

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 IPR2015-00548  
Patent 7,895,059 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 1–16 of U.S. Patent No. 7,895,059 B2 (Ex. 1001, “the ’059 patent”). Paper 1 (“Petition” or “Pet.”). Jazz Pharmaceuticals, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 9. As authorized (Paper 10), 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 16/17). Upon considering those submissions, we instituted *inter partes* review of claims 1–16 of the ’059 patent based on an obviousness ground. Paper 19 (“Dec. on Inst.”).

After institution, Patent Owner filed a Response (Paper 40, “PO Resp.”), and Petitioner filed a Reply (Paper 47, “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. 11, 18. 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, 26–35, 38–60. 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 55, “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 62) and an Opposition to Petitioner’s Motion to Allow Late Filing of Evidence Objections (Paper 60). 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 51), to which Petitioner filed a Response (Paper 52).

A combined oral hearing in this proceeding and Cases IPR2015-00545, IPR2015-00546, IPR2015-00547, IPR2015-00551, and IPR2015-00554 was held on April 19, 2016; a transcript of the hearing is included in the record (Paper 68, “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 1–16 of the ’059 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 1–16 are obvious over Advisory Committee Art (Exs. 1003–1006, collectively called “the ACA”),

including FDA Advisory Committee Transcript and Slides (Ex. 1003),<sup>1</sup> Preliminary Clinical Safety Review (Ex. 1004),<sup>2</sup> Briefing Booklet (Ex. 1005),<sup>3</sup> and Xyrem Video and Transcript (Ex. 1006).<sup>4</sup> Pet. 1, 11–39, 54–58.

*B. Related Proceedings*

The parties identify the following as related district court proceedings regarding the '059 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. 58–59; Paper 7, 1–2.

The parties also identify the following cases as involving Petitions for *inter partes* review of patents related to the '059 patent: IPR2015-00545 (Patent 8,589,182 B1); IPR2015-00546 (Patent 7,765,106 B2); IPR2015-

---

<sup>1</sup> FDA Peripheral & Central Nervous System Drugs Advisory Committee, Transcript and Slides (June 6, 2001) (“Advisory Committee Transcript and Slides”) (Ex. 1003).

<sup>2</sup> 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).

<sup>3</sup> 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).

<sup>4</sup> 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).

IPR2015-00548  
Patent 7,895,059 B2

00547 (Patent 7,765,107 B2); IPR2015-00551 (Patent 8,457,988 B1); and IPR2015-00554 (Patent 7,668,730 B2). Pet. 59; Paper 7, 2.

The parties also identify the following as Petitions for covered business method patent review (“CBM”) regarding the ’059 patent and related patents: CBM2014-00149 (the ’059 patent); 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 (Patent 7,765,107 B2). Pet. 59; Paper 7, 2. The Board has denied institution in all six of the above-mentioned CBM cases. We also denied a Petition filed by different petitioner for *inter partes* review of the same claims in the ’059 patent in IPR2015-01018.

In addition, a different Petitioner, Wockhardt Bio AG (“Petitioner Wockhardt”), filed a Petition for *inter partes* review of the ’059 patent in IPR2015-01816, 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 38 (granting institution and Petitioner Wockhardt’s Motion for Joinder in IPR2015-01816, in relation to the ’059 patent). After the oral hearing took place, however, upon the parties’ joint request (Paper 65), 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 66). Paper 67.

Patent Owner identifies the following pending U.S. patent applications claiming priority benefit from U.S. Patent Application No.

10/322,348, which the '059 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 7, 3.

*C. The '059 Patent*

The '059 patent, titled “Sensitive Drug Distribution System and Method,” issued February 22, 2011, from a continuation application of an application filed December 17, 2002. Ex. 1001. The '059 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.

