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Paper 69
Entered: July 27, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-00545
Patent 8,589,182 B1

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

I. INTRODUCTION

Amneal Pharmaceuticals, LLC ("Amneal") and Par Pharmaceutical, Inc. ("Par Inc.") (together, "Petitioner") filed a Petition requesting an *inter partes* review of claims 1–26 (all claims) of U.S. Patent No. 8,589,182 B1 (Ex. 1001, "the '182 patent"). Paper 4 ("Petition" or "Pet."). Jazz Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10. As authorized (Paper 11), Petitioner filed a response directed solely to real party in interest issues raised in the Preliminary Response (Paper 12), and Patent Owner filed a reply to that paper (Papers 17/18). Upon considering those submissions, we instituted *inter partes* review of claims 1–26 of the '182 patent. Paper 25 ("Dec. on Inst.").

After institution, Patent Owner filed a Response (Paper 46, "PO Resp."), and Petitioner filed a Reply (Paper 50, "Reply"). Petitioner supports its 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. 9, 15. Petitioner also presents another Affidavit of Mr. Butler (Ex. 1058, "Butler Third Affidavit") with its Reply. Reply 7.

With its Response, Patent Owner presents the Declarations of Joseph T. DiPiro, Pharm.D. (Ex. 2046, "DiPiro Declaration"), Bryan Bergeron, MD, FACMI (Ex. 2047, "Bergeron Declaration"), Craig F. Kirkwood, Pharm.D. (Ex. 2053, "Kirkwood Declaration"), David A. Holdford, Ph.D., FAPhA (Ex. 2056, "Holdford Declaration"), and Lyndsey J. Przybylski (Ex. 2057, "Przybylski Declaration"). PO Resp. 17–22, 27–29. Patent Owner also presents a responsive Affidavit of Christopher Butler dated November 4, 2015 (Ex. 2052, "Butler Second Affidavit"). PO Resp. 7–8.

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

A combined oral hearing in 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 68, "Tr.").

We have jurisdiction under 35 U.S.C. § 6(c). We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine Petitioner has shown by a preponderance of the evidence that claims 1–26 of the '182 patent are unpatentable. Petitioner's Motion to Allow Late Filing of Evidence Objections and Motion to Exclude are dismissed as moot.

A. Ground of Unpatentability at Issue

Petitioner contends that claims 1–26 of the '182 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),[1] FDA Preliminary Clinical Safety Review (Ex. 1004),[2] Briefing Booklet (Ex. 1005),[3] and Xyrem Video and Transcript (Ex. 1006).[4] Pet. 1, 9–37, 56–58.

B. Related Proceedings

The parties identify the following as related district court proceedings regarding the '182 patent: *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. Par Pharmaceutical., Inc.*, 2:13-cv-07884 (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. 59; Paper 7, 1–2. Patent Owner identifies two other district court proceedings concerning patents related to the '182 patent: *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, 2:14-cv-3235

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

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

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

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

(D.N.J.) and *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, 2:14-cv-5139 (D.N.J.). Paper 7, 2.

The parties identify the following as Petitions for *inter partes* review of patents related to the '182 patent: IPR2015-00546 (Patent 7,765,106); IPR2015-00547 (Patent 7,765,107); IPR2015-00548 (Patent 7,895,059); IPR2015-00551 (Patent 8,457,988); and IPR2015-00554 (Patent 7,668,730). Pet. 59; Paper 7, 2. The parties also identify the following as Petitions for covered business method patent review regarding the '182 patent and related patents: CBM2014-00149 (Patent 7,895,059); CBM2014-00150 (Patent 8,457,988); CBM2014-00151 (Patent 7,668,730); CBM2014-00153 (the '182 patent); CBM2014-00161 (Patent 7,765,106); and CBM2014-00175 (Patent 7,765,107). Pet. 59; Paper 7, 2. The Board has denied institution in all six of the above-mentioned CBM cases.

In addition, a different Petitioner, Wockhardt Bio AG ("Petitioner Wockhardt"), filed a Petition for *inter partes* review of the '182 patent in IPR2015-01813, as well as five 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 44 (granting institution and Petitioner Wockhardt's Motion for Joinder in IPR2015-01813, in relation to the '182 patent). After the oral hearing took place, however, upon the parties' joint request (Paper 65), we ordered the termination of all six proceedings as to Petitioner Wockhardt, and granted the parties' joint request to treat the

underlying settlement agreement as business confidential information (Paper 66). Paper 67.

C. The '182 Patent

The '182 patent, titled "Sensitive Drug Distribution System and Method," issued November 19, 2013, from an application filed August 27, 2012. Ex. 1001.[5] The '182 patent is directed to a method for controlling access to a sensitive prescription drug prone to potential abuse or diversion, by utilizing a central database to track all prescriptions for the sensitive drug. *Id.* at Abstract, 1:48–52. Information regarding all physicians authorized to prescribe the drug and all patients receiving the drug is maintained in the database. *Id.* Abuses are identified by monitoring the database for prescription patterns by physicians and prescriptions obtained by patients. *Id.* at Abstract, 1:52–54.

Figures 2A, 2B, and 2C comprise flow charts representing "an initial prescription order entry process for a sensitive drug." *Id.* at 4:17–18. In overview, a physician submits prescriber, patient, and prescription information for the sensitive drug to a pharmacy team, which enters the information into a computer database. *Id.* at 4:17–35, Fig. 2A (steps 202–210). 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 4:36–38.

The pharmacy workflow also includes verification of the prescribing physician's credentials. *Id.* at 5:19–34, Fig. 2B (steps 274–280). Filling the

[5] The '182 patent claims priority, through a chain of continuations, from patent application US 10/322,348 ("the '348 application") filed December 17, 2002. Ex. 1001, Related U.S. Application Data (63), 1:6–13.

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 5:35–6:3. Steps 240, 242, 246, and 258–266 of Figure 2C are reproduced below.

