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Paper 70
Entered: July 27, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-00547
Patent 7,765,107 B2

Before JACQUELINE WRIGHT BONILLA, BRIAN P. MURPHY, and JON B. TORNQUIST, *Administrative Patent Judges.*

BONILLA, *Administrative Patent Judge*.

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

I. INTRODUCTION

Amneal Pharmaceuticals, LLC, and Par Pharmaceutical, Inc. ("Par Inc.") (together, "Petitioner"), filed a Petition requesting an *inter partes* review of claims 1–6 of U.S. Patent No. 7,765,107 B2 (Ex. 1001, "the '107 patent"). Paper 4 ("Petition" or "Pet."). Jazz Pharmaceuticals, Inc. ("Patent Owner"), filed a Preliminary Response to the Petition. Paper 10. As authorized (Paper 11), Petitioner filed a response directed solely to real-party-in-interest issues raised in the Preliminary Response (Paper 12), and Patent Owner filed a reply to that paper (Papers 17/18). Upon considering those submissions, we instituted *inter partes* review of claims 1–6 of the '107 patent based on an obviousness ground. Paper 25 ("Dec. on Inst.").

After institution, Patent Owner filed a Response (Paper 46, "PO Resp."), and Petitioner filed a Reply (Paper 50, "Reply"). Petitioner supports its challenges with a Declaration by Robert J. Valuck, Ph.D., R.Ph. ("Valuck Declaration") (Ex. 1007) and the Affidavit of Christopher Butler ("Butler First Affidavit") (Ex. 1028). Pet. 9, 15. Petitioner also presents another Affidavit of Mr. Butler (Ex. 1058, "Butler Third Affidavit") with its Reply. Reply 7.

With its Response, Patent Owner presents the Declarations of Joseph T. DiPiro, Pharm.D. (Ex. 2046, "DiPiro Declaration"), Bryan Bergeron, MD, FACMI (Ex. 2047, "Bergeron Declaration"), Craig F. Kirkwood, Pharm.D. (Ex. 2053, "Kirkwood Declaration"), David A. Holdford, Ph.D., FAPhA (Ex. 2056, "Holdford Declaration"), and Lyndsey J. Przybylski (Ex. 2057, "Przybylski Declaration"). PO Resp. 18–22, 26–36, 38–47. Patent Owner also presents a responsive Affidavit of Christopher Butler dated November 4, 2015 (Ex. 2052, "Butler Second Affidavit"). PO Resp. 8–9.

In addition, Petitioner also filed a Motion to Exclude seeking to exclude certain evidence (Paper 56, "Mot. Excl."), along with a Motion to Allow Late Filing of Evidence Objections (Paper 58). Patent Owner filed an Opposition to Petitioner's Motion to Exclude (Paper 63) and an Opposition to Petitioner's Motion to Allow Late Filing of Evidence Objections (Paper 61). Petitioner filed a Reply to Patent Owner's Opposition to the Motion to Exclude (Paper 64). In addition, Patent Owner filed a Notice Regarding New Arguments and Evidence in Petitioner's Reply (Paper 52), to which Petitioner filed a Response (Paper 53).

A combined oral hearing in this proceeding and Cases IPR2015-00545, IPR2015-00546, IPR2015-00548, IPR2015-00551, and IPR2015-00554 was held on April 19, 2016; a transcript of the hearing is included in the record (Paper 69, "Tr.").

We have jurisdiction under 35 U.S.C. § 6(c). We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–6 of the '107 patent are unpatentable. Petitioner's Motion to Allow Late Filing of Evidence Objections and Motion to Exclude are dismissed as moot.

A. Grounds of Unpatentability at Issue

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. § 103 based on the ground that claims 1–6 are obvious over Advisory Committee Art (Exs. 1003–1006, collectively called "the ACA"),

including FDA Advisory Committee Transcript and Slides (Ex. 1003),[1] Preliminary Clinical Safety Review (Ex. 1004),[2] Briefing Booklet (Ex. 1005),[3] and Xyrem Video and Transcript (Ex. 1006).[4] Pet. 1, 9–34, 56–58.

B. Related Proceedings

The parties identify the following as related district court proceedings regarding the '107 patent: *Jazz Pharms., Inc. v. Par Pharm., Inc.*, No. 2:13-cv-07884 (D.N.J. Dec. 27, 2013); *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, No. 2:13-cv-00391 (consolidated) (D.N.J. Jan. 18, 2013); *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, No. 2:10-cv-06108 (consolidated) (D.N.J. Nov. 22, 2010); *Jazz Pharms., Inc. v. Ranbaxy Labs. Ltd.*, No. 2:14-cv-4467 (D.N.J. July 15, 2014); *Jazz Pharms., Inc. v. Watson Labs., Inc.*, No. 2:14-cv-7757 (D.N.J). Pet. 59–59; Paper 8, 1–2.

The parties also identify the following cases as involving Petitions for *inter partes* review of patents related to the '107 patent: IPR2015-00545 (Patent 8,589,182 B1); IPR2015-00546 (Patent 7,765,106 B2); IPR2015-

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[1] FDA Peripheral & 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 & Central Nervous System Drugs Advisory Committee, Briefing Information, 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 & Central Nervous System Drugs Advisory Committee (May 3, 2001) ("Briefing Booklet") (Ex. 1005).

[4] FDA Peripheral & 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).

00548 (Patent 7,895,059 B2); IPR2015-00551 (Patent 8,457,988 B1); and IPR2015-00554 (Patent 7,668,730 B2). Pet. 59; Paper 8, 2. The parties also identify the following cases as involving Petitions for covered business method patent review ("CBM") regarding the '107 patent and related patents: CBM2014-00149 (Patent 7,895,059 B2); CBM2014-00150 (Patent 8,457,988 B1); CBM2014-00151 (Patent 7,668,730 B2, "the '730 patent"); CBM2014-00153 (Patent 8,589,182 B1); CBM2014-00161 (Patent 7,765,106 B2); and CBM2014-00175 (the '107 patent). Pet. 59; Paper 8, 2. The Board has denied institution in all six of the above-mentioned CBM cases.

In addition, a different Petitioner, Wockhardt Bio AG ("Petitioner Wockhardt"), filed a Petition for *inter partes* review of the '107 patent in IPR2015-01820, as well as five additional Petitions challenging claims in the other patents at issue in the related *inter partes* review cases noted above. Petitioner Wockhardt also filed Motions for Joinder in all six cases in relation to the corresponding earlier filed Petitions. We originally instituted review in those cases and granted Petitioner Wockhardt's Joinder Motions. *See, e.g.*, Paper 44 (granting institution and Petitioner Wockhardt's Motion for Joinder in IPR2015-01820, in relation to the '107 patent). After the oral hearing took place, however, upon the parties' joint request (Paper 66), we ordered the termination of all six proceedings as to Petitioner Wockhardt, and granted the parties' joint request to treat the underlying settlement agreement as business confidential information (Paper 67). Paper 68.

Patent Owner identifies the following pending U.S. patent applications claiming priority benefit from U.S. Patent Application No. 10/322,348, which the '107 patent also claims the benefit of: U.S. Patent

Application No. 14/196,603, filed on March 4, 2014, U.S. Patent Application No. 14/219,904, filed on March 19, 2014, and U.S. Patent Application No. 14/219,941 filed on March 19, 2014. Paper 8, 3.

C. The '107 Patent

The '107 patent, titled "Sensitive Drug Distribution System and Method," issued July 27, 2010, from a divisional application of an application filed December 17, 2002. Ex. 1001. The '107 patent is directed to a method for controlling access to a sensitive prescription drug prone to potential abuse or diversion, by utilizing a central pharmacy and database to track all prescriptions for the sensitive drug. *Id.* at Abstract, 1:44–50. 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, 1:48–50.

Figures 2A, 2B, and 2C comprise flow charts representing "an initial prescription order entry process for a sensitive drug." *Id.* at 4:13–14. 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 4:13–31, Fig. 2A (steps 202–210). The pharmacy team then engages in "intake reimbursement" (Fig. 2A), which includes verification of insurance coverage or the patient's willingness and ability to pay for the prescription drug. *Id.* at 4:32–34.

The "pharmacy" workflow includes verification of the prescribing physician's credentials. *Id.* at 5:15–31, 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 5:31–6:4. Steps 240, 242, 246, and 258–266 of Figure 2C are reproduced below.

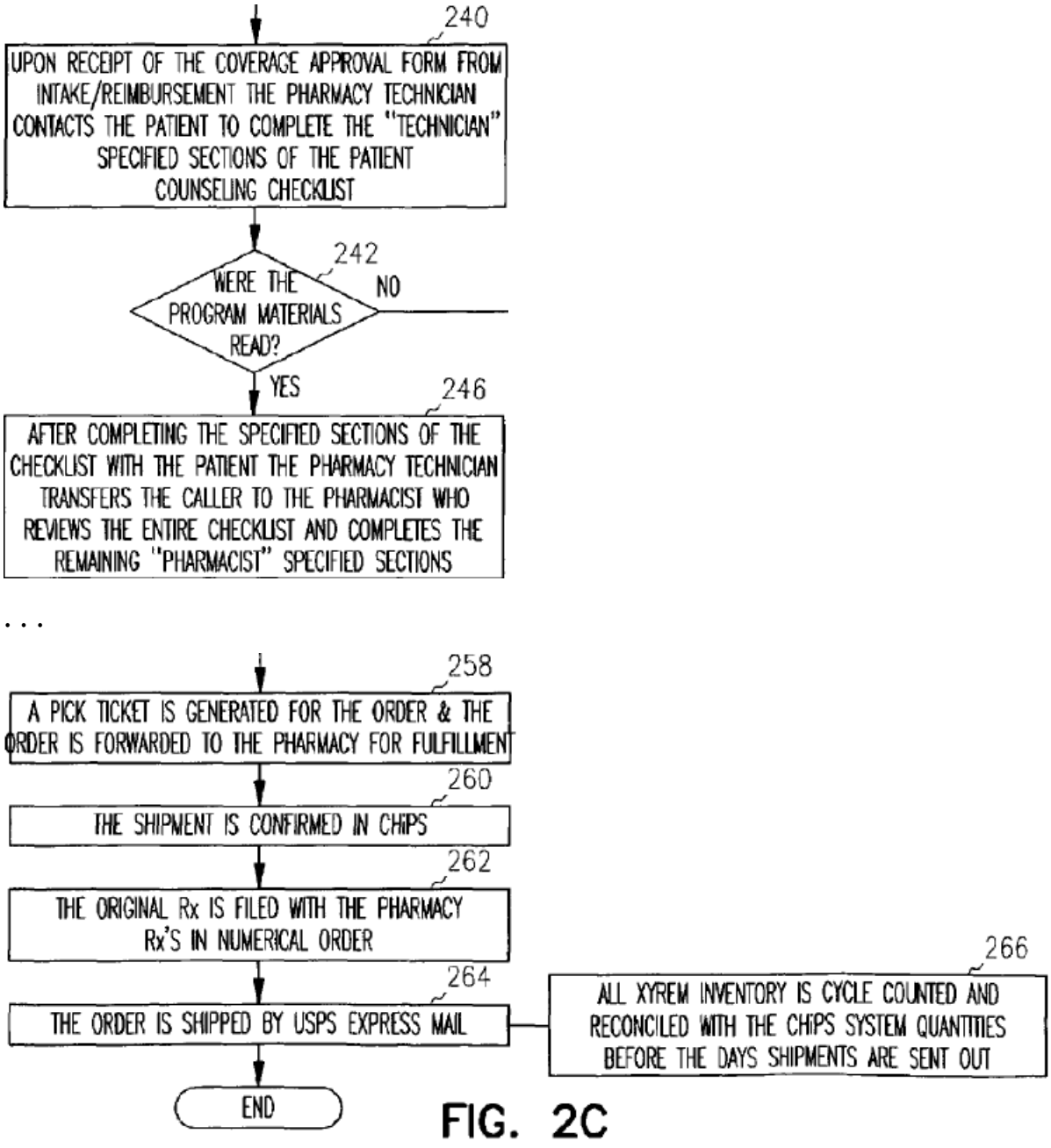

FIG. 2C

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®."[5] *Id.* at 4:34–39. 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 6:37–41, Fig. 4B (step 436).

