. Avadel responded here by (among other things) asserting a counterclaim seeking delisting of the

'963 patent. *See* Appx461–462.

In its counterclaim, Avadel alleged that the '963 patent should be delisted under 21 U.S.C. § 355(c)(3)(D)(ii)(I) because "only patents claiming a drug product, drug substance, or method of using the drug may be listed in the Orange Book," and "[t]he '963 patent only includes claims to a 'computer-implemented system for treatment of a narcoleptic patient with a prescription drug . . . ,' which are neither method claims nor claims to a drug product or drug substance." Appx461–462.

On July 23, 2021, Avadel first moved for partial judgment on the pleadings as to its delisting counterclaim for the '963 patent. Appx521. Jazz opposed the motion, arguing it should be denied because Jazz was either required or, at a minimum, permitted to list the patent in the Orange Book. Appx839–840. Jazz further argued that the delisting counterclaim could not be resolved prior to resolution of disputed claim construction issues, because the claim construction implicated whether the '963 patent is directed toward a method of using the drug, and therefore properly listed even under Avadel's interpretation of the delisting statute. Appx840–844.

The district court denied Avadel's delisting motion on October 19, 2021, explaining that "there is a question as to whether Jazz was required to submit the '963 Patent for listing in the Orange Book," and that Avadel's "arguments depend in no small part on claim construction." Appx1449. The court emphasized that Avadel's delisting counterclaim raises "the question of whether the claimed 'system' includes methods of using the approved product," *id.*, which would render the patent properly listed even under Avadel's interpretation of the delisting statute.

On June 23, 2022, after the parties had submitted claim construction briefing but before the district court had resolved those disputes, Avadel renewed its motion for partial judgment on the pleadings. Appx2478. Jazz opposed the motion, Appx3597, and the district court heard the motion on November 15, 2022.

On November 18, 2022, the district court issued both its opinion, Appx5707–5728, and order, Appx5729–5731, on claim construction, and subsequently its opinion, Appx1–9, and order, Appx10–11, granting Avadel's renewed motion under Federal Rule of Civil Procedure 12(c) for a partial judgment on the pleadings as to Avadel's delisting

counterclaim. In the claim construction opinion as to the '963 patent, the district court concluded that the claims "are directed to systems and not to methods." Appx5722.

The district court concluded that its claim construction holding led to the rejection of Jazz's argument that it was *required* to list the '963 patent in the Orange Book. *See* Appx7 (explaining that the district court's "construction of the '963 patent disposes of the inquiry" because the court concluded the patent's claims "are directed to systems not methods," and therefore do not claim "an approved method of using the drug"). Accordingly, in its delisting opinion the district court considered the only outstanding question to be whether to accept Jazz's argument that, because Jazz was "permitted" to list the '963 patent in the Orange Book, Jazz was not required to delist the patent now. Appx8. The district court rejected this argument as "not relevant," holding that, "[o]n its face, the delisting statute does not require inquiring as to whether the NDA holder was authorized to list the patent in the first instance." *Id.* ("But regardless of the propriety of Jazz's initial listing, that assertion is not relevant in view of 21 U.S.C. § 355(c)(3)(D)(ii)(I), which states that patents that do not claim either a drug or method of

using a drug may be either 'correct[ed] or delete[d].'").

The accompanying order entered judgment in favor of Avadel on Avadel's counterclaim, Count III, and ordered Jazz "by mandatory injunction under 21 U.S.C. § 355(c)(3)(D)(ii)(I)"—"within fourteen (14) days from the date of this Order"—"to submit to the FDA a request enclosing this Order to delete the '963 patent from the Orange Book entry for Xyrem®." Appx10–11.

Jazz promptly filed its notice of appeal, Appx5735, a motion for a stay pending appeal to preserve the status quo before the district court, Appx5739, and an emergency motion for a stay pending appeal before this Court. The district court denied Jazz's motion for a stay pending appeal on December 5, 2022. Appx6348. On December 14, 2022, this Court granted Jazz's motion for a stay pending appeal. *See Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC*, No. 23-1186, Doc. 28 (Order) at 1–2 (Fed. Cir. Dec. 14, 2022).

SUMMARY OF ARGUMENT

I

The district court erred in issuing the injunction requiring delisting of the '963 patent because REMS-related patents must be listed in the Orange Book as patents covering a drug's approved conditions of use and, thus, "methods of use." Even if the district court were right that the '963 patent is a system patent for patent-law purposes, a patent containing system claims can nonetheless recite "an approved method of using the drug" within the meaning of the key FDCA provision, 21 U.S.C. § 355(c)(3)(D)(ii)(I)(bb). A REMS-based distribution plan falls comfortably within the ordinary meaning of "method of using [a] drug" because the distribution plan specifies how physicians can prescribe, how pharmacists can dispense, and how patients can use, the drug.

Neither the FDCA nor its implementing regulations define "method," which should be read broadly, given that Congress did not limit the phrase "method of using [a] drug" to only methods of administering a drug or treating an indicated disease. Likewise, all indications suggest Congress did *not* intend to import patent law into

the FDCA: Congress codified the listing rules in the FDCA, distinct from the patent law provisions of the Hatch-Waxman Amendments, and Congress selected FDA, rather than the Patent Office, to administer the listing process. Moreover, FDA's implementing regulations, which are entitled to deference, plainly do not adopt a patent-law definition, because ascribing the patent-law definition to the word "method" would suggest that only process patents would be eligible for inclusion in the Orange Book, contrary to FDA's regulation affirmatively *forbidding* the submission of process patents. Thus, because FDA itself characterized the REMS that the '963 patent claims as a "condition of use" for Xyrem, and because the '963 patent claims a "condition of use," the '963 patent cannot be delisted from the Orange Book.

II

Independently, the district court erred in concluding that whether the '963 was properly listed in the first place is irrelevant to the question of whether it should be delisted. The delisting statute offers no basis to delist patents that—like the '963 patent—were appropriately included in the Orange Book under the law that applied when they were listed. When the '963 patent was listed in 2014, FDA's

implementing regulation identified two categories of patents: those that "must" be listed in the Orange Book and those that "must not." 21 C.F.R. § 314.53(b)(1). The two categories were not exhaustive, so FDA necessarily left the door open to list patents that fell into neither category. The 2021 enactment of the Orange Book Transparency Act, which provides that "[p]atent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph," 21 U.S.C. § 355(c)(2), proves this point, and the OBTA does not apply retroactively. As a result, patents properly listed before the enactment of the Orange Book Transparency Act remain so and cannot be delisted.

III

Even if patent law provided the correct framework for determining whether a patent should be listed under the FDCA, the evidence before the district court on claim construction demonstrated that the claimed system of the '963 patent is a method of use. Indeed, the computer-implemented REMS that the '963 patent claims provides a safe method by which prescribers can prescribe, pharmacists can

dispense, and patients can use, Xyrem. In short, the patent claims a method.

STANDARD OF REVIEW

The issues in this appeal all concern questions of law, including the interpretation of the FDCA and the construction of the '963 patent's claims, which are reviewed *de novo*. *See Hawkins v. United States*, 469 F.3d 993, 1000 (Fed. Cir. 2006) (statutory interpretation); *Jack Guttman, Inc. v. Kopykake Enterprises, Inc.*, 302 F.3d 1352, 1356 (Fed. Cir. 2002) (claim construction). Although the ultimate decision to grant an injunction is generally reviewed for abuse of discretion, the legal conclusions underpinning the grant of an injunction are reviewed *de novo* on appeal. *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1325 (Fed. Cir. 2004) ("As a necessary corollary to this standard of review, 'to the extent that a district court's decision to grant a[n] injunction hinges on questions of law, our review is *de novo*.'" (internal alterations omitted)). *See also Sanofi–Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006) ("To the extent the court's decision is based upon an issue of law, we review that issue de novo.").

ARGUMENT

I. THE '963 PATENT CLAIMS A CONDITION OF USE AND THEREFORE MUST BE LISTED IN THE ORANGE BOOK UNDER THE FDCA.

The question before the Court is whether the '963 patent claims an "approved method of using [a] drug," as that phrase is used in section 505 of the Federal Food, Drug, and Cosmetic Act, or "FDCA." *See* 21 U.S.C. § 355(c)(3)(D)(ii)(I)(bb). If the '963 patent does claim such an "approved method of using [a] drug," there is no statutory basis for the district court's injunction.

Avadel and the district court have consistently treated that issue as presenting only a *patent-law* question—which turns on whether the claims are best construed as "method" or "system" claims as a matter of patent law. Appx7 (treating claim construction as dispositive). But the disputed phrase in the FDCA is not directed to a patent-law question at all, and it is therefore no surprise that patent law provides the wrong framework for addressing whether a patent is properly listed in FDA's Orange Book.

As Jazz has emphasized from the outset of this case, "independent" of any claim construction dispute, Appx841, the FDCA's statutory text, context, and implementing regulations confirm that an

"approved method of using [a] drug" encompasses not just patents that claim "indications" (such as a method of using a given drug to treat a given disease) but also those that claim "*conditions of use for which approval is sought or has been granted*." 21 C.F.R. § 314.53(b)(1) (emphasis added). *See* Appx839–840. And one critical set of conditions of use for certain drugs, including Xyrem, is a Risk Evaluation and Mitigation Strategy, or "REMS." *E.g.*, Appx859. Because the elements of the REMS claimed in the '963 patent are among the approved "conditions of use" for Xyrem, Jazz was required to list the patent in the Orange Book.

A. The Interpretation Of The FDCA Is Not A Question Of Patent Law.

There are many patent-law consequences at stake in a dispute over whether a patent claims a "method" within the meaning of the patent laws. For example, a method claim is only infringed when the claimed steps are actually carried out, which means a sale of a system to carry out the claimed steps will generally not infringe a method claim. *See, e.g.*, *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993). Method claims also raise potential "divided infringement" issues, *see Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 797 F.3d

1020, 1022–23 (Fed. Cir. 2015) (*en banc*), and they are subject to special standards for infringement in the context of importation, *see* 35 U.S.C. § 271(g).

But the Orange Book listing rules codified in the FDCA have nothing to do with these kinds of patent-law problems. Instead, they are directed to questions surrounding the approval of generic or follow-on drugs. One indication of this fact is Congress's decision in enacting the Hatch-Waxman Amendments, 98 Stat. 1555 (1984), to codify the listing rules in the FDCA, alongside the requirements for approval of abbreviated new drug and 505(b)(2) applications, *see* 98 Stat. 1585–97, rather than in Title 35, where it put the "artificial" act of patent infringement under § 271(e)(2), for example, *see* 98 Stat. 1603. *See Yates v. United States*, 135 S. Ct. 1074, 1085 (2015) (plurality) (relying on Congress's codification decisions). The patent-law provisions of the Hatch-Waxman Amendments are generally in Title 35, and the FDCA-law provisions are in the FDCA. And it is undisputed that "identical language may convey varying content when used in different statutes." *Id.* at 1082.

Another indication that the disputed provision of the FDCA is addressing an FDCA issue rather than a patent-law issue is the parallelism between the FDA-approval requirements for a generic drug and the Orange Book listing rules. To obtain approval, a generic manufacturer needs to establish that its proposed product has the same active ingredient as the reference product, *see* 21 U.S.C. § 355(j)(2)(A)(ii)(I), and, critically, that the proposed labeling has the same "*conditions of use* prescribed, recommended, or suggested" as the reference product, *see id.* § 355(j)(2)(A)(i) (emphasis added). But generics are generally *not* required to make their product by the same process or use the same packaging. Similarly, when submitting patent information, innovators must identify patents claiming the "active ingredient" or a "method of using" the drug (among other patents), 21 U.S.C. § 355(b)(1)(A)(viii), but *not* patents claiming a manufacturing process or packaging. FDA's regulations further underscore the point, requiring the listing of patents claiming "conditions of use" but prohibiting the listing of "[p]rocess patents" and patents claiming "packaging." 21 C.F.R. § 314.53(b).

Furthermore, the agency that Congress empowered to administer Orange Book listing is not the Patent Office but FDA. *See* 98 Stat. 1591. To the extent the listing statute is ambiguous, this Court should defer to FDA's reasonable interpretation reflected in its regulations. *See* 21 C.F.R. § 314.53(b); *Chevron USA Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). The reason for that deference is that the statute is bound up with the statutory scheme governing drug approval, *see id.* 844 (deference tied to the "statutory scheme [an agency] is entrusted to administer"), *not* patent law.

Finally, FDA regulations are incompatible with patent-law definitions in this context, powerfully indicating that a patent-law analysis (such as claim construction) would be misplaced. For example, under the Patent Act, the words "process" and "method" mean the same thing. *See* 35 U.S.C. § 100(b). But FDA did not use those words interchangeably in 21 C.F.R. § 314.53(b)(1). To the contrary, under that regulation, applicants "must submit information" on certain "patents that claim a method of use," but they "must not" submit information on "[p]rocess patents." *Id.* Borrowing patent-law definitions would make a hash of these rules. If method-of-use patents were process patents (and

vice-versa), applicants would simultaneously have to submit them to FDA—and be forbidden to do so.

B. An "Approved Method Of Using [A] Drug" Encompasses Approved "Conditions Of Use."

Against this backdrop, the question here is whether, as a matter of FDCA law, an "approved method of using [a] drug" encompasses approved "conditions of use," such as those set forth in a REMS. The answer is yes.

"As always, we begin with the text." *Sw. Airlines Co. v. Saxon*, 142 S. Ct. 1783, 1789 (2022). Under the delisting statute, Avadel must show that the '963 patent "does not claim" an "approved method of using the drug." 21 U.S.C. § 355(c)(3)(D)(ii)(I)(bb). The key phrase—"approved method of using the drug"—is undefined, so this Court must ask what its "'ordinary, contemporary, common meaning' was when Congress enacted [the statute]." *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2362 (2019) (quoting *Perrin* v. *United States*, 444 U.S. 37, 42 (1979)).

Then (as now), the term "approved" referred to FDA's role in granting new drug applications under FDCA section 505. *See, e.g.*, 21 U.S.C. § 355(a) (interstate distribution of new drugs prohibited "unless

an approval of an application is effective"). Meanwhile, a "method" was a "procedure, technique, or planned way of doing something." *Random House Webster's College Dictionary* 776 (2005). And "to use" meant "to put into action or service," *Webster's Third New International Dictionary* 2523–24 (2002), or to "take, hold, or deploy (something) as a means of accomplishing a purpose," *The New Oxford American Dictionary* 1853 (2005). So an "ordinary speaker of English," *Comcast Corp. v. Nat'l Ass'n of Afr. Am.-Owned Media*, 140 S. Ct. 1009, 1015 (2020), would have understood the phrase "approved method of using [a] drug" to mean an FDA-authorized procedure, technique, or plan for deploying a drug or for putting it into service.[5]

The structure of the FDCA discussed above further supports an interpretation that looks to how FDA has approved the deployment of a drug. Read together, the patent listing requirements, the delisting

[5] Avadel itself framed things that way in the District of Columbia case, focusing on "ordinary English meaning" and the "broader [FDCA] context"—without invoking patent-law principles or terms of art. *Avadel CNS Pharms., LLC v. Becerra*, No. 22-cv-02159, Doc. 3-3 (Memorandum of Law in Support of Motion for a Preliminary Injunction) at 16 (D.D.C. July 21, 2022); *see also Avadel CNS Pharms., LLC v. Becerra*, No. 22-cv-02159, Doc. 31-2 (Memorandum of Law) at 26 (D.D.C. Sep. 2, 2022).

counterclaim provision, and the generic drug approval requirements are wholly consistent. A generic drug manufacturer needs to establish (among other things) that its product has the same "conditions of use prescribed, recommended, or suggested" on its labeling as the reference product, 21 U.S.C. § 355(j)(2)(A)(i), but if those conditions of use are claimed by a patent, the Hatch-Waxman Amendments contemplate potential litigation of that patent, triggered by the requisite listing of patents claiming approved methods of using the drug (§ 355(b)(1)(A)(viii)(II)) and a subsequent Paragraph IV certification (§ 355(j)(2)(A)(vii)(IV)). However, if the patent does not claim the "conditions of use" the generic manufacturer was required to copy in the first place, then the statute may provide for a delisting counterclaim. *See id.* § 355(c)(3)(D)(ii)(I). And again, that counterclaim is all about the path to approval of a generic drug; there is no independent cause of action outside of Hatch-Waxman litigation, *id.* § 355(c)(3)(D)(ii)(II).