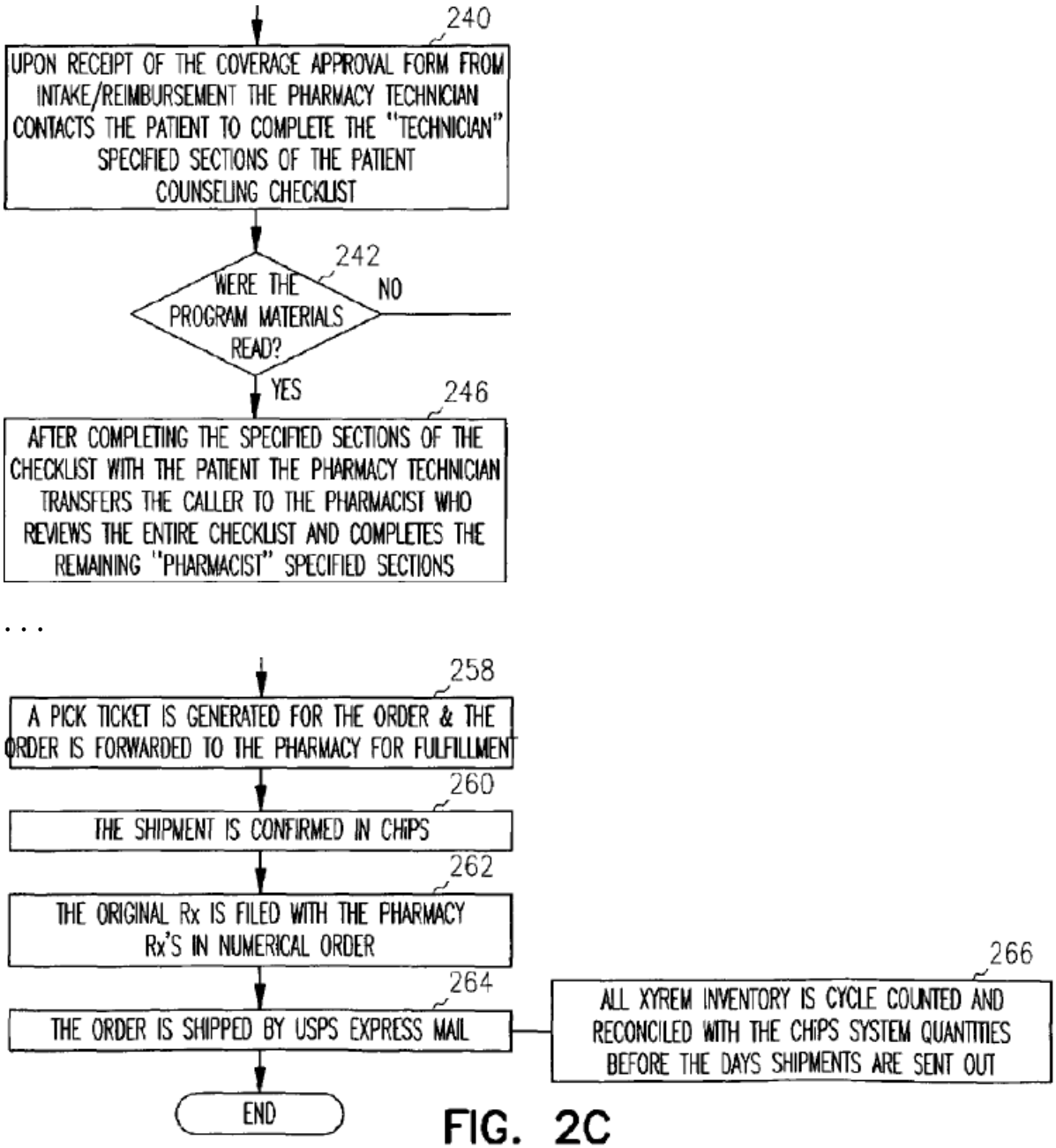


FIG. 2C

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®."[6] *Id.* at 4:38–43. If a patient requests an early prescription refill, for example, the pharmacist generates a report evaluating "the patient's compliance with therapy or possible product diversion, misuse or over-use." *Id.* at 6:42–44, Fig. 4B (step 436).

D. Illustrative Claim

The '182 patent contains multiple independent claims (1, 8, 15 and 19) and several dependent claims, of which claim 1 is illustrative and reproduced below:

> 1. A method of treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, wherein the prescription drug is sold or distributed by a company that obtained approval for distribution of the prescription drug, comprising:
>
> receiving, using a computer processor, into a single computer database of the company that obtained approval for distribution of the prescription drug, from any and all patients being prescribed the company's prescription drug, all prescriptions for the company's prescription drug with the potential for abuse, misuse or diversion;
>
> entering, using the computer processor, into the single computer database information sufficient to identify the narcoleptic patient for whom the company's prescription drug is prescribed;

[6] Xyrem® (or Xyrem) is the brand name for gamma hydroxy butyrate ("GHB"), indicated for the treatment of cataplexy (excessive daytime sleepiness) in narcoleptic patients. Ex. 1001, 3:24–29. Xyrem is a sensitive prescription drug prone to potential abuse or diversion. *Id.*

> entering, using the computer processor, into the single computer database information sufficient to identify any and all physicians or other prescribers of the company's prescription drug and information to show that the physicians or other prescribers are authorized to prescribe the company's prescription drug;
>
> entering and maintaining, using the computer processor, in the single computer database information that indicates that the narcoleptic patient or prescriber has abused, misused, or diverted the company's prescription drug; and
>
> checking for abuse, using the computer processor and the single computer database, and authorizing filling of the prescriptions for the company's prescription drug only if there is no record of incidents that indicate abuse, misuse, or diversion by the narcoleptic patient and prescriber, and if there is a record of such incidents, the single computer database indicates that such incidents have been investigated, and the single computer database indicates that such incidents do not involve abuse, misuse or diversion.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Relying on testimony by Dr. Valuck, Petitioner contends that a person of ordinary skill in the relevant art (hereafter "POSA") includes someone with a "Bachelor's or Doctor of Pharmacy degree and a license as a registered pharmacist with 3–5 years of relevant work experience, or a computer science undergraduate degree or equivalent work experience and work experience relating to business applications, including familiarity with drug distribution procedures." Pet. 2 (citing Ex. 1007 ¶ 21); *see also* Ex. 1007 ¶ 20 (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. Petitioner also asserts that a POSA would have known to look in the Federal Register and on the FDA's website to obtain information related to existing and proposed risk management programs. Pet. 14–15 (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. 15–17. 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 '182 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), 1:15–31. 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 ’182 patent priority date. Pet. 3–6; Ex. 1001, Related U.S. Application Data (63).