D. Illustrative Claims

The '107 patent contains two independent claims (1 and 4) and four dependent claims (2, 3, 5, and 6), of which claim 1 is illustrative and reproduced below:

> 1. *A computerized method to control abuse of a prescription drug* comprising:
>
> *controlling with a computer processor the distribution of said prescription drug via an exclusive central pharmacy that maintains a central database that* tracks all prescriptions of said prescription drug and *analyzes for potential abuse situations*;
>
> *receiving in the computer processor all prescription requests*, for any and all patients being prescribed the prescription drug, *only at the exclusive central pharmacy*, from any and all medical doctors allowed to prescribe the prescription drug;
>
> *processing with the computer processor all prescriptions for the prescription drug only by the exclusive central pharmacy using only the central database*;
>
> *determining with the computer processor current and anticipated patterns of potential prescription abuse* of said prescription drug from periodic reports generated only by the central database based on prescription request data from a particular medical doctor and further based on filling of

[5] Xyrem® is the brand name for gamma hydroxy butyrate ("GHB"), indicated for the treatment of cataplexy (excessive daytime sleepiness) in narcoleptic patients. Ex. 1001, 3:20–27. Xyrem® is a sensitive prescription drug prone to potential abuse or diversion. *Id.*

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

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

Ex. 1001, 8:36–9:25 (emphases added). Dependent claim 2 (and claim 5, which depends from independent claim 4) of the '107 patent recite certain "initially selected controls." *Id*. at 9:26–44, 10:39–59. Dependent claim 3

(and claim 6, which depends from independent claim 4) of the '107 patent "further comprises consulting a separate database to verify that the medical doctor is eligible to prescribe the drug." *Id*. at 9:45–47, 10:60–62.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Relying on testimony by Dr. Valuck, Petitioner contends that a person of ordinary skill in the relevant art (hereafter "POSA") includes someone with 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, including familiarity with drug distribution procedures." Pet. 2 (citing Ex. 1007 ¶ 21; *see also id.* at ¶ 20 (Dr. Valuck stating that he "at least meet[s] the criteria of a POSA" as outlined in ¶ 21 of his Declaration). Alternatively, according to Petitioner, a POSA "may have a blend of computer science and pharmacy drug distribution knowledge and/or experience," including "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*. Petitioner also asserts that a POSA would have known to look in the Federal Register and on the FDA's website to obtain information related to existing and proposed risk management programs. Pet. 15 (citing Ex. 1007 ¶ 42).

In its Response, Patent Owner challenges the sufficiency of Petitioner's evidence that a POSA would have been familiar with the Federal Register and motivated to look for notices related to drug distribution, safety, or abuse prevention. PO Resp. 16–24. Patent Owner's challenge

amounts to an attack on the knowledge and skill level of a hypothetical person of ordinary skill in the art. We are not persuaded by Patent Owner's argument.

We begin with the premise that a hypothetical POSA is presumed to be aware of the pertinent art in the field of endeavor at the time of the invention, and to be a person of ordinary creativity. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 407-09, 420–21 (2007). As the title, field of the invention, and background discussion in the '107 patent make clear, the relevant field of endeavor is the distribution of sensitive prescription drugs prone to abuse or causing serious adverse reactions. Ex. 1001, Title, 1:11–27. Petitioner provides substantial evidence of the state of the art of such sensitive drug distribution systems as of December 17, 2001, one year before the '107 patent priority date. Pet. 3–6; *see also* Ex. 1001, Related Application, 1:6–9 (indicating earliest priority date for the '107 patent).

Xyrem® is a sensitive prescription drug prone to potential abuse or diversion. Ex. 1001, 3:20–27. Prior to Xyrem, sensitive prescription drugs such as Accutane®, Clozaril®, and thalidomide were known to use controlled distribution systems to protect against potential side effects, abuse, and diversion. Pet. 4–5 (citing Ex. 1007 ¶¶ 22–25). Accutane®, a prescription drug from the 1980s that could cause birth defects, was distributed under a program requiring: i) informed consent forms completed by patient and physician; ii) patient counseling to avoid pregnancy and use of birth control; and iii) a negative blood serum test for pregnancy prior to beginning treatment. *Id.* at 4 (citing Ex. 1007 ¶ 22). Distribution of Clozaril®, indicated for treating schizophrenia but also capable of causing a fatal blood

disorder, was controlled using a national registry system and computerized database for identifying patients and physicians. *Id.* (citing Ex. 1007 ¶ 23).

In 1999, the manufacturers of thalidomide developed a system that combined the computerized registry of Clozaril® with the controls imposed by the Accutane® distribution system. *Id.* at 5 (citing Ex. 1007 ¶ 25). Based on such prior art activity, we find that by December 2002, a person of ordinary skill would have known the active ingredient in Xyrem®—sodium oxybate—was a sensitive drug susceptible to abuse and diversion, and such person would have known of several available techniques to control and mitigate the risks associated with Xyrem®'s distribution. *Id.* at 3 (citing Ex. 1007 ¶¶ 21, 41); Ex. 1007 ¶¶ 21–28.

In its Response, and during the oral hearing, counsel for Patent Owner argued that a person of ordinary skill in the art was "a person of three to five years' experience, a pharmacist, a person who sits behind the counter at Walgreens [and] is not worried about preapproved drugs." Tr. 30:17–31:9; PO Resp. 19–20. Counsel for Patent Owner further argued that a person of ordinary skill would not have had an interest or "a focus on restricted distribution of products that don't even exist yet." Tr. at 31:1–32:1.

In view of the claims at issue here, we are not persuaded that the level of ordinary skill in the art is limited to the level of skill or interest of a pharmacist that dispenses FDA-approved drugs, such as one that "sits behind the counter at Walgreens." *Id*. at 31:1–5. We adopt the level of ordinary skill in the art as described by Petitioner and its witness, Dr. Valuck, because it is consistent with the subject matter before us, the '107 patent, and with

prior art of record, such as Talk About Sleep (Ex.1033),[6] Honigfeld (Ex. 1034),[7] Elsayed (Ex. 1035),[8] and Lilly (Ex. 1010)[9]. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (stating the prior art itself can reflect the appropriate level of ordinary skill in the art).

B. Claim Construction

We interpret claims in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs. LLC v. Lee*, 136 S.Ct. 2131, 2144–46 (2016). Claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire 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 with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Claim 1 of the ’107 patent recites a “computerized method to control abuse of a prescription drug” by: (1.1) “controlling with a computer processor the distribution of said prescription drug via an exclusive central

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[6] Talk About Sleep, “An Interview with Orphan Medical about Xyrem®,” available at http://www.talkaboutsleep.com/an-interview-with-orphan-medical-about-xyrem/ (Feb. 12, 2001) (“Talk About Sleep”) (Ex. 1033).

[7] Honigfeld et al., “Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience with the Clozaril National Registry,” J. Clin. Psych. 59 (suppl. 3): 3-7 (1998) (“Honigfeld”) (Ex. 1034).

[8] Elsayed et al., U.S. Patent No. 6,045,501, filed Aug. 28, 1998, issued Apr. 4, 2000 (“Elsayed”) (Ex. 1035).

[9] Lilly et al., U.S. Patent Appl. Pub. No. 2004/0176985, filed Mar. 18, 2004, published Sept. 9, 2004 (“Lilly”) (Ex. 1010).

pharmacy that maintains a central database that tracks all prescriptions . . . and analyzes for potential abuse situations;" (1.2) "receiving in the computer processor all prescription requests . . . only at the exclusive central pharmacy;" (1.3) "processing with the computer processor all prescriptions for the prescription drug only by the exclusive central pharmacy using only the central database;" (1.4) "determining with the computer processor current and anticipated patterns of potential prescription abuse of said prescription drug from periodic reports generated only by the central database;" and (1.5) "selecting with the computer processor multiple controls for distribution by said exclusive central pharmacy." Ex. 1001, 8:36–9:25. The claim as a whole recites controlling distribution of a prescription drug to patients to guard against potential abuse.

Both Petitioner and Patent Owner present constructions for several claim terms. Pet. 8–9; PO Resp. 24–36; Reply 12–18. We discuss the different terms in turn below.

1. "exclusive central pharmacy"

In our Decision on Institution, we construed the term "exclusive central pharmacy" to mean "single or sole pharmacy." Dec. on Inst. 20–21. Our constructions are consistent with those proposed by Petitioner, and Patent Owner takes no position regarding Petitioner's arguments in this regard. Pet. 8; PO Resp. 24 n.8. Based on our review of the complete record, we do not perceive any reason or evidence that now compels any deviation from that interpretation.

2. "*determining with the computer processor . . . patterns of potential prescription abuse . . . from periodic reports generated only by the central database*"

Petitioner cites portions of the specification explaining, for example, that "***[s]everal queries and reports are run against the database*** to provide information which might reveal potential abuse of the sensitive drug, such as early refills." Pet. 8 (citing Ex. 1001, 2:19–21). Figure 7 of the '107 patent reflects prescriber, patient, prescription, and insurance information input into the database, and Figures 13A–13C reflect various types of reports that may be generated, including reports regarding "pharmacy," "inventory," "reimbursement," "patient care," and "drug information." Ex. 1001, 7:41–48, 8:22–29, Figs. 7, 13A–C. A user generates reports by running various queries through the exclusive computer database to obtain information of the type illustrated. *Id.*

The recited use of the reports is to determine "current and anticipated patterns of potential prescription 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. *Id.* at 1:31–36, 2:19–21. Figure 4B illustrates 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. *Id.* at 6:37–41, Fig. 4B (406, 432, 434, 436). The ability of a pharmacist or other user to determine potential diversion patterns from the generated reports, in order to prevent product diversion, misuse, or abuse, necessarily informs the types of reports generated and must be reflected in the claim construction.