FDA regulations support a reading that focuses on conditions of use as well. FDA's listing rule requires drug applicants to submit information on patents that "claim[] the drug or a *method of using the drug*." 21 C.F.R. § 314.53(b)(1) (emphasis added). The regulation then

clarifies that, "[f]or patents that claim a method of use, the applicant must submit information only on those patents that claim indications or other conditions of use for which approval is sought or has been granted." *Id.* The regulation thus makes clear that, in FDA's authoritative view, the phrase "approved method of using [a] drug" includes a drug's "conditions of use."

C. The '963 Patent Claims a REMS, Which Constitutes A Set Of Approved Conditions Of Use For Xyrem.

Under both the plain text of section 355(c)(3)(D)(ii)(I)(bb) and FDA's authoritative interpretation, the '963 patent belongs in the Orange Book and should not be delisted, because it claims elements of a REMS, which constitute approved "conditions of use" for Xyrem.

As explained above, *supra* note 1, a REMS is a set of procedures to ensure that drugs with higher-than-usual risk profiles can be approved as safe and effective. When such procedures are necessary, they must be included "as part of [the] application" for the drug. 21 U.S.C. § 355-1(a)(1). Distribution plans may be included as an element of a REMS when FDA has determined that the drug "can be approved only if . . . such elements are required." *Id.* § 355-1(f)(1)(A). Once in place, the REMS and its elements are described as the "approved strategy"

throughout the statute. *See, e.g.*, *id.* § 355-1(g) ("Assessment and Modification of Approved Strategy"); *see also id.* § 355(p)(1)(B) (specifying that "the requirements of the approved strategy" are enforceable by FDA).

A patent claiming elements of a REMS is properly listed in the Orange Book because an FDA-approved REMS constitutes a set of approved "conditions of use" for a given drug. Here, the Xyrem Package Insert itself makes clear that "Xyrem is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XYWAV and XYREM REMS." (Appx859.) Indeed, when FDA approved Xyrem, it imposed "specific restrictions on distribution and use"—including a "Risk Management Program" that "must include" safeguards claimed under the '963 patent. (Appx851–852.) More broadly, the FDCA makes clear that REMS elements are among the conditions of use that inform FDA's approval of a drug. *See* 21 U.S.C. § 355-1(f)(1)(A); *see also* FDA, *Guidance for Industry: Development and Use of Risk Minimization Action Plans*, 6 (Mar. 2005), https://www.fda.gov/media/71268/download (for the predecessor program to REMS, applicants should adopt "conditions of use most

likely to confer benefits and to minimize particular risks"). Were there any remaining question, the agency answered it in the District of Columbia case—explaining that "uses in [a] REMS document" "can be" listed in the Orange Book. Appx5307. That statement is consistent with the statute and regulations, represents FDA's official position based on its regulatory expertise, and reflects its longstanding judgment, to which this Court should defer.

Further, when Congress enacted the REMS statute in 2007, there were already patents listed in the Orange Book related to the risk management programs that Congress was about to deem to be REMS programs. *See* Orange Book, Patent and Exclusivity Addendum, Prescription and OTC Drug Product Patent and Exclusivity List, ADA 124, ADB 24 (26th ed. 2006) (listing numerous patents under U-371, defined as "Approval for marketing only under a special restriction program approved by FDA called 'System for Thalidomide Education and Prescribing Safety'"). Congress did not decree such patents improperly listed. Instead, it authorized FDA to facilitate generic approval where a REMS element was "claimed by a patent that has not expired" and the applicant "certifies that it has sought a license . . . and

that it was unable to obtain a license." FDA Amendments Act of 2007, Pub. L. No. 110-85, tit. IX, subtit. A, § 901(b), 121 Stat. 823, 937–38 (codified at 21 U.S.C. § 355-1(i)(1)(B)(ii)). In sum, Congress knew that patents related to REMS elements would be—and had been—properly listed in the Orange Book.

A patent claiming elements of a REMS is thus properly listed in the Orange Book, and the '963 patent is just such a patent. The patent claims elements of a REMS-based procedure for safely distributing Xyrem® to patients, as shown below:

Claimed Elements	**FDA-Approved REMS**
Fields "storing information sufficient to identify a physician or other prescriber of the company's prescription drug and information to show that the physician or other prescriber is authorized to prescribe the company's prescription drug." *See* Appx98 at 8:56–61.	"Verify in the Central Database that the patient and prescriber are enrolled." Appx897.
"[R]econcile inventory of the prescription drug before the shipments for a day or other time period are sent." Appx98 at 8:66–67.	"Track and verify receipt of each shipment of [Xyrem®] through the processes and procedures established as a requirement of the REMS." Appx898.
"[S]aid identifying that the narcoleptic patient is a cash payer by said second database query	"Monitor for all instances of patient and prescriber behavior that give rise to a

being an indicator of a potential misuse, abuse or diversion by the narcoleptic patient." Appx99 at 9:8–12.	reasonable suspicion of abuse, misuse, and diversion." Appx898.
"[N]otify the physician that is interrelated with the narcoleptic patient" if any indicators of misuse are detected. Appx98 at 9:12–14.	"Notify prescribers when patients are receiving concomitant contraindicated medications or there are signs of potential abuse, misuse, or diversion." Appx893.
"[S]electively blocks shipment of the prescription drug to the patient" based upon identification of abuse potential. *See* Appx99 at 9:14–16.	"For patients who request an early refill or if abuse, misuse or diversion is suspected: Discuss the request or concern with the prescriber." Appx897.
"[S]hipped to the narcoleptic patient if no potential misuse, abuse or diversion is found." *See* Appx99 at 9:17–20.	"Ship . . . XYREM directly to each patient or a patient-authorized adult designee through the processes and procedures established as a requirement of the REMS." Appx897.
"[I]nsurance fields, contained within the database schema, store information sufficient to identify an insurer to be contacted for payment for prescription drugs of an associated patient." *See* Appx99 at 9:49–53.	"Contact the patient's insurance provider to verify . . . XYREM prescription benefits." Appx913.
"[S]ystem is used to identify a current pattern or an anticipated pattern of abuse of the prescription drug." *See* Appx99 at 9:54–58.	"Assess the patient for . . . signs of abuse and misuse including an increase in dose or frequency of dosing, reports of lost, stolen, or spilled medication, and drug-seeking behavior." Appx894.

All of that counts as an "approved method of using the drug" because the REMS-certified pharmacy follows the procedure to "deploy" Xyrem and safely "put [it] into action or service." *Webster's Third* 2523–24; *Oxford American* 1853.

Accordingly, because the '963 patent claims an "approved method of using the drug," the district court erred by holding that the patent was subject to delisting under, 21 U.S.C. § 355(c)(3)(D)(ii)(I).

D. Jazz Presented Its FDCA Argument Below, And This Court Should Accept It Here.

From the start, Jazz has argued that "the '963 patent claims 'an approved method of using the drug' under both the relevant statute and FDA rule." Appx840. In fact, Jazz's very first brief before the district court addressing the delisting counterclaim argued that "Jazz was legally *required* to list the '963 patent" because it claims "conditions of use for Xyrem." *Id.* (emphasis in original) And Jazz could not have been clearer that these were independent grounds for denying delisting—urging the court to deny Avadel's motion "[o]n this basis alone." *Id.* When the dispute was first raised, the district court initially denied the motion, in part on the ground that there was a "question as to whether Jazz was required to submit the '963 patent for listing in the Orange

Book" in view of the FDA-approved package insert for XYREM, which indicates that XYREM is "available only" through the "XYREM REMS." Appx1449. In other words, the district court initially recognized Jazz's argument under the FDCA and saw merit in it.

To be sure, Jazz also argued that Avadel's theory depended on claim construction. But the district court misread Jazz's briefing when it reasoned, more than a year later, that Jazz had "suggest[ed]" that claim construction "disposes of" the interpretive inquiry regardless of how the claims are construed. Appx7. Not so. Jazz's position was that Avadel could not prevail without overcoming Jazz's FDCA argument and prevailing on its construction of the patent's claims. Appx840–845. In other words, claim construction would be dispositive if Avadel's construction were *rejected*, but not if Avadel's construction were accepted, as it ultimately turned out to be. The district court might have recognized this point if it had addressed the section of Jazz's brief immediately preceding the one the court cited (and relied on) in its decision. *See* Appx7 n.6 (citing Appx840–841); *see also* Appx839–840 (making FDCA argument, which was independent of claim construction).

Even if Jazz had not made the argument below, however, this Court "may address arguments beyond those originally presented" when "review[ing] the district court's interpretation of statutory and regulatory provisions." *Broad. Innovation, L.L.C. v. Charter Commc'ns, Inc.*, 420 F.3d 1364, 1366 (Fed. Cir. 2005); *see also Bozeman Fin. LLC v. Fed. Rsrv. Bank of Atl.*, 955 F.3d 971, 974 (Fed. Cir. 2020) (addressing unpreserved "issue of statutory interpretation"); *Karuk Tribe of Cal. v. Ammon*, 209 F.3d 1366, 1379 (Fed. Cir. 2000) (same); *Cemex, S.A. v. United States*, 133 F.3d 897, 902 (Fed. Cir. 1998) ("[B]ecause an issue of statutory interpretation is involved, we address [appellant's unpreserved] argument."). After all: regardless of "particular legal theories advanced by the parties," courts "retain[] the independent power to identify and apply the proper construction of governing law." *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 99 (1991). If this Court disregards the places Jazz raised the statutory-interpretation question before the district court, the Court should nevertheless exercise its power to address that question here and adopt the correct interpretation of the delisting statute, "giv[ing] effect to the text

Congress enacted." *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 228 (2008).

II. AT THE VERY LEAST, JAZZ WAS PERMITTED TO LIST THE '963 PATENT, WHICH FORECLOSES ANY DELISTING COUNTERCLAIM.

Even if Jazz were not required to list the '963 patent in the Orange Book, the district court erred in refusing to analyze whether Jazz was *permitted* to list the patent and, if so, whether permissibly-listed patents are subject to delisting. The district court's failure to address this question of statutory interpretation was reversible error because the delisting statute offers no basis to delist patents that were appropriately included in the Orange Book under the law that applied when they were listed. *See* 21 U.S.C. § 355(c)(3)(D)(ii)(I). Because the '963 patent was permissibly listed in 2014, the district court erred in concluding that it was subject to delisting.

A. FDA Regulations Did Not Prohibit Listing The '963 Patent In The Orange Book At The Time Of Listing.

When the '963 patent was listed in 2014, the listing statute directed that the "applicant shall file . . . any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug." 21 U.S.C. § 355(b)(1) (2013). Thus,

although the statute *required* that patents claiming the drug or method of using such drug be listed, the listing statute was silent as to whether any other categories of patents could be listed. FDA's regulation providing instruction on the listing statute identified two categories of patents: those that "must" be listed in the Orange Book and those that "must not." 21 C.F.R. § 314.53(b)(1). The two categories were not exhaustive. Then, as now, FDA listed four specific categories of patents in the "must not" list category: "[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates." *Id.* Avadel has never argued, and the district court never found, that the '963 patent falls within any of these four prohibited categories of patents.

Accordingly, because neither the listing statute nor FDA regulation prohibited listing of *all* patents other than those that a party must list, FDA, in implementing the statutory listing requirements enacted by Congress, left the door open for patent holders to list patents that fell into neither category. The '963 patent fell either into the must-list category—which would mean Jazz was *required* to list the '963

patent in 2014—or into neither category—in which case Jazz was at least *permitted* to list the '963 patent in 2014.

Indeed, if Jazz were prohibited from listing the '963 patent in 2014, the provision in the OBTA which expressly prohibits the listing of all patent information that is not required would be superfluous. The OBTA added to the listing statute an express provision stating that "[p]atent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph." *See* 21 U.S.C. § 355(c)(2). In other words, the OBTA eliminated the permissibly listed category by placing *all* patents that an applicant was not required to list in the "must not" list category.

Congress's determination in 2020 that this OBTA provision was necessary demonstrates the permissibility of, prior to the passage of the OBTA, listing additional patents beyond those an applicant was required to list. As the Supreme Court has explained, had Congress thought the FDCA already included such a limitation, then "Congress would have not needed to enact these additional statutory references," through the OBTA. *Carcieri v. Salazar*, 555 U.S. 379, 392 (2009). Thus, any statutory interpretation to the contrary would render wholly

superfluous this OBTA provision, contrary to well-established principles of statutory construction. *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 632 (2018) (rejecting "an interpretation of the statute that would render an entire subparagraph [of the statute] meaningless").

Accordingly, this Court should not construe the OBTA as merely a clarification of the original listing statute. As an initial matter, when Congress intends to merely clarify a prior statute, Congress says as much. *See, e.g.*, *Nat. Res. Def. Council, Inc. v. Gorsuch*, 685 F.2d 718, 721 (D.C. Cir. 1982) ("Congress, however, '(b)eliev(ed) that a statutory clarification of the question (was) needed,' and therefore added to its 1977 Clean Air Act Amendments." (alterations in original, citations omitted) (quoting S. Rep. No. 127, 95th Cong., 1st Sess. 55 (1977))), *rev'd sub nom. Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984); *Hawkins v. United States*, 469 F.3d 993, 1001–02 (Fed. Cir. 2006) ("That history indicates that the 1984 amendments to the PSOBA merely re-authorized the existing Act with four minor modifications 'which are consistent with congressional intent as expressed in the legislative history of the 1974 Act.'" (alteration omitted) (quoting S. Rep. No. 98-225, at 282 (1983), *reprinted in* 1984

U.S.C.C.A.N. 3182, 3463)). No such indication of Congress's intent exists here.

Rather, the fact that Congress, through the OBTA, later "demonstrated its ability to specify a statute's applicability . . . and indeed to make explicit refence" to patent information that could not be listed renders it "unreasonable to infer" that Congress intended the initial listing statute to prohibit the listing of all categories of patents that were not required to be listed. *Canadian Lumber Trade All. v. United States*, 517 F.3d 1319, 1343 (Fed. Cir. 2008). As the existence of the OBTA demonstrates, Congress understands how to prohibit the listing of all patent information that is not required to be listed if Congress so intends, and it did not do so in the initial listing statute.

B. The Delisting Statute Cannot Apply To Permissibly-Listed Patents.

The district court viewed the question whether Jazz was permitted to submit the '963 patent for listing in the Orange Book as irrelevant, based on the court's interpretation of the delisting statute. Appx8. In other words, the court reasoned that a delisting remedy was available under § 355(c)(3)(D)(ii)(I) *regardless* of whether the patent could (at least) permissibly be listed under FDA's regulations

implementing 21 U.S.C. § 355(b)(1)(A)(viii), so there was no need to try to reconcile the two statutory provisions. That is not how statutory interpretation is supposed to work. *See Nat'l Assn. of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 666 (2007) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." (internal quotation marks omitted)); *LaBonte v. United States*, 43 F.4th 1357, 1373 (Fed. Cir. 2022) (same). Read in context, the delisting statute cannot be understood to empower courts to order the delisting of patents that are properly listed under 21 U.S.C. § 355(b)(1)(A)(viii), as implemented by the agency empowered to administer the FDCA.