Xyrem is a sensitive prescription drug prone to potential abuse or diversion. Ex. 1001, 3:24–29. Prior to Xyrem, sensitive prescription drugs such as Accutane, Clozaril, and thalidomide were known to use controlled distribution systems to protect against potential side effects, abuse, and diversion. Pet. 4–5 (citing Ex. 1007 ¶¶ 22–25). Accutane, a prescription drug from the 1980s that could cause birth defects, was distributed under a program requiring i) informed consent forms completed by patient and physician, ii) patient counseling to avoid pregnancy and use birth control, and iii) a negative blood serum test for pregnancy prior to beginning treatment. *Id.* at 4 (citing Ex. 1007 ¶ 22). Distribution of Clozaril, indicated for treating schizophrenia but also capable of causing a fatal blood disorder, was controlled using a national registry system and computerized database for identifying patients and physicians. *Id.* at 4–5 (citing Ex. 1007 ¶ 23). In 1999, the manufacturers of thalidomide developed a system that combined the computerized registry of Clozaril with the controls imposed by the Accutane distribution system. *Id.* at 5 (citing Ex. 1007 ¶ 25). Based on such prior art activity, we find that by December 2002 a person of ordinary skill would have known the active ingredient in Xyrem – sodium oxybate, the sodium salt of gamma hydroxybutyrate – was a sensitive drug susceptible to abuse and diversion, and such person would have known of several available techniques to control and mitigate the risks associated with Xyrem’s distribution. *Id.* at 2–3 (citing Ex. 1007 ¶¶ 21, 46); Ex. 1007 ¶¶ 21–28, 46.

In its Response, and during the oral hearing, counsel for Patent Owner argued that a person of ordinary skill in the art was “a person of three to five

years' experience, a pharmacist, a person who sits behind the counter at Walgreens [and] is not worried about preapproved drugs." Tr. 30:17–31:9; PO Resp. 19–20. Counsel for Patent Owner further argued that a person of ordinary skill would not have had an interest nor "a focus on restricted distribution of products that don't even exist yet." Tr. at 31:1–32:1.

In view of the claims at issue here, we are not persuaded that the level of ordinary skill in the art is limited to the level of skill or interest of a pharmacist that dispenses FDA-approved drugs, such as one that "sits behind the counter at Walgreens." *Id*. at 31:1–5. We adopt the level of ordinary skill in the art as described by Petitioner and its witness, Dr. Valuck, because it is consistent with the subject matter before us, the '182 patent, and with prior art of record, such as Talk About Sleep (Ex.1033), Honigfeld (Ex. 1034), Elsayed (Ex. 1035), and Lilly (Ex. 1010). *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).

The independent claims of the '182 patent recite, in relevant part:

(i) A method of treating a "narcoleptic patient" with a prescription drug "that has a potential for misuse, abuse or diversion . . . comprising;"

(ii) "receiving, using a computer processor, into a single computer database . . . from any and all patients . . . all prescriptions for the . . . prescription drug" ("Step 1.1");

(iii) "entering, using the computer processor, into the single computer database information sufficient to identify the narcoleptic patient" ("Step 1.2");

(iv) "entering, using the computer processor, into the single computer database information sufficient to identify any and all physicians or other prescribers . . . authorized to prescribe the . . . prescription drug" ("Step 1.3 ");

(v) "entering and maintaining . . . in the single computer database information that indicates that the narcoleptic patient or prescriber has abused, misused, or diverted the . . . prescription drug" ("Step 1.4"); and

(vi) "checking for abuse, using . . . the single computer database, and authorizing filling of the prescriptions . . . only if there is no record of incidents that indicate abuse, misuse, or diversion by the narcoleptic patient and prescriber" ("Step 1.5").

Ex. 1001, 8:38–12:10 (*see* independent claims 1, 8, 15, and 19).

Of note, the '182 patented method requires a "single computer database" to receive "all prescriptions" "from any and all patients" (Step 1.1) in addition to storing the identifying information for the "patient" and "all physicians or other [authorized] prescribers" of the prescription drug (Steps 1.2 and 1.3). The single computer database is used to store and maintain information on whether a patient or prescriber "has abused, misused, or diverted" the prescription drug (Step 1.4). The single computer

database is used to check for abuse such that authorizing the filling of prescriptions occurs only if there is no record of incidents indicating abuse, misuse, or diversion by the patient and prescriber (Step 1.5).

Petitioner argues for the broadest reasonable interpretation of the claims as understood by one of ordinary skill in the art in light of the '182 patent specification. *Id.* at 8. Petitioner does not propose to construe any particular claim terms or phrases, but argues that the preamble language in independent claims 1, 8, 15, and 19 is not limiting. *Id.* at 8–9. In support, Petitioner argues that, although framed as "method of treatment" claims, none of the '182 patent claims recites a method step directed to treating a narcoleptic patient. *Id.* (citing Ex. 1007 ¶ 37).

Patent Owner does not address the substance of the preamble language in the independent claims. PO Resp. 23–25. Patent Owner argues that dependent claims 7, 14, and 25, which depend from independent claims 1, 8, and 19 either directly or indirectly, do recite administration of a compound for therapeutic effect, based on the recited wherein clause: "wherein said GHB drug product treats cataplexy in said narcoleptic patient." *Id.* at 24. We address the parties' arguments below.

First, we agree with Petitioner that the preamble language "[a] method of treatment of a narcoleptic patient" in the independent claims is not "necessary to give life, meaning, and vitality" to the claims of the '182 patent. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). The claims recite method steps for controlling distribution of a prescription drug prone to abuse, misuse, or diversion; the claims do not recite treating a patient, administering a compound or drug product for therapeutic effect, or other treatment-related method steps. *See*, Ex. 1007

¶ 37. Therefore, we determine the preamble language "[a] method of treatment of a narcoleptic patient" to be non-limiting.

Second, the wherein clause at issue does not recite a method step. Independent claims 1, 8, and 19 consistently recite method steps using the present participle verb form, "receiving," "entering," "checking," and "authorizing." The wherein clause, however, recites the GHB drug product "treats" cataplexy, rather than reciting a method step of "treating" cataplexy. The absence of the present participle verb form and the use of a wherein clause indicate an intended use or inherent property of the GHB drug product to treat cataplexy, not a method step. *See Credle v. Bond*, 25 F.3d 1566, 1572 (Fed. Cir. 1994) ("[B]efore each clause containing an undisputed present participle designating the method steps—'*providing* an insert;' '*joining* two opposed webs' . . . there is a comma, indicating the beginning of a new, distinct step . . . . There is no such comma preceding 'flexibly securing.' This suggests that 'securing' is not a present participle signifying a distinct method step.").