In our Decision on Institution, we construed the phrase "determining with the computer processor . . . patterns of potential prescription abuse . . . from periodic reports generated only by the central database" to mean "using the central database via the computer processor to generate periodic reports containing prescriber, patient, and/or prescription related information, which permits evaluation of potential abuse of a prescription drug." Dec. on Inst. 22.

Patent Owner indicates that it generally agrees with that construction, but proposes that the construction is incomplete in relation to the term "periodic reports." PO Resp. 25. Patent Owner contends that "periodic reports" should be construed to mean "at regular frequencies or intervals, as opposed to intermittently or upon request." *Id*. at 25–26 (citing Ex. 2046 ¶¶ 30–38; Ex. 2047 ¶¶ 28–35). In support, Patent Owner points to the specification of the '107 patent, such as Figures 13A–C, and where the specification states "[e]ach report has an associated frequency or frequencies." *Id*. at 26–27; Ex. 1001, 8:22–28.

The cited portions of the specification, however, describe Figures 13A–C as "descriptions of *sample* reports obtained by querying a central database having fields represented in Fig. 7." Ex. 1001, 8:22–24 (emphasis added); *see also id*. at 2:55–57 (also describing Figs. 13A–C as describing "sample reports"); Reply 13. Thus, we do not agree that the specification indicates that "periodic reports" as recited in the claims refers only to reports obtained at regular frequencies or intervals, even if the term includes such reports.

Patent Owner also responds to testimony by Petitioner's expert, Dr. Valuck, who states that "periodic reports" can be generated on either "an ad

hoc basis or on a regular basis." PO Resp. 28 (quoting Ex. 2044, 184:8–16). Patent Owner argues that a POSA "would understand that ad hoc reports are done for a particular purpose," and, therefore, a "POSA would not consider 'ad hoc' reports to be 'periodic.'" *Id*. at 27 (citing Ex. 2046 ¶¶ 33, 37; Ex. 2047 ¶¶ 31, 34, Ex. 1001, Figs. 4B, 13A–C)). Patent Owner also argues that Figure 4B illustrates generating "ad hoc" reports prepared for the particular purpose of investigating specific early refill requests, and not "periodic" reports as recited in the challenged claims. PO Resp. 27–28 (citing Ex. 2046 ¶ 36; Ex. 2047 ¶ 33).

We are not persuaded by Patent Owner's arguments or the testimony of Dr. DiPiro and Dr. Bergeron in support thereof. 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. *See, e.g.*, PO Resp. 28 (citing Ex. 2046 ¶ 33 (testimony by Dr. DiPiro stating that "POSA would not consider 'ad hoc' reports to be 'periodic' because they are not generated with any regular frequency."); Ex. 2047 ¶ 31 (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 '107 patent illustrates generating "ad hoc" reports, as Patent Owner contends, such disclosure supports a construction that the recited "periodic reports" include such "ad hoc" reports. Ex. 1001, 6:13–7:3; Reply 13–14 (citing Ex. 1047, 6; Ex. 1048, 9:12–19, Fig. 4, 436).

Patent Owner also points us to a Merriam-Webster's Collegiate Dictionary definition of the term "periodic," which defines the term as "occurring or recurring at regular intervals," or something that is "repeated." PO Resp. 27 (quoting Ex. 2043, 3). Petitioner points us to several other

dictionary definitions, which define "periodic" as also including "intermittent." Reply 15 (citing Ex. 1049, 3 (defining "periodic" as including "occurring repeatedly from time to time"); Ex. 1050, 3 (defining "periodic" as including "[t]aking place now and then" or "INTERMITTENT"); Ex. 1051, 3 (defining "periodic" as including "[h]appening or appearing now and then" or "intermittent, occasional"). Upon considering all of the evidence before us, we are not persuaded that the plain and ordinary meaning of "periodic" in the context of the '107 patent limits "periodic reports" to those generated only at regular intervals, as Patent Owner contends. PO Resp. 26–28. Rather, the term 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.

3. "wherein said [prescription] request data contain information identifying the patient"

Patent Owner construes the phrase "wherein said [prescription] request data contain information identifying the patient" to mean, "at a minimum: the prescription requests [for GHB] containing the patient's name, social security number, date of birth, sex, and complete address information, including city, state and zip code." PO Resp. 29–33 (citing Ex. 2046 ¶¶ 39–44; Ex. 1001, 4:14–28, 8:4–5, 39–42, 10:50–53; Ex. 2044, 97:11–98:5, 99:18–100:10). For example, Patent Owner contends that the specification of the '107 patent describes receiving at a central pharmacy all prescription requests, such as enrollment forms, which include patients'

"name, social security number, date of birth, gender, [and] contact information," as identified in Figure 9 of the specification. PO Resp. at 30 (citing Ex. 1001, 4:26–28, 8:4–5; Ex. 2044, 97:11–23, 99:18–100:10).

Petitioner responds that "information identifying the patient" is not limited to the extent that it must include all of the specific information identified by Patent Owner. Reply 15–17. Petitioner also argues that Patent Owner's construction improperly reads limitations as disclosed in Figure 9 into the claims. *Id*. We agree.

The specification of the '107 patent indicates that "*[a]n example* of one prescription and enrollment form is shown at 900 in FIG. 9." Ex. 1001, 8:4–5 (emphasis added). Thus, the enrollment form of Figure 9 describes one example of the type of information that may be information identifying a patient. The specification does not indicate, however, that "information identifying the patient," as recited in the claims, necessarily includes each and every piece of information in the enrollment form of Figure 9. Similarly, nothing in the specification suggests that excluding one or more pieces of information in the list of a "patient's name, social security number, date of birth, sex, and complete address information, including city, state and zip code," as proposed by Patent Owner, means that a prescription fails to contain "information identifying the patient," as recited in the claims.

Thus, we construe prescription "request data contain information identifying the patient" to refer to information identifying a patient, which may include the type of information presented in the enrollment form of Figure 9 and noted by Patent Owner (PO Resp. 29–30), but is not limited to that information nor requires all of that information.

4. "*wherein said [prescription] request data contain information identifying . . . credentials of the medical doctor*"

Patent Owner construes the phrase "[prescription] request data contain information identifying . . . credentials of the medical doctor" to mean, "at a minimum: the prescription requests [for GHB] containing the medical doctor's name, license number, DEA number, and physician specialty." PO Resp. 33–36 (citing Ex. 2046 ¶¶ 45–49; Ex. 1001, 4:14–26, 8:4–5, 40–43, 9:54–56; Ex. 2044, 181:1–23). For example, Patent Owner contends that the '107 patent describes receiving at a central pharmacy all prescription requests, such as enrollment forms, that include prescriber information that "contains standard contact information as well as license number, DEA number and physician specialty." *Id.* at 34–35 (citing Ex. 1001, 4:14–26, 8:4–5, 40–43, 9:54–56, Fig. 9; Ex. 2044, 181:1–23). Patent Owner also relies on testimony from Dr. DiPiro to further define "physician specialty information" in its list as "training and certification information." *Id*. at 35 (citing Ex. 2046 ¶ 47).

As Patent Owner points out, the specification of the '107 patent describes, in relation to the disclosed flowcharts presented in Figures 2A–C, that an enrollment form contains, *inter alia*, "prescriber information." Ex. 1001 4:12–23. The specification also states that the "prescriber information contains standard contact information as well as license number, DEA number and physician specialty." *Id*. at 4:24–26.

The specification also describes, however, that the flowcharts presented in Figures 2A–C describe "*a* method for sensitive drug distribution" or "*an* initial prescription order entry process for a sensitive drug." Ex. 1001, 2:28–30, 4:13–14 (emphasis added). The specification does not indicate that the methods of the challenged claims are limited to the

specific method of Figures 2A–C, nor that recited prescriptions necessarily include all information in the enrollment form used in the method of Figures 2A–C. *See, e.g.*, *id*. at 4:13–6:4 (describing the initial prescription order entry process of Figures 2A–C). Likewise, the specification does not define "credentials of the medical doctor," as recited in the challenged claims, as being limited to the "prescriber information" presented in Figure 9, which describes "an example" of a prescription and enrollment form. *Id*. at 2:47–48, 8:4–7.

Thus, we are not persuaded that the recited "credentials" necessarily include each and every piece of prescriber information described in relation to Figures 2A–C or in the enrollment form of Figure 9. The specification does not suggest that failing to include on the prescription one or more pieces of information from the list of a "medical doctor's name, license number, DEA number, and physician specialty," as proposed by Patent Owner, means that a prescription fails to contain information regarding "credentials," as recited in the claims.

We construe prescription "request data contain information identifying . . . credentials of the medical doctor" to refer to information identifying credentials, i.e., at least two credentials, of the prescribing doctor, which may include the type of prescriber information described in relation to Figures 2A–C, presented in the enrollment form of Figure 9, and noted by Patent Owner (PO Resp. 33–34), but are not limited to that information nor require all of that information.

C. Public Accessibility of Exhibits 1003–1006

The priority date of the '107 patent is December 17, 2002. Ex. 1001. Petitioner asserts that Exhibits 1003–1006 (the "Advisory Committee Art"

or "ACA") were publicly accessible printed publications under 35 U.S.C. § 102(b), in connection with the Xyrem Advisory Committee meeting held on June 6, 2001. Pet. 10–15. Patent Owner counters that Petitioner's evidence is insufficient to show that (1) Exhibits 1004–1006 were publicly accessible more than one year before December 17, 2002, or that (2) a POSA would have been "capable of locating or learning of the existence and potential relevance" of Exhibits 1003–1006. PO Resp. 3–24.

The key inquiry is whether a reference was made "sufficiently accessible to the public interested in the art" before the critical date, here December 17, 2001. *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989). "A given reference is 'publicly accessible' upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it." *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006). Indexing of a reference is not "a necessary condition for a reference to be publicly accessible," but it is one among various factors that may bear on public accessibility. *In re Lister*, 583 F.3d 1307, 1312 (Fed. Cir. 2009). "Whether a reference is publicly accessible is determined on a case-by-case basis based on the 'facts and circumstances surrounding the reference's disclosure to members of the public.'" *Voter Verified, Inc., v. Premier Election Solutions, Inc.*, 698 F.3d 1374, 1380 (Fed. Cir. 2012) (quoting *In re Lister*, 583 F.3d 1307, 1311 (Fed. Cir. 2009)). With these principles in mind, we consider the parties' arguments below.