The two provisions that the district court treated as independent are integrally related. They appear in the same section of the FDCA, and the statutory language of the delisting statute plainly (and unsurprisingly) mirrors the language of the listing statute. In the listing statute, Congress directs innovators to submit patents that "claim[] the drug for which the applicant submitted [a new drug] application" or that "claim[] a method of using such drug," 21 U.S.C. § 355(b)(1)(A)(viii), and then in the delisting statute, Congress

empowers courts to order delisting where patents do not claim "the drug for which the application was approved" or "an approved method of using the drug," *id.* § 355(c)(3)(D)(ii)(I). These two provisions need to be read together. And, critically, the statute's guidance on what should be listed (or not listed) was incomplete, leaving a "gap" for FDA to fill, which the agency did in promulgating 21 C.F.R. § 314.53(b)(1). The agency's regulation is entitled to deference. *See, e.g.*, *Patterson v. Dep't of Interior*, 424 F.3d 1151, 1159 (Fed. Cir. 2005) ("Congress left a 'gap' in the [statute] on this issue, and the regulations issued by the [Office of Personnel Management] to fill this gap are therefore entitled to deference under *Chevron*."). At least as of the time Jazz submitted the '963 patent for listing in the Orange Book, the agency's regulations implementing the FDCA's listing provisions permitted the listing of that patent. The patent cannot be subject to *delisting* based on a judicial interpretation of essentially the same statutory language elsewhere in the same section of the FDCA.

Indeed, any other approach to reconciling the listing and delisting statutory provisions would require the nonsensical assumption that Congress authorized the listing of patents that would then be subject to

delisting via litigation, rather than merely prohibiting the listing of those patents in the first instance. Such a statutory interpretation should be rejected. *Dupuch-Carron v. Sec'y of Health & Hum. Servs.*, 969 F.3d 1318, 1330 (Fed. Cir. 2020) ("Both the Supreme Court and this court, however, have repeatedly held over the years that 'if a literal construction of the words of a statute be absurd, the act must be so construed as to avoid the absurdity.'" (alterations omitted) (quoting *Holy Trinity Church v. United States*, 143 U.S. 457, 460 (1892))).

Here, the provisions in effect at time the '963 patent was listed in the Orange Book permitted the listing of that patent. Accordingly, the delisting statute cannot be read to require delisting of permissibly listed patents.[6]

[6] Contrary to Avadel's assertions below, Jazz's interpretation that reconciles the listing and delisting statutory provisions does not render the delisting counterclaim superfluous. Rather, delisting remains an available remedy pre-OBTA for the categories of patents that FDA interpreted the listing statute to prohibit. Those categories include "[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates," 21 C.F.R. § 314.53(b)(1), all of which could be subject to delisting if they were improperly listed.

C. The Orange Book Transparency Act Cannot Be Applied Retroactively To Require Delisting Of The '963 Patent.

The OBTA eliminated a gap that FDA had previously been authorized to fill by regulation. Whereas FDA was once empowered to allow *permissive* listing of patents whose listing was not expressly mandated or prohibited, the OBTA ultimately prohibited innovators from submitting any patents not *required* to be listed. Because the parallel provisions of the FDCA should be read together, this important change to the standards for *listing* likewise affects the standards for *delisting*. But the OBTA applies only prospectively, and it therefore cannot supply the basis for requiring the delisting of the '963 patent.

"Retroactivity is not favored in the law," and "congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988); *see also Landgraf v. USI Film Prods.*, 511 U.S. 244, 265 (1994). Accordingly, this Court "will construe a statute to avoid retroactivity unless there is clear evidence that Congress intended otherwise." *Hicks v. Merit Sys. Prot. Bd.*, 819 F.3d 1318, 1321 (Fed. Cir. 2016); *Presidio Components, Inc. v. Am. Tech.*

Ceramics Corp., 702 F.3d 1351, 1364 (Fed. Cir. 2012) ("An Act must clearly indicate its retroactive application."); *see also Lindh v. Murphy*, 521 U.S. 320, 328 n.4 (1997) ("[C]ases where this Court has found truly 'retroactive' effect adequately authorized by a statute have involved statutory language that was so clear that it could sustain only one interpretation.").

The statutory language at issue here cannot overcome this strong presumption against retroactivity. To the contrary, the imperative phrase in 21 U.S.C. § 355(c)(2)—"shall not be"—unambiguously shows that Congress intended only prospective application. *Ghana v. Holland*, 226 F.3d 175, 182 (3d Cir. 2000) ("shall be brought" shows Congress's "intent that the exhaustion requirement apply only to new actions"); *Salahuddin v. Mead*, 174 F.3d 271, 274 (2d Cir. 1999) ("There is no doubt that 'shall' . . . speaks to future conduct. Even the most demanding among us cannot reasonably expect that a person 'shall' do something yesterday."); *Carl Marks & Co., v. Union of Soviet Socialist Republics*, 665 F. Supp. 323, 337 (S.D.N.Y. 1987) ("The use of 'shall have' indicates prospective application."); *Martropico Compania Naviera S. A. v. Perusahaan Pertambangan Minyak Dan Gas Bumi*

Negara (Pertamina), 428 F. Supp. 1035, 1037 (S.D.N.Y. 1977) ("Indeed, the very wording of section 1330(a) that the 'district courts shall have original jurisdiction' is prospective.").

Avadel did not argue below (and cannot credibly argue here) that the statute is even ambiguous, much less that it dictates retroactive enforcement. But even if the statutory language did not expressly preclude retroactivity (it does), the adverse effects upon Jazz and other third parties would preclude retroactive application. *Lieberman v. Cambridge Partners, L.L.C.*, 432 F.3d 482, 488–89 (3d Cir. 2005) ("[A] court must examine whether the statute . . . impair[s] rights a party possessed when he acted, . . . or impose[s] new duties with respect to transactions already completed. If the statute would do any of these things, it will not be applied retroactively, absent clear congressional intent to the contrary." (internal quotation marks omitted) (quoting *Landgraf*, 511 U.S. at 280)).

Here, retroactive application would both impair rights and impose duties. Retroactive application would result in the loss of statutory rights under the Hatch-Waxman Amendments that Jazz—and anyone else who followed the law as it applied prior to the enactment of the

OBTA to permissively list patents—held through January 5, 2021, the date on which the OBTA came into effect. Moreover, retroactive application would impose new duties with respect to at least Jazz and a long list of ANDA filers who previously certified against the '963 patent in litigation spanning from 2010 until 2018, impacting already-completed transactions. And notably, Avadel has filed counterclaims that seek to impose antitrust liability premised on the allegedly improper listing of the '963 patent in the Orange Book; if the OBTA were applied retroactively, Avadel would propose that Jazz would be subject to severe penalties for improperly listing a patent that Jazz was permitted to list at the time of listing. Retroactive application is unavailable in such circumstances. *Apotex Inc. v. U.S. Food & Drug Admin.*, 414 F. Supp. 2d 61, 75 (D.D.C. 2006) (explaining that because "retroactive application to situations in which the FDA has already determined which applicant is entitled to exclusivity would disturb settled agency decisions and increase administrative burdens[,] retroactive applications of the law are not favored in the administrative law context.").

III. EVEN IF THE INTERPRETATION OF THE FDCA PRESENTED A PATENT-LAW QUESTION, THE '963 PATENT, PROPERLY CONSTRUED, CLAIMS A METHOD.

Avadel's view, adopted by the district court, is that whether a given patent claims an "approved method of using [a] drug," 21 U.S.C. § 355(c)(3)(D)(ii), turns on a patent-law question: the only patents that may be listed are those that are properly construed (*e.g.*, under *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc)) to claim a "method" for patent-law purposes. As discussed above, that is not the right test, but even if it were, the '963 patent would pass it. Properly construed, the '963 patent claims a method.

The '963 patent claims cover methods of using a computer-implemented system to safely distribute sodium oxybate for treatment of a narcoleptic patient. Specifically, the independent claims recite a "computer implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion." Appx98 at 8:39–41. While the district court concluded that a "system" cannot be a "method," the only evidence before it showed otherwise.

"It is axiomatic that [this Court] will not narrow a claim term beyond its plain and ordinary meaning unless there is support for the limitation in the words of the claim, the specification, or the prosecution history." *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1333 (Fed. Cir. 2013). Accordingly, "absent a clear disavowal or alternative lexicography by a patentee, he or she 'is free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning.'" *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1282 (Fed. Cir. 2017) (citation omitted).

Here, Jazz submitted unrebutted evidence that the plain and ordinary meaning of "system" is a "formulated, regular, or special method or plan of procedure." *See, e.g.*, Appx2884. Avadel never contested that evidence, nor did it ever provide any alternative plain meaning. And the evidence further showed that the specification of the '963 patent consistently used the term "system" according to its plain and ordinary meaning, referring to both the drug distribution "system" of the claimed invention, Appx95 at Cover ("Sensitive Drug Distribution System and Method"), as well as the separate "computer system" used to implement the claimed drug distribution system. As the description

of Figure 1 states, the described "computer system" "implement[s] the system and method of the present invention." Appx95 at 2:29–31. Thus, the claimed system (i.e., special method or plan of procedure) is carried out using the particular "computer system" described in the specification and claims. This is consistent with the inventors' use of "computer system" throughout the specification when they wanted to refer to the computer systems described therein, as opposed to the drug distribution system and method of the invention. *See* Appx95–96 at 2:29–46, 3:20–23, 3:56–4:16.

The district court never addressed the evidence that articulated the plain meaning of "system," versus "computer system," or made the requisite finding based on the intrinsic record—*i.e.*, lexicography or statements amounting to clear and unmistakable disavowal—to justify departing from the plain meaning of system.

Instead, the district court determined that "Jazz's position is strained in view of the patent's title, 'Sensitive Drug Distribution System *and* Method,'" which the Court interpreted as "distinguishing between a 'system' and a 'method.'" Appx5724. The Court also found

"Jazz's position . . . further strained given that Jazz prosecuted both system and method claims in this patent family." *Id.*

The fact that Jazz pursued claims to both "systems" and "methods" does not alter the plain meaning of either term. "[C]laim drafters can [ ] use different terms to define the exact same subject matter. Indeed this court has acknowledged that two claims with different terminology can define the exact same subject matter." *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006). That is the case here. The district court provided no rationale to deprive "system" of the full scope of its plain and ordinary meaning and instead hold that the claimed drug distribution "system" is the same as the separate "computer system" described in the specification. Indeed, such a construction would render the claim nonsensical—requiring a "computer-implemented *computer* system" instead of the "computer-implemented *drug distribution system*" actually claimed.

Thus, because the district court premised its injunction on an erroneous construction of the '963 patent, the injunction should be vacated.

CONCLUSION

For the reasons stated above, this Court should reverse the district court's order granting Avadel's motion for judgment on the pleadings and vacate the injunction directing Jazz to submit to FDA a request to delete the '963 patent from the Orange Book entry for Xyrem.

December 16, 2022

Respectfully submitted,

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ADDENDUM

Memorandum Opinion (Nov. 18, 2022)..... Appx1

Order and Judgment (Nov. 18, 2022) Appx10

U.S. Patent No. 8,731,963..... Appx75

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-691-GBW

MEMORANDUM OPINION

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November 18, 2022
Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Before the Court is Defendant Avadel CNS Pharmaceuticals LLC's ("Avadel") renewed motion for judgment on the pleadings (the "Renewed Motion") with respect to its counterclaim seeking delisting of Plaintiff Jazz Pharmaceuticals, Inc.'s ("Jazz") U.S. Patent No. 8,731,963 ("the '963 patent") from the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book"). The Renewed Motion has been fully briefed. D.I. 118, 153, 154 & 171.[1] The Court held oral argument on November 15, 2022. For the reasons set forth below, the Motion (D.I. 117) is GRANTED.

I. BACKGROUND

Jazz manufactures and sells a Xyrem®, an FDA-approved drug for treating cataplexy and excessive daytime sleepiness associated with the sleep disorder narcolepsy. The active ingredient in Xyrem® is sodium oxybate, a form of gamma-hydroxybutyrate ("GHB") that has been recognized as a dangerous substance. Given GHB's potential for misuse, the FDA conditioned its approval of Xyrem® on the implementation of a Risk Evaluation and Mitigation Strategy (REMS) to control Xyrem®'s distribution. Jazz's '963 patent is directed toward using a computer-implemented system to address certain FDA-required REMS conditions of using Xyrem® according to its approved labeling. Jazz listed the '963 patent in the Orange Book on the basis that it claims a method of using Xyrem®.[2]

[1] Jazz sought leave to file a sur-reply, which this Court granted (D.I. 169) as Avadel did not oppose. D.I. 155 & 157.

[2] Among the patents Jazz asserts in this litigation, only the '963 patent is listed in the Orange Book.

In December 2020, Avadel submitted an NDA pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to manufacture and sell FT218, its once-nightly formulation of sodium oxybate for the treatment of narcolepsy. In May 2021, Jazz initiated the instant patent infringement action against Avadel arising from Avadel's NDA, asserting five patents including the '963. Avadel counterclaimed, seeking a declaration pursuant to 21 U.S.C. § 355(c)(3)(D)(ii)(I) that orders Jazz to remove the '963 patent from the Orange Book (Count III) because it does not claim a method of using the approved drug. Thereafter, Avadel filed its first motion for judgment on the pleadings on Count III. The Court denied Avadel's motion concluding in part that Avadel's delisting arguments "depend in no small part on claim construction and the question of whether the claimed 'system' includes methods of using the approved product." D.I. 55 at 5. After the parties exchanged their proposed constructions as well as opening and responsive claim construction briefs, on June 23, 2022, Avadel filed the Renewed Motion "so that the Court may decide this issue as promptly as possible once the Court rules on the proper construction of the '963 patent claims." D.I. 118 at 3-4.

Meanwhile, the FDA required Avadel to certify to the '963 patent. Avadel had not done so, opting to file a statement indicating that its application did not implicate the '963 patent. The FDA concluded otherwise, and within 45 days of Avadel's certification, Jazz, on July 15, 2022, filed another patent infringement suit in this Court asserting the '963 patent against Avadel. C.A. No. 22-00941-GBW. That action triggered the automatic stay of FDA approval for FT218, which remains in place until the '963 patent expires and the related term of pediatric exclusivity ends in June 2023. Avadel sought relief from that certification in the United States District Court for the District of Columbia, commencing an action on July 21, 2022 against the FDA. *See Avadel CNS*

Pharmaceuticals, LLC v. Becerra, C.A. No. 22-02159 (APM). Jazz intervened and opposed Avadel's request.

As the action progressed in this Court, Avadel in September requested expedited consideration of the Renewed Motion (D.I. 162 & 167), which Jazz opposed (D.I. 165). Shortly thereafter, this Court convened a status conference to discuss the Renewed Motion and Avadel's related action pending in the District of Columbia, and scheduled a claim construction hearing for October 25, 2022. D.I. 179. After the claim construction hearing, the Court granted Avadel's request for expedition. D.I. 212.

The Court has issued its Memorandum Opinion on claim construction and concluded that the terms of the '963 patent are directed to systems, not methods. D.I. 229. The United States District Court for the District of Columbia denied Avadel's requested relief, concluding that Avadel has an adequate remedy at law via its delisting counterclaim pending in this Court. *Avadel CNS Pharms., LLC V. Becerra*, No. 22-CV-02159 (APM), 2022 WL 16650467, at *6–7 (D.D.C. Nov. 3, 2022). After obtaining leave of Court, on November 15, 2022, the Federal Trade Commission filed an *amicus curiae* brief in connection with Avadel's Renewed Motion, arguing that "REMS distribution patents as a category do not meet the requirements for Orange Book listing." D.I. 227.