Third, the last step in the claimed methods of independent claims 1, 8, and 19 recites "checking for abuse . . . and *authorizing* filling of the prescriptions . . . only if there is no record of incidents" that may indicate abuse, misuse, or diversion. Ex. 1001, 8:65–9:1; 9:49–52, 12:2–5 (emphasis added). Claims 7 and 14 depend directly from claims 6 and 13, respectively.[7] Claims 6 and 13 (and independent claim 19) do not recite an additional method step, such as mailing, providing, or delivering the GHB

[7] Claim 25 depends directly from independent claim 19.

drug product to the patient. Ex. 1001, claims 6, 13, and 24.[8] Thus, each method recited in claims 7, 14, and 25 ends with the step of authorizing a GHB prescription after checking for possible abuse. Steps for mailing, providing, or delivering the GHB drug product to the patient and/or for confirming receipt, precursor method steps to any purported treating of the patient within the context of the claims, are not recited.

Fourth, the '182 patent specification does not describe method of treatment steps for treating cataplexy with GHB. The references to treatment are brief general statements in the Prescription and Enrollment Form of Figure 9 and the Background section of the patent. Ex. 1001, 1:32–35 ("Certain agents, such as gamma hydroxy buterate (GHB) are also abused, yet also are effective for therapeutic purposes such as treatment of daytime cataplexy in patients with narcolepsy."), Fig. 9 ("Xyrem is approved for the treatment of cataplexy in patients with narcolepsy"). Those limited descriptions further support our determination that the wherein clause at issue recites only an intended use or inherent property of GHB. Neither the Summary of the Invention, the Drawing flowcharts, the Detailed Description of the Invention, nor the claims describe a method step for treating a patient as part of the claimed invention. Ex. 1001.

Considering the claim language as a whole in light of the specification, we conclude that the wherein clause recited in dependent claims 7, 14, and 25 is not a method step in the claimed method. The wherein clause, like the preamble, recites only an intended use or inherent

[8] Dependent claims 2, 9, and 20 each recite "delivering the prescription drug to the narcoleptic patient in order to treat the narcoleptic patient," but this "delivering" step is not a step in the methods of claims 7, 14, and 25.

property of the GHB drug product to treat cataplexy in a narcoleptic patient. Therefore, we determine the wherein clause in dependent claims 7, 14, and 25 is not entitled to patentable weight. *See Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.").

C. Public Accessibility of Exhibits 1003–1006

The priority date of the '182 patent is December 17, 2002. Ex. 1001, 1 (63). Petitioner asserts that Exhibits 1003–1006 (the "Advisory Committee Art" or "ACA") were publicly accessible printed publications under 35 U.S.C. § 102(b), in connection with the Xyrem Advisory Committee meeting held on June 6, 2001. Pet. 10–15. Patent Owner counters that Petitioner's evidence is insufficient to show that (1) Exhibits 1004–1006 were publicly accessible more than one year 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® (or "Xyrem"), provides helpful context. Orphan Medical is the company that developed Xyrem and prepared the drug sponsor's Briefing Booklet for the Xyrem Advisory Committee Meeting, in accordance with the Federal Advisory Committee Act ("FACA"). Ex. 1005, 1; Pet. 12–13 (citing Ex. 1005; 5 U.S.C. App 2 § 10(b) (2001)); Reply 2–3 (citing Ex. 1005, 1; Ex. 1057, 2; 5 U.S.C. App 2 § 10(b) (2001)). FDA reviewers also prepared briefing information, including the Preliminary Clinical Safety Review of the Xyrem New Drug Application ("Safety Review"). Ex. 1004. The June 6, 2001 meeting was transcribed. Ex. 1003. We provide a summary timeline below.

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

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

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

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

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

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

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

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

December 17, 2002: '182 patent application priority date

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

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

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

The Advisory Committee Meeting was convened to discuss Xyrem, with the "main focus of the deliberations . . . on risk management issues." Pet. 14 (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 2–3. The transcript of the Xyrem Advisory Committee Meeting contains several references to the "briefing documents" and

"materials" distributed prior to the meeting, although the references are not so specific as to identify Exhibits 1004, 1005, or 1006, *per se*. Ex. 1003, 12, 284, 330, 342; Tr. 9:23–11:10.

The parties' first dispute centers on when Exhibits 1004–1006 first became publicly accessible on the FDA's website. We begin with a discussion of the Federal Register Notice (Ex. 1015) 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. 12 (citing Ex. 1015). The May 14, 2001 Federal Register Notice further stated that "the minutes, transcript, and slides from the meeting" are "generally posted about 3 weeks after the meeting." *Id.* Petitioner argues that the Federal Register Notice is evidence of FDA's general practice that may be relied upon to establish an "approximate time" the Advisory Committee Art would have become available to a POSA exercising reasonable diligence. *Id.* at 12–13 and n.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. 12–14; *see also Desert Palace, Inc. v. Costa*, 539 U.S. 90, 99 (2003) ("[T]he'conventional rul[e] of civil litigation' . . . requires a plaintiff to

prove his case 'by a preponderance of the evidence,' using 'direct or circumstantial evidence.'" (internal citation omitted) (citing *Postal Serv. Bd. Of Governors v. Aikens*, 460 U.S. 711, 714, n.3 (1983))).

Regarding the Xyrem Advisory Committee Meeting transcript and presentation slides (Ex. 1003), the Internet Archive evidence shows that as of June 17, 2001, less than two weeks after the meeting, there were no links posted for the meeting transcript, presentation slides, or meeting minutes. Ex. 1018, 5.[9] 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. 13–15 (citing Ex. 1020, 8; Ex. 1028); Ex. 1020, 9.[10] 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.*

[9] 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.

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

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 transcript 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 Committee Meeting are "generally posted about 3 weeks after the meeting." Ex. 1015. The Internet Archive evidence indicates the meeting transcript, presentation slides, and meeting minutes were not posted on the FDA's website as of June 17, 2001, less than two weeks after the meeting, but were posted 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.