1. Accessibility of Exhibits 1003–1006 on FDA's Website

a. Summary timeline

A summary timeline of events, before and after the June 6, 2001 FDA Advisory Committee Meeting concerning Xyrem® (or "Xyrem"), provides helpful context. Orphan Medical is the company that developed Xyrem and prepared the drug sponsor's briefing booklet for the Xyrem Advisory Committee Meeting, in accordance with the Federal Advisory Committee Act ("FACA"). Ex. 1005, 1; Pet. 12–13 (citing Ex. 1005; 5 U.S.C. App 2 § 10(b) (2001)); Reply 2–3 (citing Ex. 1005, 1; Ex. 1057, 2; 5 U.S.C. App 2 § 10(b) (2001)). FDA reviewers also prepared briefing information, including the Preliminary Clinical Safety Review of the Xyrem New Drug Application ("Safety Review"). Ex. 1004. The June 6, 2001 meeting was transcribed. Ex. 1003. We provide a summary timeline below.

May 3, 2001: FDA Safety Review of Xyrem completed (Ex. 1004, 1)

May 3, 2001: Sponsor's Xyrem Briefing Booklet submitted to Advisory Committee (Ex. 1005, 1)

May 3, 2001: Sponsor's video of Xyrem prescription process submitted to Advisory Committee (Ex. 1005, 2 ¶ 5, 14, 312; Ex. 1006)

May 14, 2001: Federal Register Notice of Xyrem Advisory Committee Meeting (Ex. 1015, Col. 2–3)

June 6, 2001: Xyrem Advisory Committee Meeting (Ex. 1003)

June 17, 2001: Internet Archive of FDA website for Xyrem Advisory Committee (Ex. 1018, 5)

July 1, 2001: Internet Archive of FDA website for Xyrem Advisory Committee (Ex. 1019)

October 4, 2001: Internet Archive of FDA website for Xyrem Advisory Committee (Ex. 1020, 8–9)

December 17, 2002: '107 patent application priority date

August 30, 2003: Internet Archive printout of Ex. 1006 "Video Script 2/2/01" (Ex. 2052, 1–2 (¶¶ 6, 9), 482–492, 501)

September 13, 2011: Internet Archive printout of Ex. 1005 "Briefing Booklet" (Ex. 2052, 1–2 (¶¶ 6, 8), 128–481, 498)

November 21, 2011: Internet Archive printout of Ex. 1004 "Preliminary Clinical Safety Review" (Ex. 2052, 1–2 (¶¶ 6, 7), 5–127, 495).

The Advisory Committee Meeting was convened to discuss Xyrem, with the "main focus of the deliberations . . . on risk management issues." Pet. 14–15 (citing Ex. 1015; Ex. 1007 ¶ 42); Ex. 1003, 5:23–6:3. The above timeline and cited exhibits confirm Petitioner's unopposed contention that Exhibits 1004–1006 were prepared for and made available to the Xyrem Advisory Committee before the June 6, 2001 Xyrem Advisory Committee Meeting. Reply 2–3. The transcript of the Xyrem Advisory Committee Meeting contains several references to the "briefing documents" and "materials" distributed prior to the meeting, although the references are not so specific as to identify Exhibits 1004, 1005, or 1006, *per se*. Ex. 1003, 12, 284, 330, 342; Tr. 9:23–11:10.

The parties' first dispute centers on when Exhibits 1004–1006 first became publicly accessible on the FDA's website. We begin with a discussion of the Federal Register Notice and public accessibility of Exhibit 1003, the Xyrem Advisory Committee Meeting transcript.

b. Federal Register Notice and Meeting Transcript (Ex. 1003)

The May 14, 2001 Federal Register Notice provided public notice of the June 6, 2001 Xyrem Advisory Committee Meeting and identified the Universal Resource Locator ("URL" or website address) for the FDA

website on which "[b]ackground material from the sponsor and FDA will be posted 24 hours before the meeting." Pet. 12–13 (citing Ex. 1015). The May 14, 2001 Federal Register Notice further stated that "the minutes, transcript, and slides from the meeting" are "generally posted about 3 weeks after the meeting." *Id.* Petitioner argues that the Federal Register Notice is evidence of FDA's general practice that may be relied upon to establish an "approximate time" the Advisory Committee Art would have become available to a POSA exercising reasonable diligence. *Id.* at 12–13 and n.1 (citing Case IPR2014-00059, slip op. at 34 (PTAB Apr. 15, 2014) (Paper 9) (in turn citing *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986)); 5 U.S.C. App 2 §10(b) (2001)). Petitioner further relies on Internet Archive evidence to argue that Exhibits 1003–1006 were publicly accessible on the FDA's website no later than shortly after the Xyrem Advisory Committee Meeting. Pet. 14–15; *see also Desert Palace, Inc. v. Costa*, 539 U.S. 90, 99 (2003) ("[T]he 'conventional rul[e] of civil litigation' . . . requires a plaintiff to prove his case 'by a preponderance of the evidence' . . . using 'direct or circumstantial evidence.'" (internal citation omitted) (citing *Postal Serv. Bd. Of Governors v. Aikens*, 460 U.S. 711, 714, n.3 (1983))).

Regarding the Xyrem Advisory Committee Meeting transcript and presentation slides (Ex. 1003), the Internet Archive evidence shows that as of June 17, 2001, less than two weeks after the meeting, there were no links posted for the meeting transcript, presentation slides, or meeting minutes. Ex. 1018, 5.[10] The Internet Archive evidence further shows that links for the

[10] The footer of the June 17, 2001 Internet Archive page contains a URL date code of "20010617" (Ex. 1018, 5), as explained by Christopher Butler, the Office Manager of the Internet Archive. Ex. 1028 ¶ 5.

transcript pages, presentation slides, and meeting minutes were posted on the FDA website not later than October 4, 2001. Pet. 14–15 (citing Ex. 1020, 8; Ex. 1028); Ex. 1020, 9.[11] The meeting transcript file links are identified as "3754t1_01.pdf" (pages 1–100), "3754t1_02.pdf" (pages 101–200), "3754t1_03.pdf" (pages 201–300), "3754t1_04.pdf" (pages 301-381), and "3754t1.txt," respectively. Ex. 1020, 8. The meeting minutes file links are identified as "3754m1.pdf, html," and the presentation slides are identified as "3754s1.htm." *Id*. at 8–9. We note the links for the Xyrem Advisory Committee Meeting are all coded with the unique numerical identifier 3754 followed by a lower case letter to indicate the type of document, e.g., 3754t to indicate the transcript, 3754m to indicate the minutes, and 3754s to indicate the slides. *Id.*

Exhibit 1003 is comprised of 381 transcript pages, followed by the presentation slides, thus confirming the description of the Internet Archive file links as containing 381 pages. *Compare* Ex. 1003, *with* Ex. 1020, 8. We are persuaded that the Federal Register Notice is evidence of the FDA's general practice under the Federal Advisory Committee Act and tends to indicate an approximate timeframe when background information and advisory committee meeting minutes, transcripts, and presentation slides are posted on the FDA's website. Case IPR2014-00059, slip op. at 34 (PTAB Apr. 15, 2014) (Paper 9) (citing *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986)); 5 U.S.C. App 2 § 10(b) (2001) ("[T]he records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other

[11] The footer of the October 4, 2001 Internet Archive pages contains a Universal Resource Locator date code of "20011004" (Ex. 1020, 8–9). Ex. 1028 ¶ 5.

documents which were made available to or prepared for or by each advisory committee shall be available for public inspection.").

The Federal Register Notice states that the minutes, transcript, and slides of the Xyrem Advisory Committee Meeting are "generally posted about 3 weeks after the meeting." Ex. 1015. The Internet Archive evidence indicates the meeting transcript, presentation slides, and meeting minutes were not posted on the FDA's website as of June 17, 2001, less than two weeks after the meeting, but were posted no later than October 4, 2001. Ex. 1018; Ex. 1020; Ex. 1028. Thus, the Federal Register Notice is consistent with the Internet Archive evidence. Petitioner further emphasizes that Patent Owner does not contest the sufficiency of the evidence establishing the public accessibility of Exhibit 1003 on the FDA's website as of October 4, 2001. Reply 2 n.2; Tr. 6:1–9; s*ee* PO Resp. 3–15.

Thus, for the reasons given above, we find that Petitioner has established by a preponderance of the evidence that the Xyrem Advisory Committee Meeting transcript and presentation slides (Exhibit 1003) were publicly accessible on the FDA's website not later than October 4, 2001.

c. Exhibits 1004–1006

Exhibit 1004 is a Xyrem Preliminary Clinical Safety Review, asserted by Petitioner to have small portions redacted, thereby indicating an intent to make the document publicly available. Pet. 13–14. The cover page and header on every page of the Preliminary Clinical Safety Review indicates it

was authored by Dr. Ranjit B. Mani, M.D. of the FDA and completed on May 3, 2001. Ex. 1004, 1 ("Review Completed: 5/3/01").[12]

Exhibit 1005 comprises a three-page cover letter from Orphan Medical to the Xyrem Advisory Committee dated May 3, 2001, and the enclosed "Briefing Booklet" for the Advisory Committee Meeting. Pet. 13–14 (citing Ex. 1005). The cover letter states that "Xyrem safety, efficacy, pharmacokinetics, abuse pharmacology, scheduling and risk management are summarized in this booklet" Ex. 1005, 1 ¶ 3. The cover letter further references the inclusion of a "short 8-minute video on the prescription process, along with patient and physician education materials (the two binders)." *Id.* at 2 ¶ 5, 312. The Briefing Booklet itself says "AVAILABLE FOR PUBLIC DISCLOSURE WITHOUT REDACTION" on the cover. *Id.* at 4.

