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Paper 70
Entered: July 27, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-00551 (Patent 8,457,988 B1)
Case IPR2015-00554 (Patent 7,668,730 B2)[1]

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

MURPHY, *Administrative Patent Judge*.

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

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[1] This Final Written Decision addresses common issues raised in both cases. The patents at issue in IPR2015-00551 and IPR2015-00554 are related, and the arguments by Petitioner and Patent Owner are largely the same in each case. Therefore, we issue one Final Written Decision to be entered in each case. The parties are not authorized to use this caption without prior authorization of the Board.

I. INTRODUCTION

Par Pharmaceutical, Inc. ("Par Inc."), and Amneal Pharmaceuticals, LLC ("Amneal") (together, "Petitioner") filed a Petition requesting an *inter partes* review of claims 1–11 (all claims) of U.S. Patent No. 7,668,730 B2 (Ex. 1001, "the '730 patent"). IPR2015-00554, Paper 1 ("Petition" or "Pet."). [2] Jazz Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10.[3] As authorized (Paper 11), Petitioner filed a response directed solely to real party in interest issues raised in the Preliminary Response (Paper 13), and Patent Owner filed a reply to that paper (Papers 17/18). Upon considering those submissions, we instituted *inter partes* review of claims 1–11 of the '730 patent and claims 1–15 of the '988 patent. Paper 20 ("Dec. on Inst.").

After institution, Patent Owner filed a Response (Paper 39, "PO Resp."), and Petitioner filed a Reply (Paper 46, "Reply"). Petitioner supports its challenge 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, 17–18. 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,

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[2] For clarity and expediency, we treat IPR2015-00554 as representative of both cases. All citations are to IPR2015-00554 unless otherwise noted.
[3] Petitioner also filed a Petition requesting an *inter partes* review of claims 1–15 (all claims) of U.S. Patent No. 8,457,988 B1 ("the '988 patent"). IPR2015-00551, Paper 1 ("the '551 Petition" or "'551 Pet."). Patent Owner filed a Preliminary Response to that Petition. IPR2015-00551, Paper 9.

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, 27–36, 39–49, 53–57. Patent Owner also presents a responsive Affidavit of Christopher Butler dated November 4, 2015 (Ex. 2052, "Butler Second Affidavit"). PO Resp. 8.

Petitioner filed a Motion to Exclude seeking to exclude certain evidence (Paper 54), along with a Motion to Allow Late Filing of Evidence Objections (Paper 57). Patent Owner filed an Opposition to Petitioner's Motion to Exclude (Paper 61) and an Opposition to Petitioner's Motion to Allow Late Filing of Evidence Objections (Paper 59). Petitioner filed a Reply to Patent Owner's Opposition to the Motion to Exclude (Paper 63). In addition, Patent Owner filed a Notice Regarding New Arguments and Evidence in Petitioner's Reply (Paper 50), to which Petitioner filed a Response (Paper 51).

A combined oral hearing in Cases IPR2015-00545, IPR2015-00546, IPR2015-00547, IPR2015-00548, IPR2015-00551, and IPR2015-00554 was held on April 19, 2016; a transcript of the hearing is included in the record. (Paper 67, "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 Petitioner has shown by a preponderance of the evidence that claims 1–11 of the '730 patent and claims 1–15 of the '988 patent are unpatentable. We also dismiss Petitioner's Motions to Allow Late Filing of Objections and Motions to

Exclude as moot.

A. Ground of Unpatentability at Issue

Petitioner contends that claims 1–11 of the '730 patent and claims 1, 3–9, and 11–15 of the '988 patent are unpatentable under 35 U.S.C. § 103 as obvious over Advisory Committee Art (Exs. 1003–1006, collectively called "the ACA"), including the Food and Drug Administration ("FDA") Advisory Committee Transcript and Slides (Ex. 1003),[4] FDA Preliminary Clinical Safety Review (Ex. 1004),[5] Briefing Booklet (Ex. 1005),[6] and Xyrem Video and Transcript (Ex. 1006).[7] Pet. 1, 9–33, 56–58. Petitioner further contends that claims 2 and 10 of the '988 patent are unpatentable under 35 U.S.C. § 103 as obvious over the Advisory Committee Art in view of Korfhage.[8]

B. Related Proceedings

The parties identify the following as related district court proceedings:

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[4] FDA Peripheral & Central Nervous System Drugs Advisory Committee, Transcript and Slides (June 6, 2001) ("Advisory Committee Transcript and Slides") (Ex. 1003).

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

[6] 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).

[7] 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)

[8] Korfhage, Information Storage and Retrieval (John Wiley & Sons, Inc. 1997) ("Korfhage") (IPR2015-00551, Ex. 1037).

Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc., 2:10-cv-6108 (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, 2:13-cv-391(consolidated) (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Ranbaxy Laboratories Ltd.*, 2:14-cv-4467 (D.N.J.); and *Jazz Pharmaceuticals, Inc. v. Watson Laboratories, Inc.*, 2:14-cv-7757 (D.N.J). Pet. 58; Paper 8, 1. Patent Owner identifies two other district court proceedings: *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, 2:14-cv-3235 (D.N.J.) and *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, 2:14-cv-5139 (D.N.J.). Paper 8, 2.

The parties identify the following cases as involving petitions for *inter partes* review of patents related to the '730 and '988 patents: IPR2015-00545 (Patent 8,589,182); IPR2015-00546 (Patent 7,765,106); IPR2015-00547 (Patent 7,765,107); and IPR2015-00548 (Patent 7,895,059). Pet. 58–59; Paper 8, 2. The parties also identify the following cases as involving petitions for covered business method patent review regarding the '730, '988 and related patents: CBM2014-00149 (Patent 7,895,059); CBM2014-00150 (the '988 patent); CBM2014-00151 (the '730 patent); CBM2014-00153 (Patent 8,589,182); CBM2014-00161 (Patent 7,765,106); and CBM2014-00175 (Patent 7,765,107). Pet. 58; Paper 8, 2–3. The Board has denied institution in all six of the above-mentioned CBM cases.

In addition, a different Petitioner, Wockhardt Bio AG ("Petitioner Wockhardt"), filed petitions for *inter partes* review of the '730 and '988 patents in IPR2015-01818 and IPR2015-01814, respectively, as well as four additional petitions challenging claims in the other patents at issue in the related *inter partes* review proceedings 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 37 (granting institution and Petitioner Wockhardt's Motion for Joinder in IPR2015-01818, in relation to the '730 patent). After the oral hearing took place, however, upon the parties' joint request (Paper 64), 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 65). Paper 66.