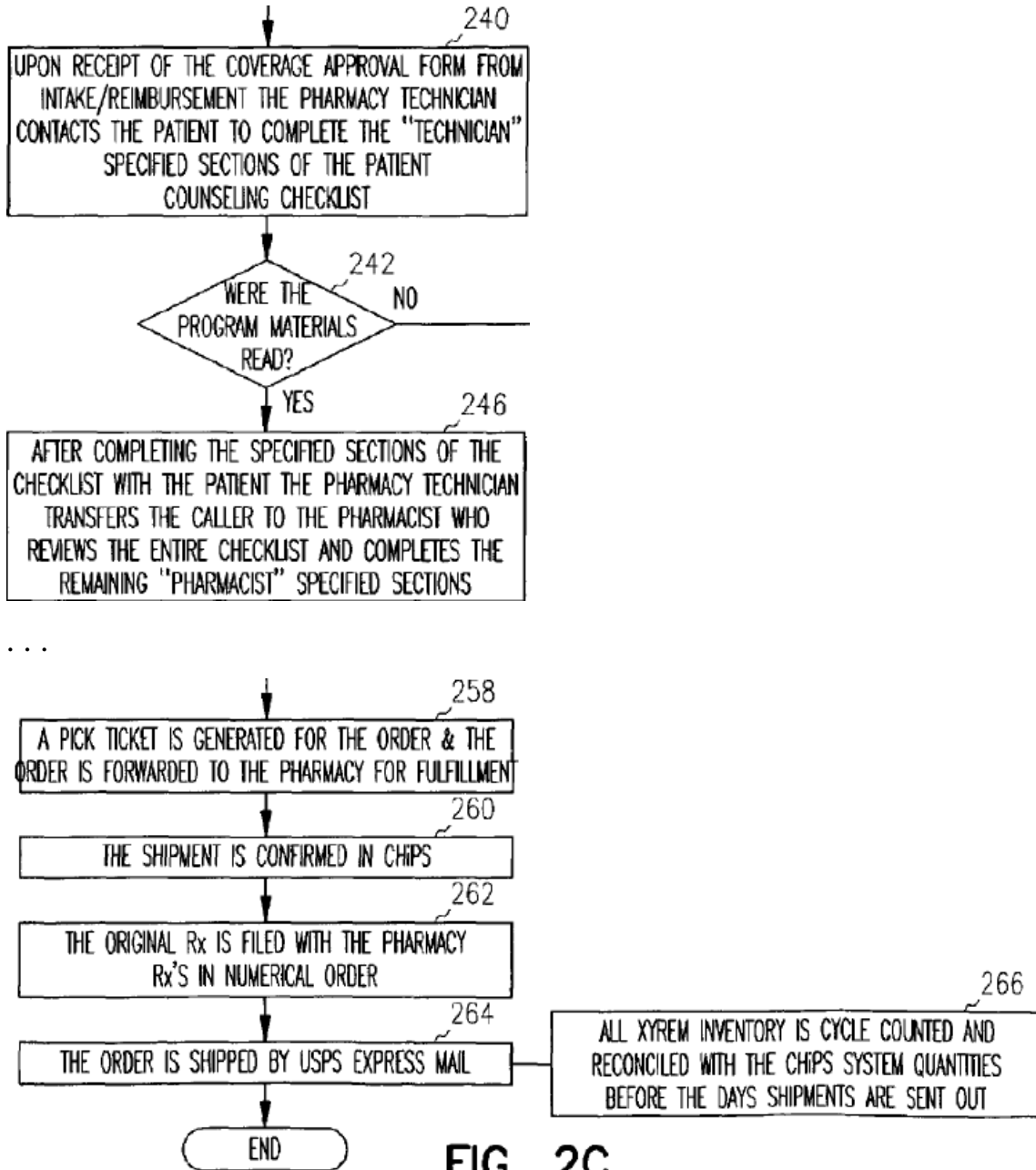


FIG. 2C

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®.”<sup>5</sup> *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 ’059 patent contains six independent claims (1, 6, 9, 12, 13, 14) and ten dependent claims (2–5, 7, 8, 10, 11, 15, 16), of which claim 1 is illustrative and reproduced below:

1. *A computerized method of distributing a prescription drug under exclusive control of an exclusive central pharmacy, the method comprising:*

*receiving in a computer processor all prescription requests, for any and all patients being prescribed the prescription drug, only at the exclusive central pharmacy from any and all medical doctors allowed to prescribe the prescription drug, the prescription requests containing information identifying patients, the prescription drug, and various credentials of the any and all medical doctors;*

*requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations, such that all prescriptions for the prescription drug are processed only by the exclusive central pharmacy using only the exclusive computer database;*

*checking with the computer processor the credentials of the any and all doctors to determine the eligibility of the doctors to prescribe the prescription drug;*

---

<sup>5</sup> 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.*



*confirming with a patient that educational material has been received and/or read prior to shipping the prescription drug;*  
*checking the exclusive computer database for potential abuse of the prescription drug;*  
*mailing or sending by courier the prescription drug to the patient only if no potential abuse is found by the patient to whom the prescription drug is prescribed and the doctor prescribing the prescription drug;*  
confirming receipt by the patient of the prescription drug; and  
*generating with the computer processor periodic reports via the exclusive computer database to evaluate potential diversion patterns.*

Ex. 1001, 8:37–9:3 (emphases added). Dependent claims 7, 10, and 15, which depend from independent claims 6, 9, and 14, respectively (which are similar to claim 1), recite that providing the prescription drug to the patient “comprises the central pharmacy authorizing the prescription drug to be dispensed to the patient by another pharmacy.” *See, e.g., id.* at 9:52–54 (claim 6). Dependent claims 8, 11, and 16 of the ’059 patent recite certain “controls,” such as “confirming with the patient that the educational material has been received and/or read by the patient, confirming receipt of the prescription drug by the patient.” *See, e.g., id.* at 9:56–66 (claim 8).