Exhibit 1006 is a video titled "Xyrem Prescription and Distribution Process," dated February 2, 2001, and transcript of the video.[13] Ex. 1006, 1.

d. Analysis: Public Accessibility of Exhibits 1004–1006

Petitioner argues that Exhibits 1004–1006 are the background material referenced in the Federal Register Notice (Ex. 1015), which would have been posted on the FDA's website approximately "24 hours before the meeting" in accordance with the Federal Advisory Committee Act and FDA

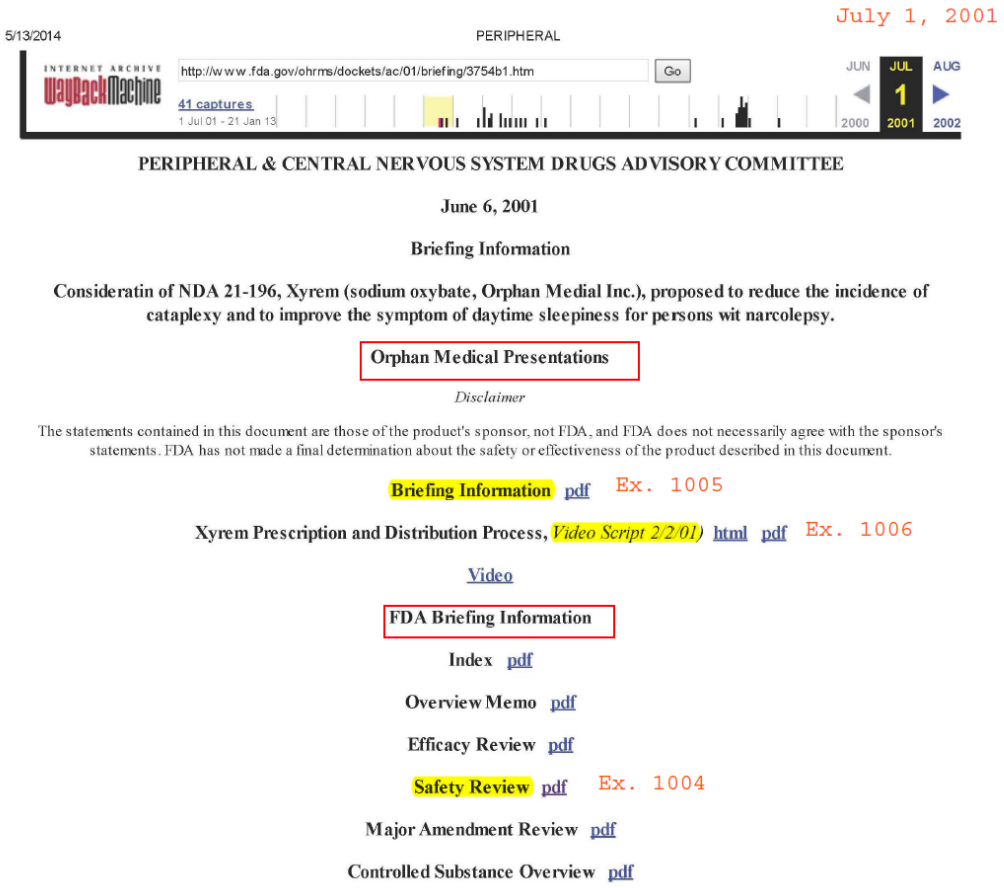
[12] The document header also includes the date "5/3/01." Ex. 1004. Dr. Mani is listed as an FDA participant in the June 6, 2001 FDA Advisory Committee meeting. Ex. 1003, 2.

[13] Petitioner has submitted Exhibit 1006 in fifteen parts, comprising fourteen parts of the video and the transcript of the entire video. All citations to Ex. 1006 are citations to the transcript ("Exhibit 1006 Xyrem Video Transcript").

practice. Pet. 12–13; Reply 2–4. Petitioner also argues the Internet Archive evidence corroborates the approximate FDA website availability date of Exhibits 1004–1006, because the evidence shows that a link to "Briefing Information" for the Xyrem Advisory Committee Meeting was publicly accessible not later than June 17, 2001. Pet. 14 (citing Ex. 1018, 5).[14] Petitioner further argues that "[f]ollowing this link demonstrates that this art [Exs. 1004–1006] was all available on July 1, 2001, at the latest." *Id.* (citing Ex. 1019). Thus, Petitioner argues that clicking on the "Briefing Information" link of the FDA's website for the Xyrem Advisory Committee Meeting (Ex. 1018, 5 or Ex. 1020, 9) would have led a POSA to Exhibit 1019, which in turn contains the links to Exhibits 1004–1006. *Id.*; Tr. 13:1–9.

Exhibit 1019 is an Internet Archive document dated July 1, 2001, titled "PERIPHERAL & CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE June 6, 2001." Ex. 1019. Exhibit 1019, including our annotations, is reproduced below:

[14] Exhibits 1018 (Internet Archive dated June 17, 2001) and 1020 (Internet Archive dated October 4, 2001) both show a link to "Briefing Information" coded as "3754b1.htm." Ex. 1018, 5; Ex. 1020, 8–9.



July 1, 2001

5/13/2014 PERIPHERAL

INTERNET ARCHIVE Wayback Machine http://www.fda.gov/ohrms/dockets/ac/01/briefing/3754b1.htm Go

41 captures 1 Jul 01 - 21 Jan 13

JUN JUL AUG 1 2000 2001 2002

PERIPHERAL & CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE

June 6, 2001

Briefing Information

Consideratin of NDA 21-196, Xyrem (sodium oxybate, Orphan Medial Inc.), proposed to reduce the incidence of cataplexy and to improve the symptom of daytime sleepiness for persons wit narcolepsy.

Orphan Medical Presentations

Disclaimer

The statements contained in this document are those of the product's sponsor, not FDA, and FDA does not necessarily agree with the sponsor's statements. FDA has not made a final determination about the safety or effectiveness of the product described in this document.

Briefing Information pdf Ex. 1005

Xyrem Prescription and Distribution Process, *Video Script 2/2/01)* html pdf Ex. 1006

Video

FDA Briefing Information

Index pdf

Overview Memo pdf

Efficacy Review pdf

Safety Review pdf Ex. 1004

Major Amendment Review pdf

Controlled Substance Overview pdf

The document heading is "Briefing Information" for the Advisory Committee's consideration of Xyrem. *Id.* Under the subheading "Orphan Medical Presentations" is i) a pdf link to "Briefing Information," asserted to be a link to Exhibit 1005, and ii) html and pdf links to "Xyrem Prescription and Distribution Process, *Video Script 2/2/01*," asserted to be links to Exhibit 1006. *Id.*; Pet. 14 (citing Ex. 1019); Tr. 8:1–8. Under the subheading "FDA Briefing Information" is a pdf link to "Safety Review," asserted to be a link to Ex. 1004. *Id.*

Patent Owner contends that Petitioner's evidence fails to prove, by a preponderance of the evidence, that Exhibits 1004–1006 qualify as publicly accessible printed publications. PO Resp. 3–4. Patent Owner challenges all of Petitioner's evidence, arguing in particular that there is "no evidence in the record that establishes that the ***links*** [in Exs. 1018 and 1019] led to the ***documents*** that are Exs. 1004–1006" before the '107 patent priority date. *Id*. at 4–9. Patent Owner further argues that neither the Federal Register Notice, the preparation dates of Exhibits 1004–1006, the presence or absence of redactions therein, nor Dr. Valuck's testimony supports Petitioner's argument. *Id*. at 4, 9–15. Patent Owner maintains that Petitioner has not satisfied its burden of proving Exhibits 1004–1006 were publicly accessible before December 17, 2002, and Exhibits 1004–1006 cannot be used as prior art to challenge the patentability of the '107 patent claims. *Id.*

Petitioner acknowledges it has not presented direct evidence that clicking on the relevant links of the FDA's website in June-July 2001 would have led a POSA to the documents of Exhibits 1004–1006, but relies on the totality of the circumstantial evidence to satisfy its burden of proof. Tr. 7:3–24. Patent Owner's attack emphasizes Petitioner's lack of such direct evidence, but does not address persuasively the cumulative effect of Petitioner's circumstantial evidence. As discussed above, it is undisputed that Exhibit 1003 was available as a file link on the FDA's website no later than October 4, 2001. It is also undisputed that Exhibits 1004–1006 were prepared and submitted to the Xyrem Advisory Committee just over one month prior to the June 6, 2001 meeting. The Safety Review (Ex. 1004) has a few redactions that tend to indicate the document was prepared for public

dissemination, and the Briefing Booklet (Ex. 1005) contains the statutory legend indicating it is available for public disclosure without redaction. Reply 2–4 (citing Ex. 1057, 4[15]). Thus, the evidence indicates Exhibits 1004–1006 were prepared, distributed to the Xyrem Advisory Committee, and available for posting to the FDA's website 24 hours prior to the meeting, as stated in the Federal Register Notice (Ex. 1015). The Federal Register Notice even provided instructions on how to locate materials from the FDA's website—"Click on the year 2001 and scroll down to the Peripheral and Central Nervous Systems Drugs meetings." Reply 5 (citing Ex. 1015).

As Petitioner points out, Patent Owner has not adduced evidence to indicate the FDA failed to follow the public inspection requirements of the Federal Advisory Committee Act and FDA's own guidance document in effect at the time. Reply 2–4 (citing Ex. 1057, 2, 4, 6, 8). FDA's guidance document states that seven business days prior to an advisory committee meeting "the sponsor package and CDER's [Center for Drug Evaluation and Research] redacted package will be submitted . . . for posting on the FDA website." Ex. 1057, 8 ¶ 9. The guidance document further states that 24 hours prior to the meeting "FDA will post on its website the sponsor package and CDER's redacted package." *Id.* at ¶ 10. If for some reason the FDA is unable to post the documentation prior to a meeting, "the two packages will be made publicly available at the location of the advisory committee meeting, and the two packages will be posted on the Agency website after the meeting." *Id.* The transcript of the Xyrem Advisory Committee Meeting contains internal references to the briefing material

[15] Our citations are to the internal numbering of the document, consistent with Petitioner's citations.

made available to the committee members and discussed at the meeting, thus tending to corroborate the availability of Exhibits 1004–1006 as of the June 6, 2001 meeting date. Reply 4 (citing Ex. 1003, 12, 179, 284, 330, 342).

Petitioner's Internet Archive evidence indicates that a file link to "Briefing Information 3754b1.htm" was posted on the FDA's website not later than June 17, 2001. Ex. 1018, 5. Petitioner's Internet Archive evidence further indicates this link led to file links for Orphan Medical's "Briefing Information" (Ex. 1005 Briefing Booklet) and Xyrem "*Video Script 2/2/01*" (Ex. 1006) and for the FDA's "Safety Review" (Ex. 1004 Preliminary Clinical Safety Review), which were posted on the FDA's website not later than July 1, 2001. Ex. 1019. We also note the URL for the FDA website address in Exhibit 1019 concludes with the code "briefing/3754b1.htm," which matches the Briefing Information code linked in Exhibit 1018.[16] Thus, the Internet Archive evidence supports Petitioner's contention that the documents of Exhibits 1004–1006 were publicly accessible on the FDA's website for the Xyrem Advisory Committee not later than July 1, 2001, in accordance with the Federal Advisory Committee Act.