C. The '730 Patent

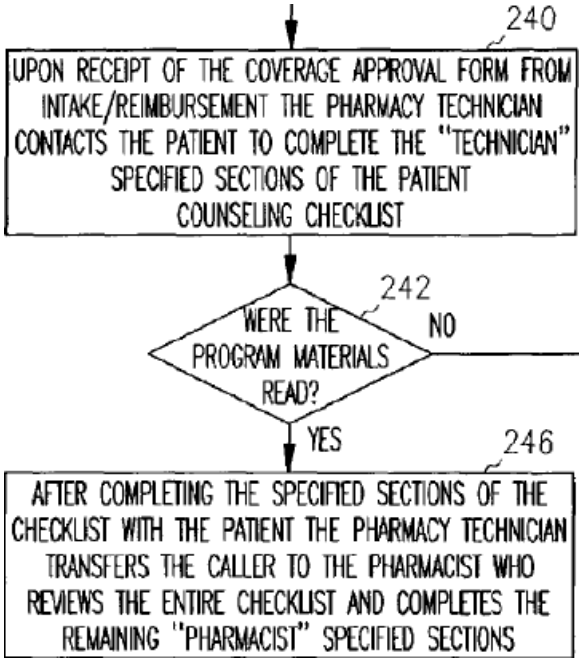
The '730 patent, titled "Sensitive Drug Distribution System and Method," issued February 23, 2010, from an application filed December 17, 2002. Ex. 1001.[9] The '730 patent is directed to a method for controlling access to a sensitive prescription drug prone to potential abuse or diversion, by utilizing a central pharmacy and database to track all prescriptions for the sensitive drug. *Id.* at Abstract, 1:38–42. 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, 1:42–44.

Figures 2A, 2B, and 2C comprise flow charts representing "an initial prescription order entry process for a sensitive drug." *Id.* at 4:7–8. 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 4:7–25, Fig. 2A (steps 202–

[9] The '730 patent issued from patent application US 10/322,348 ("the '348 application"). Ex. 1001.

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 4:26–28.

The pharmacy workflow includes verification of the prescribing physician's credentials. *Id.* at 5:9–26, 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 5:27–67. Steps 240, 242, 246, and 258–266 of Figure 2C are reproduced below.



. . .

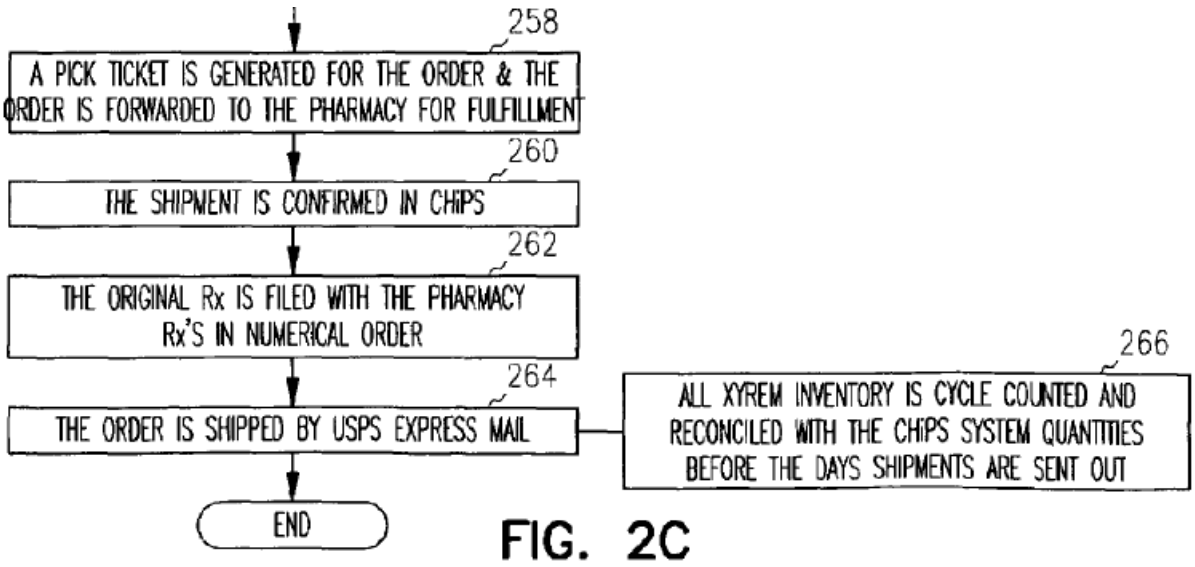


FIG. 2C

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®."[10] *Id.* at 4:28–33. 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 6:33–38, Fig. 4B (step 436). The '988 patent, which derives from the same priority application, contains the same disclosure as the '730 patent.

D. Illustrative Claim

The '730 patent contains multiple independent claims (1, 2, and 7–11) and several dependent claims (3–6), of which claim 1 is illustrative and reproduced below:

[10] Xyrem is the brand name for gamma hydroxy butyrate ("GHB"), indicated for the treatment of cataplexy (excessive daytime sleepiness) in narcoleptic patients. Ex. 1001, 3:14–19. Xyrem is a sensitive prescription drug prone to potential abuse or diversion. *Id.*

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;

confirming with a patient that educational material has been read prior to shipping the prescription drug;

checking the exclusive computer database for potential abuse of the prescription drug;

mailing 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.[11]

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, for example, including familiarity with drug distribution procedures." Pet. 2 (citing Ex. 1007 ¶ 20); *see also* Ex. 1007 ¶ 19 (Dr. Valuck stating that he "at least meet[s] the criteria of a POSA"). 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." Pet. 2–3. 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

[11] The preamble of the independent claims in the '988 patent recites a "method of treatment of a narcoleptic patient . . . while controlling potential misuse, abuse or diversion of said prescription drug, comprising . . . ." IPR2015-00551 Ex. 1001, 8:38–40. The method steps recited in the independent claims of the '988 patent, however, are very similar to the method steps recited in the independent claims of the '730 patent, such that the analysis concerning claim construction and the ACA grounds of challenge are very similar, if not identical, in the two proceedings.

programs. Pet. 17 (citing Ex. 1007 ¶ 47).In its Response, Patent Owner challenges the sufficiency of Petitioner's evidence that a POSA would have been familiar with the Federal Register and motivated to look for notices related to drug distribution, safety, or abuse prevention. PO Resp. 16–17. 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 '730 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 (54), 1:4–26. 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 '730 patent priority date. Pet. 3–6: Ex. 1001, filing date (22).