## 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. 17 (citing Ex. 1007 ¶ 48).

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. 14–23. 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 ’059 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, 1:10–27. 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 '059 patent priority date. Pet. 3–7; *see also* Ex. 1001, Related Application, 1:6–9 (indicating earliest priority date for the '059 patent).

Xyrem<sup>®</sup> 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<sup>®</sup>, Clozaril<sup>®</sup>, 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<sup>®</sup>, 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<sup>®</sup>, 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.* at 4–5 (citing Ex. 1007 ¶ 23).

In 1999, the manufacturers of thalidomide developed a system that combined the computerized registry of Clozaril<sup>®</sup> with the controls imposed by the Accutane<sup>®</sup> 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<sup>®</sup>—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 2–3 (citing Ex. 1007 ¶¶ 21, 47); 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. 17–18. 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 ’059 patent, and with prior art of record, such as Talk About Sleep (Ex.1033),<sup>6</sup> Honigfeld (Ex. 1034),<sup>7</sup> Elsayed (Ex. 1035),<sup>8</sup> and Lilly (Ex. 1036)<sup>9</sup>. *See Okajima v.*

---

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

<sup>7</sup> 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).

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

<sup>9</sup> Lilly et al., U.S. Patent Appl. Pub. No. 2004/0176985, filed Mar. 18, 2004, published Sept. 9, 2004 (“Lilly”) (Ex. 1036).

*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 '059 patent recites a method of “computerized method of distributing a prescription drug under exclusive control of an exclusive central pharmacy” by: (1.1) “receiving in a computer processor all prescription requests . . . only at the exclusive central pharmacy; (1.2) “requiring entering of the information into an exclusive computer database associated with the exclusive central pharmacy for analysis of potential abuse situations;” (1.3) “checking . . . the credentials of the any and all doctors;” (1.4) “confirming . . . that educational material has been received and/or read;” (1.5) “checking the exclusive computer database for potential abuse;” (1.6) “mailing or sending . . . the prescription drug to the patient only if no potential abuse is found;” (1.7) “confirming receipt by the patient;” and (1.8) “generating with the computer processor periodic reports via the exclusive computer database to evaluate potential diversion patterns.” Ex. 1001, 8:37–9:3. The claim as a whole recites controlling

distribution of a prescription drug to patients to guard against potential abuse and unauthorized diversion.

Both Petitioner and Patent Owner present constructions for several claim terms. Pet. 9–11; PO Resp. 23–35; Reply 12–18. We discuss the different terms in turn below.

1. “*exclusive central pharmacy*,” “*exclusive computer database*” and “*the central pharmacy authorizing the prescription drug to be dispensed to the patient by another pharmacy*”

In our Decision on Institution, we construed “exclusive central pharmacy” to mean “single or sole pharmacy,” and we construed “exclusive computer database” to mean “single or sole computer database.” Dec. on Inst. 20.

We also construed the phrase “the central pharmacy authorizing the prescription drug to be dispensed to the patient by another pharmacy” in dependent claims 7, 10, and 15 to mean “the exclusive central pharmacy may authorize another pharmacy to prepare and give the prescription drug to a patient.” *Id.* at 22–23.

Our constructions are consistent with those proposed by Petitioner, and Patent Owner takes no position regarding Petitioner’s arguments in this regard. Pet. 9–11; 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 those interpretation.

2. “*generating with the computer processor periodic reports via the exclusive computer database [to evaluate potential diversion patterns]*”

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. 10 (citing Ex. 1001, 2:19–21). Figure 7 of the ’059 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 “determining current and anticipated patterns of potential prescription abuse, misuse, or diversion,” 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 6:36–42, 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 “generating with the computer processor periodic reports via the exclusive computer database to evaluate potential diversion patterns” to mean “querying the exclusive computer database via the computer processor to generate periodic reports containing prescriber, patient, and/or prescription related information

that permits evaluation of potential abuse, misuse, or diversion 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 26–27 (citing Ex. 2046 ¶¶ 31–39; Ex. 2047 ¶¶ 29–36). In support, Patent Owner points to the specification of the ’059 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, 8:22–29.

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. 27 (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 ¶¶ 34, 38; Ex. 2047 ¶¶ 32, 35, 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 ¶ 37; Ex. 2047 ¶ 34).

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 ¶ 34 (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 ¶ 32 (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 ’059 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 ’059 patent limits “periodic reports” to those generated only at regular intervals, as Patent Owner contends. PO Resp. 25–28. 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. *“the prescription requests [for GHB] containing information identifying patients”*

Patent Owner construes that the phrase “prescription requests [for GHB] containing information identifying patients” 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. 29–32 (citing Ex. 2046 ¶¶ 40–45; Ex. 1001, 4:13–28, 8:4–5, 40–44, 10:4–7; Ex. 2044, 97:11–98:5, 99:18–100:10). For example, Patent Owner contends that the specification of the ’059 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 30–31 (citing Ex. 1001, 4:26–28, 8:4–5; Ex. 2044, 99:18–100:10, 97:11–23).

