IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL PHARMACEUTICALS PLC, AVADEL US HOLDINGS, INC., AVADEL SPECIALTY PHARMACEUTICALS, LLC, AVADEL LEGACY PHARMACEUTICALS, LLC, AVADEL MANAGEMENT CORPORATION AND AVADEL CNS PHARMACEUTICALS, LLC, Defendants.	C.A. No. 21-691-MN

DEFENDANTS' MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS

Defendants Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals, LLC (collectively "Avadel" or "Defendants"), by and through their undersigned counsel, respectfully move for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c) on Defendants' counterclaim seeking de-listing of U.S. Patent No. 8,731,963 from the Orange Book (*see* D.I. 11, Count III). The grounds for this motion are set forth in the accompanying opening brief filed contemporaneously herewith.

Dated: July 23, 2021

Of Counsel:

Kenneth G. Schuler
Marc N. Zubick
Alex Grabowski
Sarah W. Wang
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
(312) 876-7700
kenneth.schuler@lw.com
marc.zubick@lw.com
alex.grabowski@lw.com
sarah.wang@lw.com

Herman Yue
Bornali Rashmi Borah
LATHAM & WATKINS LLP
1271 Avenue of the Americas
New York, NY 10020
(212) 906-1200
Herman.Yue@lw.com
Rashmi.Borah@lw.com

MCCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Counsel for Defendants

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[PROPOSED] ORDER GRANTING
DEFENDANTS' MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS

The Court having considered Defendants' Motion for Partial Judgment on the Pleadings (the "Motion"), the relevant papers and submissions, and any opposition and reply thereto,

IT IS HEREBY ORDERED, this _____ day of _____, 2021, that Defendants' Motion is GRANTED.

The Court further ORDERS that pursuant to Fed. R. Civ. P. 12(c), judgment is entered in favor of Defendants, and against Plaintiff, on Defendants' Counterclaim, Count III.

The Court further ORDERS that Plaintiff shall have U.S. Patent No. 8,731,963 removed from the Orange Book.

_____
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL PHARMACEUTICALS PLC, ET AL., Defendants.	Case No. 21-691-MN

OPENING BRIEF IN SUPPORT OF AVADEL'S MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

REGULATIONS

I. NATURE AND STAGE OF THE PROCEEDINGS AND SUMMARY OF ARGUMENT

Jazz brought this suit asserting five patents, only one of which—U.S. Patent No. 8,731,963 (the "'963 patent")—is listed in the Orange Book for Jazz's twice-nightly sodium oxybate product XYREM®. The '963 patent, however, is directed to a computer system for storing information concerning prescriptions of a prescription drug and thus fails to meet the statutory requirements for Orange Book listing. It contains no claims directed to a drug substance, a drug product, or an FDA-approved method of using a drug. Avadel[1] respectfully requests that the Court grant judgment on the pleadings pursuant to FED. R. CIV. P 12(c) with respect to its counterclaim seeking de-listing of Jazz's '963 patent from the Orange Book. D.I. 11 at ¶¶ 25-32. Judgment on the pleadings should be granted because "no material issue of fact remains to be resolved" and Avadel "is entitled to judgment as a matter of law." *See Minnesota Lawyers Mut. Ins. Co. v. Ahrens*, 432 Fed. App'x 143, 147 (3d Cir. 2011) (quoting *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008)).

II. LEGAL STANDARD

The FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") provides a list of patents that the holder of a New Drug Application ("NDA") believes covers the active ingredient, formulation, or method of using the drug product covered by the NDA. *Caraco Pharm. Labs. Ltd. v. Novo Nordisk AS*, 556 U.S. 399, 406 (2012).

The Hatch-Waxman Act recites 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

[1] "Avadel" refers collectively to Defendants Avadel CNS Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, Avadel Pharmaceuticals PLC, Avadel Specialty Pharmaceuticals, LLC, and Avadel US Holdings, Inc.

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]." 21 U.S.C. § 355(b)(1)(A)(viii)(I-II); *see also* 21 CFR 314.53(b) (explaining that an NDA holder must list "each patent that claims the drug or a method of using the drug that is the subject of the NDA or amendment or supplement to it and with respect to which a claim of patent 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 product."). Because the FDA "does not independently assess the [listed] patent's scope," a party sued for infringement of a listed patent may "assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information" listed in the Orange Book. *Caraco*, 556 U.S. at 406, 408-09.

Under Third Circuit law, judgment on the pleadings is appropriate where "the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." *See Minnesota Lawyers Mut. Ins.*, 432 Fed. App'x at 147.

III. FACTUAL BACKGROUND

A. Avadel's Single-Dose Narcolepsy Treatment

Unlike the typical pharmaceutical patent infringement case involving a defendant seeking to market a generic version of a brand-name drug, this case involves an innovative new drug product developed by Avadel, the defendant. D.I. 11 at 1. Avadel's revolutionary new ***once***-nightly at bedtime formulation of sodium oxybate (currently designated FT218) is designed to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy. *Id.* In contrast, Jazz's ***twice***-nightly sodium oxybate formulation, XYREM®, which has been on the market for nearly two

decades, requires patients to wake up in the middle of the night to take a second dose in order to treat their sleep disorder. *Id.* at 1-2. Avadel's formulation thus fills a significant, unmet need for a sleep disorder treatment that allows the patient to have an uninterrupted night's sleep. *Id.* at 2. Moreover, in part because FT218 is a new drug, rather than a generic version of Jazz's XYREM® product, Avadel did not file paragraph IV certifications against any of Jazz's Orange Book listed patents for XYREM®, and the '963 patent is the only Orange Book Listed patent that Jazz has asserted in this case.

B. The '963 Patent Is Directed To "A Computer-Implemented System"

The PTAB previously invalidated claims 24, 26, and 27 of the '963 patent, along with all claims of the six other issued patents in the family. Exhibit A, *Amneal Pharm. LLC v. Jazz Pharm., Inc.*, IPR2015-01903, Paper 31, Final Written Decision at 3 (Mar. 22, 2017), *aff'd, Jazz Pharm., Inc. v. Amneal Pharm. LLC*, 895 F.3d 1347, 1363 (Fed. Cir. 2018). Thus, only claims 1-23, 25, and 28 of the '963 patent remain.

It is undisputed (and undisputable) that these remaining claims of the '963 patent do not recite a drug substance, a drug product, or a method of using a drug. Instead, they are plainly directed to a "***computer-implemented system*** for treatment of a narcoleptic patient with a prescription drug . . . ," comprising, *inter alia*, "a [] computer database," "computer memories," and "a data processor." D.I. 11 at ¶ 28; *see also* D.I. 1, Ex. A at claims 1, 23, and 24.[2] Claim 1, an exemplary independent claim, has been reproduced below:

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

[2] All emphasis added unless otherwise noted.

> 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.

Despite the fact that the ’963 patent is unmistakably directed to “a computer-implemented system” rather than a drug or a method of using a drug, Jazz nevertheless listed it in the Orange Book in connection with Jazz’s XYREM® product. D.I. 1 at ¶ 28.

IV. THE '963 PATENT IS NOT PROPERLY ORANGE BOOK LISTED BECAUSE IT DOES NOT CLAIM "A DRUG SUBSTANCE" "A DRUG PRODUCT," OR "A METHOD OF USING [A] DRUG"

The '963 patent is not properly Orange Book listed because it claims a "system," not a drug substance, drug product, or method of using a drug, as required by statute. As Congress has legislated, a patentee can obtain patent coverage for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. As explained by the Supreme Court, a process is "a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing." *Gottschalk v. Benson*, 409 U.S. 63, 70, 175 USPQ 673, 676 (1972) (quoting *Cochrane v. Deener*, 94 U.S. 780, 788, 24 L. Ed. 139, 141 (1876)). *See also In re Nuijten*, 500 F.3d 1346, 1355, 84 USPQ2d 1495, 1501 (Fed. Cir. 2007) ("The Supreme Court and this court have consistently interpreted the statutory term 'process' to require action."); *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1316, 75 USPQ2d 1763, 1791 (Fed. Cir. 2005) ("[A] process is a series of acts.") (quoting *Minton v. Natl. Ass'n. of Securities Dealers*, 336 F.3d 1373, 1378, 67 USPQ2d 1614, 1681 (Fed. Cir. 2003)). As defined in 35 U.S.C. § 100(b), the term "process" is synonymous with "method."

The '963 patent contains no method or process claim. This is evident from the plain language of the '963 patent's remaining claims, which all explicitly recite a "system" rather than a "process" or "method," as Jazz has incorrectly asserted. D.I. 11 at ¶ 29. Consistent with this "system" language, the recited elements are those of a computer system, not a method, such as "one or more computer memories," "a single computer database having a database schema," "prescription fields, contained within the database schema," and "a data processor," among others. *See, e.g.*, D.I. 1, Ex. A at claims 1, 23, and 24. Moreover, neither "process" or "method" appears in any of the remaining claims of the '963 patent, nor do any of those claims recite "an act, or a

series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing." *Gottschalk*, 409 U.S. at 70; *see* '963 patent at *passim*.

Lest there be any doubt that the '963 patent is directed to a "system," rather than "methods," Jazz itself has characterized the '963 patent claims as "system" claims in proceedings before the Patent Trial and Appeal Board. Exhibit B, *Amneal Pharm. LLC v. Jazz Pharm., Inc.*, IPR2015-01903, Paper 14, Patent Owner Response at 2 (Jun. 3, 2016) (characterizing the challenged claims as being directed to "computer-implemented systems").

The Federal Circuit has also made clear that system and method claims are "separate statutory classes of invention." *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005) (citing *Ex parte Lyell*, 17 USPQ2d 1548 (1990); *In re Kuehl*, 475 F.2d 658, 665 (1973); *and Rubber Co. v. Goodyear*, 76 U.S. 788, 796 (1869)). Thus, having conceded that the claims of the '963 patent are system claims, Jazz cannot also argue that those claims still qualify as "method" claims for purposes of the Orange Book listing.

Despite the unambiguous claim language of the '963 patent and Jazz's own admissions that the patent claims are directed to a "computer-implemented system," Jazz listed the '963 patent in the Orange Book. This was improper, and the '963 patent should be removed.

V. CONCLUSION

In light of the foregoing, Avadel respectfully requests that Jazz be ordered to remove the '963 patent from the Orange Book.

Dated: July 23, 2021

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Counsel for Defendants

Of Counsel:

Kenneth G. Schuler
Marc N. Zubick
Alex Grabowski
Sarah W. Wang
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
(312) 876-7700
kenneth.schuler@lw.com
marc.zubick@lw.com
alex.grabowski@lw.com
sarah.wang@lw.com

Herman Yue
Bornali Rashmi Borah
LATHAM & WATKINS LLP
1271 Avenue of the Americas
New York, NY 10020
(212) 906-1200
Herman.Yue@lw.com
Rashmi.Borah@lw.com

EXHIBIT A

Trials@uspto.gov
Tel: 571-272-7822

Paper 31
Entered: March 22, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, LLC and
PAR PHARMACEUTICAL, INC.,
Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-01903
Patent 8,731,963 B1

Before JACQUELINE WRIGHT BONILLA, *Vice Chief Administrative Patent Judge*, SUSAN L. C. MITCHELL and BRIAN P. MURPHY, *Administrative Patent Judges*.

MURPHY, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Amneal Pharmaceuticals, LLC ("Amneal") and Par Pharmaceutical, Inc. ("Par Inc.") (together, "Petitioner"), filed a Petition requesting an *inter partes* review of claims 1–28 (all claims) of U.S. Patent No. 8,731,963 B1 (Ex. 1001, "the '963 patent"). Paper 1 ("Petition" or "Pet."). Jazz Pharmaceuticals, Inc. ("Patent Owner") did not file a Preliminary Response to the Petition. On March 25, 2016, we instituted an *inter partes* review of claims 24, 26, and 27 of the '963 patent. Paper 10.