We are not persuaded by Patent Owner's argument that Petitioner's Internet Archive evidence is insufficient, given the totality of evidence presented in this case. PO Resp. 5–9. For example, Patent Owner submits the Second Affidavit of Christopher Butler and asserts that, if one clicks on the links shown in Exhibits 1019, the earliest archive dates for the URLs corresponding to Exhibits 1004–1006 are dated after the '107 priority date:

[16] The 3754 code is consistent with the code used for other Xyrem Advisory Committee documents, as discussed above in subsection II.*C.1.b*.

August 30, 2003, for Exhibit 1006; September 13, 2011 for Exhibit 1005; and November 21, 2011 for Exhibit 1004. *Id.* at 8–9 (citing Ex. 2052, 6, 129, 483, 495, 498, and 501). As Petitioner explains, however, quoting from a Third Affidavit of Christopher Butler, the first available archive or "captured" date of a URL "does not represent the first time that the pdf was posted online at that address and it is possible that the pdf was available at this URL on an earlier date." Reply 6–7 (citing Ex. 1058 ¶¶ 6–8). The pdf "may have been available days, weeks, months, or years prior to the date it was first captured." Ex. 1058 ¶ 6; *see also Rackspace US, Inc. v. Personalweb Techs., LLC*, Case IPR2014-00059, slip op. at 35 (PTAB April 15, 2014) (Paper 9) ("[T]he mere fact that a 'downloaded' copy of [the prior art reference] has a date subsequent to the critical date is not sufficient to rebut Rackspace's supporting evidence that [the reference] was posted originally on publicly accessible sites well known to those interested in the art before the critical date.").

We further note that Patent Owner's Internet Archive evidence corroborates the fact that pdf files for each of Exhibits 1004–1006 were linked to the FDA's website with the code "briefing/3754b1." Ex. 2052, 5 (Ex. 1004 "Preliminary Clinical Safety Review" - "briefing/3754b1_02_section %203.pdf"), 128 (Ex. 1005 "Briefing Booklet" - "briefing/3754b1_01_1-orphan-medical.pdf "), 482 (Ex. 1006 "Video Script 2/2/01" - "briefing/3754b1_01_2-orphan-medical%20video%20tape%20Revised%20Script.pdf"). "Briefing/3754b1" is the same code linking the "Briefing Information" to the FDA's website as of June 17, 2001 (Ex. 1018, 5) and July 1, 2001 (Ex. 1019). As in

Rackspace, Patent Owner's evidence of a later archive date for a reference does not overcome Petitioner's evidence supporting an earlier posting date.

Patent Owner also cites to the Board's decision on institution in *ServiceNow, Inc. v. Hewlett-Packard Co.*, Case IPR2015-00707 (PTAB Aug. 26, 2015) (Paper 12) ("*ServiceNow*") in support of its argument. PO Resp. 6–7. In *ServiceNow*, the Board denied institution, reasoning in part that a similar affidavit from Mr. Butler did not "make the critical link between the alleged identification of [the prior art reference] on the 'download page' and the exhibits relied upon in support of the asserted grounds." *ServiceNow*, slip op. at 14. The facts and evidence of *Service Now* are distinguishable from the present case. *ServiceNow* did not concern documents that were required by applicable laws and regulations to be published within a certain period of time. Nor did *ServiceNow* relate to documents that, according to agency guidance, are to be published on the same website that is noticed in the Federal Register, as corroborated by contemporaneous Internet Archive evidence. The evidence in the present case, moreover, goes beyond a discussion of the Internet Archive evidence discussed in the *ServiceNow* case, where the prior art documents at issue had not even been properly authenticated. *Id.* at slip op. at 14. Authentication of Exhibits 1004–1006 is not an issue here. Reply 6 (citing Paper 27).[17]

[17] Patent Owner's citation to *Coalition for Affordable Drugs III LLC, v. Jazz Pharms., Inc.*, Case IPR2015-01018, slip op. at 14–15 (PTAB Oct. 15, 2015) (Paper 17), is similarly unavailing. PO Resp. 11–12. The evidence and arguments presented in the *Coalition* case were different from the evidence and arguments presented here. In particular, we noted in the *Coalition* case that the Xyrem Advisory Committee Meeting transcript (Ex. 1003, here) did not appear as a link in the Internet Archive documents relied upon by petitioner in that case.

For the reasons given above, we find Petitioner's evidence sufficient to prove by a preponderance that Exhibits 1004–1006 were publicly accessible on the FDA's website not later than July 1, 2001.

2. Whether a POSA exercising reasonable diligence would have been capable of locating Exhibits 1003–1006

Petitioner, in reliance on Mr. Valuck's testimony, argues that a POSA would have been able to locate Exhibits 1003–1006 by exercising reasonable diligence, including being able to locate the Federal Register Notice for the Xyrem Advisory Committee Meeting and following the links. Pet. 14–15 (citing Ex. 1007 ¶ 42; Ex. 1015). Petitioner argues, in particular, that a POSA would have known to look in the Federal Register and on the FDA's website for information related to existing and proposed risk management programs. *Id.* (citing Ex. 1007 ¶ 42). Petitioner further argues that, because the FDA's website address (URL) was provided in the Federal Register Notice, Exhibits 1004–1006 would have been available to and readily located by a POSA more than one year prior to the '107 patent priority date. *Id*.

Patent owner argues that Petitioner's evidence does not establish that a POSA would have been motivated to look for the Federal Register Notice (Ex. 1015) or capable of finding it. PO Resp. 14–24. Patent Owner reasons that without access to the Federal Register Notice, a POSA would not have been able to access Exhibits 1003–1006. *Id.* at 14–15. Thus, Patent Owner argues that Petitioner has not established the public accessibility of Exhibits 1003–1006 by a preponderance of the evidence. *Id.*

We reiterate our analysis and findings in Section II.A., above, that a POSA includes a registered pharmacist with 3–5 years of relevant work experience, including familiarity with drug distribution procedures. A

POSA also may have a blend of computer science and pharmacy drug distribution knowledge and/or experience, including experience relating to computerized drug distribution systems. We agree with Petitioner that Patent Owner's argument truncates the definition of a POSA "to eliminate those individuals 'with a specific focus on drug distribution, safety, and abuse'—i.e., any ***interested persons,***" which is contrary to the applicable test for assessing public accessibility. Reply 8 (quoting PO Resp. 19); *see Bruckelmyer*, 445 F.3d at 1378 (Fed. Cir. 2006) ("A given reference is 'publicly accessible' 'upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons *interested and ordinarily skilled in the subject matter* or art exercising reasonable diligence, can locate it.'") (emphasis added).

We are not persuaded by Patent Owner's attack on Dr. Valuck's testimony (Ex. 2044, 79:25–83:4; Ex. 2045, 293:2–294:11, 337:1–338:20; 342:14–344:2), or by Dr. DiPiro's, Dr. Bergeron's, Dr. Van Buskirk's, Dr. Kirkwood's, or Dr. Holder's testimony, because Patent Owner applies an unsupported, unduly limiting definition of a POSA. PO Resp. 16–24 (citing Ex. 2046 ¶¶ 51, 53, 54, 55–58; Ex. 2047 ¶ 38; Ex. 2053 ¶ 5; Ex. 2054, 114:23–115:22, 139:9–17; Ex. 2056 ¶ 7). By definition, a POSA is someone interested in drug distribution, safety, and abuse. Patent Owner's own expert, Dr. DiPiro, implicitly acknowledges that a POSA who is focused on drug distribution, safety, and abuse prevention would have had reason to look to the Federal Register and FDA Advisory Committee meeting notices. Ex. 2046 ¶¶ 55–56; PO Resp. 19 (citing Ex. 2046 ¶ 55).

Dr. DiPiro also stated, under cross-examination, that he had no opinion as to whether an "interested" POSA would have consulted the

Federal Register for notices relevant to drug distribution, safety, and abuse. Ex. 1056, 293:1–17, 302:17–303:17. As noted above in our discussion of a POSA, by December 2001, a POSA would have known the active ingredient in Xyrem—sodium oxybate—was a sensitive drug susceptible to abuse and diversion, and such person would have known of several available techniques to control and mitigate the risks associated with Xyrem's distribution, thereby providing sufficient motivation to have located the Federal Register Notice and FDA website for Xyrem. Ex. 1007 ¶¶ 20–28, 42, 45; Ex. 2045, 293:2–294:11.

Thus, we find that a POSA would have known to look in the Federal Register and on the FDA's website for information related to existing and proposed risk management programs, such as the controlled distribution system for Xyrem. Ex. 1007 ¶ 42.

Patent Owner's further argument, that an interested POSA would not have been capable of finding the Federal Register Notice of the Xyrem Advisory Committee Meeting, is similarly unavailing. PO Resp. 21–24. The Federal Register provides notice to interested individuals of the actions of federal agencies. *See Aris Gloves, Inc v. United States,* 154 F. Supp. 203, 209 (Cust. Ct. 1957), *aff'd,* 281 F.2d 954 (C.C.P.A. 1958) ("Congress, by statutory enactment, has designated the 'Federal Register' as the official publication in which notices by departments of the Federal Government shall appear."). The Federal Register Notice for the Xyrem Advisory Committee Meeting stated that a "main focus of the deliberations will be on risk management issues" related to Xyrem, a subject of direct interest to a POSA as defined above. Ex. 1007 ¶ 42 (quoting Ex. 1015). The Federal Advisory Committee Act requires that an advisory committee meeting notice

"shall be published in the Federal Register" and that "[i]nterested persons shall be permitted to attend" such meetings. 5 U.S.C. app 2 § 10(a)(2)-(3). Courts have consistently held that "[a]s a general rule, 'publication in the Federal Register is legally sufficient notice to all interested or affected persons.'" *Williams v. Mukasey*, 531 F.3d 1040, 1042 (9th Cir. 2008) (citation omitted). Patent Owner does not provide persuasive countervailing evidence or argument that an interested POSA would have been incapable of locating the Federal Register Notice for the Xyrem Advisory Committee Meeting.

For the reasons given above, we find that Petitioner has shown by a preponderance of the evidence that Exhibits 1003–1006 were publicly accessible to an interested POSA exercising reasonable diligence more than one year before the December 17, 2002 priority date of the '107 patent. Thus, we proceed to consider Petitioner's unpatentability grounds.

D. Asserted Obviousness of claims 1–6 of the '107 Patent over the Advisory Committee Art (Exs. 1003–1006)

Petitioner contends that the subject matter of claims 1–6 of the '107 patent would have been obvious over the ACA (Exhibits 1003–1006) because the ACA is a public disclosure of the proposed risk management system for Xyrem—the same system covered by the '107 patent. Pet. 16–36; Reply 1. Petitioner relies on the Declaration testimony of Dr. Valuck in support of its argument that a POSA would have had reason to combine the ACA documents. *Id*. at 16–17 (citing Ex. 1007). Specifically, Petitioner asserts the Preliminary Clinical Safety Review (Ex. 1004), Briefing Booklet (Ex. 1005), and Xyrem Video and Transcript (Ex. 1006) were "all distributed *together* for a single meeting before the FDA seeking approval for prescription Xyrem®," and the FDA Advisory Committee Transcript and

Slides (Ex. 1003) "was a public transcript of the meeting itself." *Id*. at 16–17 (citing Ex. 1007 ¶ 45) (emphasis added). In addition, according to Petitioner, all four ACA documents "clearly relate to the same restricted distribution program, which the meeting was convened to discuss," and are "all linked from a single web page." *Id*. at 17.