II. LEGAL STANDARD

Pursuant to Rule 12(c) of the Federal Rules of Civil Procedure, a party may move for judgment on the pleadings "[a]fter pleadings are closed – but early enough not to delay trial." FED. R. CIV. P. 12(c). When evaluating a motion for judgment on the pleadings, the Court must "view the facts presented in the pleadings and the inferences to be drawn therefrom in the light most

favorable to the nonmoving party." *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008) (quoting *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290-91 (3d Cir. 1988)).

"The purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on the competing pleadings and exhibits thereto, and documents incorporated by reference." *Venetec Int'l, Inc. v. Nexus Med., LLC*, 541 F.Supp.2d 612, 617 (D. Del. 2008); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (explaining that any documents integral to pleadings may be considered in connection with Rule 12(c) motion). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Burlington Coat Factory*, 114 F.3d at 1420. Ultimately, a motion for judgment on the pleadings can be granted "only if no relief could be afforded under any set of facts that could be proved." *Turbe v. Gov't of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991).

III. DISCUSSION

Avadel argues that the '963 patent must be delisted because it claims a "system," not a method of using a drug. D.I. 118 at 6. Jazz argues that, even if the '963 patent claims systems, Jazz was permitted to list it in the Orange Book because 21 U.S.C. § 355(c)(2) of the Orange Book Transparency Act (OBTA) (which forbids "[p]atent information that is not the type of patent information required by subsection (b)(1)(A)(viii)" to be submitted for listing in the Orange Book) does not apply retroactively and, therefore, does not support delisting. D.I. 153 at 14-15.

A. The '963 Patent Does Not Claim a Method of Using a Drug

The "Orange Book" is an FDA database "that contains summary information about active drug patents submitted by patentholders." *Becerra*, 2022 WL 16650467, at *2. The Hatch-Waxman Act identifies two requirements for a patent to be eligible for listing in the Orange Book.

First, the patent must be one for which "infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(A)(viii). Second, the patent must claim one of the following three categories of subject matter: "a drug substance (active ingredient)," "a drug product (formulation or composition)," or "a method of using such drug for which approval is sought or has been granted in the [patent holder's NDA]." *Id.*

The "FDA does not make a determination as to whether particular patents should be listed in the Orange Book." *Bayer Schering Pharma AG & Bayer HealthCare Pharms., Inc. v. Lupin, Ltd.*, 676 F.3d 1316, 1324-25 (Fed. Cir. 2012). Instead, the FDCA creates a unique right of action under which an NDA applicant may "assert a counterclaim seeking an order requiring the [patentholder] to correct or delete" an Orange Book listing blocking the FDA's approval of its application. 21 U.S.C. § 355(c)(3)(D)(ii)(I). The relevant statutory provision applying to NDA applicants provides:

> If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) of this section or this subsection on the ground that the patent does not claim either–
>
> (aa) the drug for which the application was approved; or
>
> (bb) an approved method of using the drug.

21 U.S.C. § 355(c)(3)(D)(ii)(I); *accord Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408-09 (2012) (explaining 21 U.S.C. § 355(j)(5)(C)(ii)(I), the corollary delisting provision for an ANDA applicant, authorizes an ANDA applicant sued for patent infringement to "assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information submitted by the [brand to the Orange Book] on the ground that the patent does not

claim either '(aa) the drug for which the [brand's NDA] was approved; or "(bb) an approved method of using the drug") (citing 21 U.S.C. § 355(j)(5)(C)(ii)(I)).[3]

Here, the '936 patent does not belong in the Orange Book. The parties do not dispute that the '963 patent does not claim a drug for which the application was approved under subsection (aa). With respect to subsection (bb), the '963 patent does not claim "an approved method of using the drug" because the claims of '963 patent are directed to systems, not methods. D.I. 229. As Jazz suggests, the Court's construction of the '963 patent disposes of the inquiry.[4] Also, Jazz advances no theory that the '963 patent, construed as claiming systems, could constitute "an approved method of using the drug."

Jazz contends that granting Avadel's Renewed Motion would impermissibly apply the OBTA retroactively. According to Jazz, the OBTA, enacted in 2021, cannot not reach back to punish Jazz for listing the '963 patent in 2014. D.I. 153 at 14-18. However, Avadel's counterclaim arises under the delisting statute, 21 U.S.C. § 355(c)(3)(D)(ii)(I), affording Avadel a present right to seek delisting under the identified conditions. While 21 U.S.C § 355(c)(2) of the OBTA provides that "[p]atent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph," that provision on its face does not

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[3] Although *Caraco* addressed the delisting counterclaim available to ANDA applicants under 21 U.S.C. § 355(j)(5)(C)(ii)(I), Avadel maintains and Jazz does not dispute that *Caraco's* analysis applies to 21 U.S.C. § 355(c)(3)(D)(ii)(I), which is the parallel provision applicable to 505(b)(2) NDA applicants.

[4] In Jazz's answering brief opposing Avadel's first motion for judgment on the pleadings seeking delisting of the '963 patent, Jazz argued, "Avadel's delisting argument is premised entirely on its theory that the '963 patent claims a 'system' as opposed to a 'method.' This is, plain and simple, claim construction . . . To accept Avadel's arguments and to find that the '963 patent is improperly listed in the Orange Book, the Court would have to construe the claims and hold that the '963 patent covers no methods at all." D.I. 43 at 9-10.

impact an applicant's right to a delisting counterclaim under 21 U.S.C. § 355(c)(3)(D)(ii)(I).[5] As the Supreme Court recognized in *Caraco*, an applicant sued for patent infringement may simply "assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information submitted by the [brand] under subjection (b) or (c) of § 355 on the ground that the patent does not claim either" a "drug" or "an approved method of using the drug." 566 U.S. at 408-09 (citing 21 U.S.C. § 355(j)(5)(C)(ii)(I)); *accord In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 4 (1st Cir. 2020). Thus, whether the OBTA applies retroactively is not relevant to Avadel's delisting counterclaim. Moreover, the delisting statute was enacted in 2003—long before Jazz submitted the '963 patent for listing in the Orange Book in 2014. *Becerra*, 2022 WL 16650467 at *6–7.

Jazz also appears to argue that, because it was allegedly "permitted" to list the '963 patent in the Orange Book, it need not delist it now. D.I. 153 at 14-18. But regardless of the propriety of Jazz's initial listing, that assertion is not relevant in view of 21 U.S.C. § 355(c)(3)(D)(ii)(I), which states that patents that do not claim either a drug or method of using a drug may be either "correct[ed] or delete[d]." On its face, the delisting statute does not require inquiring as to whether the NDA holder was authorized to list the patent in the first instance. *See also Caraco*, 566 U.S. at 409 ("The counterclaim [for an ANDA filer under 21 U.S.C. § 355(j)(5)(C)(ii)(I)] thus enables a generic competitor to obtain a judgment directing a brand to 'correct or delete' certain patent information that is blocking the FDA's approval of a generic product.").

Thus, Avadel has satisfied the statutory requirements to seek an order requiring Jazz to correct or delete information in the Orange Book related to the '963 patent.

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[5] The Court takes no position on the retroactive application of 21 U.S.C. § 355(c)(3)(D)(ii)(I).

B. Jazz Must Request the FDA to Delete the '963 Patent from the Orange Book

Because the '963 patent does not claim a drug for which the application was approved or an approved method of using the drug, this Court will issue an order directing Jazz to correct or delete the patent information submitted by Jazz in the Orange Book. 21 U.S.C. § 355(c)(3)(D)(ii)(I). The Code of Federal Regulations further provides:

> If the NDA holder is required by court order to amend patent information or withdraw a patent from the list, it must submit an amendment to its NDA that includes a copy of the order, within 14 days of the date the order was entered, to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266. The amendment to the NDA must bear the identification described in paragraph (d)(6) of this section.

21 C.F.R. § 314.53(f)(2)(i). Thus, the Court will issue an accompanying order consistent with these provisions.

Jazz argues that "[u]nder FDA regulations, Jazz has 30 days to correct any patent listing that is affected by order of a District Court, without that correction having any impact on Avadel's patent certification. 21 C.F.R. § 314.94(a)(12)(vi)(A)(3)." D.I. 153 at 18. However, that regulation appears directed to ANDA applicants, which Avadel is not. *See* 21 C.F.R. § 314.94 (titled "Content and format of an ANDA"). Accordingly, this Court will order Jazz to request deletion of the '963 patent from the Orange Book listing for Xyrem® within 14 days of the Court's Order.

IV. CONCLUSION

For the foregoing reasons, Avadel's Renewed Motion is granted. The Court will issue an Order consistent with this Opinion.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-691-GBW

ORDER AND JUDGMENT

WHEREAS, the Court has reviewed the parties' filings related to Defendant Avadel CNS Pharmaceuticals LLC's ("Avadel") renewed motion for judgment on the pleadings (the "Renewed Motion", D.I. 117) with respect to its counterclaim seeking delisting of Plaintiff Jazz Pharmaceuticals, Inc.'s ("Jazz") U.S. Patent No. 8,731,963 ("the '963 patent") from the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book"); and

WHEREAS, the Court issued a Memorandum Opinion concluding that Avadel is entitled to an Order requiring Jazz to delete the patent information from the Orange Book because the '963 patent does not claim either "the drug for which the application was approved" or "an approved method of using the drug" consistent with 21 U.S.C. § 355(c)(3)(D)(ii)(I).

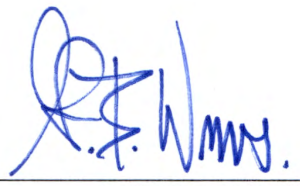
THEREFORE, IT IS HEREBY ORDERED, that Avadel's Renewed Motion is GRANTED.

IT IS FURTHER ORDERED that, within fourteen (14) days from the date of this Order, Jazz is directed by mandatory injunction under 21 U.S.C. § 355(c)(3)(D)(ii)(I) to submit to the

FDA a request enclosing this Order to delete the '963 patent from the Orange Book entry for Xyrem®;

IT IS FURTHER ORDERED AND ADJUDGED that judgment is entered in favor of Avadel and against Jazz on Count III of Avadel's Answer to Complaint for Patent Infringement, Defenses, and Counterclaims (D.I. 11).

SO ORDERED this 18th day of November, 2022.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

US008731963B1

(12) **United States Patent**
Reardan et al.

(10) **Patent No.: US 8,731,963 B1**
(45) **Date of Patent: *May 20, 2014**

(54) **SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD**

(75) Inventors: **Dayton T. Reardan**, Shorewood, MN (US); **Patti A. Engel**, Eagan, MN (US); **Bob Gagne**, St. Paul, MN (US)

(73) Assignee: **Jazz Pharmaceuticals, Inc.**, Palo Alto, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/592,202**

(22) Filed: **Aug. 22, 2012**

Related U.S. Application Data

(63) Continuation of application No. 13/013,680, filed on Jan. 25, 2011, now abandoned, which is a continuation of application No. 12/704,097, filed on Feb. 11, 2010, now Pat. No. 7,895,059, which is a continuation of application No. 10/322,348, filed on Dec. 17, 2002, now Pat. No. 7,668,730.

(51) **Int. Cl.**
G06Q 10/00 (2012.01)

(52) **U.S. Cl.**
USPC **705/2**; 705/3; 707/803

(58) **Field of Classification Search**
USPC 707/803; 705/2, 3
See application file for complete search history.

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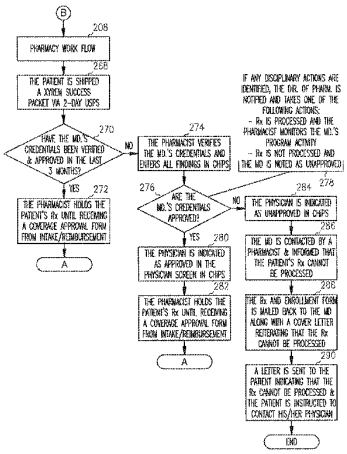
(Continued)

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(57) **ABSTRACT**

A drug distribution system and method utilizes a central pharmacy and database to track all prescriptions for a sensitive drug. Information is kept in the database regarding all physicians allowed to prescribe the sensitive drug, and all patients receiving the drug. Abuses are identified by monitoring data in the database for prescription patterns by physicians and prescriptions obtained by patients. Further verification is made that the physician is eligible to prescribe the drug by consulting a separate database, and optionally whether any actions are taken against the physician. Multiple controls beyond those for normal drugs are imposed on the distribution depending on the sensitivity of the drug.

28 Claims, 16 Drawing Sheets



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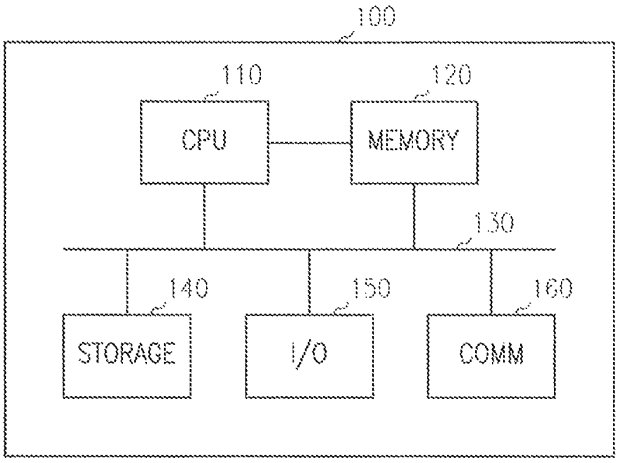