Petitioner supports its challenge with a Declaration of Robert J. Valuck, Ph.D., R.Ph. Ex. 1007.

After institution, Patent Owner filed a Response. Paper 14 ("PO Resp."). Patent Owner supports its Response with a Declaration of Joseph T. DiPiro, Pharm.D. (Ex. 2005) and a Declaration of Bryan Bergeron, M.D., FACMI (Ex. 2006).

Petitioner filed a Reply. Paper 22 ("Reply").

An oral hearing was held on October 14, 2016, and a transcript of the oral hearing is of record. Paper 30 ("Tr.").

The evidence in this case tells the tale of an invention, but one in which Patent Owner's right to exclude was compromised because too much time passed between first disclosure and the patent application priority filing date. Most aspects of the claimed invention at issue were disclosed publicly during the course of FDA review of an orphan drug called Xyrem, indicated for the treatment of narcolepsy. The claimed invention is directed to a computer-based system for strictly controlling distribution of sensitive drugs such as Xyrem. The controlled distribution system was developed in response to an FDA mandate, but the record evidence shows that more than

one year passed after public disclosure of the controlled distribution system for Xyrem® in connection with an FDA Advisory Committee meeting. The result is a determination of unpatentability of the three patent claims at issue in the trial.

We have jurisdiction under 35 U.S.C. § 6. This Decision is a final written decision under 35 U.S.C. § 318(a) as to the patentability of the challenged claims. For the reasons that follow, based on our review of the complete trial record, we determine Petitioner has shown by a preponderance of the evidence that claims 24, 26, and 27 of the '963 patent are unpatentable.

A. Related Proceedings

The parties identify the following as related district court proceedings regarding the '963 patent: *Jazz Pharms., Inc. v. Amneal Pharms. LLC*, 2:13-cv-00391 (consolidated) (D.N.J.); *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, 2:10-cv-06108 (consolidated) (D.N.J. Nov. 22, 2010); *Jazz Pharms., Inc. v. Wockhardt Bio AG., Inc.*, 2:15-cv-05619 (D.N.J.); and *Jazz Pharms., Inc. v. Lupin Ltd.*, 2:15-cv-6548 (D.N.J.). Pet. 59; Paper 8. Patent Owner identifies another litigation that concerns patents related to the '963 patent, *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, 2:10-cv-6108 (D.N.J.). Paper 8.

The parties further identify the following as petitions for *inter partes* review of patents related to the '963 patent: U.S. Patent Nos. 7,668,730 (IPR2015-00554); 7,765,106 (IPR2015-00546); 7,765,107 (IPR2015-00547); 7,895,059 (IPR2015-00548); 8,457,988 (IPR2015-00551); and 8,589,182 (IPR2015-00545). Pet. 59; Paper 8. The Board has issued final written decisions in all six of the aforementioned proceedings finding the challenged claims on which we instituted trial unpatentable. The Board also

has issued decisions denying Patent Owner's requests for rehearing in all six proceedings.

B. Ground of Unpatentability at Issue

Petitioner contends that claims 24, 26, and 27 of the '963 patent are unpatentable under 35 U.S.C. § 103 as obvious over Exhibits 1003–1006 (collectively the "Advisory Committee Art" or "ACA"), including the Food and Drug Administration ("FDA") Advisory Committee Transcript and Slides (Ex. 1003),[1] FDA Preliminary Clinical Safety Review (Ex. 1004),[2] Briefing Booklet (Ex. 1005),[3] and Xyrem Video and Transcript (Ex. 1006)[4], in view of Korfhage.[5] Pet. 48–58.

C. The '963 Patent

The '963 patent, titled "Sensitive Drug Distribution System and Method," issued May 20, 2014, from an application filed August 22, 2012.

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[1] FDA Center for Drug Evaluation and Research, Peripheral and Central Nervous System Drugs Advisory Committee, Transcript and Slides (June 6, 2001) ("Advisory Committee Transcript and Slides") (Ex. 1003).

[2] Ranjit B. Mani, FDA Peripheral and Central Nervous System Drugs Advisory Committee, Division of Neuropharmacological Drug Products, Preliminary Clinical Safety Review of NDA 21-196 (May 3, 2001) ("Preliminary Clinical Safety Review") (Ex. 1004).

[3] Xyrem® (sodium oxybate) oral solution NDA #21-196: Briefing Booklet for the FDA Peripheral and Central Nervous System Drugs Advisory Committee (May 3, 2001) ("Briefing Booklet") (Ex. 1005).

[4] FDA Peripheral and Central Nervous System Drugs Advisory Committee, Briefing Information, Xyrem Prescription and Distribution Process Video and Transcript (Feb. 2, 2001) ("Xyrem Video and Transcript") (Ex. 1006).

[5] Robert R. Korfhage, *Information Storage and Retrieval* (John Wiley & Sons, Inc. 1997) ("Korfhage"). Ex. 1037.

Ex. 1001.[6] The '963 patent is directed to a computer-implemented system for controlling access to an abuse-prone prescription drug by using a central pharmacy and computer database to track all prescriptions, patients, and prescribers. *Id.* at Abstract, 1:48–52. Information regarding all physicians authorized to prescribe the drug and all patients receiving the drug is maintained in the database. *Id.* Abuses are identified by monitoring the database for prescription patterns by physicians and prescriptions obtained by patients. *Id.* at Abstract, 1:52–54.

Figures 2A, 2B, and 2C comprise flow charts representing "an initial prescription order entry process for a sensitive drug." *Id.* at 4:17–18. In overview, a physician submits prescriber, patient, and prescription information for the sensitive drug to a pharmacy team, which enters the information into a computer database. *Id.* at 4:17–35, Fig. 2A (steps 202–210). Figure 9 is an example of the information to be provided by the physician in a prescription and enrollment form. *Id.* at 8:6–9. The pharmacy team then engages in "intake reimbursement," which includes verification of insurance coverage or the patient's willingness and ability to pay for the prescription drug. *Id.* at 4:36–38, Fig. 2A.

The "pharmacy" workflow also includes verification of the prescribing physician's credentials. *Id.* at 5:19–36, Fig. 2B (steps 274–280). Filling the prescription includes confirming the patient has read educational materials regarding the sensitive drug, confirming the patient's receipt of the sensitive drug, and daily cycle counting and inventory reconciliation. *Id.* at

[6] The '963 patent issued from a series of continuation applications, the earliest of which is U.S. Patent Application No. 10/322,348 filed December 17, 2002. Ex. 1001 (63).

5:37–6:7. Steps 240, 242, 246, and 258–266 of Figure 2C are reproduced below.

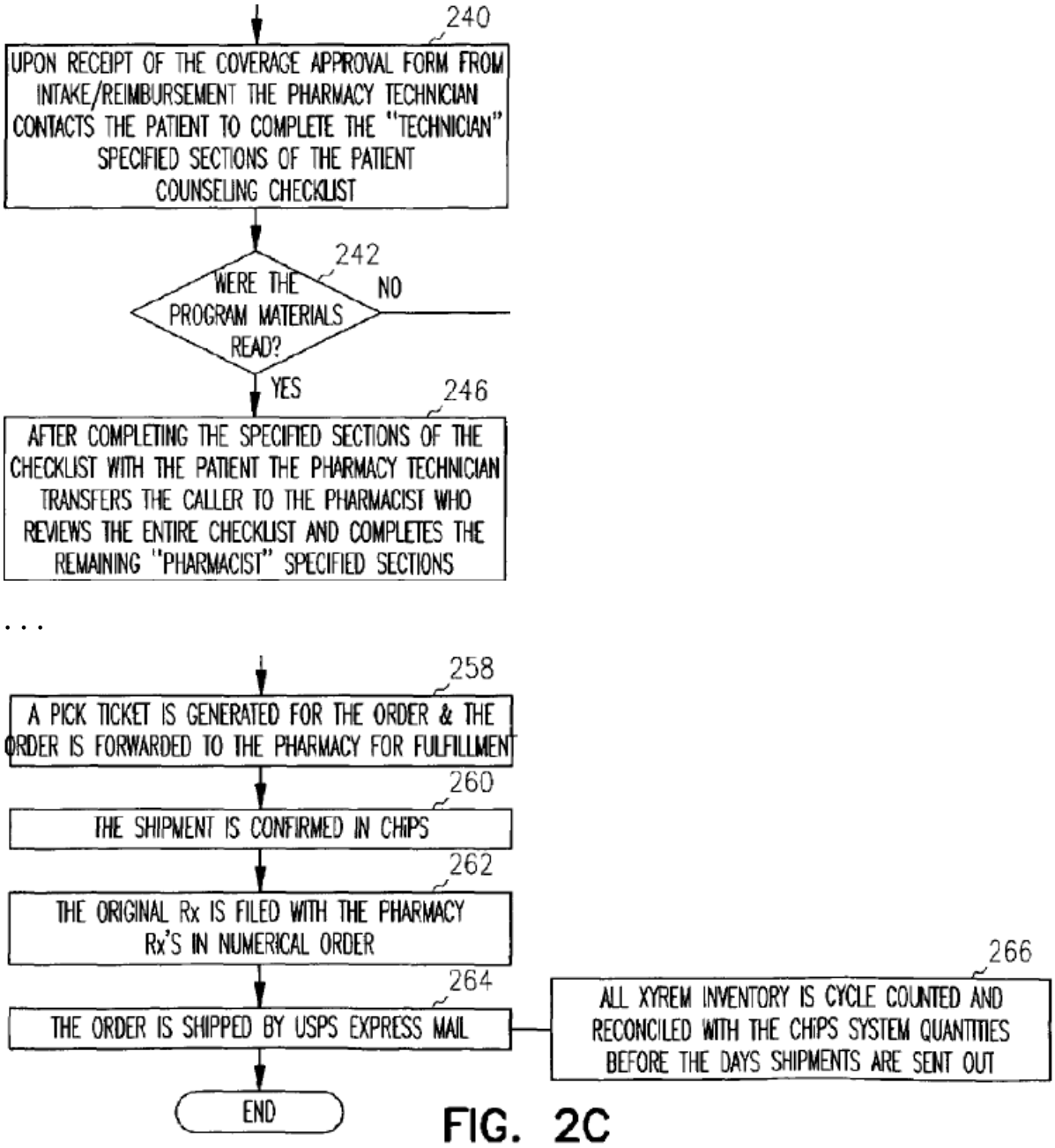

FIG. 2C

Figure 2C, above, depicts a portion of a prescription fulfillment flow diagram. *Id.* at Fig. 2C. The "CHiPS" system, referenced in steps 260 and 266, is an application database "used to maintain a record of a client home

infusion program (CHIP) for Xyrem®."[7] *Id.* at 4:38–43. If a patient requests an early prescription refill, for example, the pharmacist generates a report evaluating "the patient's compliance with therapy or possible product diversion, misuse or over-use." *Id.* at 6:40–44, Fig. 4B (step 436).

D. Illustrative Claim

Claims 24, 26, and 27 of the '963 patent are at issue. Claim 24 is illustrative and reproduced below (bracketed numbers added for ease of reference). Ex. 1001, 11:7–10.