We agree with Petitioner's analysis and determine 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 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.

Petitioner further relies on Dr. Valuck's Declaration testimony in support of its argument that all method steps recited in independent claim 1, identified as steps 1.1–1.6, are disclosed in the ACA. *Id.* at 17–34 (citing Ex. 1007 ¶¶ 45–75). Petitioner also cites to specific disclosures in the ACA and to Dr. Valuck's Declaration testimony in support of its argument that the method steps recited in claims 2–6 are disclosed in the ACA. *Id.* at 34–36 (citing Ex. 1003; Ex. 1004; Ex. 1005; Ex. 1006; Ex. 1007 ¶¶ 71–74, 76, 77, 79, 80, 83).

Dr. Valuck's Declaration outlines each step of the claims and provides reasons for his opinion that each limitation is disclosed in the ACA, referring to specific citations in the references. Dec. on Inst. 28–35. For example, with regard to step 1.1— "controlling with a computer processor the distribution of said prescription drug via an exclusive central pharmacy that maintains a central database that tracks all prescriptions . . . and analyzes for potential abuse situations" (Ex. 1001, 8:38–42)—Dr. Valuck describes

where each aspect of the claim limitation is found in the ACA. Ex. 1007 ¶¶ 24, 27, 52–56. Petitioner also points us directly to where the different portions of the ACA describe each aspect of step 1.1. Pet. 19–22 (citing Ex. 1003, 24:21–25, 177:24–178:11, 184:25–185:4; slides 146–147; Ex. 1004, 108, 110; Ex. 1005, cover letter, 300, 304; Ex. 1006, 4 n.14, 10 n.42).

In this regard, the Petition also cites to where the ACA refers to "one single national specialty pharmacy" that will handle distribution of Xyrem. Pet. 20 (citing Ex. 1003, 177:24–178:11; Ex. 1005, 306; Ex. 1007 ¶ 52). The Petition further points us to where Ex. 1003 "discloses that the exclusive central pharmacy maintains a central data repository that 'allows for identification of a number of unusual types of behavior, including any duplicate prescriptions, any attempts of overprescribing, or any attempts at over-use by patients.'" *Id*. (citing Ex. 1003, 184:25–185:4; Ex. 1007 ¶ 53). In addition, the Petition points us to where Ex. 1004 "discloses flagging for monitoring and documenting '[r]epeat instances of lost, stolen, destroyed, or spilled prescriptions/ supplies.'" *Id*. (citing Ex. 1004, 110; Ex. 1007 ¶ 53).

In relation to step 1.4 (Ex. 1001, 8:51–59), Petitioner points out that the ACA discloses registering "every patient and prescribing physician" in "a secure database" (Ex. 1004, 110; Ex. 1007 ¶ 65) and shows pharmacy staff receiving prescription requests and entering them into a computer (Ex. 1006, V7 00:00-00:16; Ex. 1007 ¶ 65). Pet. 25; *see also* Ex. 1006, 5 n.17 (referring to "Orphan personnel at computer screen"). Petitioner also points us to where the ACA discloses a system, used in relation to Xyrem® (having a form of GHB), that generates data by "recording prescribers, patients and dosing that could provide information for any possible investigations and

prosecutions for state and federal authorities." Pet. 26 (citing Ex. 1006, 4 n.13–14; Ex. 1007 ¶ 67).

In addition, Petitioner points to where the ACA describes that a database "can be queried to provide information such as '[p]rescriptions by physician specialty . . . by patient name . . . by volume (frequency) . . . [and] by dose.'" *Id*. (citing 1004, 110; Ex. 1007 ¶ 67). Petitioner further points to where the ACA discloses "using the central data repository to identify patterns of abuse and diversion." Pet. 26 (citing Ex. 1003, 184:24–185:7; slide 158; Ex. 1005, 306, 307, 311; Ex. 1007 ¶ 67). In addition, page 306 of the Briefing Booklet states that "database checks (AMA, NPD and State Medical Boards available on-line) will periodically occur to ensure that physician eligibility has not changed." Ex. 1005, 306; Pet. 26.

In relation to step 1.5, Petitioner further points us to where, for example, the ACA discloses "verifying the prescription," "obtaining patient information," and "verifying the physician is eligible to prescribe the prescription drug . . . ." Pet. 28–29 (citing Ex. 1003, Tr., 180:14–182:2, slides 152, 153; Ex. 1004, 109; Ex. 1005, 310; Ex. 1006, Tr., 6 n.21).

In its Response, Patent Owner contends that Petitioner fails to establish by a preponderance of the evidence that the ACA would have rendered the challenged claims obvious. PO Resp. 36–47. Specifically, Patent Owner contends that Petitioner has not shown sufficiently that the ACA discloses or suggests step 1.4 in relation to prescription "request data contain information identifying the patient" and "credentials of the medical doctor," or the recited "periodic reports." Patent Owner's argument is based, in part, on its proposed claim constructions, which we have rejected, above.

1. Step 1.4: "*[prescription] request data contain information identifying the patient, [GHB as] the drug prescribed, and credentials of the medical doctor*"

Patent Owner argues that the ACA does not disclose, teach, or suggest that "information identifying the patient" or "credentials" of the prescribing doctor are provided on a prescription, as recited in the challenged claims. PO Resp. 36–38. Patent Owner contends that the ACA discloses that such information is provided by other sources "that are not the prescription forms themselves." *Id*. at 38. Instead, in relation to the "prescriptions containing information identifying the patient" limitation, Patent Owner argues that the ACA discloses that "information identifying the patient" is provided by (1) a telephone call to the physician after the prescription is received, or (2) a registry application completed by the patient. *Id*. at 38–39 (citing Ex. 1005, 310; Ex. 1004, 114; Ex. 1003, 181:18–22; Ex. 2046 ¶¶ 62–65).

In this regard, Patent Owner point us to page 310 of the Briefing Booklet (Ex. 1005) in the ACA material. PO Resp. 38. On this page, the ACA describes that "a physician . . . will write a prescription for Xyrem and fax it to the specialty pharmacy." Ex. 1005, 310 ¶ 4. After receiving the prescription, "the specialty pharmacy will contact the physician's office to confirm patient information," as a vehicle to "'catch' any prescriptions written on stolen or counterfeit prescription pads." *Id.* at 310 ¶ 5. The same paragraph on this page also states that "[d]uring the call, the patient's name, social security number, telephone number and insurance information will also be obtained." *Id*.

Notably, on this page, the ACA indicates that the "specialty pharmacy," i.e., a "single, central pharmacy" (Ex. 1005, 306, 308), "*confirm[s]*" patient information, for example during a call to the

prescribing doctor's office. *Id*. at 310 ¶ 5 (emphasis added). Thus, the Briefing Booklet in the ACA at least suggests, if not discloses, that the central pharmacy obtained patient information previously, i.e., information from the prescription faxed by the physician that the central pharmacy later confirms during the call. Even assuming the pharmacy obtains additional information during the call, the ACA at least suggests that the central pharmacy already has at least some patient information, as obtained from the prescription itself, and as recited in the challenged claims, before making the call.

Patent Owner also points us to a particular page in the Preliminary Clinical Safety Review (Ex. 1004) of the ACA in relation to a "registry application." PO Resp. 38–39 (citing Ex.1004, 114). The cited section of the ACA indicates that a "patient registry application" (Ex. 1004, 114) is part of "Printed Materials" provided in a binder to a patient (*id.* at 113), which a patient reads after watching a "draft video 'story-board' prepared by the sponsor" (*id.*), as part of the "Xyrem® Patient Success Program" (*id.*). Ex. 1004, 111–114. That material is shipped to the patient along with the prescription drug itself, i.e., after the first prescription is sent initially to the pharmacy. Ex. 1004, 109. We are not persuaded that the ACA teaches or suggests, however, that the closed-loop distribution system (Ex. 1004, 108–110; Ex. 1005, 304–311) obtains patient information only through the registry application from the Xyrem® Patient Success Program or when confirming patient information by contacting the doctor's office after the pharmacy receives the prescription, as Patent Owner suggests. PO Resp. 38–39.

Petitioner shows sufficiently that the ACA discloses, or at least suggests, that a pharmacist in the described closed-loop distribution system, upon receipt of a prescription, will "verify the prescription" and confirm information presented in the prescription, including patient information, by contacting the prescribing physician. *See, e.g.*, Ex. 1003, 181:1–22 (Advisory Committee Transcript, stating that "[w]hat [the central pharmacy] will do is when that prescription comes in they will call the prescribing physician's office to determine that, in fact, that patient is real and a prescription has, in fact, been written for that patient"); *id*. at slide 153 (stating that the specialty pharmacy will "Verify the Rx"), Ex. 1004, 109–110; Ex. 1005, 310; Pet. 21; Ex. 1007 ¶¶ 58–59; Reply 22. Thus, Petitioner sufficiently establishes that the centralized pharmacy described in the ACA at least suggests receiving "request data contain information identifying the patient," as recited in the challenged claims.

In relation to the "request data contain information identifying . . . credentials of the medical doctor" limitation, Patent Owner contends that the ACA discloses that "credentials" information would be obtained from: (1) Orphan Medical pre-screening efforts before the launch of Xyrem; (2) a telephone call to the physician after the prescription is received; (3) a registry application completed by the patient; or (4) external DEA databases and state medical boards. PO Resp. 39–41 (citing Ex. 1005, 306, 310; Ex. 1006, 6 n.21, Ex. 1004, 109, 114, Ex. 1003, 181:4–14, slide 152; Ex. 2046 ¶¶ 66–72). According to Patent Owner, the prescriptions themselves would not be the source of such information, as required in the challenged claims. *Id*. at 42.

The ACA discloses, however, that the centralized "specialty" pharmacy "*verifies* [a] physician is 'eligible' to prescribe Xyrem" by looking at credentials, such as "MD licensure" and "[c]urrent CIII prescribing privileges" on a DEA database, after the physician "faxes a special Rx to Specialty Pharmacy." Ex. 1003, slides 146, 151, 152 (emphasis added); Pet. 29; Ex. 1007 ¶¶ 55–56. The ACA also discloses that "[u]pon receipt of a prescription," the pharmacy in the closed-loop distribution system identifies the prescribing physician's "name, license and DEA registration," and "then verif[ies] that the physician is eligible to prescribe Xyrem®." Ex. 1004, 109; Ex. 1005, 310; Ex. 1003, 181:1–14; Pet. 26–27, 28 (citing Ex. 1007 ¶ 67).