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 ’059 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), but is not limited to that information nor requires all of that information.

4. *“the prescription requests [for GHB] containing information identifying . . . various credentials of the any and all [medical doctors/authorized prescribers]”*

Patent Owner construes the phrase “prescription requests [for GHB] containing information identifying . . . various credentials of the any and all [medical doctors/authorized prescribers]” to mean, “at a minimum: the prescription requests [for GHB] containing the prescriber’s name, license

number, DEA number, and physician specialty.” PO Resp. 33–35 (citing Ex. 2046 ¶¶ 46–50; Ex. 1001, 4:14–26, 8:4–5, 40–44, 10:4–7; Ex. 2044, 181:1–23). For example, Patent Owner contends that the ’059 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, 40–44, 10:4–7, 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 ¶ 48).

As Patent Owner points out, the specification of the ’059 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 “various 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 “various 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 “prescriber’s doctor’s name, license number, DEA number, and physician specialty,” as proposed by Patent Owner (PO Resp. 33), means that a prescription fails to contain information regarding “various credentials,” as recited in the claims.

We construe prescription “the prescription requests [for GHB] containing information identifying . . . various credentials of the any and all [medical doctors/authorized prescribers]” to refer to information identifying various credentials, i.e., at least two different types of credentials, of the authorized prescriber, 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), 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 ’059 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. 12–17. 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. 3–23.

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<sup>®</sup> (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. 14–15 (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: ’059 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. 16–17 (citing Ex. 1015; Ex. 1007 ¶ 48); 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. 14 (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 14–15 and n.2 (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. 16–17; *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.<sup>10</sup> The Internet Archive evidence further shows that links for the transcript pages, presentation slides, and meeting minutes were posted on the FDA website not later than October 4, 2001. Pet. 16–17 (citing Ex. 1020, 8; Ex. 1028); Ex. 1020, 9.<sup>11</sup> The meeting transcript file links are identified as

---

<sup>10</sup> 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.

<sup>11</sup> 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.

“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 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; *see* 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. 15–16. 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”).<sup>12</sup>

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. 14–15 (citing Ex. 1005). The cover letter states that “Xyrem safety, efficacy, pharmacokinetics, abuse pharmacology, scheduling and risk management

---

<sup>12</sup> 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.

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.<sup>13</sup> 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 practice. Pet. 14–15; 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. 16 (citing Ex. 1018, 5).<sup>14</sup>

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

---

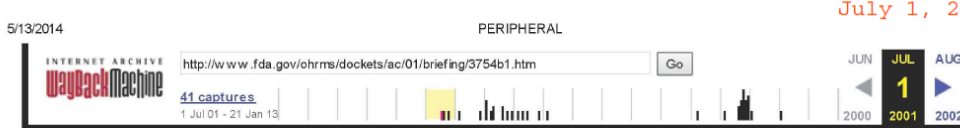
<sup>13</sup> Petitioner has submitted Exhibit 1006 in fifteen parts, comprising fourteen parts of the video and the transcript of the entire video. All citations to Ex. 1006 are citations to the transcript (“Exhibit 1006 Xyrem Video Transcript”).

<sup>14</sup> 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.

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:

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  
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. 16 (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 ’059 patent priority date. *Id.* at 6–9. 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 4–5, 9–14. 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 ’059 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<sup>15</sup>). 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

---

<sup>15</sup> Our citations are to the internal numbering of the document, consistent with Petitioner’s citations.

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 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.<sup>16</sup> 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

---

<sup>16</sup> The 3754 code is consistent with the code used for other Xyrem Advisory Committee documents, as discussed above in subsection II.C.1.b.



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. 6–9. 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 '059 priority date: 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.*, 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 22).<sup>17</sup>

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. 16–17 (citing Ex. 1007 ¶ 48; 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 ¶ 48). 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 ’059 patent priority date. *Id.*

---

<sup>17</sup> 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. 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.

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. 14–23. 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. 15–23 (citing Ex. 2046 ¶¶ 52, 54–58; Ex. 2047 ¶ 39; 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, 48; 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 ¶ 48.

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. 21–23.

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 ¶ 48 (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 ’059 patent. Thus, we proceed to consider Petitioner’s unpatentability grounds.

*D. Asserted Obviousness of claims 1–16 of the '059 Patent over the Advisory Committee Art (Exs. 1003–1006)*

Petitioner contends that the subject matter of claims 1–16 of the '059 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 '059 patent. Pet. 18–39; 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 18 (citing Ex. 1007). Specifically, Petitioner asserts that 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 FDA Advisory Committee Transcript and Slides (Ex. 1003) “were a public transcript of and presentation given at the meeting itself.” *Id.* at 18 (citing Ex. 1007 ¶ 52). 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 18–19.