Xyrem is a sensitive prescription drug prone to potential abuse or diversion. Ex. 1001, 3:14–19. Prior to Xyrem, sensitive prescription drugs such as Accutane, Clozaril, and thalidomide were known to use controlled distribution systems to protect against potential side effects, abuse, and diversion. Pet. 4–5 (citing Ex. 1007 ¶¶ 21–24). Accutane, a prescription drug from the 1980s that could cause birth defects, was distributed under a program requiring i) informed consent forms completed by patient and physician, ii) patient counseling to avoid pregnancy and use of birth control, and iii) a negative blood serum test for pregnancy prior to beginning

treatment. *Id.* at 4 (citing Ex. 1007 ¶ 21). Distribution of Clozaril, indicated for treating schizophrenia but also capable of causing a fatal blood disorder, was controlled using a national registry system and computerized database for identifying patients and physicians. *Id.* at 4–5 (citing Ex. 1007 ¶ 22). In 1999, the manufacturers of thalidomide developed a system that combined the computerized registry of Clozaril with the controls imposed by the Accutane distribution system. *Id.* at 5 (citing Ex. 1007 ¶ 24). Based on such prior art activity, we find that by December 2002 a person of ordinary skill would have known the active ingredient in Xyrem – sodium oxybate – was a sensitive drug susceptible to abuse and diversion, and such person would have known of several available techniques to control and mitigate the risks associated with Xyrem's distribution. *Id.* at 3 (citing Ex. 1007 ¶ 20); Ex. 1007 ¶¶ 21–27, 47.

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. 20. Counsel for Patent Owner further argued that a person of ordinary skill would not have had an interest or "a focus on restricted distribution of products that don't even exist yet." Tr. 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 '730 patent, and with

prior art of record, such as Talk About Sleep (Ex.1033), Honigfeld (Ex. 1034), Elsayed (Ex. 1035), and Lilly (Ex. 1036). *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that the prior art itself can reflect the appropriate level of ordinary skill in the art).

B. Claim Construction

For *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the patent specification. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Claim terms are generally 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 in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Claim 1 of the '730 patent claims a method of "distributing a prescription drug" under "exclusive control" of an "exclusive central pharmacy." Ex. 1001, 8:38–40, 10:17–19. The claimed method recites receiving all prescription requests "only at the exclusive central pharmacy;" entering the physician, patient, and prescription information into an "exclusive computer database;" and utilizing a series of checks and controls to prevent "potential abuse" and "evaluate potential diversion patterns." *Id.* at 8:41–9:3. The series of checks and controls are claimed as follows: "entering . . . information . . . for analysis of potential abuse situations;" "checking . . . credentials . . . to determine the eligibility of the doctors to prescribe the prescription drug;" "checking . . . for potential abuse of the

prescription drug;" "mailing the prescription drug to the patient only if no potential abuse is found by the patient . . . and the doctor;" and "generating . . . periodic reports . . . to evaluate potential diversion patterns." *Id.* The claimed method steps correspond to portions of the intake, pharmacy, and prescription fulfillment workflows described in the patent. The claim as a whole recites a method for controlling access to a prescription drug to guard against potential abuse and unauthorized diversion.

Both Petitioner and Patent Owner present constructions for several claim terms. Pet. 9–11; PO Resp. 24–36; Reply 12–18. We discuss the different terms in turn below.

1. "*exclusive central pharmacy*" and "*exclusive computer database*"

In our Decision on Institution, we construed the term "exclusive central pharmacy" to mean "single or sole pharmacy," and the term "exclusive computer database" to mean "single or sole computer database." Dec. on Inst. 21. Our constructions are consistent with those proposed by Petitioner, and Patent Owner takes no position regarding Petitioner's arguments in this regard. Pet. 10; PO Resp. 25 n.8. Based on our review of the complete record, we do not perceive any reason or evidence that now compels any deviation from these interpretations.

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 (quoting Ex. 1001, 2:13–15). Figure 7 of the '730

patent reflects prescriber, patient, prescription, and insurance information input into the database, and Figures 13A–13C reflect various types of reports that may be generated, including reports regarding "pharmacy," "inventory," "reimbursement," "patient care," and "drug information." Ex. 1001, 7:41–48, 8:22–29, Figs. 7, 13A–C. A user generates reports by running various queries through the exclusive computer database to obtain information of the type illustrated. *Id.*

The recited use of the reports is "to evaluate potential diversion patterns," 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 1:24–29, 2:13–15. 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 6:33–39, Fig. 4B (406, 432, 434, 436). The ability of a pharmacist or other user to evaluate 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 diversion, misuse, or abuse of a prescription drug." Dec. on Inst. 22–23.

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. 26. 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 ¶¶ 30–38; Ex. 2047 ¶¶ 28–35). In support, Patent Owner points to the specification of the '730 patent, such as Figures 13A–C, and where the specification states "[e]ach report has an associated frequency or frequencies." *Id*. at 27; Ex. 1001, 8:26–27.

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 2:49–51 (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 refer only to reports obtained at regular frequencies or intervals, even if the term includes such reports.

Patent Owner also responds to testimony by Petitioner's expert, Dr. Valuck, who states that "periodic reports" can be generated on either "an ad hoc basis or on a regular basis." PO Resp. 28 (quoting Ex. 2044, 184:8–16). Patent Owner argues that a POSA "would understand that ad hoc reports are done for a particular purpose," and, therefore, a "POSA would not consider 'ad hoc' reports to be 'periodic.'" *Id*. at 28–29 (citing Ex. 2046 ¶¶ 33, 36; Ex. 2047 ¶¶ 31–33, 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. 28–29 (citing Ex. 2046 ¶ 36; Ex. 2047 ¶ 33).

We are not persuaded by Patent Owner's arguments or the testimony of Dr. DiPiro and Dr. Bergeron in support thereof. Patent Owner does not explain adequately why generating a report for a particular purpose or "ad hoc" precludes it from being a report generated periodically. *See, e.g.*, PO Resp. 28 (citing Ex. 2046 ¶ 33 (testimony by Dr. DiPiro stating that "POSA would not consider 'ad hoc' reports to be 'periodic' because they are not generated with any regular frequency."); Ex. 2047 ¶ 31 (testimony by Dr. Bergeron stating same). As noted above, the specification does not limit "periodic reports" to those generated with "regular frequency." Moreover, to the extent that Figure 4B in the '730 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, 6:9–7:2; Reply 13–14 (citing Ex. 1047, 6; Ex.1048, 9 (ll. 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. 28 (citing 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 '730 patent limits "periodic reports" to those generated only at regular intervals, as Patent Owner contends. PO Resp. 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 contends that the phrase "prescription requests [for GHB] containing information identifying patients" in the challenged claims means, "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. 30–33 (citing Ex. 2046 ¶¶ 39–44; Ex. 1001, 4:8–22, 8:4–5, 40–44, 10:20–23; Ex. 2044, 97:11–98:5, 99:18–100:10). For example, Patent Owner contends that the specification of the '730 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 31 (citing Ex. 1001, 4:20–22, 8:4–5; Ex. 2044, 97:11–23, 99:18–100:10).