FIG. 1

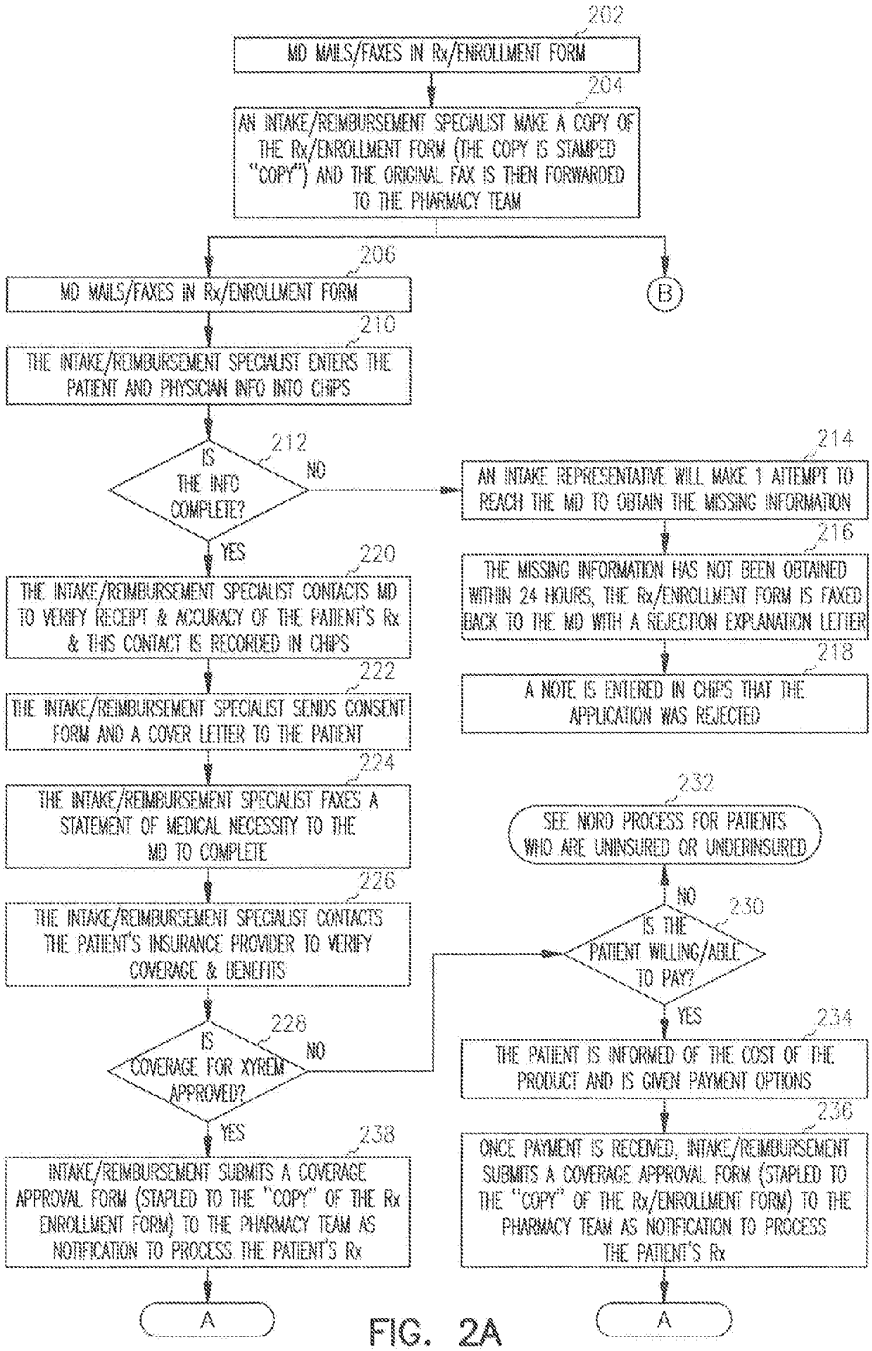

202
MD MAILS/FAXES IN Rx/ENROLLMENT FORM
204
AN INTAKE/REIMBURSEMENT SPECIALIST MAKE A COPY OF THE Rx/ENROLLMENT FORM (THE COPY IS STAMPED "COPY") AND THE ORIGINAL FAX IS THEN FORWARDED TO THE PHARMACY TEAM
206
MD MAILS/FAXES IN Rx/ENROLLMENT FORM
B
210
THE INTAKE/REIMBURSEMENT SPECIALIST ENTERS THE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

FIG. 2A

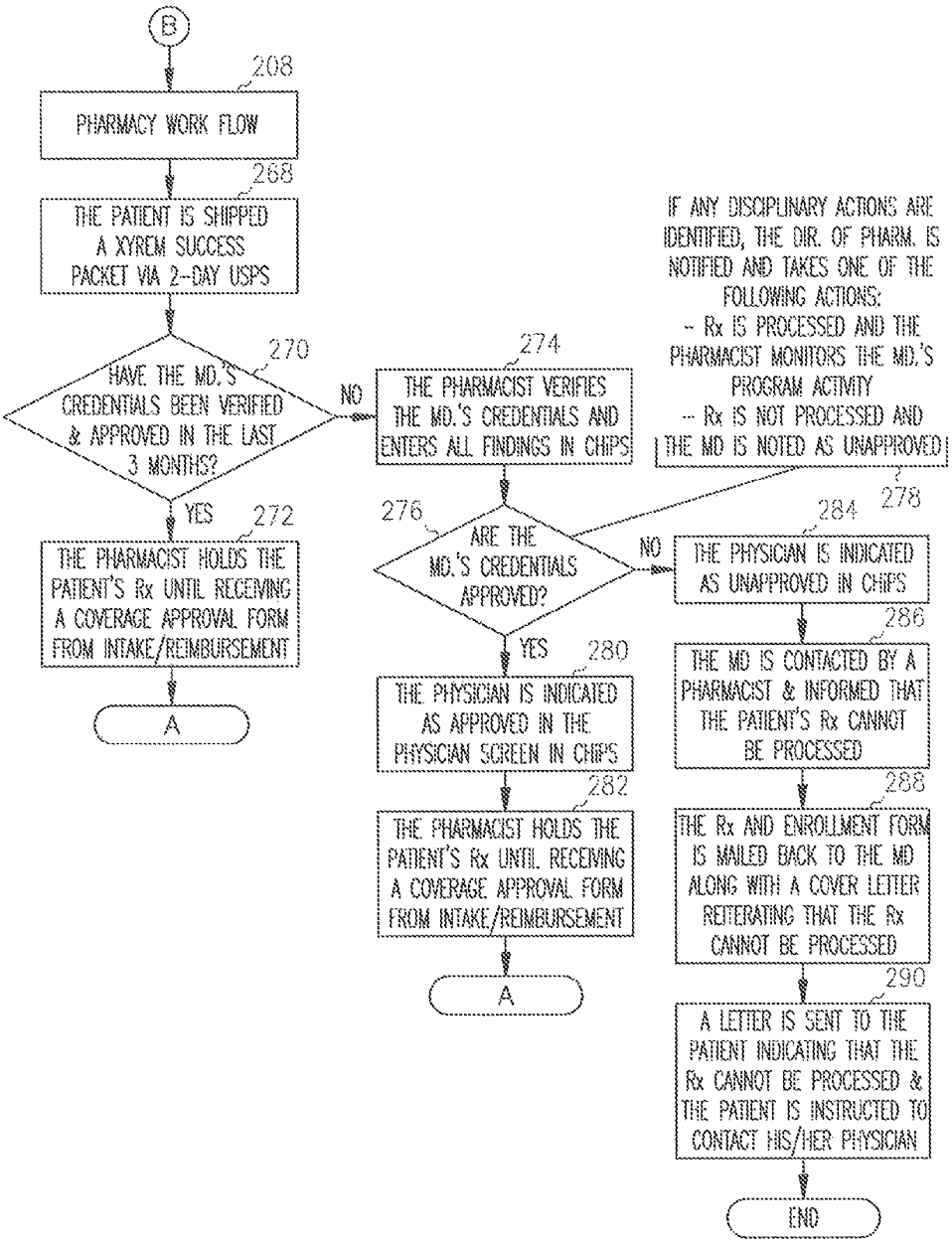

B
208
PHARMACY WORK FLOW
268
THE PATIENT IS SHIPPED A XYREM SUCCESS PACKET VIA 2-DAY USPS
270
HAVE THE MD.'S CREDENTIALS BEEN VERIFIED & APPROVED IN THE LAST 3 MONTHS?
NO
YES
272
THE PHARMACIST HOLDS THE PATIENT'S Rx UNTIL RECEIVING A COVERAGE APPROVAL FORM FROM INTAKE/REIMBURSEMENT
A
274
THE PHARMACIST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

FIG. 2B

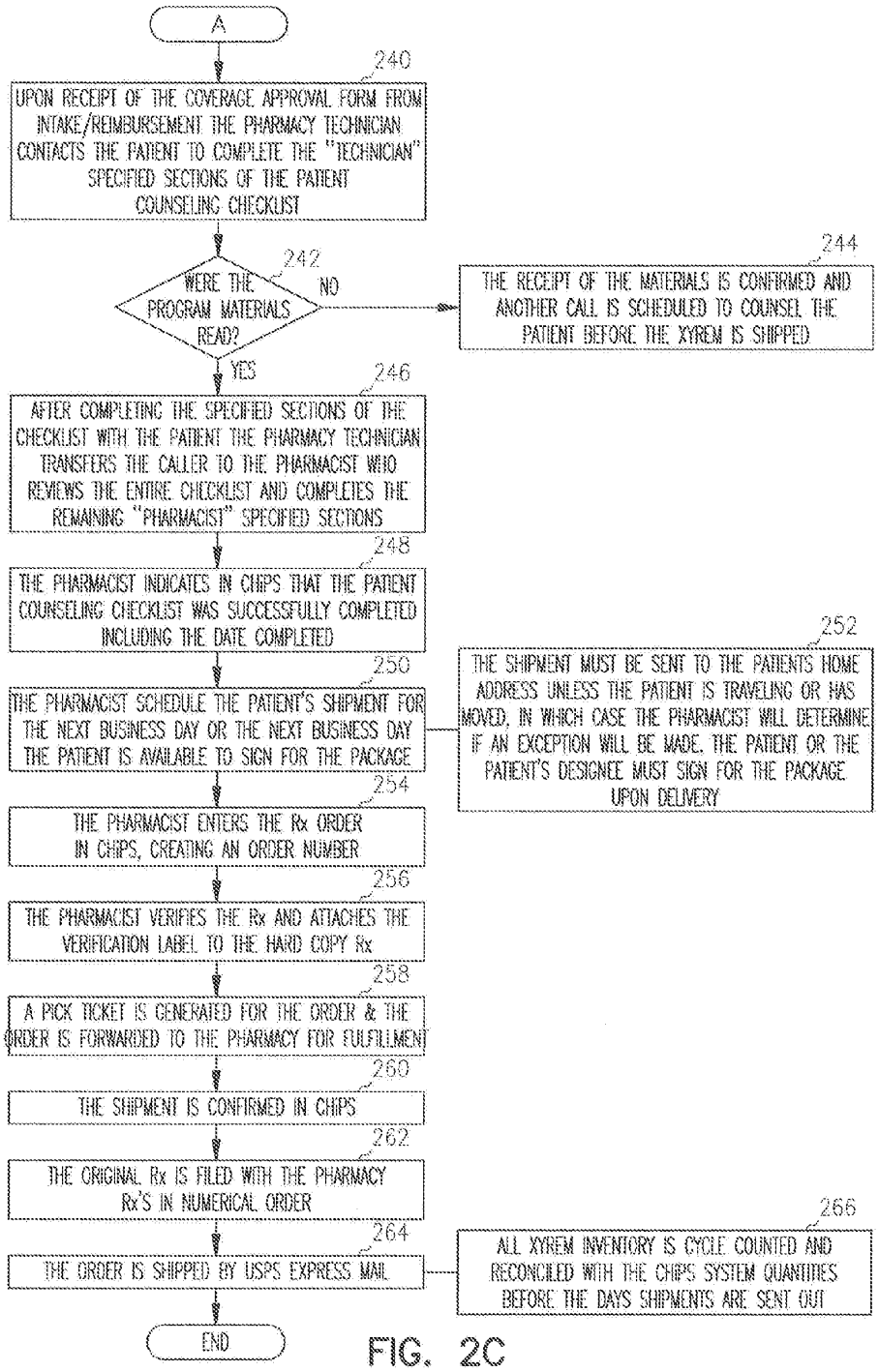

A
240
UPON RECEIPT OF THE COVERAGE APPROVAL FORM FROM INTAKE/REIMBURSEMENT THE PHARMACY TECHNICIAN CONTACTS THE PATIENT TO COMPLETE THE "TECHNICIAN" SPECIFIED SECTIONS OF THE PATIENT COUNSELING CHECKLIST
242
WERE THE PROGRAM MATERIALS READ?
NO
244
THE RECEIPT OF THE MATERIALS IS CONFIRMED AND ANOTHER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

FIG. 2C

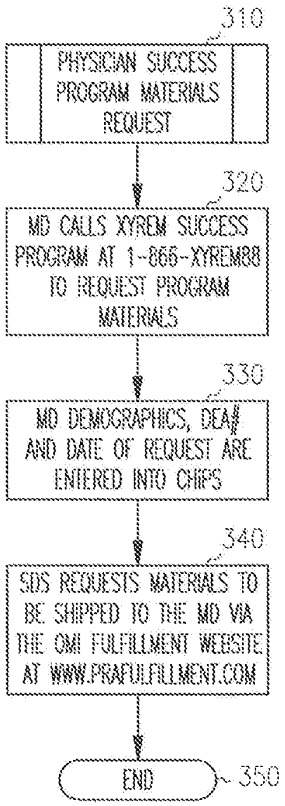

310
PHYSICIAN SUCCESS PROGRAM MATERIALS REQUEST
320
MD CALLS XYREM SUCCESS PROGRAM AT 1-866-XYREM88 TO REQUEST PROGRAM MATERIALS
330
MD DEMOGRAPHICS, DEA# AND DATE OF REQUEST ARE ENTERED INTO CHPS
340
SDS REQUESTS MATERIALS TO BE SHIPPED TO THE MD VIA THE OMI FULFILLMENT WEBSITE AT WWW.PSNFULFILLMENT.COM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

FIG. 3

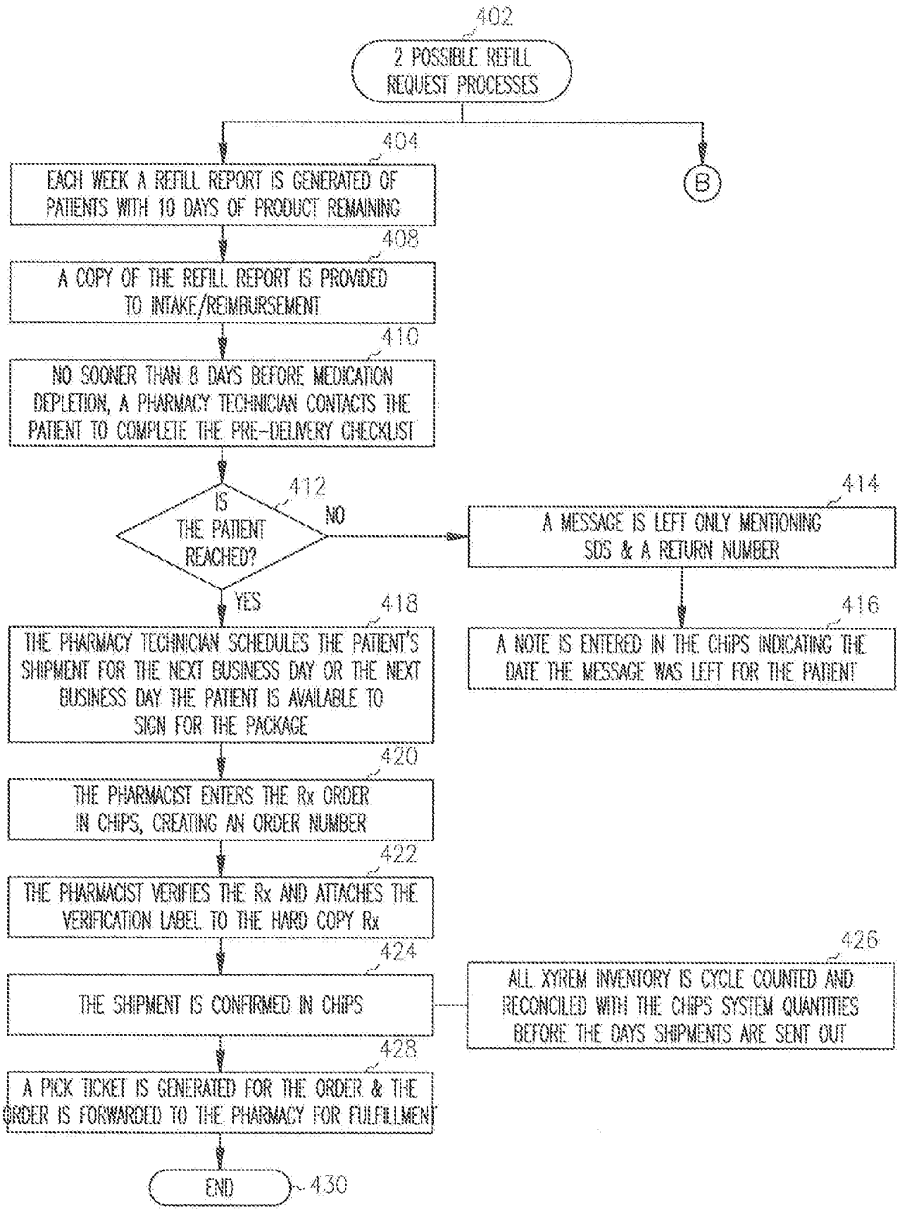

402
2 POSSIBLE REFILL REQUEST PROCESSES
404
EACH WEEK A REFILL REPORT IS GENERATED OF PATIENTS WITH 10 DAYS OF PRODUCT REMAINING
B
408
A COPY OF THE REFILL REPORT IS PROVIDED TO INTAKE/REIMBURSEMENT
410
NO SOONER THAN 8 DAYS BEFORE MEDICATION DEPLETION, A PHARMACY TECHNICIAN CONTACTS THE PATIENT TO COMPLETE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