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 the preamble and all method steps recited in independent claim 1, identified as steps 1.1–1.8, are disclosed in the ACA.

*Id.* at 20–32 (citing Ex. 1007 ¶¶ 53–85). 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 2–16 are disclosed in the ACA. *Id.* at 32–39 (citing Ex. 1003; Ex. 1004; Ex. 1005; Ex. 1006; Ex. 1007).

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. 29–36. For example, with regard to step 1.1 (Ex. 1001, 8:39–47), Dr. Valuck describes where each aspect of the claim limitation is found in the ACA. Ex. 1007 ¶¶ 24, 55, 58–62. Petitioner also points us directly to where the different portions of the ACA describe each aspect of step 1.1. Pet. 24–27 (citing Ex. 1003, 180:6–16, 181:1–22, slides 151–153; Ex. 1004, 109; Ex. 1005, 306, 310, Ex. 1006, 5 n.20, 6 n.21, n.24; Ex. 1007 ¶¶ 58, 59). For instance, the Petition cites to where the ACA refers to a “single, central pharmacy” that receives all prescription forms for Xyrem<sup>®</sup>. Ex. 1005, 306, 310; Pet. 24–25 (citing Ex. 1005, 306, 310; Ex. 1003, 180:6–16, slide 151, 146; Ex. 1006, 5 n.20, 10 n.42; Ex. 1007 ¶ 58).

The Petition also contains citations to the ACA and Dr. Valuck’s Declaration to support Petitioner’s argument that a person of ordinary skill in the art would have known that the “unique prescribing forms” described in the ACA would have included the information recited in step 1.1. Pet. 24–25. Petitioner further contends that an ordinary artisan would have understood the prescribing forms disclosed in the ACA to be “synonymous with the claimed prescription requests” that identify patients, the drug, and credentials of the medical doctors from those requests. *Id.* at 24–25 (citing



Ex. 1003, 181:1–10, slide 152; Ex. 1004, 109 (“Databank which contains current information about the authority of individual physicians to prescribe controlled substances”); Ex. 1005, 310 (specialized pharmacy collects “data such as patient names and medication dose”); Ex. 1006, 6 n.21 (“specialty pharmacy first verifies if the prescribing physician is on Orphan Medical’s list of targeted physicians and has active DEA and State License”); Ex. 1007 ¶¶ 58, 59).

In relation to step 1.4 (Ex. 1001, 8:57–59), Petitioner cites evidence indicating that ACA “describes modifying the distribution system to confirm with a patient that educational material has been received and/or read prior to shipping the prescription drug.” *Id.* (citing Ex. 1003, 371:10–12, 374:7–20; Ex. 1004, 115; Ex. 1007 ¶ 72).

In relation to step 1.8 (Ex. 1001, 9:1–3), Petitioner points to where the ACA discloses “using the central data repository to identify patterns of abuse and diversion.” Pet. 31 (citing Ex. 1003, 184:24–185:7; slide 158; Ex. 1005, 306, 307, 311; Ex. 1007 ¶ 82). Petitioner further points us to Page 306 of the Briefing Booklet, which 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. 31.

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. Patent Owner contends that Petitioner has not shown sufficiently that the ACA discloses or suggests step 1.1 in relation to the “prescription requests [for GHB] containing information identifying patients” and “various credentials of the

any and all [medical doctors/authorized prescribers],” or step 1.8 in relation to the recited “periodic reports.” PO Resp. 36.

In addition, Patent Owner argues that Petitioner has not established sufficiently that the ACA discloses or suggests step 1.4 in relation to “confirming with a patient that educational material has been received and/or read prior to shipping the prescription drug.” *Id.* Patent Owner also argues that Petitioner has not established sufficiently that the ACA discloses or suggests that a “another pharmacy places controls on the distribution of the prescription drug,” as recited in dependent claims 8, 11, 16, which depend from dependent claims 7, 10, and 15, which depend from independent claims 6, 9, and 14. *Id.*

Patent Owner’s argument is based, in part, on its proposed claim constructions, which we have rejected, above.

1. Step 1.1: “*prescription requests containing information identifying patients, . . . and various credentials of the any and all medical doctors [or authorized prescribers]*”

Patent Owner argues that the ACA does not disclose, teach, or suggest that “information identifying patients” or “various credentials” of the authorized prescribers are provided on a prescription, as recited in the challenged claims. PO Resp. 37–39. Patent Owner contends that the ACA discloses that such information is provided by other sources “are not the prescription requests themselves.” *Id.* at 38.

Instead, in relation to the “prescription requests containing information identifying patients” limitation, for example, 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 ¶¶ 61–66)

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. 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 “prescription requests for GHB containing information identifying patients,” as recited in the challenged claims.