Thus, for the reasons given above, we find that Petitioner has established by a preponderance of the evidence that the Xyrem Advisory

Committee Meeting transcript and presentation slides (Exhibit 1003) were publicly accessible on the FDA's website not later than October 4, 2001.

c. Exhibits 1004–1006

Exhibit 1004 is a Xyrem Preliminary Clinical Safety Review, asserted by Petitioner to have small portions redacted, thereby indicating an intent to make the document publicly available. Pet. 13. 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").[11]

Exhibit 1005 comprises a three-page cover letter from Orphan Medical to the Xyrem Advisory Committee dated May 3, 2001, and the enclosed "Briefing Booklet" for the Advisory Committee Meeting. Pet. 13 (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.

[11] 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.

Exhibit 1006 is a video titled "Xyrem Prescription and Distribution Process," dated February 2, 2001, and transcript of the video.[12] Ex. 1006, 1.

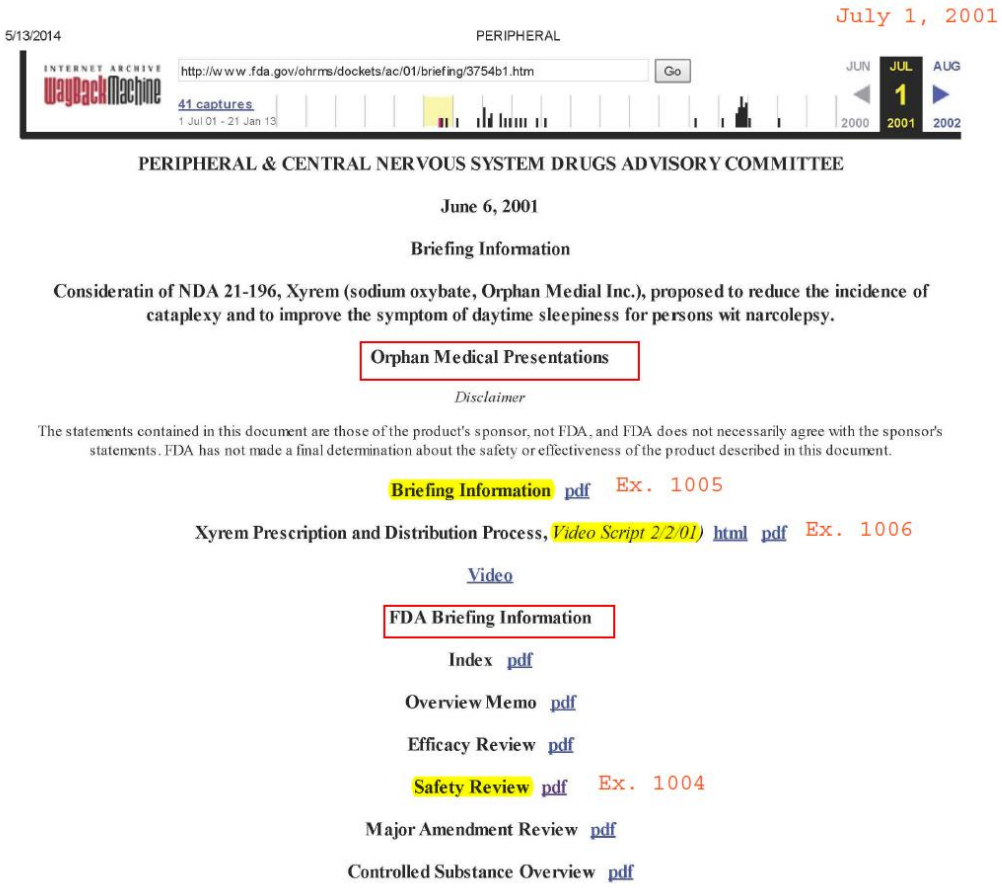
d. Analysis: Public Accessibility of Exhibits 1004–1006

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

[12] 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").

[13] 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.

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



July 1, 2001

5/13/2014 PERIPHERAL

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

41 captures 1 Jul 01 - 21 Jan 13

JUN JUL 1 AUG 2000 2001 2002

PERIPHERAL & CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE

June 6, 2001

Briefing Information

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

Orphan Medical Presentations

Disclaimer

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

Briefing Information pdf Ex. 1005

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

Video

FDA Briefing Information

Index pdf

Overview Memo pdf

Efficacy Review pdf

Safety Review pdf Ex. 1004

Major Amendment Review pdf

Controlled Substance Overview pdf

The document heading is "Briefing Information" for the Advisory Committee's consideration of Xyrem. *Id.* Under the subheading "Orphan Medical Presentations" is i) a pdf link to "Briefing Information," asserted to be a link to Exhibit 1005, and ii) html and pdf links to "Xyrem Prescription

and Distribution Process, *Video Script 2/2/01*," asserted to be links to Exhibit 1006. *Id.*; Pet. 14 (citing Ex. 1019); Tr. 8:1–8. Under the subheading "FDA Briefing Information" is a pdf link to "Safety Review," asserted to be a link to Ex. 1004. *Id.*

Patent Owner contends Petitioner's evidence fails to prove, by a preponderance of the evidence, that Exhibits 1004–1006 qualify as publicly accessible printed publications. PO Resp. 3–23. 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 '182 patent priority date. *Id.* at 5–8. Patent Owner further argues that neither the Federal Register Notice, the preparation dates of Exhibits 1004–1006, the presence or absence of redactions therein, nor Dr. Valuck's testimony supports Petitioner's argument. *Id.* at 4–5, 8–13. 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 '182 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 persuasively address 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 3–4 (citing Ex. 1057, 4[14]). Thus, the evidence indicates Exhibits 1004–1006 were prepared, distributed to the Xyrem Advisory Committee, and available for posting to the FDA's website 24 hours prior to the meeting, as stated in the Federal Register Notice (Ex. 1015). The Federal Register Notice even provided instructions on how to locate materials from the FDA's website – "Click on the year 2001 and scroll down to the Peripheral and Central Nervous Systems Drugs meetings." Reply 5 (citing Ex. 1015).

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

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

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.[15] Thus, the Internet Archive evidence supports Petitioner's contention that the documents of Exhibits 1004–1006 were publicly accessible on the FDA's website for the Xyrem Advisory Committee not later than July 1, 2001, in accordance with the Federal Advisory Committee Act.