FIG. 4A

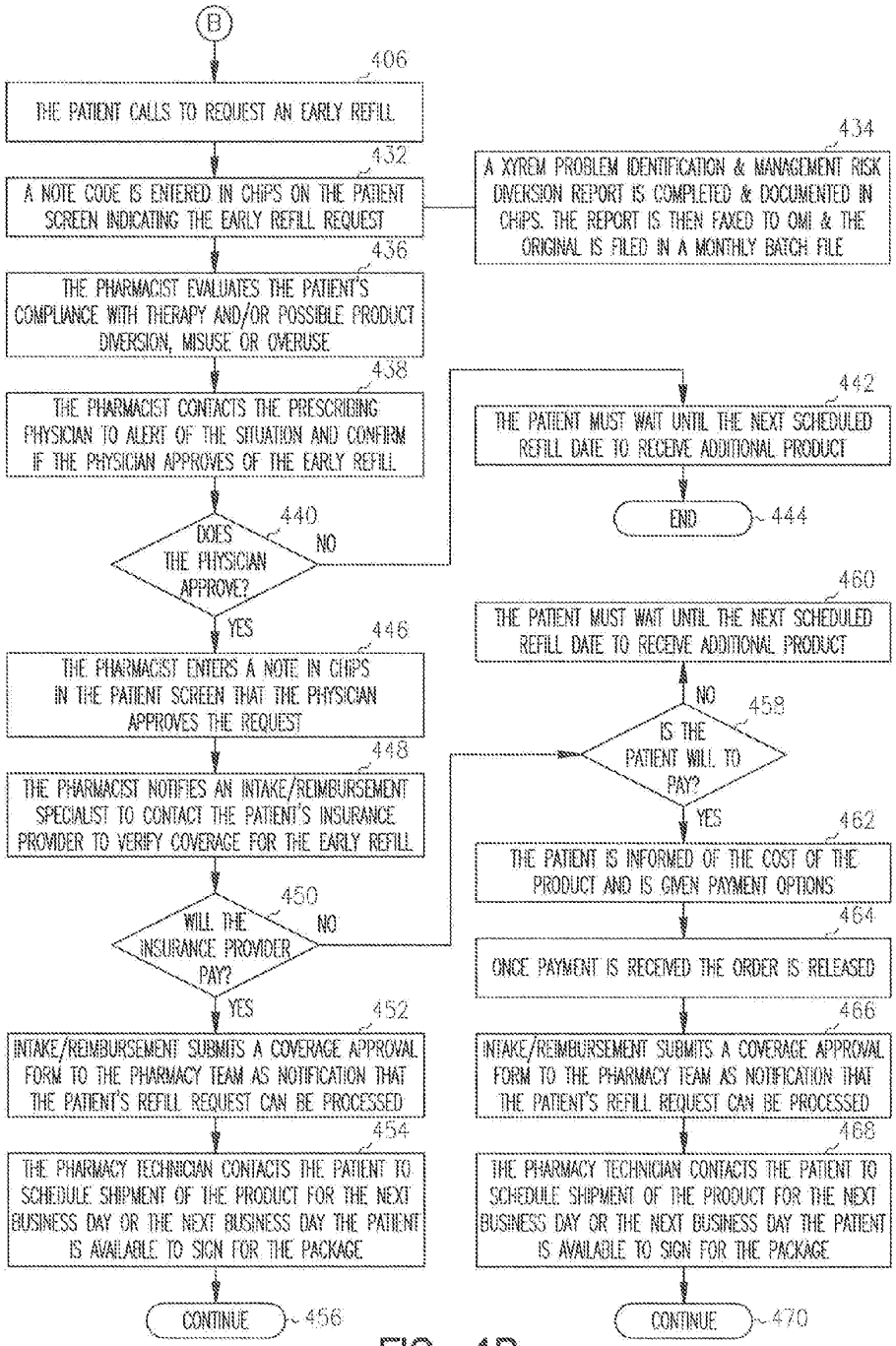

B
406
THE PATIENT CALLS TO REQUEST AN EARLY REFILL
432
A NOTE CODE IS ENTERED IN CHIPS ON THE PATIENT SCREEN INDICATING THE EARLY REFILL REQUEST
434
A XYROM PROBLEM IDENTIFICATION & MANAGEMENT RISK DIVERSION REPORT IS COMPLETED & DOCUMENTED IN CHIPS. THE REPORT IS THEN FAXED TO OMI & THE ORIGINAL IS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

FIG. 4B

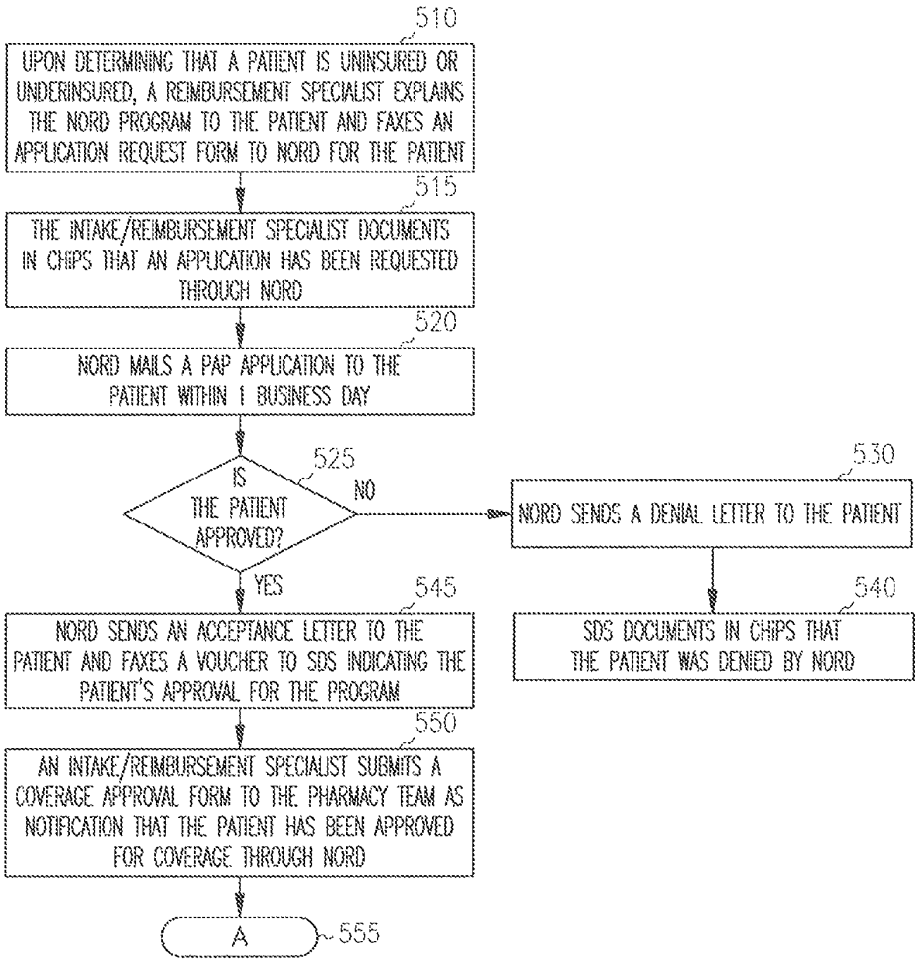

510
UPON DETERMINING THAT A PATIENT IS UNINSURED OR UNDERINSURED, A REIMBURSEMENT SPECIALIST EXPLAINS THE NORD PROGRAM TO THE PATIENT AND FAXES AN APPLICATION REQUEST FORM TO NORD FOR THE PATIENT
515
THE INTAKE/REIMBURSEMENT SPECIALIST DOCUMENTS IN CHIPS THAT AN APPLICATION HAS BEEN REQUESTED THROUGH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

FIG. 5

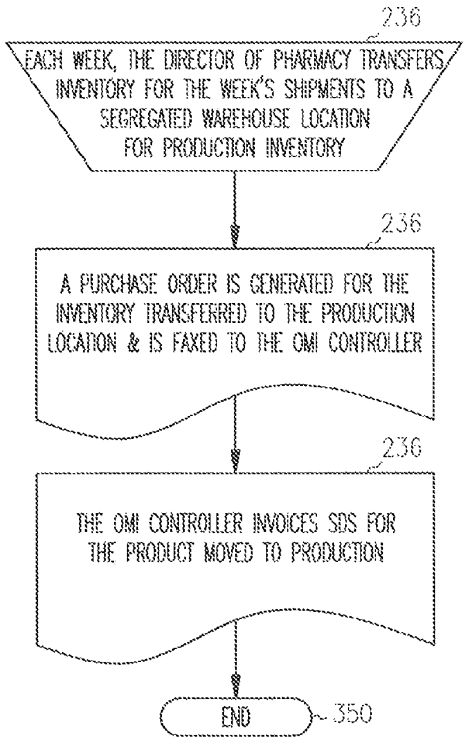


FIG. 6

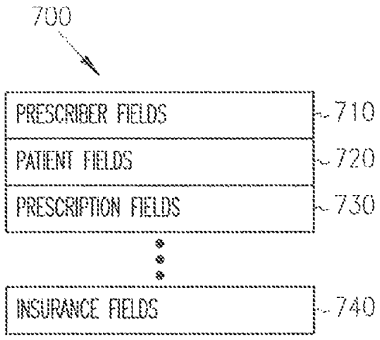


FIG. 7

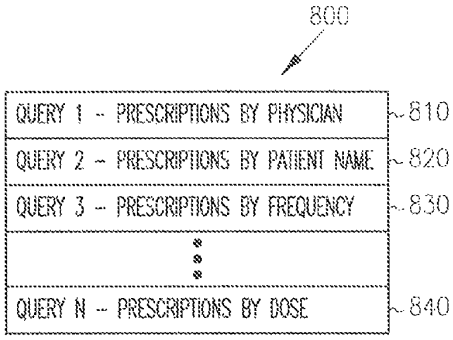


FIG. 8

900

PRESCRIPTION AND ENROLLMENT FORM

PRESCRIBER INFORMATION

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

PRESCRIPTION FORM

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

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

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

PATIENT INFORMATION

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

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

FIG. 9

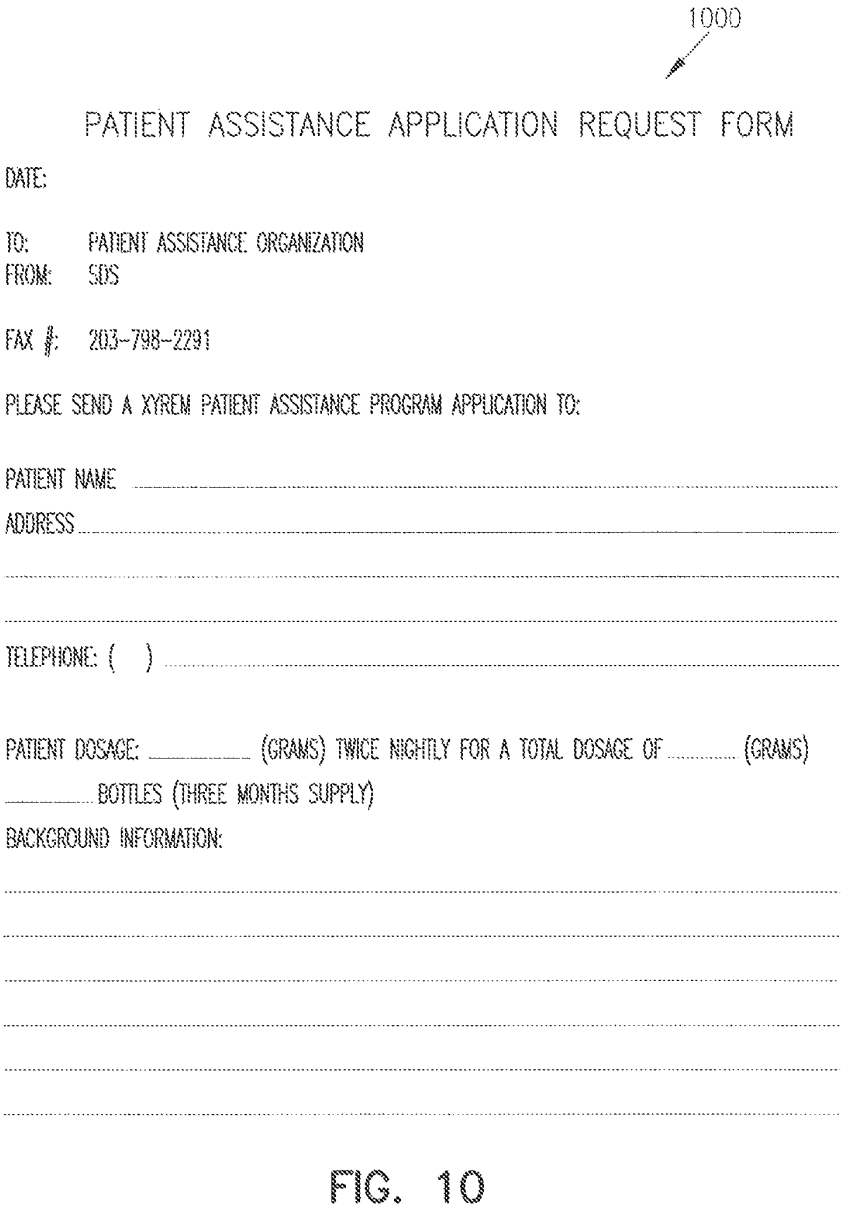

1000
PATIENT ASSISTANCE APPLICATION REQUEST FORM
DATE:
TO: PATIENT ASSISTANCE ORGANIZATION
FROM: SDS
FAX #: 203-798-2291
PLEASE SEND A XYREM PATIENT ASSISTANCE PROGRAM APPLICATION TO:
PATIENT NAME
ADDRESS
TELEPHONE: ( )
PATIENT DOSAGE: (GRAMS) TWICE NIGHTLY FOR A TOTAL DOSAGE OF (GRAMS)
BOTTLES (THREE MONTHS SUPPLY)
BACKGROUND INFORMATION:

FIG. 10

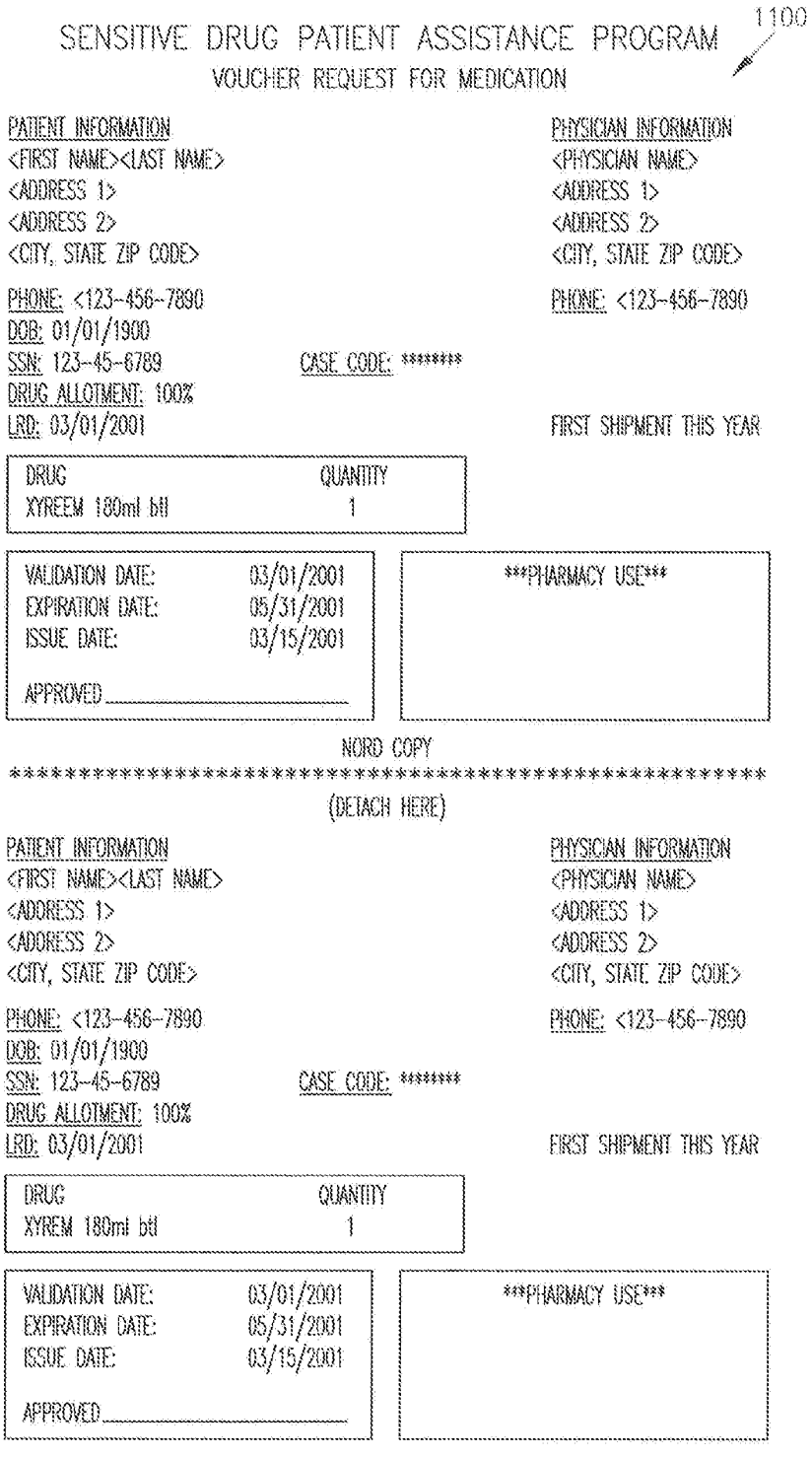

SENSITIVE DRUG PATIENT ASSISTANCE PROGRAM
1100
VOUCHER REQUEST FOR MEDICATION
PATIENT INFORMATION
<FIRST NAME><LAST NAME>
<ADDRESS 1>
<ADDRESS 2>
<CITY, STATE ZIP CODE>
PHONE: <123-456-7890
DOB: 01/01/1900
SSN: 123-45-6789
CASE CODE: ********
DRUG ALLOTMENT: 100%
LRD: 03/01/2001
PHYSICIAN INFORMATION
<PHYSICIAN NAME>
<ADDRESS 1>
<ADDRESS 2>
<CITY, STATE ZIP CODE>
PHONE: <123-456-7890
FIRST SHIPMENT THIS YEAR
DRUG
QUANTITY
XYREEM 180ml bll
1
VALIDATION DATE: 03/01/2001
EXPIRATION DATE: 05/31/2001
ISSUE DATE: 03/15/2001
APPROVED
PHARMACY USE
NORD COPY
****
(DETACH HERE)
PATIENT INFORMATION
<FIRST NAME><LAST NAME>
<ADDRESS 1>
<ADDRESS 2>
<CITY, STATE ZIP CODE>
PHONE: <123-456-7890
DOB: 01/01/1900
SSN: 123-45-6789
CASE CODE: ********
DRUG ALLOTMENT: 100%
LRD: 03/01/2001
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FIRST SHIPMENT THIS YEAR
DRUG
QUANTITY
XYREM 180ml bll
1
VALIDATION DATE: 03/01/2001
EXPIRATION DATE: 05/31/2001
ISSUE DATE: 03/15/2001
APPROVED
PHARMACY USE

FIG. 11

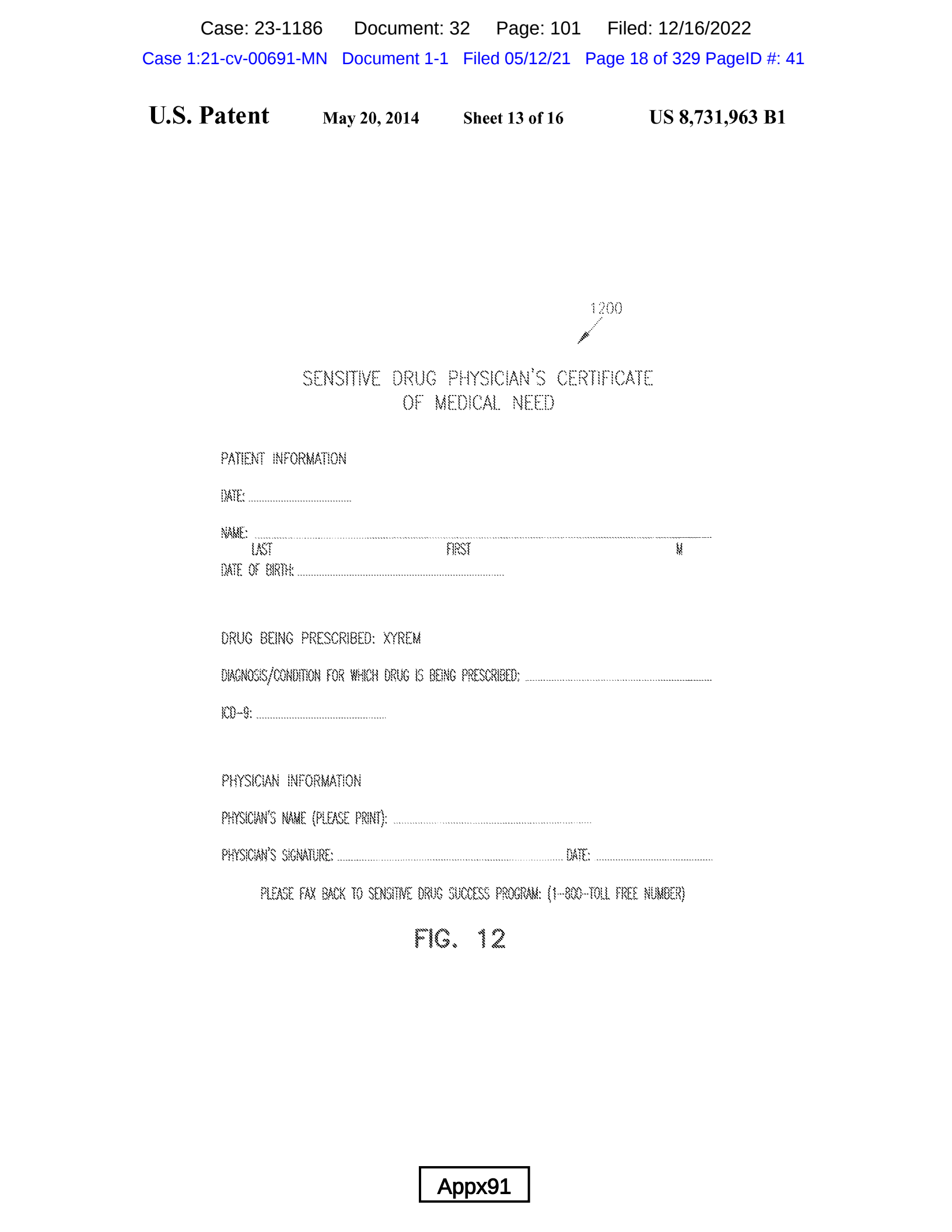
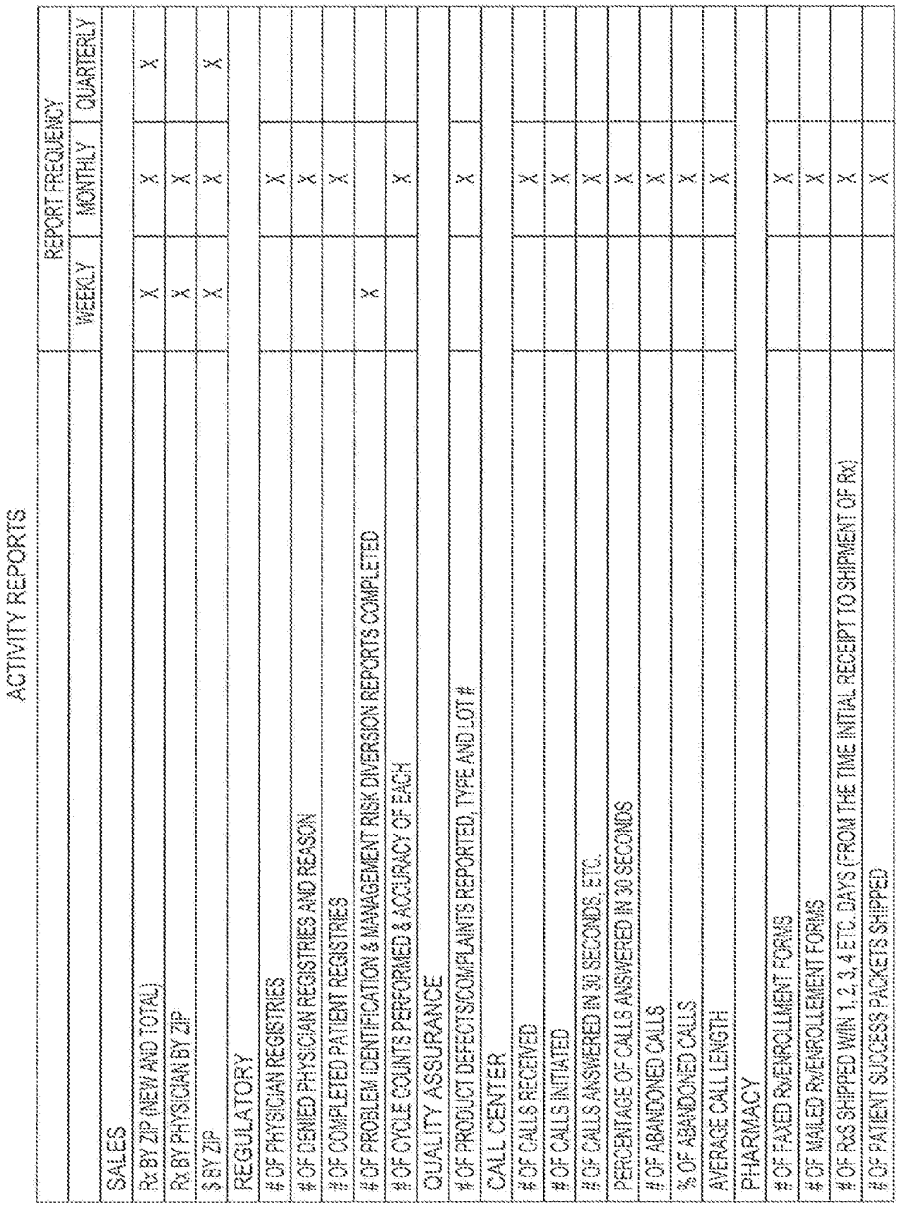

1200
SENSITIVE DRUG PHYSICIAN'S CERTIFICATE
OF MEDICAL NEED
PATIENT INFORMATION
DATE: .....
NAME: .....
LAST FIRST M
DATE OF BIRTH: .....
DRUG BEING PRESCRIBED: XYREM
DIAGNOSIS/CONDITION FOR WHICH DRUG IS BEING PRESCRIBED: .....
ICD-9: .....
PHYSICIAN INFORMATION
PHYSICIAN'S NAME (PLEASE PRINT): .....
PHYSICIAN'S SIGNATURE: ..... DATE: .....
PLEASE FAX BACK TO SENSITIVE DRUG SUCCESS PROGRAM: (1-800-TOLL FREE NUMBER)

FIG. 12



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

FIG. 13A

ACTIVITY REPORTS

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

FIG. 13B

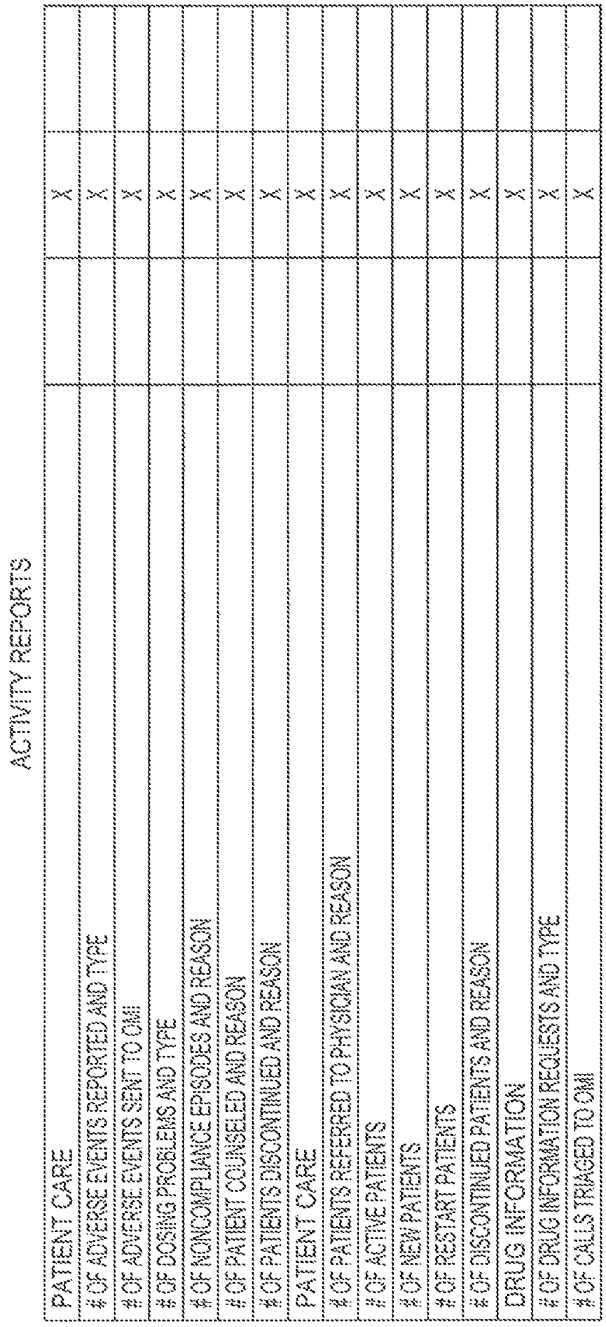

ACTIVITY REPORTS
PATIENT CARE
OF ADVERSE EVENTS REPORTED AND TYPE
OF ADVERSE EVENTS SENT TO OMI
OF DOSING PROBLEMS AND TYPE
OF NONCOMPLIANCE EPISODES AND REASON
OF PATIENT COUNSELED AND REASON
OF PATIENTS DISCONTINUED AND REASON
PATIENT CARE
OF PATIENTS REFERRED TO PHYSICIAN AND REASON
OF ACTIVE PATIENTS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

FIG. 13C

SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD

RELATED APPLICATION

This application a Continuation of U.S. application Ser. No. 13/013,680, filed on Jan. 25, 2011, which is a Continuation of U.S. application Ser. No. 12/704,097, filed on Feb. 11, 2010 and issued on Feb. 22, 2011 as U.S. Pat. No. 7,895,059, which is a Continuation of U.S. application Ser. No. 10/322,348, filed on Dec. 17, 2002 and issued on Feb. 23, 2010 as U.S. Pat. No. 7,668,730, which applications are incorporated by reference herein in their entirety.