In relation to the “prescription requests containing . . . various credentials of the any and all medical doctors [or authorized prescribers]” limitation, Patent Owner contends that the ACA discloses that “various 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 ¶¶ 67–72). According to Patent Owner, the prescriptions themselves would not be the source of such information, as required in the challenged claims. *Id.* at 41.

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. 24–25; Ex. 1007 ¶¶ 58–62. 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. 24–28 (citing Ex. 1007 ¶¶ 59, 60, 66).

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 “prescription requests containing . . . various credentials of the any and all medical doctors [or authorized prescribers],” as recited in the challenged claims and construed above. Pet. 24–27; *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 1.8: “*generating with the computer processor periodic reports via the exclusive computer database to evaluate potential diversion patterns*”

Patent Owner argues that the ACA does not disclose, teach, or suggest “generating with the computer processor periodic reports via the exclusive computer database,” as recited in the challenged claims. PO Resp. 42–47. 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 ¶¶ 73, 74, 76–79; Ex. 2047 ¶¶ 40–48).

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. 24–27; 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. 24–27), 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. 24–27 (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. 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. 27; 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 discloses an exclusive central pharmacy that controls the distribution of a sensitive drug, such as GHB, by “generating with the computer processor periodic reports via the exclusive computer database to evaluate potential diversion patterns,” as recited in step 1.8 of challenged claims. Pet. 24–27; *see also* *KSR*, 550 U.S. at 418; *In re Bell*, 991 F.2d at 785.

3. Step 1.4: “*confirming with a patient that educational material has been received and/or read prior to shipping the prescription drug*”

Patent Owner argues that Petitioner has not established sufficiently that the ACA discloses or suggests step 1.4 in relation to “confirming with a patient that educational material has been received and/or read prior to shipping the prescription drug.” Pet. 36, 51–60. According to Patent Owner, “in the system proposed by Orphan Medical in the ACA, confirmation that the patient received and/or read educational materials could only occur *after, not prior*, to shipping/providing the prescription drug/GHB.” *Id.* at 51.

Patent Owner further contends that Petitioner has not shown sufficiently that:

a POSA would have been motivated to modify the risk management system proposed by Orphan Medical in the ACA to require “confirming with a patient that [GHB] educational material has been received and/or read *prior* to [shipping/providing the prescription drug/GHB],” instead of *after*, with a reasonable expectation of success.

*Id.* at 36. Patent Owner argues that the Petition “is silent on this necessary proof,” and it “is only in ¶ 72 of Dr. Valuck’s declaration that an alleged motivation could arguably be found.” *Id.* at 53.

In addition to paragraph 72 Dr. Valuck’s declaration, however, Petitioner points us to other evidence in support of its position that the ACA “describes modifying the distribution system to confirm with a patient that educational material has been received and/or read prior to shipping the prescription drug.” Pet. 19 (citing Ex. 1003, Tr., 371:10–12, 374:7–20; Ex. 1004, 115; Ex. 1007 ¶72). For example, as acknowledge by Patent Owner, in the Advisory Committee Transcript and Slides (Ex. 1003), the Advisory Committee addressed questions as to whether patients should sign an informed consent form, or return a registry form, before receiving an initial shipment of the drug. Ex. 1003, Tr., 371:10–12, 374:7–20; Pet. 29; PO Resp. 53–54. Patent Owner contends that the cited disclosures “are merely *questions* from the Advisory Committee Meeting attendees,” and that Petitioner has not established those attendees are POSAs. PO Resp. 53. Patent Owner also argues that responses to those questions in the transcript would have led a POSA to understand that requiring confirmation that the educational material is received and/or read prior to shipping the prescription drug/GHB would not have been “preferred.” *Id.* at 54–56.

We disagree with Patent Owner’s inference that members of the Advisory Committee were not POSAs, i.e., people interested in the

distribution, safety, and abuse of a sensitive drug. Testimony of the Advisory Committee members cited by Patent Owner (PO Resp. 53–56 (citing Ex. 1003)) indicates that the members were interested in, and discussed at length, the distribution, safety, and abuse of Xyrem<sup>®</sup>.

In addition, even assuming the Advisory Committee, as disclosed in the ACA, indicated a preference for one course of action over another, that disclosure does not dictate that a less “preferred” option is not obvious. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) (stating that a “reference does not teach away . . . if it merely expresses a general preference for an alternative invention but does not ‘criticize, discredit, or otherwise discourage’ investigation into the invention claimed” (quoting *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)); Reply 24. We are not persuaded that testimony of Advisory Committee members, as cited by Patent Owner (PO Resp. 53–56 (citing Ex. 1003)), criticizes, discredits, or otherwise discourages providing educational materials regarding Xyrem<sup>®</sup> before shipping the drug to a patient. We agree with Petitioner that by asking questions on this point, the Advisory Committee suggested at least some value in taking that course of action. Reply 24.