Petitioner responds that "information identifying the patient" is not limited to the extent that it must include all of the specific information

identified by Patent Owner. Reply 15–17. Petitioner also argues that Patent Owner's construction improperly reads limitations as disclosed in Figure 9 into the claims. *Id*. We agree.

The specification of the '730 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 requests [for GHB] containing information identifying patients" 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. 30), 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 contends that "the prescription requests [for GHB] containing information identifying . . . various credentials of any and all [medical doctors/authorized prescribers]" means "at a minimum, the prescriber's contact information, license number, DEA number, and training

and certification information (physician specialty information)." PO Resp. 33–36 (citing Ex. 2046 ¶¶ 45–49; Ex. 1001, 4:8–14, 4:20–22, 8:4–5, 40–44, 10:20–23; Ex. 2044, 181:1–23). For example, Patent Owner contends that the '730 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 35 (citing Ex. 1001, 4:8–14, 4:20–22, 8:4–5, 40–44, 10:20–23, 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 36 (citing Ex. 2046 ¶ 47).

As Patent Owner points out, the specification of the '730 patent describes, in relation to the disclosed flowcharts presented in Figures 2A–C, that an enrollment form contains, *inter alia*, "prescriber information." Ex. 1001, 4:7–17. The specification also states that the "prescriber information contains standard contact information as well as license number, DEA number and physician specialty." *Id*. at 4:18–20.

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, 2:22–24, 4:7–8 (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 4:7–5:67 (describing the initial prescription order entry process of Figures 2A–C). Likewise, the specification does not define

"various credentials of the any and all medical doctors," 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 2:41–42, 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 "medical doctor's name, license number, DEA number, and physician specialty," as proposed by Patent Owner, means that a prescription fails to contain information regarding "various credentials," as recited in the claims.

We construe "the prescription requests [for GHB] containing information identifying . . . various credentials of 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 prescribing doctor, which may include the type of prescriber information described in relation to Figures 2A–C, presented in the enrollment form of Figure 9, and noted by Patent Owner (PO Resp. 34–35), 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 '730 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 prior to 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, 1311 (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, 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: '730 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. 17 (citing Ex. 1015; Ex. 1007 ¶ 47); 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. 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. The Federal Register Notice and Meeting Transcript

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 (quoting 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 n.2 (citing Case IPR2014-00059, slip op. at 34 (Apr. 15, 2014) (Paper 9) (in turn citing *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1988)); 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. 15–17; *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) (quoting *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.[12] 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;

[12] 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.

Ex. 1028); Ex. 1020, 9.[13] The meeting transcript file links are identified as "3754t1_01.pdf" (pages 1–100), "3754t1_02.pdf" (pages 101–200), "3754t1_03.pdf" (pages 201–300), "3754t1_04.pdf" (pages 301-381), and "3754t1.txt," respectively. Ex. 1020, 8. The meeting minutes file links are identified as "3754m1.pdf, html," and the presentation slides are identified as "3754s1.htm." *Id.* at 8–9. We note the links for the Xyrem Advisory Committee Meeting are all coded with the unique numerical identifier 3754 followed by a lower case letter to indicate the type of document, e.g., 3754t to indicate the transcript, 3754m to indicate the minutes, and 3754s to indicate the slides. *Id.*

Exhibit 1003 is comprised of 381 transcript pages, followed by the presentation slides, thus confirming the description of the Internet Archive file links (3754t) 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 (Apr. 15, 2014) (Paper 9) (citing *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1988)); 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

[13] The October 4, 2001 Internet Archive page contains a URL date code of "20011004" (Ex. 1020, 8–9). Ex. 1028 ¶ 5.

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 three weeks after the meeting, but were posted not later than October 4, 2001. Ex. 1018; Ex. 1020; Ex. 1028. Thus, the Federal Register Notice is consistent with the Internet Archive evidence. Petitioner further emphasizes that Patent Owner does not contest the sufficiency of the evidence establishing the public accessibility of Exhibit 1003 on the FDA's website as of October 4, 2001. Reply 2 n.2; Tr. 6:1–9; s*ee* PO Resp. 4–14.

Therefore, 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. 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").[14]

Exhibit 1005 comprises a three-page cover letter from Orphan Medical to the Xyrem Advisory Committee dated May 3, 2001, and the

[14] 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.

enclosed "Briefing Booklet" for the Advisory Committee Meeting. Pet. 15 (citing Ex. 1005). The cover letter states that "Xyrem safety, efficacy, pharmacokinetics, abuse pharmacology, scheduling and risk management are summarized in this booklet." Ex. 1005, 1 ¶ 3. The cover letter further references the inclusion of a "short 8-minute video on the prescription process, along with patient and physician education materials (the two binders)." *Id.* at 2 ¶ 5, 312. The Briefing Booklet itself says "AVAILABLE FOR PUBLIC DISCLOSURE WITHOUT REDACTION" on the cover. *Id.* at 4.

Exhibit 1006 is a video titled "Xyrem Prescription and Distribution Process," dated February 2, 2001, and transcript of the video.[15] Ex. 1006, 1.