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

We are not persuaded by Patent Owner's argument that Petitioner's Internet Archive evidence is insufficient, given the totality of evidence presented in this case. PO Resp. 5–8. 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 '182 priority date: August 30, 2003, for Exhibit 1006; September 13, 2011, for Exhibit 1005; and November 21, 2011, for Exhibit 1004. *Id.* at 7–8 (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 *18 (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. 6–7. In *ServiceNow*, the Board denied institution, reasoning in part that a similar affidavit from Mr. Butler did not "make the critical link between the alleged identification of [the prior art reference] on the 'download page' and the exhibits relied upon in support of the asserted grounds." *ServiceNow*, slip op. at *14. The facts and evidence of *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.* Authentication of Exhibits 1004–1006 is not an issue here. Reply 6 (citing Paper 27).[16]

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

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

Petitioner, in reliance on Mr. Valuck's testimony, argues that a POSA would have been able to locate Exhibits 1003–1006 by exercising reasonable diligence, including being able to locate the Federal Register Notice for the Xyrem Advisory Committee Meeting and following the links. Pet. 14–15 (citing Ex. 1007 ¶ 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.* (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 effectively indexed and accessible to persons of ordinary skill more than one year prior to the '182 patent priority date. Reply 5 (citing Ex. 1015).

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

Patent owner argues that Petitioner's evidence does not establish that a POSA would have been motivated to look for the Federal Register Notice (Ex. 1015) or capable of finding it. PO Resp. 14–23. Patent Owner reasons that without access to the Federal Register Notice, a POSA would not have been able to access Exhibits 1003–1006. *Id.* at 14–15. Thus, Patent Owner argues that Petitioner has not established the public accessibility of Exhibits 1003–1006 by a preponderance of the evidence. *Id.*

We reiterate our analysis and findings in Section II.A., above, that a POSA includes a registered pharmacist with 3–5 years of relevant work experience, including familiarity with drug distribution procedures. A POSA also may have a blend of computer science and pharmacy drug distribution knowledge and/or experience, including experience relating to computerized drug distribution systems. We agree with Petitioner that Patent Owner's argument truncates the definition of a POSA "to eliminate those individuals 'with a specific focus on drug distribution, safety, and abuse'—i.e., any ***interested persons,***" which is contrary to the applicable test for assessing public accessibility. Reply 8–9 (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. 16–20 (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 ¶¶ 21–28, 47; Ex. 2045, 293:2–294:11.

Thus, we find that a POSA would have known to look in the Federal Register and on the FDA's website for information related to existing and proposed risk management programs, such as the controlled distribution system for Xyrem. Ex. 1007 ¶ 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 '182 patent. Therefore, we proceed to consider Petitioner's unpatentability grounds.

D. Asserted Obviousness of claims 1-26 of the '182 Patent over the Advisory Committee Art (Exs. 1003–1006)

Petitioner contends that the subject matter of claims 1–26 (all claims) of the '182 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 '182 patent. Pet. 16–37; 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 and distributed together for the Advisory Committee Meeting and "relate to the same restricted distribution program, which the meeting was convened to discuss." Pet. 16–17 (citing Ex. 1007 ¶ 50). 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 17 (citing Ex. 1007 ¶ 50) (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 assertion that the ACA would have provided a POSA with a reasonable expectation that the "GHB drug product treats cataplexy in said narcoleptic patient," as recited in claims 7, 14, and 25, an issue we address below. PO

Resp. 25–33. 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 1.1–1.5, are disclosed in the ACA. *Id.* at 17–19 (citing Ex. 1007 ¶¶ 51–69). 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 2–26 are disclosed in the ACA. *Id.* at 27–37 (citing Ex. 1003; Ex. 1004; Ex. 1005; Ex. 1006; Ex. 1007 ¶¶ 71, 73, 75–79, 81, 83, 85–87, 89, 90, 93). With regard to independent claims 8, 15, and 19, Petitioner contends that many limitations are similar to those of claim 1, and the ACA discloses all limitations in those claims. *Id.* at 30–35.

Patent Owner argues that Petitioner has not proved by a preponderance of the evidence that the ACA would have rendered claims 7, 14, and 19–25 obvious to a POSA. PO Resp. 25–33. Patent Owner argues that the ACA would not have disclosed, taught, or suggested the verifying step in claims 19–25—"verifying two or more of the following *using the computer processor* prior to providing the . . . drug to the narcoleptic patient: patient name; patient address; that the patient has received educational material regarding the single prescription drug; a quantity of the single prescription drug; and dosing directions for the single prescription drug" (hereafter "verifying step")—because the ACA discloses the specified

information is verified by a human rather than the computer processor. *Id.* at 25–30 (emphasis added). Patent Owner also argues the ACA would not have provided a POSA with a reasonable expectation that the "GHB drug product treats cataplexy in said narcoleptic patient," as recited in dependent claims 7, 14, and 25. *Id.* at 30–33.

We address the parties' arguments below.

1. Claims 1–18, 26

We find Dr. Valuck's Declaration testimony, which consistently explains each step of claims 1–18 and 26 and the reasons for his opinion that each claim limitation is found in the ACA along with specific evidentiary citations, to be persuasive. Ex. 1007 ¶¶ 51–83. We also are persuaded by Dr. Valuck's Declaration testimony that there would have been sufficient reason to combine the ACA documents because each document is related to the same Xyrem risk management program discussed at the Advisory Committee Meeting, and a person of ordinary skill would have understood the documents comprising the ACA (Exs. 1003–1006) to constitute "a cohesive teaching." Pet. 16–17 (citing Ex. 1007 ¶ 50).

Therefore, as stated above, we first determine that Petitioner has proved by a preponderance of the evidence that a POSA would have had sufficient motivation to combine the ACA references for the reasons given by Petitioner based on the cited evidence, particularly Dr. Valuck's testimony. Ex. 1007 ¶ 50.

a. Steps 1.1–1.5

With regard to Steps 1.1–1.5 of independent claims 1, 8, and 15, Dr. Valuck describes his opinion, in detail, where the claim limitations are found in the ACA. Ex. 1007 ¶¶ 53–69, 78. With regard to Step 1.1, Petitioner

provides evidence that the ACA discloses a single national pharmacy responsible for receiving Xyrem prescribing forms "necessary in order for the prescriptions to be filled." Pet. 20 (citing Ex. 1003, 180:6–16, Slide 151; Ex. 1005, 310; Ex. 1006, 5 n.20; Ex. 1007 ¶ 54). Although Petitioner does not cite text from the ACA stating that the Xyrem database is "computerized," Petitioner (i) relies on the description of the Xyrem closed distribution system, (ii) cites an illustration of a pharmacist at a computer terminal (*Id.* at 21, 22 (citing Ex. 1003, slide 146)), and (iii) argues that a person of ordinary skill would have understood and appreciated that such a closed distribution system, using a single national pharmacy to centralize large amounts of patient, prescriber, and prescription related data, would need to be computerized. *Id.* at 21–22 (citing Ex. 1003, 16:4–7, 24:21–25, 259:4; Ex. 1005, 1; Ex. 1007 ¶¶ 55, 56). Further, Petitioner provides evidence that a person of ordinary skill would have understood the ACA as disclosing the use of a single computer database to receive all prescriptions and to register "'every patient and prescribing physician' in 'a secure database'." Pet. 23 (citing Ex. 1004, 110; Ex. 1007 ¶ 57).