The invention claimed is:

> 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:
>
> [24.1] 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;
>
> [24.2] said central computer database being distributed over multiple computers;
>
> [24.3] said prescription fields, contained within the database schema, storing prescriptions for the prescription drug with the potential for abuse, misuse or diversion;

[7] Xyrem is the brand name for gamma-hydroxybutyrate ("GHB"), indicated for the treatment of cataplexy (excessive daytime sleepiness) in narcoleptic patients. Ex. 1001, 3:24–34. Xyrem is a prescription drug prone to potential abuse or diversion. *Id.*

> [24.4] 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;
>
> [24.5] 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;
>
> [24.6] 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; [and]
>
> [24.7] 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.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, we construe claim terms of an unexpired patent according to their broadest reasonable interpretation in light of the patent specification. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable interpretation standard, we assign claim terms their ordinary and customary meaning, as understood by one of ordinary skill in the art, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249,

1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

"periodic reports"

Claim 27 depends from claim 24 and recites "wherein the current pattern or the anticipated pattern [of abuse] are identified using periodic reports generated from the single computer database." Patent Owner argues that "periodic reports," in the context of the quoted claim phrase, means reports generated at regular frequencies or intervals, as opposed to reports generated intermittently or upon request. PO Resp. 4–8. Patent Owner asserts that the proposed construction "gives meaning" to the word "periodic" and is supported by the '963 patent specification, the plain and ordinary meaning of periodic, and the understanding of a person of ordinary skill in the art ("POSA").[8] *Id.* at 4. In particular, Patent Owner argues that "periodic" includes reports such as those depicted in Figures 13A–C, but

[8] Petitioner relies on Dr. Valuck's testimony (Ex. 1007 ¶ 21) to describe a POSA as having a "Bachelor's or Doctor of Pharmacy degree and a license as a registered pharmacist with 3-5 years of relevant work experience, or a computer science undergraduate degree or equivalent work experience and work experience relating to business applications, for example, including familiarity with drug distribution procedures." (*Id.*) "Alternatively, a POSA may have a blend of computer science and pharmacy drug distribution knowledge and/or experience." (*Id.*) "[S]uch a POSA may have computer science education qualifications and experience relating to computerized drug distribution systems, or pharmacy education qualifications and experience relating to computerized drug distribution systems." (*Id.*). Patent Owner does not dispute Petitioner's description of a POSA. Therefore, we adopt and apply Petitioner's description of a POSA to our analysis in this Decision.

excludes so-called "ad hoc" risk diversion reports of the type depicted in Figure 4B (432, 434, 436) of the '963 patent. *Id.* at 4–8.

Petitioner opposes Patent Owner's proposed construction and challenges Patent Owner's contention that risk diversion reports of the type described and depicted in Figure 4B are an unclaimed embodiment. Reply 5–6 (citing PO Resp. 8 n.3). Petitioner further contends that Patent Owner's proposed construction directly contradicts the '963 patent prosecution history. *Id.* at 6. Petitioner argues that, in an Appeal Brief filed in the prosecution history of related great-grandparent U.S. Patent No. 7,668,730, patent applicants cited Figure 4B and corresponding disclosure in the specification as support for the "periodic reports" claim term. *Id.* (citing Ex. 1041, 6;[9] Ex. 1042, 9, lines 12–19[10] and Fig. 4 (436)). We agree with Petitioner.

Independent claim 24 recites "database queries that operate over data related to the prescription fields, prescriber fields, and patient fields." The database queries allow a user to check the recited data fields for potential abuse situations. The "periodic reports" recited in dependent claim 27 are generated from querying the recited data fields, and those "periodic reports" allow a user to identify the recited "current pattern or . . . anticipated pattern of abuse," such as when a patient requests the same prescription from multiple doctors, a patient requests an early prescription refill, or a prescriber writes multiple prescriptions for a patient. Ex. 1001, 1:35–40,

[9] Citations are to the internal page numbers of the document, rather than the exhibit page numbers.
[10] The citation corresponds to the '963 patent text at Column 6, lines 40–50 (Ex. 1001).

2:14–16 ("[I]f a prescription refill is requested by the patient prior to the anticipated due date, such refills will be questioned."). Figure 4B illustrates an early refill request, the generation of a "risk diversion report," an evaluation of "possible product diversion, misuse or over-use" of a prescription drug, and a resolution of any suspected abuse. *Id.* at 6:40–53, Fig. 4B (406, 432–446). An early refill risk diversion report is precisely the type of "periodic report" generated from querying the patient, prescriber, and prescription data fields that allows a pharmacist to identify a current or anticipated pattern of abuse. The ability of a pharmacist or other user to evaluate potential diversion patterns from the report necessarily informs the types of "periodic reports" generated and must be reflected in the claim construction.

Figures 13A–13C reflect additional types of "Activity Reports" that may be generated from querying the data fields, including reports regarding "Sales," "Regulatory," "Pharmacy," "Inventory," "Reimbursement," "Patient Care," and "Drug Information." Ex. 1001, 7:43–48, 8:24–31, Figs. 7, 13A–C. A user generates the reports by running various queries through the exclusive computer database to obtain information of the type illustrated. *Id.* Patent Owner relies on the description of the reports depicted in Figures 13A–C, where the specification states "[e]ach report has an associated frequency or frequencies," as limiting "periodic reports" to those generated at regular frequencies or intervals and excluding those generated intermittently or upon request, such as early refill risk diversion reports (Fig. 4B). PO Resp. 4–5 (quoting Ex. 1001, 8:28–29; citing Ex. 1001, Figs. 13A–C; Ex. 2005 ¶ 30; Ex. 2006 ¶ 28).

The cited portions of the '963 patent specification refer to Figures 13A–C as "descriptions of *sample* reports obtained by querying a central database having fields represented in Fig. 7." Ex. 1001, 8:24–26 (emphasis added); *see also id*. at 2:59–61 (also describing Figs. 13A–C as "sample reports"). The description of sample reports is hardly exclusionary of the type of ad hoc early prescription refill report described in Figure 4B, which involves generating a risk diversion report whenever a patient calls to request an early refill. *Id.* at Fig. 4B (406, 432, 434). Thus, we do not agree that the specification excludes the generation of ad hoc or intermittent reports from the term "periodic reports," or refers only to reports obtained at regular frequencies or intervals, even if the term "periodic" includes such reports. To the contrary, the '963 patent specification and prosecution history support the inclusion of ad hoc reports, such as risk diversion reports generated whenever an early prescription refill is requested, within the meaning of the term "periodic reports."

Federal Circuit case law, moreover, requires a clear and unambiguous disclaimer or disavowal of claim scope to support a claim construction that excludes disclosed embodiments. *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1369 (Fed. Cir. 2003) (finding prosecution history did not show clear and unambiguous disavowal and that district court's construction would effectively exclude a disclosed embodiment, which "is rarely, if ever, correct and would require highly persuasive evidentiary support" (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996))). Patent Owner relies on *Enpat, Inc. v. Microsoft Corp.*, 26 F. Supp. 2d 806, 808–09 (E.D. Va. 1998) to support its argument for limiting "periodic reports" to only those reports generated at regular frequencies or intervals.

PO Resp. 5 (citing *Enpat* for the construction of "periodic" in a software claim requiring issuance of reports "on a periodic basis" to mean reports issued at "fixed intervals, rather than intermittently or on request." *Enpat*, 26 F. Supp. 2d at 808). The district court decision in *Enpat* is consistent with *Invitrogen*, because the *Enpat* court explained that the patent specification at issue expressly distinguished between reports generated "periodically" and special reports generated "on request," in a software program designed to "run[] at fixed intervals (example: at the end of the day)." *Enpat*, 26 F. Supp. 2d at 808. There are no such clear disavowals of Figure 4B or comparable distinguishing statements made in the '963 patent specification or prosecution history that would clearly and unambiguously limit the word "periodic" as proposed by Patent Owner.

Moreover, we agree with Petitioner that Patent Owner's argument is inconsistent with the prosecution history, where patent applicants cited Figure 4B and corresponding disclosure as support for the "periodic reports" claim term. Reply 6–7 (citing Ex. 1041, 6; Ex. 1042, 9, lines 12-19 and Fig. 4 (436); Ex. 2012, 353:6–355:10). We do not credit Dr. Bergeron's speculative opinion testimony that, because Box 434 in Figure 4B was not cited by patent applicants during prosecution, a POSA would have expected it was "because Figure 4B did not provide support for the generating periodic report part of the claim term." PO Resp. 7 (citing Ex. 2012, 347:21–348:20). To the extent Patent Owner further relies on extrinsic expert testimony in support of its position, Patent Owner does not explain adequately why generating a report for a particular purpose or "ad hoc" precludes it from being a report generated periodically. PO Resp. 5–6 (citing Ex. 2005 ¶¶ 28–31 (testimony by Dr. DiPiro stating that a "POSA

would not consider 'ad hoc' reports to be 'periodic' because they are not generated with any regular frequency."); Ex. 2006 ¶¶ 27–29 (testimony by Dr. Bergeron stating same)). As noted above, the specification does not limit "periodic reports" to those generated with "regular frequency." Moreover, to the extent that Figure 4B in the '963 patent illustrates generating "ad hoc" reports, as Patent Owner acknowledges, such disclosure supports a construction that the recited "periodic reports" include such "ad hoc" reports. Ex. 1001, 6:40–7:6; Reply 6 (citing Ex. 1041, 6; Ex. 1042, 9, lines 12–19 and Fig. 4 (436)).

Dr. Valuck's deposition testimony, also cited by Patent Owner, is consistent with the '963 patent specification and related prosecution history. PO Resp. 5 (citing Ex. 2007, 184:8–16); *see also* Ex. 2007, 182:6–185:1. Dr. Valuck testified that reports generated to investigate abuse can be generated on either "an ad hoc basis or a regular basis." Ex. 2007, 184:8–16. His testimony is consistent with our reading of the '963 patent specification that would include ad hoc reports within the meaning of "periodic reports."

Finally, Patent Owner's reliance on a dictionary definition of "periodic" does not persuade us to limit the construction of "periodic reports" to those generated only at regular intervals, a construction at odds with the '963 patent specification and prosecution history. PO Resp. 6 (citing Ex. 2005 ¶ 32; Ex. 2006 ¶ 30; Ex. 2010, 3). Petitioner provides other dictionary definitions, which define "periodic" as also including "intermittent." Ex. 1045, 3 (Col. 3, defining "periodic" as including "occurring repeatedly from time to time: RECURRENT, INTERMITTENT"); Ex. 1046, 3 (Col. 1, defining "periodic" as including

"[t]aking place now and then" or "INTERMITTENT"); Ex. 1047, 3 (Col. 1, defining "periodic" as including "[h]appening or appearing now and then" or "intermittent, occasional"). The plain and ordinary meaning of the term "periodic reports" includes reports generated at regular intervals and reports generated "now and again" or "intermittently," without any particular regularity in time between events.

Thus, we construe "periodic reports" as recited in the challenged claims to refer to reports that are generated at regular intervals or intermittently, i.e., now and again, including those not generated at regular intervals.

B. Public Accessibility of Exhibits 1003–1006

Petitioner asserts the references comprising the ACA (Exhibits 1003–1006) were publicly accessible as printed publications in connection with an FDA Advisory Committee meeting regarding Xyrem held on June 6, 2001 (the "Advisory Committee Meeting"). Pet. 11–16. The ACA includes a disclosure of the proposed risk management system for Xyrem—the same sensitive drug described in the '963 patent. Ex. 1001, 3:24–36. The documents at issue are alleged to have been published in electronic form and made available on the FDA's website more than one year before the '963 patent's earliest priority filing date. Pet. 13–14.