d. Analysis: Public Accessibility of Exhibits 1004–1006

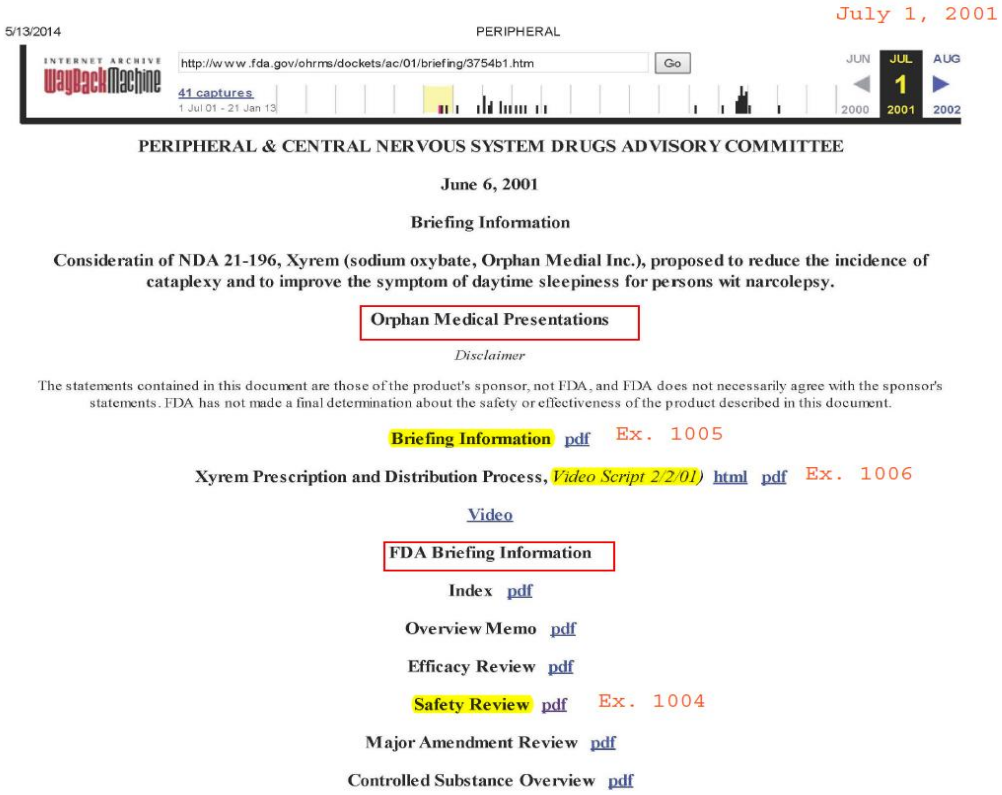
Petitioner argues that Exhibits 1004–1006 are the background material referenced in the Federal Register Notice (Ex. 1015), which would have been posted on the FDA's website approximately "24 hours before the meeting" in accordance with the Federal Advisory Committee Act and FDA practice. Pet. 14–15; 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).[16]

[15] 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").

[16] 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.

Petitioner further argues that "[f]ollowing this link from the 'Briefing Information' demonstrates that this art [Exs. 1004–1006] was all available on July 1, 2001, at the latest." *Id.* (citing Ex. 1019). Thus, Petitioner argues that clicking on the "Briefing Information" link of the FDA's website for the Xyrem Advisory Committee Meeting (Ex. 1018, 5 or Ex. 1020, 9) would have led a POSA to the web page of 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:



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," there is a pdf link to "Safety Review," asserted to be a link to Ex. 1004. *Id.*

Patent Owner contends Petitioner's evidence fails to prove, by a preponderance of the evidence, that Exhibits 1004–1006 qualify as publicly accessible printed publications. PO Resp. 4–5. 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, 1019] led to the ***documents*** that are Exs. 1004–1006" before the '730 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 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 '730 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 2–3 (citing Ex. 1057, 4[17]). 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 (quoting 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

[17] 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 8 ¶ 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.[18] 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

[18] 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 Butler Second Affidavit 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 '730 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 the Butler Third Affidavit, 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 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 institution decision in *ServiceNow, Inc. v. Hewlett-Packard Co.*, Case IPR2015-00707 (PTAB Aug. 26, 2015) (Paper 12) in support of its argument. PO Resp. 7–8. 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 (Aug. 26, 2015). The facts and evidence of *ServiceNow* 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 *14. Authentication of Exhibits 1004–1006 is not an issue here. Reply 6 (citing Paper 22).[19]

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 ¶ 47; 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.* at 17 (citing Ex. 1007 ¶ 47). Petitioner further argues that, because the FDA's website address (URL) was provided in the Federal Register Notice, Exhibits 1004–1006 were "indexed and accessible to persons of ordinary skill" more than one year prior to the '730 patent priority date. *Id.* at 15.

[19] 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 15. Therefore, 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. 20); *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), or by Dr. DiPiro's, Dr. Bergeron's, Dr. Van Buskirk's, Dr. Kirkwood's, or Dr. Holder's testimony, because Patent Owner applies an unsupported,

unduly limiting definition of a POSA. PO Resp. 16–18 (citing Ex. 2046 ¶¶ 52, 54, 55, 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. 18 (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 ¶¶ 20–27, 47; Ex. 2045, 293:2–294:11.

Therefore, 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 ¶ 47.

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 ¶ 47 (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 '730 patent. Therefore, we proceed to consider Petitioner's unpatentability grounds.

D. Asserted Obviousness of claims 1–11 of the '730 Patent and claims 1, 4–9, and 12–15 of the '988 Patent over the Advisory Committee Art (Exs. 1003–1006)

Petitioner contends that the subject matter of claims 1–11 (all claims) of the '730 patent (and claims 1, 4–9, and 12–15 of the '988 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 '730 and '988 patents. Pet. 18–38; Reply 1. Petitioner relies on the Declaration testimony of Dr. Valuck in support of its argument that a POSA would have had "ample" reason to combine the ACA documents because the documents were prepared for the Advisory Committee Meeting and "relate to the same restricted distribution program, which the meeting was convened to discuss." Pet. 19 (citing Ex. 1007 ¶ 51). Petitioner asserts, in particular, the Preliminary Clinical Safety Review (Ex. 1004), Briefing Booklet (Ex. 1005), and Xyrem Video and Transcript (Ex. 1006) were "all distributed *together* for a single meeting before the FDA seeking approval for prescription Xyrem®," and the FDA Advisory Committee Transcript and Slides (Ex. 1003) was "a public transcript of and presentation given at the meeting itself." *Id*. at 19 (citing Ex. 1007 ¶ 51) (emphasis added). In addition, according to Petitioner, all four ACA documents "clearly relate to the same restricted distribution program, which the meeting was convened to discuss," and are "all linked from a single [web] page." *Id*.

Patent Owner does not address directly the cited evidence in the context of motivation to combine the ACA. Patent Owner challenges the motivation of a POSA to confirm that a patient has read the Xyrem educational material prior to shipping the drug product to the patient (step

1.4), an issue we address below. PO Resp. 37, 49–59. 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 drug distribution system, were discussed together at the same Xyrem Advisory Committee Meeting, and were made available via file links from a single FDA web page.

Petitioner further relies on Dr. Valuck's Declaration testimony in support of its argument that all method steps recited in independent claim 1, identified as Steps 1.1–1.8, are disclosed in the ACA. *Id.* at 19–33 (citing Ex. 1007 ¶¶ 52–84). 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 2–11 are disclosed in the ACA. *Id.* at 33–38 (citing Ex. 1003; Ex. 1004; Ex. 1005; Ex. 1006; Ex. 1007 ¶¶ 81, 89, 90, 93–95, 97, 98). With regard to independent claims 7–11, Petitioner contends that the limitations are similar to those of claim 1 and the ACA discloses all limitations. *Id.* at 36–38. Petitioner contends that the differences in claim language "do not change how the ACA is applied to the claims." *Id.* at 36.