Contrary to Patent Owner’s arguments, the FDA Advisory Committee expressly considered the alternative of confirming that the patient has read the Xyrem educational material prior to shipping the first prescription. The FDA reviewers specifically listed as an additional “Risk Management Recommendation[.]” to the drug sponsor to include: “Obtaining the patient’s signed confirmation that he/she fully understands how GHB is to be used prior to the first prescription being mailed.” Ex. 1004, 115 (14.4); *see also*

Ex. 1007 ¶ 72 (quoting the same passage); Pet. 29 (citing Ex. 1004, 115). We are satisfied that the ACA discloses a process step to a POSA for confirming that a patient has read the Xyrem educational material prior to shipping the first dose of a potentially dangerous drug. Ex. 1007 ¶ 72.

We also find that the teachings in the ACA identified by Petitioner and discussed by Dr. Valuck suggest, if not teach expressly, the step of confirming with a patient that educational materials were received and/or read prior to shipping Xyrem<sup>®</sup>. Pet. 29 (citing (Ex. 1003, Tr., 371:10–12. 374:7–20; Ex. 1004, 115; Ex. 1007 ¶ 72). Both parties agree that the ACA teaches sending the Xyrem<sup>®</sup> educational material (“Xyrem Patient Success Program”) with their first shipment of Xyrem, consistent with the “preferred” course of action noted by Patent Owner. Pet. 29 (citing Ex. 1003, 182:3–8); PO Resp. 51 (citing Ex. 1003 at 182:3–8, slide 157; Ex. 1006, 8–9 n.34–n.37, V10 at 00:05-00:40), *id.* at 54–56 (addressing what some Committee members indicated was “preferred”), 58. Disclosures in the Preliminary Clinical Safety Review (Ex. 1004, 115), as discussed above, especially in view of the questions raised by the Advisory Committee, sufficiently suggest or teach as an alternative, and establish that a POSA would have had reason, to confirm with a patient that educational material had been received and/or read *prior* to shipping Xyrem. *See, e.g.*, Ex. 1003, Tr., 374:7–20 (raising the idea of patients signing a form confirming that they “read the materials” “before they even got the first dose”).

Patent Owner does not persuade us otherwise by arguing that “the ACA discloses to a POSA that the ‘registry *information*’ in Ex. 1004 is not the same as the educational based ‘registry *form*’ discussed in Ex. 1003.” PO Resp. 54 n.17. Patent Owner’s arguments in this regard do not address

the teachings in the Preliminary Clinical Safety Review (Ex. 1004, 115) discussed above, regardless of any distinction between “registry information” and a “registry form.” Nor are we persuaded otherwise by Patent Owner’s assertions regarding Dr. Valuck’s testimony regarding his alleged “process” of analyzing the ACA prior art, as this testimony and argument also fail to address the teachings in the Preliminary Clinical Safety Review (Ex. 1004, 115) discussed above. PO Resp. 59–60 (quoting Ex. 2044, 198:6–22).

Based on the complete record before us, we find Petitioner establishes by a preponderance of the evidence that the ACA discloses a method of distributing a prescription drug that comprises “confirming with a patient that educational material has been received and/or read prior to shipping the prescription drug,” as recited in step 1.4 of challenged claims. Pet. 29; *see also KSR*, 550 U.S. at 418; *In re Bell*, 991 F.2d at 785.

4. Dependent claims 8, 11, 16: “*another pharmacy places controls on the distribution of the prescription drug*”

In relation to the above-quoted limitation recited in dependent claims 8, 11, and 16, Petitioner contends that the ACA “explicitly discloses shipping the prescription GHB from the exclusive central pharmacy to another pharmacy for patient pick-up. Pet. 36–37 (citing Ex. 1004, 110; Ex. 1007 ¶ 102). In addition, Petitioner points us to where the ACA “envision[s] that mechanisms will be put in place to ‘verify[] the second pharmacy’s ability to protect against diversion of GHB before shipping.’” *Id.*

Patent Owner argues that the ACA “discloses to a POSA that any controls on abuse, misuse, and diversion are always employed by *only* the central pharmacy.” PO Resp. 48 (citing Ex. 2046 ¶¶ 86–87). According to Patent Owner, Petitioner “admits this.” *Id.* (citing Pet. 38 (citing Ex. 1003,

184:10–15, 371:10–12, slide 157; Ex. 1004, 109, 110, 115; Ex. 1006, 7 n.26, 9 n. 35; Ex. 1007 ¶ 105)).