Rather than argue the merits of the printed publication issue in the present proceeding, Patent Owner submits that we should apply the decision reached in the final decisions of the Board on the identical issue raised by the parties in IPR2015-00545, IPR2015-00546, IPR2015-00547, IPR2015-00548, IPR2015-00551, and IPR2015-00554. PO Resp. 3. Patent Owner

does not cite any evidence in the present proceeding directed to the public accessibility issue. *Id.*

Petitioner replies that in the related *inter partes* review proceedings the Board issued final written decisions, dated after Patent Owner's Response, determining that the ACA was publicly accessible and qualifies as prior art under 35 U.S.C. § 102(b). Reply 4 (citing Case IPR2015-00551, slip op. at 38 (PTAB July 27, 2016 (Paper 70))). Petitioner is correct. Therefore, we adopt our finding in IPR2015-00551 for the same reasons given therein, namely that Petitioner has shown by a preponderance of the evidence that Exhibits 1003–1006 (the ACA) were publicly accessible to an interested POSA exercising reasonable diligence more than one year before the December 17, 2002 earliest priority date of the '963 patent. Case IPR2015-00551, slip op. at 21–38 (PTAB July 27, 2016 (Paper 70)); 35 U.S.C. § 102(b). Petitioner's evidence of record regarding the public accessibility issue in IPR2015-00551 is also of record in the present case, and the exhibit numbers are the same, but for a few exceptions.[11] *See* Exhibits 1003–1006, 1007 (¶ 64), 1015, 1019, 1020, 1027, 1028, 1052, and 1053.

C. Asserted Obviousness of Claims 24, 26, and 27 of the '963 Patent

Petitioner contends that claims 24, 26, and 27 of the '963 patent would have been obvious to a POSA over the ACA (Exhibits 1003–1006) in

[11] Exhibits 1017 and 1018 do not appear in the docket of IPR2015-01903, but their absence does not materially affect the outcome of our decision on the issue. Exhibits 1052 and 1053 in IPR2015-01903 correspond to Exhibits 1057 and 1058 in IPR2015-00551, respectively, otherwise the exhibit numbering is identical.

view of Korfhage. Pet. 48–54. Patent Owner opposes on two grounds. PO Resp. 9–20. First, Patent Owner argues that a POSA would not have been motivated to combine the ACA and Korfhage to arrive at a "central computer database being distributed over multiple computers" (Element 24.2). *Id.* at 9–14. Second, with respect to claim 27, Patent Owner argues that the ACA would not have disclosed, taught, or suggested the recited "periodic reports" to a POSA. *Id.* at 15–20. We address the parties' arguments below.

1. *"[24.2] said central computer database being distributed over multiple computers"*

Claim 24 recites "[24.1] . . . a central computer database . . . for receiving prescriptions from any and all patients being prescribed the company's prescription drug . . . having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields." Ex. 1001, 11:12–19. Claim 24 also recites "[24.6] . . . one or more database queries that operate over data related to the prescription fields, prescriber fields, and patient fields . . . [24.7] . . . [to] check[] for abuse within the central computer database." *Id.* at 11:34–12:2. Database Elements 24.1 and 24.6 recite functions of the database, whereas Element 24.2 at issue here recites a particular database architecture – "said central computer database being distributed over multiple computers." Claim 26 recites the same database architecture, "the central computer database is distributed among multiple computers."[12]

[12] The parties have not argued for any substantive distinction between the two recited database architectures, and we discern none.

a. Claim 24 Elements not in dispute

The preamble of claim 24 and Elements 24.1 and 24.3–24.7 are not in dispute. The preamble of claim 24 and Elements 24.1 and 24.3–24.6 are very similar to the preamble of claim 1 and Elements 1.1–1.5. Pet. 18–30. Element 24.7 is similar to claims 2 and 3. *Id.* at 34–35, 50–51. Petitioner relies on Dr. Valuck's Declaration testimony in support of its argument that the elements recited in independent claim 1, including the preamble and Elements 1.1–1.5 that correspond to the preamble of claim 24 and Elements 24.1 and 24.3–24.6, are disclosed in the ACA. *Id.* (citing, *inter alia*, Ex. 1007 ¶¶ 70–95); *see also id.* at 50–51 (citing, *inter alia*, Ex. 1007 ¶¶ 141–43). We have considered Petitioner's evidence and argument that the preamble of claim 24 and Elements 24.1, 24.3–24.7 are disclosed in the ACA. Pet. 18–30 (claim 1 Preamble and Elements 1.1–1.5), 34–35 (claims 2 and 3), 50–51 (Elements 24.6 and 24.7). Patent Owner does not offer any opposing argument. PO Resp. 9–20. We rely on Petitioner's evidence and adopt its analysis that the preamble of claim 24, Element 24.1, and Elements 24.3–24.7 are disclosed in the ACA. After considering Petitioner's arguments and underlying evidence cited in support, we are persuaded that Petitioner sufficiently establishes that the ACA discloses the above-mentioned non-disputed limitations of claim 24.

b. Overview of the ACA

In overview, the ACA discloses a single national pharmacy for receiving and storing prescription, patient, and physician information in a "central data repository." Pet. 23–24, 51 (citing Ex. 1003, 177:24–178:11,

184:24–185:7, Slides 146, 147; Ex. 1005, 306[13]; Ex. 1006, 6 n.24; Ex. 1007 ¶ 75). "Every patient and prescribing physician will be registered . . . [in] a secure database." *Id.* at 24 (citing Ex. 1004, 110; *see also* Ex. 1003, 16:4–7, 259:3–5; Ex. 1007 ¶ 76). The ACA also discloses the capability of obtaining the prescription, patient, and prescriber information stored in the central database. *Id.* at 24–26 (citing Ex. 1004, 110 ("From this database it will be possible to obtain . . . [p]rescriptions by physician specialty . . . by patient name . . . by volume (frequency) [and] . . . by dose."), 114 ("[P]atient registry application . . . is to contain . . . [p]atient name, address, telephone number, . . . [and] [p]hysician name, specialty, clinic name and address."); Ex. 1005, 304 ("Prescribing information, including frequency and dosing data, can be accessed from a single source."); Ex. 1006, 4 n.14 ("closed-loop distribution system . . . will also be able to generate data, recording prescribers, patients and dosing that could provide information for any possible investigations . . . ."), 6 n.24 ("it's possible to keep all the data about inventory, physicians, reimbursement, patients, and delivery in one efficient and quickly-accessible location."), 7 n.25; Ex. 1007 ¶¶ 76–79). The ACA further discloses the capability for a pharmacist to check for abuse within the database and intervene if potential abuse is identified. Pet. 34–35, 51 (citing Ex. 1003, 184:24–185:7, Slide 158; Ex. 1004, 110; Ex. 1005, 300, 304, 306, 307; Ex. 1006, 8 n.29, 9 n.38; Ex. 1007 ¶¶ 98, 100, 141–143).

Petitioner relies on the Declaration testimony of Dr. Valuck in support of its argument that a person of ordinary skill in the art would have had

[13] The parties cite to the internal page numbers of the Briefing Booklet rather than the exhibit page numbers. We do the same.

reason to combine the ACA documents because the documents were prepared for the Advisory Committee Meeting and "relate to the same restricted and computer-implemented distribution program, which the meeting was convened to discuss." *Id.* at 17 (citing Ex. 1007 ¶ 68). Petitioner asserts, in particular, the Preliminary Clinical Safety Review (Ex. 1004), Briefing Booklet (Ex. 1005), and Xyrem Video and Transcript (Ex. 1006) were "all distributed *together* for a meeting before the FDA seeking approval for prescription Xyrem," and the FDA Advisory Committee Transcript and Slides (Ex. 1003) was "a transcript of the meeting itself." *Id.* In addition, all four ACA documents "clearly relate to the same restricted and computer-implemented distribution program, which the meeting was convened to discuss," and are "all linked from a single [web] page." *Id.* 17–18 (citing Ex. 1027, 11).

Patent Owner does not address the cited evidence in the context of whether there was a motivation to combine the ACA documents. PO Resp. 9–20.

We agree with Petitioner's evidence and analysis. The evidence before us, including the testimony of Dr. Valuck discussed above, sufficiently shows that a POSA would have had ample motivation to combine the ACA documents, which were prepared at the same time, relate to the same drug product and the same restricted drug distribution system, were discussed together at the same Xyrem Advisory Committee Meeting and were made available via file links from a single FDA web page.

c. Korfhage

Korfhage is a 1997 book dedicated to the subject of information storage and retrieval. Ex. 1037. Chapter 12 is titled "Document Access." *Id.* at 271.[14] Korfhage begins chapter 12 by explaining the importance of having electronic access to complete documents in computer accessible form. *Id.* Korfhage describes how technical advances in sophisticated electronic document production systems, document scanners, and optical character recognition software have resulted in "an increasing number of documents . . . being generated and made available in electronic form." *Id.* at 272.

Section 12.4, titled "Distributed Document Systems," leads off with the recognition that "[c]ost, efficiency, and the [sheer] number of documents being published are driving information systems to the use of distributed document sets and *distributed processing*." *Id.* at 276 (emphasis added). Dr. Valuck, an expert in drug safety, drug abuse prevention, and computer-controlled distribution of restricted drug products (Ex. 1007 ¶¶ 10–20), explains Korfhage's reference to "distributed processing" as "a standard design for a single database to be distributed among multiple computers where the database queries over all the data." *Id.* ¶ 138. Korfhage discloses that a system user is interested in locating and obtaining a document regardless of where it resides "either physically or within a computer system." Ex. 1037, 276. Korfhage further explains that a user prefers "to

[14] The parties cite to the internal page numbers of the Korfhage book rather than the exhibit page numbers. We do the same.

view the system as accessing a single logical database in response to a query, even when the system must consult multiple physical databases." *Id.*

d. Analysis

Petitioner acknowledges that the ACA does not expressly disclose Element 24.2 (or the comparable recitation in claim 26) reciting the central computer database as "being distributed over multiple computers." Pet. 52 (citing Ex. 1007 ¶ 144). Petitioner argues that a POSA would have had ample motivation to distribute the central computer database of the ACA over multiple computers as disclosed in Korfhage ("distributed processing"), in order to "increase the efficiency of the distribution of Xyrem by the central pharmacy's pharmacists (i.e. 'user accommodation')." *Id.* (citing Ex. 1007 ¶ 144; Ex. 1037, 276). As Petitioner notes, Korfhage expressly suggests distributing a database over multiple computers to accommodate "cost, efficiency, and the [sheer] number of documents." *Id.* at 49 (quoting Ex. 1037, 276; citing Ex. 1007 ¶ 138).

Patent Owner argues that Petitioner has not provided sufficient evidence of motivation to combine ACA and Korfhage without using hindsight. PO Resp. 10. Patent Owner asserts, in particular, that nothing in Korfhage relates to drug distribution, pharmacy practice, or drug abuse, misuse, or diversion. *Id.* (citing Ex. 1037; Ex. 2006 ¶ 45). Patent Owner also argues that Petitioner has not identified any problem with using a "conventional computer" to house the "centralized (i.e., non-distributed) database disclosed in the ACA" that would have led a POSA to use a distributed database system, such as disclosed in Korfhage, to accommodate large numbers of documents in a cost efficient manner. *Id.* at 10–11(citing Ex. 2006 ¶¶ 46–47; *Leo Pharm. Prods. v. Rea*, 726 F.3d 1346, 1354 (Fed.

Cir. 2013) ("Only after recognizing the existence of the problem would an artisan *then* turn to the prior art . . . ."). Patent Owner further argues that Korfhage discloses "too many options for database architectures" and teaches away from using distributed databases because Korfhage discloses that "three ***major problems*** arise" when attempting to have a single query operate over multiple physical databases. *Id.* at 11–14 (quoting Ex. 1037 at 276-277).

We are persuaded that Petitioner has proved by a preponderance of the evidence that a POSA would have been motivated to distribute the ACA's single, centralized computer database over multiple computers, for reasons of cost, efficiency, and the anticipated volume of prescription-related information to be received, entered, and queried. Pet. 25–30 (citing, *inter alia*, Ex. 1003, 24:21–25; Ex. 1004, 110; Ex. 1005, cover letter; Ex. 1006, 6 n.24; Ex. 1007 ¶¶ 78, 79, 85–87), 51–52 (citing Ex. 1007 ¶ 144; Ex. 1037, 276).