In view of evidence in this regard, Petitioner sufficiently establishes that the ACA at least suggests that the centralized pharmacy receives information regarding two or more different credentials of the prescribing physician from the prescription itself, which the pharmacy then verifies by looking at certain databases or information elsewhere. Thus, Petitioner sufficiently establishes that the ACA at least suggests that the centralized pharmacy described in the ACA receives "request data contain information identifying . . . credentials of the medical doctor," as recited in the challenged claims and construed above. Pet. 26–28; *see also KSR*, 550 U.S. at 418 (stating that 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."); *In re Bell*, 991 F.2d 781, 785 (Fed. Cir. 1993) (noting that "a reference must be considered not only for what it

expressly teaches, but also for what it fairly suggests." (quoting *In re Burckel*, 592 F.2d 1175, 1179 (CCPA 1979))).

2. Step 1.4: "*determining with the computer processor . . . patterns of potential prescription abuse of said prescription drug from periodic reports generated only by the central database based on prescription request data"*

Patent Owner argues that the ACA does not disclose, teach, or suggest "periodic reports generated only by the central database based on prescription request data," as recited in the challenged claims. PO Resp. 41–47. Patent Owner contends that the ACA "does not disclose that reports to evaluate diversion are generated: (1) periodically, i.e., at regular frequencies or intervals, as opposed to intermittently or upon request; and (2) by using the central database." *Id*. at 42 (citing Ex. 2046 ¶¶ 72, 73, 75–78; Ex. 2047 ¶¶ 39–47).

Both Petitioner and Patent Owner point to certain portions of the ACA in relation to this limitation. For example, both point to pages 306–308 of the Briefing Booklet (Ex. 1005). Pet. 25–27; PO Resp. 42–44. Page 306 of the Briefing Booklet, for example, discloses checking or searching certain external databases to determine if prescribing physicians are licensed to prescribe controlled substances. Ex. 1005, 306 ¶ 3. Patent Owner argues that this disclosure refers to querying external databases, not the exclusive computer database, as required in the claims. PO Resp. 43.

Page 306 of the Briefing Booklet further discloses, however, 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 also 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 the prescribing physicians, including patients who attempt to duplicate prescriptions. *Id*. at 307 ¶¶ 4–5; *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").

In addition, 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 Preliminary Clinical 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. 25–27), at least suggest generating reports of relevant data collected by the exclusive central computer system itself in the central pharmacy system, not just querying external databases, as Patent Owner argues (PO Resp. 42–44). We also find that Petitioner establishes sufficiently that those disclosures suggest using such reports to determine patterns of potential prescription abuse, misuse, or diversion. Pet. 25–27 (citing and discussing, for example, Ex. 1005, 306, 307, 311, and Ex. 1004, 110).

In its Response, Patent Owner also relies on its claim construction of "periodic reports" when arguing that reports generated "upon request" or "ad hoc," as taught in the ACA, are not "periodic reports." PO Resp. 44–47. As noted above, however, we construe "periodic reports" to refer to reports that are generated at regular intervals *or* intermittently, i.e., now and again. That construction includes reports that are generated "upon request" or "ad hoc," as they correspond to reports generated intermittently or now and again.

Patent Owner acknowledges that the ACA "discloses generating retrospective reports to aid in diversion investigations," but contends that such disclosures "would not have disclosed, taught, or suggested the claimed prospective reports to evaluate potential diversion patterns." PO Resp. 45–46. 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." Pet. 26; Ex. 1005, 311 ¶ 5 (emphasis added). That disclosure, in combination with other teachings in the Briefing Booklet and elsewhere in the ACA, indicate 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.

Based on the complete record before us, we find that Petitioner establishes by a preponderance of the evidence that the ACA suggests, if not discloses, an exclusive central pharmacy that controls the distribution of a sensitive drug, such as GHB, by "determining with the computer processor . . . patterns of potential prescription abuse of said prescription drug from

periodic reports generated only by the central database based on prescription request data," as recited in step 1.4 of challenged claims. Pet. 25–27; *see also KSR*, 550 U.S. at 418; *In re Bell*, 991 F.2d at 785.

3. *Other steps recited in challenged claims 1–6*

Based on our review of the complete record, we find that all limitations and steps of independent claim 1 were suggested or disclosed in the ACA, and Petitioner establishes by a preponderance of the evidence that the subject matter of claim 1 would have been obvious over the ACA. Pet. 17–34 (addressing steps 1.1–1.5 in claim 1).

We also find, in relation to claims 2–6, that Petitioner's analysis regarding claim 1 equally applies, and that the ACA discloses all aspects of the other claims that differ from claim 1. For example, in relation to claim 4, Petitioner contends that this claim is similar to claim 1 except that it recites "gamma hydroxy butyrate" in place of "prescription drug" in claim 1. Pet. 34. Petitioner points to where the ACA discloses "the use of sodium oxybate (another name for gamma hydroxyl butyrate)." *Id*. (citing Ex. 1005, cover letter, Ex. 1007 ¶ 77).

Regarding dependent claims 2 and 5, we agree with Petitioner that those claims "are merely a verbatim subset of the controls recited in claim 1," which the ACA discloses. *Id*. at 34–35 (citing Ex. 1007 ¶¶ 71–74, 79, 80). Regarding dependent claims 3 and 6, we also find that the ACA discloses consulting a separate database to verify eligibility of the medical doctors, as recited in those claims. *Id*. at 35–36 (citing Ex. 1003, slide 152; Ex.1004, 109; Ex. 1005, 310; AMN1007 ¶ 83).

In addition, as discussed above, we find that a POSA would have had reason to combine teachings in the ACA material, not least of which because

Exhibits 1004–1006 were distributed at the same public meeting held in preparation for FDA approval of Xyrem®, and Exhibit 1003 is a copy of a transcript and slides from that meeting.

With the exception of certain limitations recited in step 1.4 (or corresponding steps in similar claims), which we discussed above, Patent Owner does not otherwise challenge Petitioner's arguments and evidence in support of its obviousness analysis. PO Resp. 37– 49. Thus, to the extent not stated expressly above, we adopt Petitioner's arguments and evidence in support of our findings that the ACA discloses, or at least suggests, the remaining steps recited in claim 1 and claims 2–6 of the '107 patent.

4. *Conclusion*

For the reasons discussed above, Petitioner has established by a preponderance of the evidence that the subject matter of claims 1–6 would have been obvious over the ACA.

III. PETITIONER'S MOTION TO EXCLUDE EVIDENCE

Petitioner moves to allow late filing of evidentiary objections (37 C.F.R. § 42.5(c)), a necessary predicate to consideration of Petitioner's motion to exclude portions of Exhibits 2046 (¶¶ 51–58) and 2047 (¶¶ 37–39), and to exclude Exhibits 2049, 2050, 2054, and 2057. *See* 37 C.F.R. § 42.64(b), (c); Paper 56 ("Motion to Exclude"); Paper 58 ("Motion to Allow Late Filing of Evidence Objections"). We need not consider Petitioner's motions in view of our decision regarding whether a POSA would have been capable of locating the Federal Register Notice (Ex. 1015), set forth in Section II.C.2., above, the issue to which the objected-to exhibits are addressed. Therefore, Petitioner's motions are dismissed as moot.

IV. NOTICE REGARDING NEW ARGUMENTS AND EVIDENCE IN PETITIONER'S REPLY

Patent Owner filed a "Notice Regarding New Arguments and Evidence in Petitioner's Reply," and Petitioner filed a Response. Paper 52; Paper 53. Patent Owner contends that Petitioner's Reply arguments regarding public accessibility, and related citations to Exhibit 1003 (pages 12, 179, 284, 330, and 342), Exhibit 1017, and Exhibit 1057, were raised for the first time in the Reply. Paper 52. Petitioner responds that its Reply arguments and evidence identified by Patent Owner were a direct rebuttal to arguments raised by Patent Owner in its Response. Paper 53.

First, we do not rely on Exhibit 1017 in support of this Decision. Second, Exhibit 1003 was filed in support of the Petition and cited throughout the Petition, including with respect to the issue of public accessibility. Pet. 10–15. Third, particularly regarding Exhibit 1057 (FDA Guidance document) the mere fact that a petitioner submits rebuttal arguments and evidence not previously identified in the petition does not automatically suffice to establish their impropriety. The very nature of a reply is to rebut the patent owner's response. 37 C.F.R. § 42.23(b).

As Patent Owner's Notice states, Exhibit 1057 was first submitted in support of Petitioner's Reply but it "relates to previously submitted evidence," specifically Exhibits 1004 and 1005. Paper 52, 1; Paper 53, 1. Exhibit 1057 was submitted in direct response to Patent Owner's challenge to the evidentiary weight to be given the redactions in Exhibits 1004 and the public disclosure legend on the cover of Exhibit 1005, in support of Petitioner's argument of public accessibility of those two documents. *See* Pet. 13–15; PO Resp. 9–12; Reply 2–4.

Patent Owner, therefore, was on notice and responded to Petitioner's argument and evidence on the issue of whether Exhibits 1004 and 1005 were publicly accessible prior to the '107 patent priority date. *See Genzyme Therapeutic Prods. Ltd. v. Biomarin Pharm. Inc.*, Nos. 2015–1720, 2015–1721, 2016 WL 3254734 at *4–5 (Fed. Cir. June 14, 2016) ("The purpose of the trial in an *inter partes* review proceeding is to give the parties an opportunity to build a record by introducing evidence—not simply to weigh evidence of which the Board is already aware. The critical question . . . is whether [patent owner] received 'adequate notice of the issues that would be considered, and ultimately resolved, at that hearing.'" (citation omitted)).

Thus, we determine that Petitioner's reliance on the identified arguments and evidence was directly responsive to arguments raised in the Patent Owner Response challenging the evidentiary weight to be given Exhibits 1004 and 1005 on the issue of public accessibility, and accordingly, have given appropriate consideration to the identified arguments and evidence.

V. CONCLUSION

Taking account of the arguments and evidence presented during trial, we determine that Petitioner establishes by a preponderance of the evidence that claims 1–6 of the '107 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over the ACA.

VI. ORDER

For the foregoing reasons, it is

ORDERED that claims 1–6 of the '107 patent are unpatentable;

FURTHER ORDERED that Petitioner's Motion to Allow Late Filing of Evidence Objections and Motion to Exclude are dismissed as moot; and

FURTHER ORDERED that, because this is a Final Written Decision, 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.

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