Petitioner also provides extensive citations to, and analysis of, the evidence in support of its argument that the ACA discloses Steps 1.2–1.5 of the '182 patent. Pet. 24–27 (citing Ex. 1003, 16:4–7, 177:24–178:11, 181:1–18, 184:24–185:14, 259:4, Slides 142, 146, 147, 158, 159; Ex. 1004, 109, 110; Ex. 1005, 298, 304–306, 308, 310, 311; Ex. 1006, 4 n.13–14, 6 n.24, 7 n.25, 8 n.29, 9 n.38; Ex. 1007 ¶¶ 60–63, 65, 67, 68). We note, in particular, Petitioner provides evidence sufficient to prove its assertion that the ACA discloses the limitation of Step 1.5, which requires checking the single computer database for possible abuse and authorizing filling a

prescription "only if there is no record of . . . abuse, misuse, or diversion by the narcoleptic patient and prescriber." *Id.* at 26–27 (citing, *inter alia*, Ex. 1007 ¶¶ 67–68). Petitioner emphasizes that "'***information is available prior to filling the prescription*** so appropriate pharmacist intervention can occur.'" *Id.* at 27 (quoting Ex. 1003, 185:5–7).

The claim charts for Steps 1.1–1.3 appear in paragraphs 58 and 63 of Dr. Valuck's Declaration, in further support of his opinion, and the claim charts are in proper form. Ex. 1007 ¶¶ 58, 63. Similarly, the claim charts for Steps 1.4 and 1.5 are in paragraphs 65 and 68. *Id.* at ¶¶ 65, 68. The Petition, moreover, contains eight pages of detailed analysis with citations to the ACA and Dr. Valuck's Declaration in support of Petitioner's argument that Steps 1.1–1.5 are disclosed in the ACA, none of which is challenged by Patent Owner. Pet. 20–27; s*ee* PO Resp. 25–33.

Based on the complete record before us, we find the Petitioner has proved by a preponderance of the evidence that the ACA discloses Steps 1.1–1.5.

b. Other steps recited in claims 1–18, 26

We also are persuaded that, with respect to Steps 1.1–1.5, independent claims 8 and 15 are very similar to claim 1 such that Petitioner's analysis regarding claim 1 equally applies, and that the ACA discloses the aspects of those claims that differ from claim 1. *Id.* at 30–35; Ex. 1007 ¶¶ 78, 80–82. In addition, we are persuaded that Petitioner has proved by a preponderance of the evidence that the ACA discloses the elements recited in dependent claims 2–7, 9–14, 16–18, and 26. Pet. 27–30, 32, 35–37; Ex. 1007 ¶¶ 70–77, 79, 83, 94). Patent Owner does not challenge these proofs, apart from

the wherein clause recited in dependent claims 7, 14, and 25, which we discuss below.

Therefore, to the extent not stated expressly, above, we adopt Petitioner's arguments and evidence in support of our findings that the ACA discloses the steps recited in claims 1–18 and 26 of the '182 patent.

2. The "wherein" clause and claims 7, 14, and 25

We determined in section II.B., above, that the wherein clause in dependent claims 7, 14, and 25—"wherein said GHB drug product treats cataplexy in said narcoleptic patient"—is not entitled to patentable weight. Our determination renders Patent Owner's argument, that the "wherein" clause is not disclosed in the ACA, legally irrelevant. Even if we were to give the "wherein" clause patentable weight, the ACA discloses, or at least suggests, that Xyrem—the GHB drug product—treats cataplexy in a narcoleptic patient. Reply 15–16; *see 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))).

The ACA discloses the use of GHB for the treatment of cataplexy in narcoleptic patients. Petition at 29 (citing Ex. 1003, Tr. 24:14-17; Ex. 1004, 8; Ex. 1005, cover letter, 127[17]; Ex. 1006, 1 n.3); Ex. 1007 ¶ 77. It is true

[17] Citations are to the internal pagination of the document.

that the ACA discloses the drug sponsor's request for FDA approval of a proposed indication for the treatment of cataplexy in narcoleptic patients. Reply 15 (citing Ex. 1003 at 24:14-17 ("The proposed indication for which we are asking FDA for marketing approval is to reduce the incidence of cataplexy and to improve the symptom[s] of daytime sleepiness in patients with narcolepsy.") (emphasis added)); *see also* Ex. 1004 at 8 (2.1 "Indication"); Ex. 1005 at 1. The request, however, is based on substantial efficacy data that includes nearly 100 pages of summarized clinical data. Ex. 1005, 35–127. The data supports a statistically significant reduction in cataplexy attacks, at least among patients receiving a dosage of 9 grams per day of GHB. *Id.* at 63. The efficacy review of GHB concludes with the summary that dosages between 3 and 9 grams per day "are effective in the treatment of narcolepsy (reducing the frequency of cataplexy attacks and excessive daytime sleepiness . . . associated with narcolepsy)." *Id.* at 127.

Patent Owner argues that because the drug sponsor "proposed" the use of GHB for the treatment of cataplexy in narcoleptic patients, but such use had not yet been approved by the FDA, a POSA would not have had a reasonable expectation of success for such treatment. PO Resp. 30-31. To the contrary, the proposed use of GHB for the treatment of cataplexy in narcoleptic patients, supported by controlled clinical trials that resulted in statistically significant efficacy data, is persuasive evidence that a POSA would have reasonably expected success in the use of GHB to treat cataplexy. Even absent FDA approval for the proposed indication, the disclosure of the proposed indication and supporting data disclosed in the ACA is sufficient to at least suggest the obviousness of using GHB drug product to treat cataplexy in a narcoleptic patient. As Petitioner notes, the

Advisory Committee voted 6–3 in favor of the drug sponsor having demonstrated GHB's efficacy for the proposed indication to treat cataplexy. Reply 16 (citing Ex. 1003, 299:6-300:13). We also are persuaded by Dr. Valuck's testimony that the ACA documents "would have led a POSA to predictable results with a reasonable expectation of success." Ex. 1007 ¶ 50.