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. 31–36. For example, with regard to Step 1.1—

> 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

(Ex. 1001, 8:40–47)—Dr. Valuck describes where each aspect of the claim limitation is found in the ACA. Ex. 1007 ¶¶ 56–61. The claim chart for Step 1.1 appears in paragraph 61 of Dr. Valuck's Declaration, which supports his opinion, and the claim chart is in proper form. *Id.* ¶ 61. In addition, the Petition contains three pages of analysis with specific citations to the ACA and Dr. Valuck's Declaration in support of Petitioner's argument that Step 1.1 is disclosed in the ACA. Pet. 25–27.

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. 36–59. Specifically, Patent Owner contends that Petitioner has not shown sufficiently that the ACA discloses or suggests Step 1.1 in relation to "prescription requests containing information identifying patients" and "various credentials of the any and all medical doctors," Step 1.8 in relation to the recited "periodic reports," or Step 1.4 in relation to confirming a patient has read educational material "prior to shipping the prescription drug." Patent Owner's arguments are based, in part, on its proposed claim constructions, which we have rejected, above.

1. *Step 1.1: "receiving in a computer processor all prescription requests . . . the prescription requests containing information identifying patients, the prescription drug, and various credentials of the any and all medical doctors"*

The Petition 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 of the '730 patent. Pet. 25–26 (citing, *inter alia*, Ex. 1003, 180:6–181:22, 391–93

(Slides 151–53); Ex. 1004, 109; Ex. 1005, 306, 310; Ex. 1006, Tr. 5 n.20, 6 n.21, n.24; Ex. 1007 ¶¶ 57–59).

Patent Owner argues that the ACA does not disclose, teach, or suggest that "information identifying patients" or "information identifying . . . various credentials" of the medical doctors are provided on a prescription, as recited in the challenged claims. PO Resp. 37–38. Patent Owner contends that the ACA discloses that such information is provided by other sources "that are not the prescription requests themselves." *Id*. at 39. Patent Owner argues 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 39–40 (citing Ex. 1005, 310; Ex. 1004, 114; Ex. 1003, 181:18–22; Ex. 2046 ¶¶ 62–65).

In relation to the "prescription requests containing information identifying patients" limitation, both Petitioner and Patent Owner point us to page 310 of the Briefing Booklet (Ex. 1005) in the ACA material. Pet. 25; PO Resp. 39. 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 Preclinical Safety Review (Ex. 1004) of the ACA in relation to a "registry application." PO Resp. 40 (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. 40.

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. 25; Ex. 1007 ¶¶ 57–59; Reply 21. Thus, Petitioner sufficiently establishes that the centralized pharmacy described in the ACA at least suggests receiving "prescription requests containing information identifying patients," as recited in the challenged claims.

In relation to the "prescription requests containing information identifying . . . various credentials of the any and all medical doctors" 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. 40–42 (citing Ex. 1003, 181:4–14, slide 152; Ex. 1004, 109, 114; Ex. 1005, 306, 310; Ex. 1006, 6 n.21; Ex. 2046 ¶¶ 59–71). According to Patent Owner, the prescriptions themselves would not be the source of such information, as required in the challenged claims. *Id*. at 42.

The ACA discloses, however, that the centralized "specialty" pharmacy "*verifies* [a] physician is 'eligible' to prescribe Xyrem" by looking at credentials, such as "MD licensure" and "[c]urrent CIII prescribing privileges" on a DEA database, after the physician "faxes a special Rx to Specialty Pharmacy." Ex. 1003, slides 146, 151, 152 (emphasis added); Pet. 25; Ex. 1007 ¶¶ 58–59. 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. 25–26 (citing Ex. 1007 ¶¶ 58–59).

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 information identifying . . . various credentials of the medical doctor," as recited in the challenged claims and construed above. Pet. 25–26; *see also KSR*, 550 U.S. at 418 (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 . . . to evaluate potential diversion patterns"

Patent Owner argues the ACA does not disclose generation of "periodic reports" in accordance with Step 1.8. PO Resp. 43–48. 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 querying the exclusive computer database." *Id*. at 43 (citing Ex. 2046 ¶¶ 72, 73, 75–78; Ex. 2047 ¶¶ 39–47).

Both Petitioner and Patent Owner point to certain portions of the ACA in relation to this limitation. For example, both point to pages 306–308 of the Briefing Booklet (Ex. 1005). Pet. 32–33; PO Resp. 43–45. 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 associated with the exclusive central pharmacy, as required in the claims. PO Resp. 44.

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").

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

We find that such disclosures in the ACA, as identified and discussed by Petitioner (Pet. 32), at least suggest generating reports of relevant data collected by the exclusive central database associated with the exclusive central pharmacy, not just querying external databases, as Patent Owner argues (PO Resp. 43–45). 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. 32 (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. 46–48. 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. 47. As noted above, however, Petitioner points us to page 311 of the Briefing Booklet, which discloses that "centrally located real-time data collected by the specialty pharmacy will be invaluable to the identification of suspicious prescribing or use, *and* will aid appropriate state and federal investigation and prosecution" (Ex. 1005, 311 ¶ 5 (emphasis added)). Pet. 32 (citing Ex. 1005, 311 ¶ 5). 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 the Petitioner establishes by a preponderance of the evidence that the ACA discloses an exclusive central database associated with the exclusive central pharmacy that controls the distribution of a sensitive drug by "generating with the computer processor periodic reports . . . to evaluate potential diversion patterns," as recited in Step 1.8 of challenged claims. Pet. 32–33; *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 read prior to shipping [providing] the prescription drug [GHB]"

Patent Owner also argues that Step 1.4 is not satisfied because the ACA discloses delivering the Xyrem educational material to the patient with the patient's first prescription of Xyrem, rather than "prior to" shipping the first prescription. PO Resp. 49–59. 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 49.

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** shipping/providing the prescription drug/GHB, with a reasonable expectation of success.

Id. at 37. Patent Owner argues that the Petition "is silent on this necessary proof," and it "is only in ¶ 71 of Dr. Valuck's declaration that an alleged motivation could arguably be found." *Id*. at 51.