We begin by crediting Dr. Valuck's testimony that it was a standard design practice for a single database "to be distributed among multiple computers where the database queries over all the data." Ex. 1007 ¶¶ 138, 144. Dr. Valuck testifies that distributed processing systems (i.e., multiple computers) of the type expressly disclosed in Korfhage, were well-known in the art and that information systems were being driven toward distributed processing to reduce cost, improve efficiency, and handle large numbers of documents. *Id.* With regard to efficiency in the pharmacy setting Dr. Valuck testified:

> And, similarly, as I mentioned, with the volume of transactions and patients and prescriptions and prescribers and

> reports and all -- all of the different things that are done in the course of drug distribution, there are extremely large quantities of documents generated.
>
> And doing things more efficiently is always the motivation and the need and -- the quest, if you will, is to do them as efficiently as possible given that -- that tremendous volume of them.

Ex. 2008, 290:2–18. We find Dr. Valuck's testimony regarding efficiency to be persuasive.

With respect to the volume of data to be received, entered, and queried, Petitioner points out the ACA's disclosure of an "important benefit of using a single, specialty pharmacy for the distribution of Xyrem is that it is possible to ***keep*** [i.e., 'store in one or more computer memories'] all the data about inventory, physicians, reimbursements, patients, and delivery in one efficient and quickly-accessible location." Pet. 25 (quoting Ex. 1006, 6 n.24; citing Ex. 1007 ¶ 78). Petitioner, in reliance on Dr. Valuck's testimony, persuasively explains how a POSA would have understood the ACA as describing a single computer database that "stores information about a large number of patients and prescribers." *Id.* at 26 (citing Ex. 1007 ¶ 79). Furthermore, Petitioner's argument that the ACA recognizes "the necessity of collecting data for a significant number of patients, thus implying utilizing a conventional computer" to accelerate prescription processing, does not suggest excluding the use of multiple computers to house the central database, as asserted by Patent Owner. PO Resp. 10 (citing Pet. 22, 29; Ex. 2006 ¶¶ 46–47). Although establishing a database on a single "conventional computer" was an option, it was also known as a standard design practice to implement a single database among multiple

conventional computers, i.e. distributed processing. Ex. 1007 ¶ 138 (citing Ex. 1037, 276). The anticipated volume of information to be entered, stored, queried, and sorted for the types of analyses, investigations, and reports contemplated by the ACA system for controlling distribution of Xyrem, and the desire to control cost and improve processing efficiency, were all legitimate and well-documented reasons for distributing the ACA's central computer database "over multiple computers."

Petitioner's evidence persuades us that the use of multiple computers, to provide the capacity and efficiency needed to control nationwide distribution of the prescription drug disclosed in the ACA, would have been a predictable use of a known distributed processing system according to its established function. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). Contrary to Patent Owner's argument, an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418. As noted in *KSR*:

> If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

KSR, 550 U.S. at 417. We find the quoted passages from *KSR* particularly applicable to the facts of the present case, with respect to the combination of the ACA and Korfhage to use distributed processing in a pharmacy setting for controlled distribution of Xyrem.

Here, the choice of distributed processing architecture would have been well within capabilities of a POSA when setting up the ACA Xyrem database. Ex. 1007 ¶¶ 138, 144. Use of distributed processing (multiple computers) as described in Korfhage would have been known, available, and predictable for establishing a single, centralized database to control nationwide distribution of Xyrem. The capacity and efficiency supplied by distributed processing would have facilitated querying multiple data fields populated with the identifying information of a large number of prescriptions, patients, and prescribers throughout the country. There is, moreover, no requirement that Korfhage expressly relates to drug distribution, pharmacy practice, or drug abuse, misuse, or diversion, as urged by Patent Owner, in order for a POSA to combine its teachings with the ACA. PO Resp. 10.

Similarly, we credit Dr. Valuck's testimony over that of Dr. Bergeron (Ex. 2006 ¶ 48) and find that Korfhage's disclosure of distributed processing as one of several known database architectures would have been well within the skill level of a POSA, rather than posing "too many options for database architecture" without providing sufficient guidance on which option to choose. PO Resp. 11 (citing Ex. 2006 ¶¶ 47–48). Dr. Valuck's deposition testimony, cited by Patent Owner in support of its argument, is similarly unavailing and selectively quoted out of context. For example, on page 286 of his deposition transcript, Dr. Valuck testified to more than Korfhage "would suggest a lot of possibilities" regarding setting up a database. PO Resp. 11 (citing Ex. 2008, 286:11–17). The next sentence of his answer states: "Chief among them, the concept of distributive – distributed networks and – and distributed processing." Ex. 2008, 286:11–19. On page

318 of his deposition transcript, Dr. Valuck testified to more than the existence of "various forms and different architectures for accomplishing the same tasks in different ways." PO Resp. 11 (citing Ex. 2008, 318:3–15). Dr. Valuck testified as follows:

> Q. But in your declaration, you combine the advisory committee materials with the distributed document systems appearing at page 276 of Korfhage, not with any of the other potential architectures; correct?
>
> . . . .
>
> A. Again, I looked at all of the advisory committee art, taking my experience from what -- what is well known to a POSA in the field as -- as different examples of those. I also took Korfhage. I believe from these things that are -- are already there, that are already out there, that those various forms and different architectures for accomplishing the same tasks in different ways are there and have been there.

Ex. 2008, 318:3–15. Dr. Valuck answered the same question again, explaining that:

> Q. In your declaration, you do not combine the advisory committee materials with any other database architectures; correct?
>
> . . . .
>
> A. Again, I do it in the way that a POSA would know from -- from experience and what exists in practice. That there are different architectures and that a POSA would know that. Through their – through experience and training and what makes them a POSA would know that, and the art discloses that. And I meant that here with -- with Korfhage as well.

Id. at 319:22–320:7. Dr. Valuck's deposition testimony is consistent with his Declaration testimony and is not evidence of improper hindsight, as alleged by Patent Owner. PO Resp. 12–13 (citing Ex. 2007, 198:6–22; Ex.

2008, 316:15–22). Dr. Valuck's testimony, taken as a whole, supports a finding that distributed processing, as described in Korfhage, was a known, available, and predictable technique for establishing a single database distributed over multiple computers.

We also agree with Petitioner that Korfhage does not teach away from the use of distributed database systems, particularly given the acknowledgment of Dr. Bergeron that Korfhage offered solutions to the problems identified. Ex. 1037, 276–77; Ex. 1049, 317:13–320:12. Korfhage sets up "[t]hree major problems" in the context of "different databases," only to set forth solutions to those problems. Ex. 1037, 276–77. Under cross-examination by Petitioner's counsel, Dr. Bergeron readily acknowledged that Korfhage's discussion of data redundancy and matching document evaluation "problems" were paired with disclosed solutions, which undercut his declaration testimony (Ex. 2006 ¶¶ 50–53) relied upon by Patent Owner. Ex. 1049, 317:13–320:12. Our Decision credits Dr. Bergeron's deposition testimony, which acknowledges the distributed database system solutions disclosed in Korfhage, rather than the speculative new problems hypothesized in Patent Owner's Response.

For example, Patent Owner argues that if the prior art ACA system for distributing Xyrem were to be run on a distributed database of the type suggested by Korfhage, a "data redundancy" problem might create a false indication of duplicate prescriptions that could prevent a patient from receiving her prescription drug. PO Resp. 13–14 (citing Ex. 2006 ¶¶ 51–52). Patent Owner also urges that, on the other hand, if the duplicate prescription data is "eliminated" because a pharmacist believes it was caused by data redundancy, then a potential abuse situation would be overlooked. *Id.* We

do not find such testimony persuasive in view of Korfhage's express disclosures, Dr. Valuck's testimony, and Dr. Bergeron's deposition testimony. Ex. 1007 ¶¶ 138, 141–144; Ex. 1037, 276–77; Ex. 1049, 317:13–320:12. Patent Owner's argument is not persuasive given that the ACA drug distribution system was designed as a single, centralized database to allow a pharmacist to identify and resolve duplicate prescriptions before deciding whether to distribute the drug to a patient (or delete a duplicate prescription caused by data redundancy). Ex. 1003, 184:24–185:7; Ex. 1005, 314 ¶ 6.

At oral argument, counsel for Patent Owner focused on the second paragraph of Korfhage Section 12.4 (Ex. 1037, 276), which describes a computer system having "different databases" or "multiple databases." Tr. 20:21–21:11, 23:20–24:7, 25:12–15, 33:5–22. As pointed out by Petitioner's counsel in rebuttal, the last sentence in the first paragraph of Korfhage Section 12.4 concludes with the dependent clause "*even when* the system must consult multiple physical databases." Ex. 1037, 276 (emphasis added); Tr. 44:6–12. Korfhage's use of "even when," in the context of the first paragraph, indicates that Korfhage is referring to two possibilities, either a single physical database or multiple physical databases. *Id.* That reading is consistent with Korfhage's reference to a single database embodied in "distributed processing" architecture, as explained by Dr. Valuck, and to a user's preference to view the computer system as "accessing a single logical database in response to a query." *Id.* Moreover, as explained above, the ACA discloses a single, centralized database for controlling distribution of Xyrem; there is no suggestion or reason for the ACA system to store Xyrem prescription, prescriber, and patient data in anything other than a single, centralized database. Therefore, we are not

persuaded by the argument of Patent Owner's counsel focusing on problems generated from using different databases.

For the reasons given above, we are persuaded Petitioner has shown by a preponderance of the evidence that the subject matter of claims 24 and 26 of the '963 patent would have been obvious to a POSA in view of the Advisory Committee Art and Korfhage.

2. The "periodic reports" of Claim 27

Claim 27 depends from claim 24 and recites "wherein the current pattern or the anticipated pattern [of abuse] are identified using periodic reports generated from the single computer database." Ex. 1001, 12:31–33.[15]

a. Contentions of the parties

Petitioner relies on Dr. Valuck's Declaration testimony that it would have been obvious to a POSA from the ACA disclosures to use database queries to generate periodic reports for analysis and identification of patterns of abuse and to initiate investigations. Pet. 41–43, 54 (citing Ex. 1007 ¶¶ 120–122; also citing Ex. 1004, 110, 115; Ex. 1005, 304, 310, 311; Ex. 1006, 4 n.14, 7 n.25, 8 nn.29 and 33, 9 n.38, and 10 nn.41 and 42). Petitioner emphasizes that the ACA discloses generating data by using a computer to "record[] prescribers, patients, and dosing that could provide information for any possible investigations and prosecutions for state and federal authorities." *Id.* at 42 (quoting Ex. 1006, 4 n.14; also citing Ex. 1006, 4 n.13; Ex. 1007 ¶ 122.). The ACA discloses that the "Xyrem risk

[15] The same claim limitation is recited in claim 14, to which Petitioner refers in support of its assertion of obviousness for claim 27. Pet. 53–54.

management system ensures that the centralized pharmacy will identify patients who are attempting to duplicate prescriptions. All data collected will be available to state and federal authorities, on whatever timeframe they determine to be appropriate." *Id.* (quoting Ex. 1005, 307; also citing Ex. 1007 ¶ 122.). Petitioner argues that a POSA, therefore, would have understood such data generation, obtained by querying the prescription, prescriber, and patient data fields in the centralized computer database, is synonymous with generating periodic reports from the database to evaluate potential diversion patterns. *Id.* at 42–43 (citing Ex. 1003, 24:21-24; Ex. 1005, cover letter at 1; Ex. 1006, 10 n.42; Ex. 1007 ¶¶ 121–22.)