FIELD OF THE INVENTION

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

BACKGROUND OF THE INVENTION

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

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

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

SUMMARY OF THE INVENTION

A drug distribution system and method utilizes a central pharmacy and database to track all prescriptions for a sensitive drug. Information is kept in a central database regarding all physicians allowed to prescribe the sensitive drug, and all patients receiving the drug. Abuses are identified by monitoring data in the database for prescription patterns by physicians and prescriptions obtained by patients. Further verification is made that the physician is eligible to prescribe the drug by consulting a separate database for a valid DEA license, and optionally state medical boards to determine whether any corrective or approved disciplinary actions relating to controlled substances have been brought against the physician. Multiple controls beyond those for traditional drugs are imposed on the distribution depending on the sensitivity of the drug.

Education is provided to both physician and patient. Prior to shipping the drug for the first time, the patient is contacted to ensure that product and abuse related educational materials have been received and/or read. The patient may provide the name of a designee to the central pharmacy who is authorized

to accept shipment of the drug. Receipt of the initial drug shipment is confirmed by contacting the patient. Either a phone call or other communication to the patient within a set time after delivery may be made to ensure receipt. Further, a courier service's tracking system is used to confirm delivery in further embodiments. If a shipment is lost, an investigation is launched to find it.

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

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

FIG. **7** is a block diagram of database fields.

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

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

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

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

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

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

DETAILED DESCRIPTION OF THE INVENTION

In the following description, reference is made to the accompanying drawings that form a part hereof, and in which is shown by way of illustration specific embodiments in

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

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

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

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

In a further embodiment, bulk sodium oxybate is manufactured at a single site, as is the finished drug product. Following manufacture of the drug product, it is stored at a facility compliant with FDA Schedule III regulations, where a consignment inventory is maintained. The inventory is owned by a company, and is managed by a central pharmacy, which maintains the consignment inventory. Xyrem® is distributed and dispensed through a primary and exclusive central pharmacy, and is not stocked in retail pharmacy outlets. It is distributed by overnight carriers, or by US mail in one embodiment to potentially invoke mail fraud laws if attempts of abuse occur.

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

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

The prescriber information contains standard contact information as well as license number, DEA number and physician specialty. Patient and prescription information includes name, social security number, date of birth, gender, contact information, drug identification, patient's appropriate dosage, and number of refills allowed, along with a line for the prescriber's signature. Patient insurance information is also provided.

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

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

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

at **228**, the intake reimbursement specialist also submits the coverage approval form with the enrollment form to the pharmacy team as notification to process the patient's prescription. Processing of the prescription is described below.

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

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

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

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

If the program materials, were read at **242**, the checklist is completed at **246** and the technician transfers the patient to the pharmacist who reviews the entire checklist and completes remaining pharmacist specified sections. At **248**, the pharmacists indicates in the database that the patient counseling and checklist was successfully completed, indicating the date completed.

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

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

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

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

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

In the first path, a copy of the report is provided to an intake reimbursement specialist at **408**. No sooner than 8 days before the medication depletion, a pharmacy technician contacts the patient at **410** to complete the pre-delivery **30** checklist. At **412**, if the patient is not reached, a message is left mentioning the depletion, and a return number at **414**. A note is also entered into the database indicating the date the message was left at **416**.

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

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

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

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

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

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

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

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

The central database described above is a relational database running on the system of FIG. **1**, or a server based system having a similar architecture coupled to workstations via a network, as represented by communications **160**. The database is likely stored in storage **140**, and contains multiple fields of information as indicated at **700** in FIG. **7**. The organization and groupings of the fields are shown in one format for convenience. It is recognized that many different organizations or schemas may be utilized. In one embodiment, the groups of fields comprise prescriber fields **710**, patient fields **720**, prescription fields **730** and insurance fields **740**. For purposes of illustration, all the entries described with respect to the above processes are included in the fields. In further embodiments, no such groupings are made, and the data is organized in a different manner.

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

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

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

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

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

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

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

The invention claimed is:

1. A computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, comprising:

one or more computer memories for storing a single computer database having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields;

said prescription fields, contained within the database schema, storing prescriptions for the prescription drug with the potential for abuse, misuse or diversion, wherein the prescription drug is sold or distributed by a company that obtained approval for distribution of the prescription drug;

said patient fields, contained within the database schema, storing information sufficient to identify the narcoleptic patient for whom the company's prescription drug is prescribed;

said prescriber fields, contained within the database schema, storing information sufficient to identify a physician or other prescriber of the company's prescription drug and information to show that the physician or other prescriber is authorized to prescribe the company's prescription drug;

a data processor configured to:

process a database query that operates over all data related to the prescription fields, prescriber fields, and patient fields for the prescription drug; and

reconcile inventory of the prescription drug before the shipments for a day or other time period are sent by using

said database query to identify information in the prescription fields and patient fields;

wherein the data processor is configured to process a second database query that identifies that the narcoleptic patient is a cash payer and a physician that is interrelated with the narcoleptic patient through the schema of the single computer database;

said identifying that the narcoleptic patient is a cash payer by said second database query being an indicator of a potential misuse, abuse or diversion by the narcoleptic patient and being used to notify the physician that is interrelated with the narcoleptic patient through the schema of the single computer database.

2. The system of claim **1**, wherein the data processor selectively blocks shipment of the prescription drug to the patient based upon said identifying by the database query.

3. The system of claim **1**, wherein the prescription drug is shipped to the narcoleptic patient if no potential misuse, abuse or diversion is found for the narcoleptic patient.

4. The system of claim **1**, wherein the single computer database is an exclusive database that receives data associated with all patients being prescribed the prescription drug that is associated with the company.

5. The system of claim **1**, wherein an exclusive central pharmacy controls the single computer database.

6. The system of claim **1** wherein the prescription drug comprises gamma hydroxyl butyrate (GHB).

7. The system of claim **1**, wherein the single computer database comprises a relational database.

8. The system of claim **1**, wherein the single computer database is distributed among multiple computers and the database query operates over all data relating to said prescription fields, prescriber fields, and patient fields for the prescription drug.

9. The system of claim **1**, wherein the data processor is configured to initiate an inquiry to a prescriber when one or more prescription fields, patient fields, or prescriber fields are incomplete in the computer database.

10. The system of claim **1**, wherein the data processor is configured to process a third database query that identifies an expected date for a refill of the prescription drug.

11. The system of claim **10**, wherein the expected date is based on a prescription for the prescription drug and a date of a previous filling of the prescription.

12. The system of claim **11**, wherein the prescription identifies an amount of the prescription drug to be provided and a schedule for consumption of the prescription drug.

13. The system of claim **1**, wherein the database schema further contains and interrelates insurance fields, wherein the insurance fields, contained within the database schema, store information sufficient to identify an insurer to be contacted for payment for prescription drugs of an associated patient.

14. The system of claim **1**, wherein the single computer database is used to identify a current pattern or an anticipated pattern of abuse of the prescription drug; wherein the current pattern or the anticipated pattern are identified using periodic reports generated from the single computer database.

15. The system of claim **14**, wherein one or more controls for distribution of the prescription drug are selected based on the identified pattern.

16. The system of claim **15**, wherein the one or more controls are submitted to an approval body for approval of distribution of the prescription drug.

17. The system of claim **1**, wherein additional controls for distribution are selected in a negotiation with an approval body to garner the approval of distribution.

18. The system of claim **17**, wherein the data processor is used to add further controls until approval is obtained.

19. The system of claim **18**, wherein the approval body is the Food and Drug Administration (FDA) or the Drug Enforcement Agency (DEA).

20. The system of claim **1**, wherein current inventory is cycle counted and reconciled with database quantities before shipments for a day or other time period are sent.

21. The system of claim **1**, wherein the single computer database comprises an exclusive computer database of the company that obtained approval for distribution of the prescription drug, wherein all prescriptions for the company's prescription drug are stored only in the exclusive computer database of the company, and wherein the company's prescription drug is sold or distributed by the company using only the exclusive computer database of the company.

22. The system of claim **1**, wherein the single computer database comprises a single computer database of the company that obtained approval for distribution of the prescription drug, wherein the prescription fields store all prescription requests, for all patients being prescribed the company's prescription drug, only in the single computer database of the company, from all physicians or other prescribers allowed to prescribe the company's prescription drug, such that all prescriptions for the company's prescription drug are processed using only the single computer database of the company.

23. A computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, comprising:

one or more computer memories for storing a single computer database having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields;

said prescription fields, contained within the database schema, storing prescriptions for the prescription drug with the potential for abuse, misuse or diversion, wherein the prescription drug is sold or distributed by a company that obtained approval for distribution of the prescription drug;

said patient fields, contained within the database schema, storing information sufficient to identify the narcoleptic patient for whom the company's prescription drug is prescribed;

said prescriber fields, contained within the database schema, storing information sufficient to identify a physician or other prescriber of the company's prescription drug and information to show that the physician or other prescriber is authorized to prescribe the company's prescription drug;

a data processor for processing a database query that operates over all data related to the prescription fields, prescriber fields, and patient fields for the prescription drug;

said database query identifying information in the prescription fields and patient fields for reconciling inventory of the prescription drug before the shipments for a day or other time period are sent, wherein an inventory reconciliation is performed where current inventory is counted and reconciled with database quantities before shipments for a day or other time period are sent, and wherein the data processor is configured to selectively block shipment of the prescription drug based on the inventory reconciliation;

wherein the data processor is configured to process a second database query that identifies that the narcoleptic patient is a cash payer and a physician that is interrelated with the narcoleptic patient through the schema of the single computer database;

said identifying that the narcoleptic patient is a cash payer by said second database query being an indicator of a potential misuse, abuse or diversion by the narcoleptic patient and being used to notify the physician that is interrelated with the narcoleptic patient through the schema of the single computer database.

24. A computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, wherein the prescription drug is sold or distributed by a company that obtained approval for distribution of the prescription drug, comprising:

one or more computer memories for storing a central computer database of the company that obtained approval for distribution of the prescription drug, for receiving prescriptions from any and all patients being prescribed the company's prescription drug, said central computer database having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields;

said central computer database being distributed over multiple computers;

said prescription fields, contained within the database schema, storing prescriptions for the prescription drug with the potential for abuse, misuse or diversion;

said patient fields, contained within the database schema, storing information sufficient to identify the narcoleptic patient for whom the company's prescription drug is prescribed;

said prescriber fields, contained within the database schema, storing information sufficient to identify any and all physicians or other prescribers of the company's prescription drug and information to show that the physicians or other prescribers are authorized to prescribe the company's prescription drug;

one or more data processors for processing one or more database queries that operate over data related to the prescription fields, prescriber fields, and patient fields for the prescription drug;

said one or more database queries checking for abuse within the central computer database, wherein the filling of the prescriptions is authorized for the company's prescription drug only if there is no record of incidents that indicate abuse, misuse, or diversion by the narcoleptic patient and prescriber and if there is a record of such incidents, the central computer database indicates that such incidents have been investigated, and the central computer database indicates that such incidents do not involve abuse, misuse or diversion.

25. The system of claim **24**, wherein the one or more database queries are processed by the one or more data processors for identifying: that the narcoleptic patient is a cash payer and a physician that is interrelated with the narcoleptic patient through the schema of the single computer database;

said identifying that the narcoleptic patient is a cash payer by said second database query being an indicator of a potential misuse, abuse or diversion by the narcoleptic patient and being used to notify the physician that is interrelated with the narcoleptic patient through the schema of the single computer database.

26. The system of claim **24**, where the central computer database is distributed among multiple computers, and where the one or more database queries operate over all data relating to said prescription fields, prescriber fields, and patient fields for the prescription drug.

27. The system of claim **24**, wherein the central computer database is used to identify a current pattern or an anticipated pattern of abuse of the prescription drug;

wherein the current pattern or the anticipated pattern are identified using periodic reports generated from the single computer database.

28. The system of claim **24**, wherein current inventory is cycle counted and reconciled with database quantities before shipments for a day or other time period are sent.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,731,963 B1
APPLICATION NO. : 13/592202
DATED : May 20, 2014
INVENTOR(S) : Reardan et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

ON THE TITLE PAGE:

On page 2, in column 2, under "Other Publications", line 1, delete "mailed" and insert --filed--, therefor

On page 2, in column 2, under "Other Publications", line 24, delete "mailed" and insert --filed--, therefor

On page 2, in column 2, under "Other Publications", line 42, delete "mailed" and insert --filed--, therefor

On page 2, in column 2, under "Other Publications", line 54, delete "mailed" and insert --filed--, therefor

On page 3, in column 2, under "Other Publications", line 54, delete "Sodiium" and insert --Sodium--, therefor

On page 3, in column 2, under "Other Publications", line 57, delete "Sodiium" and insert --Sodium--, therefor

IN THE DRAWINGS:

On sheet 9 of 16, Fig. 6, delete "236" and insert --610--, therefor

On sheet 9 of 16, Fig. 6, delete "236" and insert --612--, therefor

On sheet 9 of 16, Fig. 6, delete "236" and insert --630--, therefor

Signed and Sealed this
Eighteenth Day of November, 2014

Michelle K. Lee

Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office

CERTIFICATE OF CORRECTION (continued)
U.S. Pat. No. 8,731,963 B1

On sheet 9 of 16, Fig. 6, delete "350" and insert --640--, therefor

On sheet 12 of 16, Fig. 11, delete "XYREEM" and insert --XYREM--, therefor

IN THE SPECIFICATION:

In column 4, line 21, delete "RX/enrollment" and insert --Rx/enrollment--, therefor

In column 6, line 16, delete "302" and insert --402--, therefor

In column 6, line 25, after "pre-delivery", delete "30", therefor

IN THE CLAIMS:

In column 11, line 14, in Claim 24, after "drug,", insert --and--, therefor

(12) **INTER PARTES REVIEW CERTIFICATE** (1148th)
United States Patent
Reardan et al.

(10) **Number: US 8,731,963 K1**
(45) **Certificate Issued: Apr. 3, 2019**

(54) **SENSITIVE DRUG DISTRIBUTION SYSTEM AND METHOD**

(75) Inventors: **Dayton T. Reardan**; **Patti A. Engel**; **Bob Gagne**

(73) Assignee: **Jazz Pharmaceuticals, Inc.**

Trial Number:

IPR2015-01903 filed Sep. 14, 2015

Inter Partes Review Certificate for:

Patent No.: **8,731,963**
Issued: **May 20, 2014**
Appl. No.: **13/592,202**
Filed: **Aug. 22, 2012**

The results of IPR2015-01903 are reflected in this inter partes review certificate under 35 U.S.C. 318(b).

INTER PARTES REVIEW CERTIFICATE
U.S. Patent 8,731,963 K1
Trial No. IPR2015-01903
Certificate Issued Apr. 3, 2019

AS A RESULT OF THE INTER PARTES REVIEW PROCEEDING, IT HAS BEEN DETERMINED THAT:

Claims **24**, **26** and **27** are cancelled.

* * * * *

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) and Federal Circuit Rule 32(b)(1). The brief contains 11,159 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 365 in 14-point Century Schoolbook font.

December 16, 2022

/s/ Steven J. Horowitz

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