Petitioner acknowledges that Orphan Medical proposed a system where the patient reads the educational material after receiving the drug product. Pet. 30 (citing Ex. 1003, 182:3–8). Petitioner, however, cites additional evidence indicating the Xyrem Advisory Committee considered an alternative process. In addition to paragraph 71 of Dr. Valuck's declaration, Petitioner provides other evidence to support 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. 30 (citing Ex. 1003, 371:10–12, 374:7–20; Ex. 1004, 115; Ex. 1007 ¶71). 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. 30; PO Resp. 51–52. Patent Owner contends the cited disclosures "are merely ***questions*** from the Advisory Committee Meeting attendees," and that Petitioner has not established those attendees are POSAs. PO Resp. 52. 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 51–53.

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. 51–55 (citing Ex. 1003)) indicates that the members were interested in, and discussed at length, the distribution, safety, and abuse of Xyrem.

In addition, even assuming the Advisory Committee 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. 51–55 (citing Ex. 1003)), criticizes, discredits, or otherwise discourages providing educational materials regarding Xyrem 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 ¶ 71 (quoting the same passage). 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 ¶ 71.

We also find the portions of 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. Pet. 30 (citing (Ex. 1003, Tr., 371:10–12. 374:7–20; Ex. 1004, 115; Ex. 1007 ¶ 71). Both parties agree that the ACA teaches sending the Xyrem educational material ("Xyrem Patient Success Program") with their first shipment of Xyrem, consistent with the

"preferred" course of action noted by Patent Owner. Pet. 30 (citing Ex. 1003, 182:3–8); PO Resp. 49 (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 53–55 (addressing what some Committee members indicated was "preferred"). 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, 374:7–20 (raising the idea of patients signing a form confirming that they "read the materials" "before they even get 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. 52 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 critique of Dr. Valuck's testimony and his alleged "process" of analyzing the ACA prior art, because this testimony and argument fail to address the teachings in the Preliminary Clinical Safety Review (Ex. 1004, 115) discussed above. PO Resp. 57–58 (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. *See also KSR*, 550 U.S. at 418; *In re Bell*, 991 F.2d at 785.

4. Other steps recited in challenged claims

Based on our review of the complete record, we determine that Petitioner establishes by a preponderance of the evidence that all limitations and steps of independent claim 1 are disclosed, or at least suggested, in the ACA. Pet. 19–33 (addressing Steps 1.1–1.8 in claim 1). To the extent not expressly stated above, we adopt Petitioner's argument and evidence in support of such findings.

Petitioner also establishes by a preponderance of the evidence that, in relation to claims 2–11 (independent claims 2, 7–11), Petitioner's analysis regarding claim 1 equally applies and that the ACA discloses the aspects of those claims that differ from claim 1. Pet. 33–38. For example, we are persuaded that Petitioner establishes by a preponderance of the evidence that the ACA discloses the limitations recited in claims 2–6. Pet. 33–35 (citing Ex. 1003, 177:24–178:11, 184:24–185:7, slide 147; Ex. 1004, 108 [and 109]; Ex. 1005, 304[308], 306 [310]; Ex. 1006, 4 n.13–14, 6 n.24; Ex. 1007 ¶ 81). Claim 7, for another example, recites step 7.5 "requiring checking of the exclusive computer database for potential abuse associated with the patient and the authorized prescriber," rather than "checking the exclusive computer database for potential abuse of the prescription drug," as recited in the corresponding steps of claims 1 and 2. Pet. 35–36. Petitioner's evidence establishes that the ACA's central data repository "allows for identification of a number of unusual types of behavior, including any duplicate prescriptions, any attempts of over-prescribing, or any attempts at over-use by patients." *Id.* at 36 (citing Ex. 1003, 184:24-185:4; Ex. 1004, Preclinical

Safety Review at 110 (describing flagging of repeat instances of lost, stolen, destroyed, or spilled prescriptions.)). We agree with Petitioner that checking for duplicate prescriptions or attempts at over-prescribing would constitute checking for potential abuse associated with the authorized prescriber, while checking for "attempts at over-use by patients" would constitute checking the exclusive database for potential abuse associated with the patient. *Id.*

With the exception of certain limitations recited in Steps 1.1, 1.4, and 1.8 (or corresponding steps in similar claims), discussed above, Patent Owner does not otherwise challenge Petitioner's arguments and evidence in support of Petitioner's obviousness analysis. PO Resp. 36–59. Therefore, 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 steps recited in claim 1 and claims 2–11 of the '730 patent.

5. Conclusion

For the reasons discussed above, we determine Petitioner has proved by a preponderance of the evidence that the subject matter of claims 1–11 of the '730 would have been obvious to a POSA over the ACA. [20]

E. Asserted Obviousness of Claims 2, 3, 10, and 11 of the '988 Patent

Independent claims 1 and 9 of the '988 patent recite a "method of treatment of a narcoleptic patient with a prescription drug while controlling potential misuse, abuse or diversion of said prescription drug." Ex. 1001,

[20] For the same reasons, we reach the same conclusion with respect to Ground 1 of the '551 Petition challenging claims 1, 3–9, and 11–15 of the '988 patent as obvious to a POSA based on the ACA. To the extent dependent claims 3 and 11 of the '988 patent recite a limitation not addressed in Section II.D., above, the issue is addressed in Section II.E.

8:38–40, 9:40–42.[21] The body of the claims, however, does not recite a step for treating a narcoleptic patient. *Id.* at 8:41–9:13, 9:43–10:28. The limitations recited in the independent claims of the '988 patent, otherwise, are very similar to the limitations recited in the independent claims of the '730 patent. Many of the dependent claims in the '988 patent also recite method steps very similar to those recited in the '730 patent claims. *Id.* at 9:14–36, 10:29–53.

Petitioner's proofs, regarding its contention that the subject matter of claims 1, 3–9, and 11–15 of the '988 patent would have been obvious to a POSA in view of the Advisory Committee Art (Exs. 1003–1006), mirror the proofs described above with respect to the claims of the '730 patent. Pet. 12–37. Patent Owner's opposition likewise mirrors its opposition to the claims challenged in the '730 patent. PO Resp. 1–55. Therefore, for the same reasons set forth in Section II.D., above, we reach the same conclusion of obviousness for the subject matter of the challenged claims in the '988 patent. We address only the dependent claims of the '988 patent requiring separate discussion.