Patent Owner argues the ACA would not have disclosed, taught, or suggested the claimed "periodic reports." PO Resp. 15–20. Patent Owner contends that the ACA "does not teach reports to identify current or anticipated patterns of abuse that are generated: (1) periodically, i.e., at regular frequencies or intervals, as opposed to intermittently or upon request; and (2) by querying the exclusive computer database." *Id.* at 15 (citing Ex. 2005 ¶¶ 34–36, 38–42; Ex. 2006 ¶¶ 32–41). Patent Owner argues that although the ACA specifies the information available in the "central data repository," the ACA does not disclose, teach, or suggest running queries on that data to generate reports, much less periodic reports. *Id.* at 16 (citing Ex. 1003, 184:24-185:7, Slides at 158; Ex. 1005, 304, 310–11; Ex. 2006 ¶ 34). Patent Owner emphasizes the disclosure that "[t]he database will be made available for review by the DEA as well as other federal and state agencies ***upon request***" (Ex. 1004, 110 (emphasis added); *see also* Ex. 2006 ¶ 36), and therefore a POSA would understand reports generated "upon request" are "ad hoc" reports, ***not*** "periodic" reports. PO Resp. 17 (citing Ex. 2005

¶ 28; Ex. 2006 ¶ 36). Patent Owner further argues that the ACA only discloses generating retrospective reports to aid in investigations of abuse, not the claimed prospective reports to identify "current or anticipated patterns of abuse." *Id.* at 18–19 (citing Ex. 2005 ¶ 39; Ex. 2006 ¶ 38).

b. Analysis

Patent Owner's first argument is rooted in its proposed claim construction of "periodic reports," which we have rejected. As explained in Section II.A, above, "periodic reports" refer to reports that are generated at regular intervals *or* intermittently, i.e., now and again. "Periodic" reports are not limited to reports generated only at regular intervals or frequencies. Our construction includes reports that are generated "upon request" or "ad hoc," as they correspond to reports generated intermittently or now and again. Therefore, we reject Patent Owner's argument to the extent it requires an inappropriately narrow claim construction of "periodic reports."

Petitioner and Patent Owner point to certain portions of the ACA in relation to the "periodic reports" limitation. For example, both point to pages 306–308 of the Briefing Booklet (Ex. 1005). Pet. 42; PO Resp. 16–18. Page 306 of the Briefing Booklet discloses that a single, central pharmacy collects and records data, such as information as to which patients received educational material and "pharmacy data on prescribing physicians," including "physician name, physician specialty, and frequency of prescribing." Ex. 1005, 306 ¶ 5. Page 307 discloses that the centralized pharmacy collects and provides to state and federal authorities, such as state medical boards and the FDA, data regarding patient use and prescribing physicians, including patients who attempt to duplicate prescriptions. *Id*. at 307 ¶¶ 4–6; *see also id.* at 308 (indicating that the specialty pharmacy will

engage in "[d]ata collection" (Fig. 8.3) and "[p]rovide responsible assistance to law enforcement investigations and prosecution if illicit use occurs").

Page 311 of the Briefing Booklet discloses that "centrally located, real-time data collected by the specialty pharmacy will be invaluable to the identification of suspicious prescribing or use, and will aid appropriate state and federal investigation and prosecution." *Id*. at 311 ¶ 5. Similarly, in a different section of the ACA, the Preclinical Safety Review (Ex. 1004), on page 110, teaches that its closed-loop distribution system comprises a database that includes information about patients and prescribing physicians, including prescribing frequency. Ex. 1004, 110 ¶ 1. Here, the ACA discloses that federal and state agencies can obtain information from this database "upon request." *Id*.

We find that such disclosures in the ACA, as identified and discussed by Petitioner (Pet. 41–42), at least suggest generating reports from querying relevant data collected by the single, centralized database. We credit Dr. Valuck's testimony that a POSA would have understood that generating data, by querying the database data fields, "is synonymous with generating periodic reports via the exclusive computer database to evaluate potential diversion pattern[s]." Ex. 1007 ¶ 122. We also find Petitioner establishes sufficiently that the ACA disclosures suggest using such reports to determine patterns of potential prescription abuse, misuse, or diversion, such as when an early refill request is requested or suspicious prescriber behavior arises. Pet. 41–42 (citing and discussing, for example, Ex. 1004, 110, 115; Ex. 1005, 304, 306–308, 310–11, and Ex. 1007 ¶¶ 120, 121).

Patent Owner acknowledges that the ACA "discloses generating retrospective reports to aid in investigations of abuse," but contends that

such disclosures "would not have disclosed, taught, or suggested the claimed prospective reports" to evaluate potential diversion patterns. PO Resp. 18–19 (citing Ex. 1004, 110; Ex. 1005, 306; Ex. 2005 ¶ 39; Ex. 2006 ¶ 38). As noted above, however, Petitioner points us to page 311 of the Briefing Booklet, which discloses that "centrally located real-time data collected by the specialty pharmacy will be invaluable to the identification of suspicious prescribing or use, *and* will aid appropriate state and federal investigation and prosecution." Ex. 1005, 311 ¶ 5 (emphasis added); Pet. 41–42. That disclosure, in combination with other teachings in the Briefing Booklet and elsewhere in the ACA, indicates that even if reports are used in investigations and during prosecution by law enforcement, those reports also are used to determine patterns of potential prescription abuse, misuse, or diversion in the first instance, as recited in the challenged claims. Ex. 1007 ¶¶ 120–21.

Based on the complete record before us, we determine Petitioner has established by a preponderance of the evidence that the ACA discloses: "the central computer database is used to identify a current pattern or an anticipated pattern of abuse . . . using periodic reports generated from the single computer database," as recited in claim 27. *See KSR*, 550 U.S. at 418 ("[A] court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.").

III. CONCLUSION

For the reasons given above, we are persuaded Petitioner has shown by a preponderance of the evidence that claims 24, 26, and 27 of the '963 patent are unpatentable.

This is a Final Written Decision under 35 U.S.C. § 318(a). Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IV. ORDER

Accordingly, it is

ORDERED that claims 24, 26, and 27 of the '963 patent have been shown by a preponderance of the evidence to be unpatentable as obvious over the ACA and Korfhage.

FOR PETITIONERS:

Janine Carlan
Richard Berman
Bradford C. Frese
ARENT FOX LLP
janine.carlan@arentfox.com
richard.berman@arentfox.com
Bradford.Frese@arentfox.com

FOR PATENT OWNER:

F. Dominic Cerrito
Evangeline Shih
Frank C. Calvosa
QUINN EMANUEL URQUHART & SULLIVAN, LLP
nickcerrito@quinnemanuel.com
evangelineshih@quinnemanuel.com
frankcalvosa@quinnemanuel.com

John V. Biernacki
JONES DAY
jvbiernacki@jonesday.com

EXHIBIT B

Paper No.__
Filed: June 3, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC and PAR PHARMACEUTICAL, INC.

Petitioner,

v.

JAZZ PHARMACEUTICALS, INC.

Patent Owner

Case IPR2015-01903
Patent 8,731,963

PATENT OWNER RESPONSE PURSUANT TO 37 C.F.R. § 42.120

Paper No.__
Filed: June 3, 2016

TABLE OF CONTENTS

Page

I. INTRODUCTION

Amneal Pharmaceuticals LLC and Par Pharmaceutical, Inc. ("Petitioners") filed an IPR petition ("Petition" or "Pet.") seeking cancelation of claims 1-28 of U.S. Patent No. 8,731,963 (the "'963 patent"). Petitioners presented two grounds of unpatentability: Ground 1 – claims 1-7 and 9-23 as allegedly obvious over the Advisory Committee Art (Exs. 1003-1006) (the "ACA"); and Ground 2 – claims 8 and 24-28 as allegedly obvious over ACA in view of Korfhage (Ex. 1037). *See* Pet. 9. The Board rejected Ground 1 in its entirety, and partially instituted review on Ground 2 as it relates to claims 24, 26, and 27. *See* Paper 10. As explained below, claims 24, 26, and 27 would not have been obvious.

First, Petitioners have failed to meet their burden of proving that the ACA is prior art to the '963 patent.

Second, even assuming that the ACA is prior art—it is not—Petitioners have failed to meet their burden of showing that the ACA in view of Korfhage would have rendered the challenged claims obvious.

Accordingly, Jazz respectfully requests that the Board confirm the patentability of claims 24, 26, and 27 of the '963 patent.

II. BACKGROUND

Petitioners are defendants in a Hatch-Waxman lawsuit involving the '963 patent; Petitioners are seeking to make generic versions of Xyrem® which are covered by the '963 patent. Xyrem is the only FDA-approved treatment for cataplexy and excessive daytime sleepiness, both debilitating symptoms of narcolepsy. Ex. 2001 at 1; Ex. 2002 at 1. Xyrem's active ingredient is a sodium salt of gammahydroxybutyric acid ("GHB"), a substance which has been legislatively defined as a "date rape" drug. Ex. 2003 at 1; Ex. 2004 at 3.

FDA would not have approved Xyrem without a method of restricting access to the drug that could ensure that its benefits would outweigh the risks to patients and third parties. In fact, FDA approved Xyrem under 21 CFR § 314.520 ("Subpart H"), which allows FDA to approve drugs that are effective, but can only be used safely under restricted conditions. Ex. 2001 at 1; Ex. 2002 at 1.

Claims 24, 26, and 27 of the '963 patent claim computer-implemented systems for treating a narcoleptic patient with a prescription drug that has a potential for misuse, abuse, or diversion, while preventing that misuse, abuse, and diversion by means of various controls. *See* 1001 at 11:7-12:10, 12:23-33; *see also id.* at Abstract, 1:41-45. Each of these claims requires a central computer database to be distributed over multiple computers, and a query that operates over the distributed databases. *See id.* at 11:7-12:10, 12:23-33. Claim 27 additionally

requires using periodic reports, generated from the single computer database, to identify a current pattern or an anticipated pattern of abuse of the prescription drug. *See id.* at 12:23-33.

III. ARGUMENT

A. Petitioners have failed to show, by a preponderance of the evidence, that the ACA (Exs. 1003-1006) is prior art

The parties have briefed and argued Petitioners' failure to show that the ACA qualifies as prior art in related IPRs 2015-00545, -546, -547, -548, -551, and -554. Jazz submits that the Board should apply the decision it reaches in those IPRs here.

B. Claim Construction

In an IPR, claims are to be given their broadest reasonable interpretation in light of the specification in which they appear. *See* 37 C.F.R. § 42.100(b). Claim terms are also to be given their ordinary and customary meaning as would be understood by a POSA, in the context of the entire patent's disclosure, at the time of the invention. *In re Translogic Tech.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In the Institution Decision, the Board "determine[d] that no claim terms require express construction for purposes of this Decision." Paper 10 at 8. Jazz respectfully submits, however, that the phrase "wherein the current pattern or the anticipated pattern [of abuse] are identified using periodic reports generated from the single computer database" in dependent claim 27 requires construction.

Specifically, the phrase requires that the reports are generated: (1) from the single computer database; and (2) on a periodic basis, i.e., at regular frequencies or intervals, as opposed to intermittently or upon request.

Accordingly, Jazz submits that the phrase "wherein the current pattern or the anticipated pattern [of abuse] are identified using periodic reports generated from the single computer database" in claim 27 should be construed to mean: querying the single computer database to generate, ***at regular frequencies or intervals, as opposed to intermittently or upon request***, reports containing prescriber, patient, and/or prescription related information to identify a current pattern or an anticipated pattern of abuse of the prescription drug. *See* Ex. 2005 ¶¶ 26-33; Ex. 2006 ¶¶ 25-31. Jazz's construction gives meaning to the word "periodic" and is supported by the '963 patent's specification, a POSA's understanding of the term, and the plain and ordinary meaning of the word periodic.