Therefore, for the reasons given above, we determine Petitioner has proved by a preponderance of the evidence that the subject matter of claims 7, 14, and 25 of the '182 Patent, even if we were to give the "wherein" clause patentable weight, would have been obvious to a POSA over the ACA.

3. Claims 19–25, the "verifying" step

Petitioner provides evidence that the steps in claim 19, some of which are very similar to Steps 1.1–1.3, are disclosed in the ACA. Pet. 32–35 (citing Ex. 1007 ¶¶ 85–91). With respect to the step challenged by Patent Owner—"verifying two or more of the following *using the computer processor* prior to providing the single prescription drug to the . . . patient: patient name; patient address; that the patient has received educational material regarding the single prescription drug; . . . and dosing directions for the single prescription drug"—Petitioner cites substantial evidence in support thereof. Pet. 34–35 (citing Ex. 1003, 181:16–182:8, 371:10–12, 374:7–20, Slide 154; Ex. 1004, 109, 115; Ex. 1005, 309, 310; Ex. 1006, 7 n.28, 8 n.30–32; Ex. 1007 ¶¶ 89, 90). Patent Owner argues that Petitioner's evidence does not show the recited patient information being verified "*by* a computer processor," but rather shows such verification being done by a human. PO Resp. 26–27.

The claim limitation at issue does not recite that the patient information must be verified "by" a computer processor and not a human, only that the computer processor is used (presumably by a human) to verify the patient information. For example, page 310 of the Briefing Booklet (Ex. 1005) in the ACA material 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 from the prescription faxed by the physician, entered the patient information into the computer database using the computer processor, and then "confirms" the patient information in the database during the call.

Dr. Valuck testified at his deposition to like effect. He stated:

> I refer to the video in my discussion after para 88. Both starting in para 89 and para 90 [Ex. 1007] in the video about the process and the pharmacy and staff of the pharmacy using the computer to perform various tasks, including verification of patient information, name and

> address, receipt of educational material. The computer is used in the video at all these steps. I believe it would be the interpretation and understanding of a POSA that they would be using the computer for these -- for these steps.

Reply 13 (citing Ex. 2044, 163:18–164:2). The ACA further discloses a centralized location, a "central data repository," for all prescription controls and records. *Id.* at 14 (citing Ex. 1003, 178:8-11, 184:24-185:4, Slides, 146-147; Ex. 1005, 306; Ex. 1006, 6 n.24; Ex. 1007 ¶ 60). Because the prescription identifies the patient's address for shipping the drug product, the registration information entered into the database using the computer processor contains the patient's name, address, and other identifying information. *Id.* (citing Ex. 1004, 110, 114 ("Every patient … will be registered with … a secure database. . . . A patient registry application … contain[s] the following information: [p]atient name, address, telephone number, fax number, e-mail address, date of birth, gender, social security number, patient record number.")). Thus, the ACA discloses that the pharmacy has patient registry information available for entry into the computer database, prior to dispensing the drug—and a natural use for that database information would be to verify the patient's name, address, and other information "using the computer processor" as recited in claim 19. *Id.* (citing Ex. 1007 ¶ 62).

Petitioner shows by a preponderance of the evidence that the ACA discloses, or at least suggests, using a computer processor to enter patient information into the computer database and later verifying the patient information entered into the database 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; Ex. 1007 ¶¶ 57–59. Thus, we are persuaded Petitioner has established by a preponderance of the evidence that the ACA discloses, or at least suggests the "verifying" step "using a computer processor," as recited in claim 19.

The limitations in claims 20–25 are identical to the limitations in claims 2–7, respectively, except for their dependence from claim 19. Pet. 35–36 (citing Ex. 1007 ¶ 93 (incorporating ¶¶ 44, 70–77, 84–92)). Petitioner has established by a preponderance of the evidence that those limitations are disclosed in the ACA. *Id.* Patent Owner does not challenge Petitioner's evidence supporting the disclosure of those limitations in the ACA. *See* PO Resp. 25–33.

4. Conclusion

For the reasons given above, we determine Petitioner has proved by a preponderance of the evidence that the subject matter of claims 1–26 of the '182 patent would have been obvious to a POSA over the ACA.

III. PETITIONER'S MOTION TO EXCLUDE EVIDENCE

Petitioner moves to allow late filing of evidentiary objections (37 C.F.R. § 42.5(c)), a necessary predicate to consideration of Petitioner's motion to exclude portions of Exhibits 2046 (¶¶ 11–18) and 2047 (¶¶ 23–25), and to exclude Exhibits 2049, 2050, 2054, and 2057. *See* 37 C.F.R. § 42.64(b), (c); Paper 56 ("Motion to Exclude"); Paper 58 ("Motion to Allow Late Filing of Evidence Objections"). We need not consider

Petitioner's motions in view of our decision regarding whether a POSA would have been capable of locating the Federal Register Notice (Ex. 1015), set forth in section II.C.2., above, the issue to which the objected-to exhibits are addressed. Therefore, Petitioner's motions are dismissed as moot.

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

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

First, we do not rely on Exhibit 1017 in support of this Decision. Second, Exhibit 1003 was filed in support of the Petition and cited throughout the Petition, including with respect to the issue of public accessibility. Pet. 10–14. 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 52, 1; Paper 53, 1.

Exhibit 1057 was submitted in direct response to Patent Owner's challenge to the evidentiary weight to be given the redactions in Exhibits 1004 and the public disclosure legend on the cover of Exhibit 1005, in support of Petitioner's argument of public accessibility of those two documents. *See* Pet. 13; PO Resp. 9–11; 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 '182 patent priority date. *See Genzyme Therapeutic Prods. Ltd. v. Biomarin Pharm. Inc.*, 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 1–26 of the '182 patent are

unpatentable as obvious over the Advisory Committee Art pursuant to 35 U.S.C. § 103.

VI. ORDER

Accordingly, it is

ORDERED that claims 1–26 of the '182 patent are unpatentable; and

FURTHER ORDERED that Petitioner's Motion to Allow Late Filing of Evidence Objections and Motion 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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