1. Obviousness of Dependent Claims 3 and 11

Claims 3 and 11 depend from claims 1 and 9, respectively, and further recite "the exclusive central pharmacy authorizing the company's prescription drug to be dispensed to the narcoleptic patient by another pharmacy." *Id.* at 9:21–23, 10:37–39. Petitioner asserts the subject matter of claims 3 and 11 would have been obvious over the Advisory Committee Art. Pet. 17–19. As noted by Petitioner, the Advisory Committee Art

[21] The citations in this section are to the papers and exhibits in IPR2015-00551.

expressly discloses a situation where the prescription drug may be "ship[ped] . . . from the exclusive central pharmacy to another pharmacy for patient pick-up." Ex. 1004, 110 (second bullet from top); *Id.* at 34 (citing Ex. 1004, 110; Ex. 1007 ¶ 98). The Advisory Committee Art further discloses that the sponsor "has a mechanism for verifying the second pharmacy's ability to protect against diversion of GHB before shipping the drug there." Ex. 1004, 110. Patent Owner does not comment on Petitioner's evidence with respect to claims 3 and 11. *See* PO Resp. 34–55. We agree with Petitioner's argument and evidence in support thereof.

The evidence cited by Petitioner establishes by a preponderance that the Advisory Committee Art discloses the "other pharmacy" limitation recited in claims 3 and 11 of the '988 patent. Therefore, for the reasons given above, we are persuaded Petitioner has shown by a preponderance of the evidence that the subject matter of claims 3 and 11 of the '988 patent would have been obvious over the Advisory Committee Art pursuant to 35 U.S.C. § 103.

2. Obviousness of Claims 2 and 10 over the Advisory Committee Art in view of Korfhage

Claims 2 and 10 depend from claims 1 and 9, respectively, and further recite "one or more of the exclusive central pharmacy and the exclusive central database are distributed over multiple computers, and wherein a query operates over all data in all the distributed databases relating to the prescriptions, the doctors, and the narcoleptic patients." Petitioner asserts the subject matter of claims 2 and 10 would have been obvious over the ACA in view of Korfhage. Pet. 52–53. Patent Owner opposes. PO Resp. 56–60. We address the parties' arguments below.

Petitioner explains that Korfhage discloses a database that can be distributed over multiple computers to accommodate "[c]ost, efficiency, and the [sheer] number of documents." Pet. 53 (quoting Ex. 1037, 276 [294], Ex. 1007 ¶ 157). Korfhage also suggests that a single query can operate over the distributed database computers to accommodate user preference "to view the system as accessing a single logical database in response to a query, even when the system must consult multiple physical databases." *Id.* Petitioner argues that, because the Advisory Committee Art teaches a central database that may be queried to minimize prescription drug abuse, it would have been obvious to modify the Advisory Committee Art to incorporate a distributed database system such as disclosed in Korfhage to accommodate cost, efficiency, the number of prescription requests, and associated data. *Id.*

Patent Owner argues that Petitioner has not provided sufficient evidence of motivation to combine the references without using hindsight. PO Resp. 56. Patent Owner asserts, in particular, that nothing in Korfhage relates to drug distribution, pharmacy practice, or drug abuse, misuse, or diversion. *Id.* (citing Ex. 1037; Ex. 2047 ¶ 57). Patent Owner argues that Petitioner has not identified any problem with using a "centralized (i.e., non-distributed) database disclosed in the [Advisory Committee Art]" that would have led a POSA to use a distributed database system, such as disclosed in Korfhage, to accommodate large numbers of documents in a cost efficient manner. *Id.* at 57 (citing Ex. 2047 ¶¶ 58–59; *Leo Pharm. Prods. v. Rea*, 726 F.3d 1346, 1354 (Fed. Cir. 2013) ("Only after recognizing the existence of the problem would an artisan *then* turn to the prior art . . . .")). Patent Owner further argues that Korfhage teaches away from using distributed databases because Korfhage discloses that "three **major problems** arise" when

attempting to have a single query operate over multiple physical databases. *Id.* at 59.

We are persuaded that Petitioner has proved by a preponderance of the evidence that one of ordinary skill would have been motivated to modify the Advisory Committee Art distribution system to include multiple computers in a distributed database system for reasons of cost, efficiency, and the anticipated volume of prescription-related information to be received, entered, and queried. Pet. 53 (citing Ex. 1007 ¶ 57; Ex. 1037, 294). Dr. Valuck testifies that distributed distribution systems such as disclosed in Korfhage were well-known in the art and that information systems were being driven toward distributed databases to reduce cost, improve efficiency, and handle large numbers of documents. Ex. 1007 ¶ 157. He further testifies that the Advisory Committee Art teaches a prescription information system where database queries are performed to control distribution and minimize abuse of prescription drugs. *Id.*

Petitioner's evidence persuades us that use of a distributed database system for controlling distribution of prescription drugs and executing a database query would have been a predictable use of a known distributed data system according to its established function. *See KSR*, 550 U.S. at 417. Contrary to Patent Owner's argument, an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418. Here, the choice of a distributed database system would have been well within capabilities of a POSA, as defined above. Use of such systems, as described in Korfhage, would have been a known, available, and predictable

use of a distributed database for controlling distribution of Xyrem. There is no requirement that Korfhage relate to drug distribution, pharmacy practice, or drug abuse, misuse, or diversion, as urged by Patent Owner. We also agree with Petitioner that Korfhage does not teach away from the use of distributed database systems, particularly given the acknowledgment of Dr. Bergeron that Korfhage offered solutions to the problems identified. Reply 25 (citing Ex. 1037, 276–77; Ex. 1054, 317:13–320:12).

For the reasons given above, we are persuaded Petitioner has shown a by a preponderance of the evidence that the subject matter of claims 2 and 10 of the '988 patent would have been obvious to a POSA in view of the Advisory Committee Art and Korfhage.

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 54 ("Motion to Exclude"); Paper 57 ("Motion to Allow Late Filing of 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 50; Paper 51. 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 50. 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 51.

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. 11–14. 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 50, 1; Paper 51, 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. 14–15; PO Resp. 9–12; Reply 2–4. Patent Owner, therefore, was on

notice and responded to Petitioner's argument and evidence on the issue of whether Exhibits 1004 and 1005 were publicly accessible prior to the '730 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)).

Therefore, 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

For the reasons given above, we are persuaded Petitioner has shown by a preponderance of the evidence that claims 1–11 of the '730 patent and claims 1, 3–9, and 11–15 of the '988 patent are unpatentable as obvious over the Advisory Committee Art pursuant to 35 U.S.C. § 103. We are further persuaded Petitioner has shown by a preponderance of the evidence that claims 2 and 10 of the '988 patent are unpatentable as obvious over the Advisory Committee Art and Korfhage pursuant to 35 U.S.C. § 103.

VI. ORDER

Accordingly, it is

ORDERED that claims 1–11 of the ’730 patent and claims 1–15 of the ’988 patent are unpatentable; and

FURTHER ORDERED that Petitioner’s Motions to Allow Late Filing of Objections and Motions to Exclude are dismissed as moot.

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

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