We do not agree that Petitioner “admits” that “any controls on abuse, misuse, and diversion are always employed by *only* the central pharmacy.” *Id.* Rather, Petitioner agrees with Patent Owner that the ACA teaches that relevant controls are employed by the central pharmacy, but further contends that a “POSA would have understood that the ACA discloses placing the same controls on the distribution of the prescription drug by the ‘another pharmacy.’” Pet. 38 (citing Ex. 1007 ¶ 105). Petitioner further argues that “[s]uch controls placed on the ‘another pharmacy’ would be in line with the ACA’s express goals of preventing abuse and diversion.” *Id.* (citing Ex. 1003, 184:24–185:7, slides 158–159; Ex. 1005, 304, 305, and 311; Ex. 1006, Tr., 8 n.29, 9 n.38; Ex. 1007 ¶ 105).

Patent Owner acknowledges that the ACA discloses that Xyrem® “may be shipped . . . to another pharmacy for patient pick-up” and that the ACA discusses “a mechanism for verifying the second pharmacy’s ability to protect against diversion of GHB before shipping the drug there.” Ex. 1004, 110; PO Resp. 49; Pet. 36. Patent Owner argues that this reference to “another pharmacy” is “as a mere waypoint for the distribution” of the drug, and that the disclosures in relation to “verifying” “make[] clear” that controls are maintained by the central pharmacy, and fails to disclose or suggest that the other pharmacy would have any relevant controls. PO Resp. 49–50 (citing Ex. 2046 ¶¶ 89–91).

Upon review of the cited disclosures in the ACA by both parties (e.g., Ex. 1004, 110), we find that Petitioner establishes sufficiently that the ACA at least suggests that a second pharmacy, i.e., “another pharmacy” as

expressly disclosed in the ACA, could be involved in the distribution process and, in that situation, the central pharmacy would verify that the other pharmacy places controls on drug distribution, using at least some of the same controls used by the central pharmacy and recited in claims 8, 11, and 16.

Even if the central pharmacy continues to engage in relevant controls on its own behalf, we are persuaded that the ACA sufficiently suggests that “another pharmacy” also would need and use similar controls regarding distribution of the drug. Ex. 1004, 110. We are persuaded that such controls regarding the disclosed “another pharmacy” would be “in line with the ACA’s express goals of preventing abuse and diversion,” as Petitioner argues. Pet. 38.

We are not persuaded by Patent Owner’s argument that placing controls on “another pharmacy” would “conflict[] with the ‘benefit’ described in the ACA” because “the controls would then be in two or more places.” PO Resp. 50 (citing Ex. 2046 ¶¶ 92–93). We find that the ACA at least suggests that placing controls in more than one place in the “unusual occurrence” that use of another pharmacy is required by the patient’s insurance company. Ex. 1004, 110.

Based on the complete record before us, we find Petitioner establishes by a preponderance of the evidence that the ACA at least suggests a computerized method where “another pharmacy places controls on the distribution of the prescription drug,” as recited in dependent claims 8, 11, and 16. Pet. 38–39; *see also* *KSR*, 550 U.S. at 418; *In re Bell*, 991 F.2d at 785.

*5. Other steps recited in challenged claims 1–16*

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 the subject matter of claim 1 would have been obvious over the ACA. Pet. 18–32 (addressing steps 1.1–1.8 in claim 1).

We also find, in relation to claims 2–16, 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, regarding dependent claims 2–7, 9, 10, and 12–15, we find that the ACA discloses the features recited in those claims. Pet. 32–37. 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<sup>®</sup>, and Exhibit 1003 is a copy of a transcript and slides from that meeting.

With the exception of certain limitations recited in steps 1.1, 1.4, and 1.8 (or corresponding steps in similar claims) and claims 8, 11, and 16, which we discussed above, Patent Owner does not otherwise challenge Petitioner’s arguments and evidence in support of its obviousness analysis. PO Resp. 36–60. 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 2–16 of the ’059 patent.



### 6. *Conclusion*

For the reasons discussed above, Petitioner has established by a preponderance of the evidence that the subject matter of claims 1–16 of the '059 patent 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 55 (“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 51; Paper 52. 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 51. 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 52.

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. 13–17. 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 51, 1; Paper 52, 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. 15–16; 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 ’059 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 1–16 of the '059 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 1–16 of the '059 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.

IPR2015-00548  
Patent 7,895,059 B2

FOR PETITIONERS:

Richard Berman  
[richard.berman@arenfox.com](mailto:richard.berman@arenfox.com)

Janine Carlan  
[janine.carlan@arenfox.com](mailto:janine.carlan@arenfox.com)

Bradford Frese  
[bradford.frese@arenfox.com](mailto:bradford.frese@arenfox.com)

FOR PATENT OWNER:

Francis Cerrito  
[nickcerrito@quinnemanuel.com](mailto:nickcerrito@quinnemanuel.com)

Evangeline Shih  
[evangelineshah@quinnemanuel.com](mailto:evangelineshah@quinnemanuel.com)

Frank C. Calvosa  
[frankcalvosa@quinnemanuel.com](mailto:frankcalvosa@quinnemanuel.com)

John Biernacki  
[jvbiernacki@jonesday.com](mailto:jvbiernacki@jonesday.com)