First, the specification supports Jazz's construction. *See* Ex. 2005 ¶¶ 27, 29-31; Ex. 2006 ¶¶ 26, 28-29. Specifically, the specification explains that Figures 13A-C are "reports obtained by querying a central database having the fields represented in Fig. 7."[1] Ex. 1001 at 8:23-25; *see also id.* at 8:29-30 ("The reports are obtained by running queries against the database. . . ."). The specification

[1] The fields in Fig. 7 contain prescriber, patient, and/or prescription related information. *See* Ex. 1001 at Fig. 7.

further explains: ***"Each report has an associated frequency or frequencies."*** *Id.* at 8:28-29 (emphasis added). Figures 13A-C of the '963 patent also show that reports regarding prescriber, patient, and/or prescription related information—that allow for identification of a current pattern or an anticipated pattern of abuse of the prescription drug—are run at regular frequencies or intervals, as opposed to intermittently or upon request. *Id.* at Figs. 13A-C. Thus, the specification supports Jazz's construction. *See* Ex. 2005 ¶ 30; Ex. 2006 ¶ 28; *Enpat, Inc. v. Microsoft Corp.*, 26 F. Supp. 2d 806, 808-09 (E.D. Va. 1998) (construing "periodic" to mean "fixed intervals, rather than intermittently or on request" where the specification disclosed the task being performed on a "pre-determined frequency").

Second, Jazz's construction is also supported by the understanding of a POSA. As Petitioners' expert, Dr. Valuck, testified during deposition, reports to investigate abuse can be generated on either "an ad hoc basis or on a regular basis." Ex. 2007 at 184:8-16.[2] A POSA would understand that ad hoc reports are done for a particular purpose. 2005 ¶ 28; Ex. 2006 ¶ 27. A POSA would not consider "ad hoc" reports to be "periodic." *Id.*; *see also* Ex. 2007 at 184:8-16.

[2] The parties have agreed that the expert depositions from IPRs 2015-00545, -546, -547, -548, -551, and -554 can be used in this proceeding. *See* Ex. 2009.

Third, the plain and ordinary meaning of the word periodic supports Jazz's construction. Merriam-Webster's Collegiate Dictionary defines "periodic" as:

> **pe·ri·od·ic** \ˌpir-ē-ˈä-dik\ *adj* (1642) **1** : occurring or recurring at regular intervals **2 a** : consisting of or containing a series of repeated stages, processes, or digits : CYCLIC ⟨~ decimals⟩ ⟨a ~ vibration⟩ **b** : being a function any value of which recurs at regular intervals **3** : expressed in or characterized by periodic sentences

Ex. 2010 at 3. The dictionary reinforces the concept that "periodic" requires events to occur at regular intervals. *See* Ex. 2005 ¶ 32; Ex. 2006 ¶ 30.

Jazz notes that, in related IPRs, the Board cited Figure 4B as illustrative of "a refill request process that permits a pharmacist to identify an early refill request, generate a 'risk diversion report,' and evaluate 'possible product diversion, misuse or over-use' of a prescription drug." *See, e.g.*, IPR2015-00551, Paper 19 at 22-23. As mentioned above, however, Dr. Valuck explained at his deposition that diversion reports can be generated on either "an ad hoc basis or on a regular basis." Ex. 2007 at 184:8-16. A POSA would understand that the reports generated in Figure 4B are "ad hoc" reports done for the particular purpose of investigating specific early refill requests, and ***not*** "regular" or "periodic" reports as set forth in claim 27. Ex. 2005 ¶ 31; Ex. 2006 ¶ 29.

In reply, Petitioners may argue that the '963 patent's parent application's file history supports a finding that Figure 4B should be considered a periodic report because the '963 applicants cited select portions of Figure 4B as support for a

similar periodic report claim element. That portion of the file history is reproduced below.

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

Ex. 2011 at 8.

But, as Dr. Bergeron explained at his deposition, the claim element in the parent application's file history has two parts – a generating reports part and an evaluation of potential diversion patterns part. *See* Ex. 2012 at 342:6-343:23. Dr. Bergeron further explained that a POSA would understand that the portions of Figure 4B that the applicants relied upon during prosecution do not say anything about generating reports. *See id.* at 339:8-23, 323:25-347:11. Instead, the portions the applicants cited refer only to the evaluation step. *See id.* Further, the only portion of Figure 4B that discloses any type of report is Box 434, and the applicants chose ***not*** to cite that box during prosecution as support for the periodic report claim element. As Dr. Bergeron explained, a POSA would expect that Box 434 was not cited because Figure 4B did not provide support for the generating periodic report part of the claim term. *See id.* at 347:21-348:20. Thus, the '963 patent's parent application's file history does not support a finding that Figure 4B should be considered a periodic report.

Accordingly, the distinction between running "ad hoc" reports (Ex. 1001 at Fig. 4B) and running set-frequency/periodic reports (Ex. 1001 at Figs. 13A-C) in the '963 patent's specification further supports Jazz's construction. *See* Ex. 2005 ¶¶ 29-31; Ex. 2006 ¶¶ 28-29; *Enpat*, 26 F. Supp. 2d at 808 (holding that the specification distinguishing between periodic and on request tasks supported a construction of periodic that means "fixed intervals, rather than intermittently or on request").[3]

For the reasons set forth above, the Board should adopt Jazz's construction.

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[3] "[R]ead in the context of the specification, the claims of the patent need not encompass all disclosed embodiments." *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008). Indeed, "[Federal Circuit] precedent is replete with examples of subject matter that is included in the specification, but is not claimed." *Id.* (holding that "the mere fact that there is an alternative embodiment disclosed in the [patent-in-suit]" does not mean it is encompassed by the claims); *see also Schoenhaus v. Genesco, Inc.*, 440 F.3d 1354, 1359 (Fed. Cir. 2006); *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1108 (Fed. Cir. 1996); *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562-63 (Fed. Cir. 1991). The diversion reports in Figure 4B are an unclaimed embodiment.

C. Petitioners have failed to prove, by a preponderance of the evidence, that the ACA in view of Korfhage would have rendered claims 24, 26, and 27 of the '963 patent obvious

Petitioners have failed to meet their burden of showing that the ACA qualifies as prior art. Even assuming, however, that the ACA is prior art, Petitioners have not met their burden of proving that the ACA in view of Korfhage would have rendered claims 24, 26, and 27 obvious. Specifically, Petitioners have failed to meet their burden of showing that: (1) a POSA would have been motivated to combine the ACA with Korfhage to arrive at the "central computer database being distributed over multiple computers" required for claims 24, 26, and 27 and (2) the ACA would have disclosed, taught, or suggested the periodic reports in dependent claim 27.

1. A POSA would not have been motivated to combine the ACA and Korfhage to arrive at the claimed "central computer database being distributed over multiple computers"

Claims 24, 26, and 27 each require that the central computer database is distributed over multiple computers. Ex. 1001 at claims 24, 26, 27. Petitioners do not identify anything in the ACA that would have disclosed, taught, or suggested a central computer database being distributed over multiple computers. *See generally* Pet; Ex. 1007; Ex. 2006 ¶ 43. To the contrary, Petitioners and Dr. Valuck admit that this limitation does not appear in the ACA. *See* Pet. 52;

Ex. 1007 ¶ 144. Thus, Petitioners argue that a POSA would have combined the ACA with Korfhage. *See* Pet. 52. Petitioners are wrong.

Without the benefit of hindsight and the claimed inventions in hand, a POSA would not have been motivated to look to Korfhage, much less single out the one page discussing a distributed computer architecture. Ex. 2006 ¶ 44. Korfhage is a treatise on Information Storage and Retrieval within computer systems. *See generally* Ex. 1037. Nothing in Korfhage relates to drug distribution or pharmacy practice generally, and nothing relates to drug abuse, misuse, or diversion. *See generally* Ex. 1037; Ex. 2006 ¶ 45. The general concepts simply never appear. *See generally* Ex. 1037.[4] Petitioners cherry-pick two passages from page 276 of the 349 page treatise that relate to "Distributed Document Systems," but their only explanation for doing so is to "increase the efficiency of the distribution of Xyrem." Pet. 52. Elsewhere in the Petition, however, Petitioners argue that large numbers of Xyrem prescriptions can be handled in an "acelerate[d]" manner using a "***conventional*** computer," and that the ACA discloses the use of such a conventional computer. Pet. 22, 29 (emphasis added). Indeed, a POSA would have understood that any computer database would sufficiently accommodate drug distribution by the central pharmacy. Ex. 2006 ¶¶ 46-47.

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[4] Thus, Dr. Valuck's testimony that Korfhage "appl[ies] to pharmacy practice" is entirely unsupported. *See* Ex. 2007 at 206:10-207:3.

In short, Petitioners have not identified any problem with the centralized (i.e., non-distributed) database disclosed in the ACA. *See generally* Pet; Ex. 1007; Ex. 2006 ¶ 47. Thus, a POSA would not have been motivated to look for any substitution, let alone the specific distributed-database architecture in Korfhage. *See Leo Pharm. Prods. v. Rea*, 726 F.3d 1346, 1354 (Fed. Cir. 2013) ("Only after recognizing the existence of the problem would an artisan *then* turn to the prior art. . . .") (emphasis in original).

Further, even if there was a known problem in the prior art, Korfhage discloses too many options for database architectures to a POSA and provides no guidance on which option to choose. *See* Ex. 2006 ¶ 48. Indeed, Petitioners' declarant admitted that Korfhage "would suggest a lot of possibilities." Ex. 2008 at 286:11-17; *see also id.* at 316:23-317:8 (Dr. Valuck admitting that distributed database document systems are not the only database architecture for handling documents for pharmacies), 317:12-14 (Dr. Valuck admitting that Korfhage "covers a host of possibilities for systems"), 318:3-15 (Dr. Valuck testifying that there are "various forms and different architectures for accomplishing the same tasks in different ways"). Dr. Valuck further admitted that "all these different forms were . . . existing in the art and existing in practice for many years in various systems and various permutations and forms." *Id.* at 317:16-23; *see also id.* at 320:3-4 ("[T]here are different architectures and [] a POSA would know that.").

Thus, rather than showing a "finite number of identified, predictable solutions" (*KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 421(2007)), Dr. Valuck admitted that the prior art was replete with a host of possible database architectures.

Notably, Dr. Valuck admitted that he did not consider these other systems because he "was not asked to opine on . . . all of the different possibilities." Ex. 2008 at 316:15-22. Instead, Dr. Valuck admitted that his "whole obviousness opinion" was based on impermissible hindsight:

> A. Again, I looked for where the claim elements were disclosed in the prior art.
>
> . . .
>
> Q. Right. So you used the patent as a guide to pick the elements out of the prior art.
>
> A. Well, again, my – ***my whole obviousness opinion is based on starting with the elements*** and referring to prior art and all available prior art through the eyes of a person of ordinary skill. That was the process I used.

Ex. 2007 at 198:6-22 (emphasis added). It is improper, however, to pick and choose in hindsight from the prior art. *See Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448 (Fed. Cir. 1986) (reversing obviousness holding and explaining that the prior art must be considered as a whole); *KSR*, 550 U.S. at 421 (noting that fact finders must guard against "the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning");

In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."). Thus, Petitioners' obviousness analysis fails because it provides no reason to arrive at the specific distributed database architecture in Korfhage. *See* Ex. 2006 ¶ 49.

Further, Petitioners and Dr. Valuck ignore that Korfhage teaches away from using distributed databases and, therefore, teaches away from combining Korfhage with the ACA, because it discloses to a POSA that "three ***major problems*** arise" when a user attempts to have a single query operate over multiple physical databases. *See* Ex. 1037 at 276-277 (describing problems); *see also* Ex. 2006 ¶¶ 50-53. While Dr. Valuck testified that he "wasn't asked to provide an opinion on problems associated with distributed database systems for . . . [his] declarations" (Ex. 2008 at 320:24-321:5), he eventually conceded that Korfhage expressly discloses such problems. *See id.* at 323:15-324:15; *see also id.* at 321:21-322:8 (Dr. Valuck testifying that the "problems arise from the situation described where the user . . . is interested in locating and obtaining a document regardless of where it resides, either physically or within a computer system").

A POSA would have understood that the second "major problem" in Korfhage would have been particularly relevant to the distribution system disclosed in the ACA. Ex. 2006 ¶¶ 51-52. Specifically, Korfhage explains that

"[t]he second problem is that of data redundancy. Different databases may include copies of the same or equivalent document." Ex. 1037 at 276. Korfhage suggests that "eliminating the duplication requires relatively little work," but "in some instances the documents may be sufficiently different to cause problems." *Id.* As Petitioners admit, the ACA explains that the "central data repository 'allows for the identification of duplicate prescriptions.'" Pet. 31. The return of redundant data in the distributed databases might create a false indication of duplicate prescriptions that could prevent a patient from receiving her prescription drug. Ex. 2006 ¶ 52. On the other hand, if the duplicate prescription data is "eliminat[ed]" because a pharmacist believes it was caused by data redundancy, then a potential abuse situation would be overlooked. *Id.*

The "major problems" disclosed in Korfhage would have expressly taught a POSA away from combining it with the ACA and modifying the distribution system disclosed in the ACA. *Id.* ¶ 53. "[R]eferences that teach away cannot serve to create a prima facie case of obviousness." *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001).

Accordingly, Petitioners have failed to meet their burden of proving that claims 24, 26, and 27 would have been obvious.

2. The ACA would not have disclosed, taught, or suggested the claimed periodic reports

Petitioners' challenge also fails for claim 27 because they failed to meet their burden of showing that the ACA would have disclosed, taught, or suggested the additional limitation of claim 27: "wherein the current pattern or the anticipated pattern [of abuse] are identified using periodic reports generated from the single computer database." Petitioners rely on the ACA alone for alleged disclosure of this claim limitation. *See* Pet. 53-54, *see also id.* at 41-43 (citing only the ACA and not Korfhage).

As discussed above, "wherein the current pattern or the anticipated pattern [of abuse] are identified using periodic reports generated from the single computer database" should be construed to mean: querying the single computer database to generate, at regular frequencies or intervals, as opposed to intermittently or upon request, reports containing prescriber, patient, and/or prescription related information to identify a current pattern or an anticipated pattern of abuse of the prescription drug. *See supra* at pp. 3-8. The ACA does not teach this limitation because it does not teach reports to identify current or anticipated patterns of abuse that are generated: (1) periodically, i.e., at regular frequencies or intervals, as opposed to intermittently or upon request; and (2) by querying the single computer database. *See* Ex. 2005 ¶¶ 34-36, 38-42; Ex. 2006 ¶¶ 32-41.

First, Petitioners argue that the "ACA discloses using the central data repository to identify patterns of abuse and diversion." Pet. 42 (citing Ex. 1003 at 184:24-185:7, Slides at 158; Ex. 1005 at 304, 310-11); *see also* Ex. 1007 ¶ 121 (citing same). While these disclosures specify the information available in the "central data repository," none disclose, teach, or suggest running queries on that data to generate any types of reports, much less periodic reports. *See* Ex. 1003 at 184:24-185:7, Slides at 158; Ex. 1005 at 304, 310-11; Ex. 2006 ¶ 34.

Second, Petitioners argue that "the ACA describes preventing diversion and illicit use, as well as providing assistance to 'law enforcement for investigation and prosecution efforts,' as a goal of the system." Pet. 42 (citing Ex. 1003 at 15:6-8; Ex. 1004 at 110; Ex. 1005 at 298, 301, 306-308); *see also* Ex. 1007 ¶ 121 (citing same). Petitioners also argue that the central pharmacy "employs numerous mechanisms, controls, and verification procedures to ensure that Xyrem is not obtained fraudulently or abused or diverted by the patient or prescriber." Pet. 41 (citing Ex. 1003 at 184:24-185:7, Slides at 158; Ex. 1004 at 110; Ex. 1005 at 304, 310, 311; Ex. 1006 at 4 n.14, 8 nn. 29, 33 and 9 n.38); *see also* Ex. 1007 ¶ 120 (citing same). Petitioners further argue that "[i]t would have been obvious to a POSA that, for the database to determine such abuse or patterns of abuse . . . it must be queried periodically to generate reports" and that a POSA "would have understood that such data generation obtained through querying via the central data

repository is synonymous with generating periodic reports via the computer database to evaluate potential diversion patterns." Pet. 41-43 (citing Ex. 1003 at 24:21-24; Ex. 1004 at 110, 115; Ex. 1005 at cover letter, 304, 310, 311; Ex. 1006 at 4 n.14, 7 n.25, 8 nn.29, 33, 9 n.38, 10 nn.41-42; V5 00:10-00:27, V13 00:17-00:31; Ex. 1003 at 24:21-24); *see also* Ex. 1007 ¶¶ 120, 122 (citing same).

Petitioners are wrong. The cited evidence would not have disclosed, taught, or suggested generating periodic reports. *See* Ex. 1003 at 15:6-8, 24:21-24, 184:24-185:7, Slides at 158; Ex. 1004 at 110, 115; Ex. 1005 at cover letter, 298, 301, 304, 306-308, 310, 311; Ex. 1006 at 4 n.14, 7 n.25, 8 nn.29, 33, 9 n.38, 10 nn.41-42; V5 00:10-00:27, V13 00:17-00:31; Ex. 1003 at 24:21-24; Ex. 2006 ¶¶ 35-36. Instead, the evidence cited discloses that "[t]he database will be made available for review by the DEA as well as other federal and state agencies ***upon request***." Ex. 1004 at 110 (emphasis added); *see also* Ex. 2006 ¶ 36. A POSA would understand reports generated "upon request" are "ad hoc" reports, ***not*** "periodic" reports. Ex. 2006 ¶ 36; *see also id.* ¶ 27; Ex. 2005 ¶ 28. Further, as discussed in detail below, the ACA discloses that the proposed system "preserves [the] important feature" of ***not*** having the central pharmacy police medicine. Instead, the ACA contemplated having the central pharmacy become involved in an investigation of abuse only on an ad hoc basis, after authorities asked for its

assistance. *See infra* at pp. 19-20. In other words, the ACA only taught the generation of ad hoc reports.

Third, Petitioners argue that "the ACA discloses generating data by 'recording prescribers, patients, and dosing that could provide information for any possible investigations and prosecutions for state and federal authorities' using a computer." Pet. 32 (citing Ex. 1006 at 4 nn.13-14; V5 00:10-00:27); *see also* Ex. 1007 ¶ 122 (citing same). Petitioners also argue that the ACA discloses that "[a]ll data collected will be available to state and federal authorities, on whatever timeframe they determine appropriate," and imply that "timeframe" refers to periodic reporting. Pet. 42 (citing Ex. 1005 at 307); Ex. 1007 ¶ 122.

But Petitioners ignore that "[g]enerating data . . . for any possible investigations and prosecutions" is not the same as generating periodic reports. *See* Ex. 2005 ¶¶ 38-41; Ex. 2006 ¶¶ 37-40. The ACA's full disclosure teaches a POSA that any reports generated for state or federal agencies are done so "upon request" to assist the authorities with cases of abuse, which the ACA indicates will be rare. Ex. 2005 ¶ 39; Ex. 2006 ¶ 38; Ex. 1004 at 110; Ex. 1005 at 306 ("Available data … will assist appropriate authorities in an investigation, ***should one become necessary***. The centralized, real-time nature of these data will allow for ***rapid identification in the rare case of diversion***.") (emphasis added).) Thus, the ACA only discloses generating retrospective reports to aid in investigations of

abuse. The ACA would not have disclosed, taught, or suggested the claimed prospective reports to identify current or anticipated patterns of abuse. Ex. 2005 ¶ 39; Ex. 2006 ¶ 38

Indeed, the ACA discloses to a POSA that the pharmacy can only assist with an investigation once it becomes necessary and has begun. Ex. 2005 ¶ 40. Specifically, the ACA discloses that "[t]he practicalities of how prescriptions are filled in the U.S. do not allow for a specialty pharmacy to 'police' the practice of medicine." Ex. 1005 at 307. Instead, "the current system used in the U.S. for managing the risks associated with controlled substances allows for appropriate stakeholders to police individual physician and patient behavior. The Xyrem system preserves this important feature." *Id.*; *see also id.* (noting the pharmacy will cooperate with the appropriate stakeholders—"state and federal authorities, including State Medical Boards, DEA and FDA, in any investigation dealing with physician or patient behavior").

Based on the ACA's disclosures, a POSA would have understood that the "timeframe" statement cited by Petitioners is similar to the statement in Ex. 1005 that the centralized data "allow[s] for rapid identification in the rare case of diversion." Ex. 1005 at 306. Specifically, a POSA would have understood that the statement boasts the benefit of centralized data being available in real-time, which is that potential investigations will be able to proceed without delay from the

pharmacy. Ex. 2005 ¶ 41; Ex. 2006 ¶¶ 39-40. The timeframe is contingent on particular events. It is not an implication of periodic reporting. *Id.*

Accordingly, Petitioners have failed to meet their burden of proving that claim 27 would have been obvious for this additional reason.

IV. CONCLUSION

For the foregoing reasons, Petitioners have failed to prove, by a preponderance of the evidence, that claims 24, 26, and 27 of the '963 patent would have been obvious.

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Respectfully submitted,

By: /F. Dominic Cerrito (Reg. No. 38,100)/

F. Dominic Cerrito (Reg. No. 38,100)
Eric C. Stops (Reg. No. 51,163)
Evangeline Shih (Reg. No. 50,170)
Frank C. Calvosa (Reg. No. 69,064)
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
General Tel: (212) 849-7000
Fax: (212) 849-7100
nickcerrito@quinnemanuel.com
ericstops@quinnemanuel.com
evangelineshih@quinnemanuel.com
frankcalvosa@quinnemanuel.com

John V. Biernacki
Reg. No. 40,511
JONES DAY
North Point

901 Lakeside Avenue
Cleveland, Ohio 44114
General Tel: (216) 586-3939
Direct Tel: (216) 586-7747
Fax: (216) 579-0212
jvbiernacki@jonesday.com
Attorneys for Jazz Pharmaceuticals, Inc.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC and PAR PHARMACEUTICAL, INC.,

Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.

Patent Owner

Case IPR2015-01903
Patent 8,731,963

CERTIFICATE OF SERVICE

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned hereby certifies that PATENT OWNER RESPONSE PURSUANT TO 37 C.F.R. § 42.120 and Exhibits (2001-2013) were served on June 3, 2016 by filing these documents through the Patent Review Processing System, as well as e-mailing copies to bradford.frese@arentfox.com, janine.carlan@arentfox.com, richard.berman@arentfox.com, and XYREM@arentfox.com.

Date: June 3, 2016

Respectfully submitted,

By: /F. Dominic Cerrito (Reg. No. 38,100)/

F. Dominic Cerrito (Reg. No. 38,100)
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
General Tel: (212) 849-7000
Fax: (212) 849-7100
nickcerrito@quinnemanuel.com

Lead counsel for Jazz Pharmaceuticals, Inc.

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This paper complies with the type-volume limitation of 37 C.F.R. § 42.24. The paper contains 4,439 words, excluding the parts of the paper exempted by § 42.24(a).

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Date: June 3, 2016

Respectfully submitted,

By: /F. Dominic Cerrito (Reg. No. 38,100)/

F. Dominic Cerrito (Reg. No. 38,100)
QUINN EMANUEL URQUHART & SULLIVAN LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
Tel: (212) 849-7000
Fax: (212) 849-7100
nickcerrito@quinnemanuel.com

Lead counsel for Jazz Pharmaceuticals Ireland Ltd. and Jazz Pharmaceuticals, Inc.