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Paper 11
Entered: January 13, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case CBM2014-00149 (Patent 7,895,059 B2)
Case CBM2014-00150 (Patent 8,457,988 B1)
Case CBM2014-00151 (Patent 7,668,730 B2)
Case CBM2014-00153 (Patent 8,589,182 B1)[1]

Before LORA M. GREEN, BRIAN P. MURPHY, and JON B. TORNQUIST, *Administrative Patent Judges.*

MURPHY, *Administrative Patent Judge*.

DECISION
Denying Institution of Covered Business Method Patent Review
37 C.F.R. § 42.208

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[1] This Decision addresses the same jurisdictional issue raised in all four cases. The patents at issue in CBM2014-00149, CBM2014-00150, CBM2014-00151, and CBM2014-00153 are all related, and the jurisdictional arguments by Petitioners and Patent Owner are largely the same in each case. Therefore, we issue one Decision to be entered in each case.

I. INTRODUCTION

Par Pharmaceutical, Inc. ("Par"), Roxane Laboratories, Inc. ("Roxane"), and Amneal Pharmaceuticals, LLC ("Amneal")(together, "Petitioner") filed several Petitions, including a Petition requesting covered business method patent review of claims 1–11 (all claims) of U.S. Patent No. 7,668,730 B2 (Ex. 1001, "the '730 patent"),[2] pursuant to 35 U.S.C. § 321 and § 18 of the Leahy-Smith America Invents Act (Pub. L. No. 112-29, 125 Stat. 284 (2011)) ("AIA"). Paper 1 ("Pet."). Jazz Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 324, which provides that a covered business method ("CBM") patent review may not be instituted unless information presented in the Petition "would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable."

Petitioner challenges claims 1–11 of the '730 patent as unpatentable under 35 U.S.C. §§ 101, 102(b), and 103(a). Pet. 29–30. Based on the information presented in the Petition and Preliminary Response, we determine Petitioner has not demonstrated that the '730 patent is a "covered business method patent" pursuant to the statutory definition in § 18(d)(1) of the AIA. Therefore, for the reasons given below, we deny the Petition.

[2] For clarity and expediency, we treat CBM2014-00151 as representative of all four cases and note that Par and Roxane filed the Petition in CBM2014-00151. All citations are to CBM2014-00151 unless otherwise noted.

A. Related Proceedings

The parties identify the following as related district court proceedings regarding the '730 patent: *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, 2:10-cv-6108 (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC and Par Pharmaceutical, Inc.*, 2:13-cv-391 (consolidated with 2:13-cv-7884) (D.N.J.); and *Jazz Pharmaceuticals, Inc. v. Ranbaxy Laboratories Ltd., et al.*, 2:14-cv-4467 (D.N.J.). Pet. 78–79; Paper 8, 2–3.

The parties identify the following as petitions for covered business method review of patents related to the '730 patent: *Amneal Pharmaceuticals, LLC et al. v. Jazz Pharmaceuticals, Inc.*, CBM2014-00149 (filed June 24, 2014) (US 7,895,059 B2); *Amneal Pharmaceuticals, LLC et al. v. Jazz Pharmaceuticals, Inc.*, CBM2014-00150 (filed July 7, 2014) (US 8,457,988 B1); and *Amneal Pharmaceuticals, LLC et al. v. Jazz Pharmaceuticals, Inc.*, CBM2014-00153 (filed July 9, 2014) (US 8,589,182 B1). Pet. 78–79; Paper 8, 3.

Patent Owner identifies the following pending U.S. patent applications claiming priority benefit from US Patent Application No. 10/322,348—the application from which the '730 patent issued: US Patent Application No. 14/196,603, filed March 4, 2014; US Patent Application No. 14/219,904, filed March 19, 2014; and US Patent Application No. 14/219,941, filed March 19, 2014. Paper 8, 3.

B. 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.[3] 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 202–210). 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. Steps 226–230, 234–238 of Figure 2A are reproduced below:

[3] US 7,895,059 B2 ("the '059 patent") issued from a continuation application of US 10/322,348 ("the '348 application"), which issued as the '730 patent. CBM2014-00149 Ex. 1001, 1:6–8. US 8,457,988 B1 ("the '988 patent") and US 8,589,182 B1 ("the '182 patent") issued from a series of divisional and/or continuation applications of the '348 application. CBM2014-00150 Ex. 1001, 1:6–13; CBM2014-00153 Ex. 1001, 1:6–13.

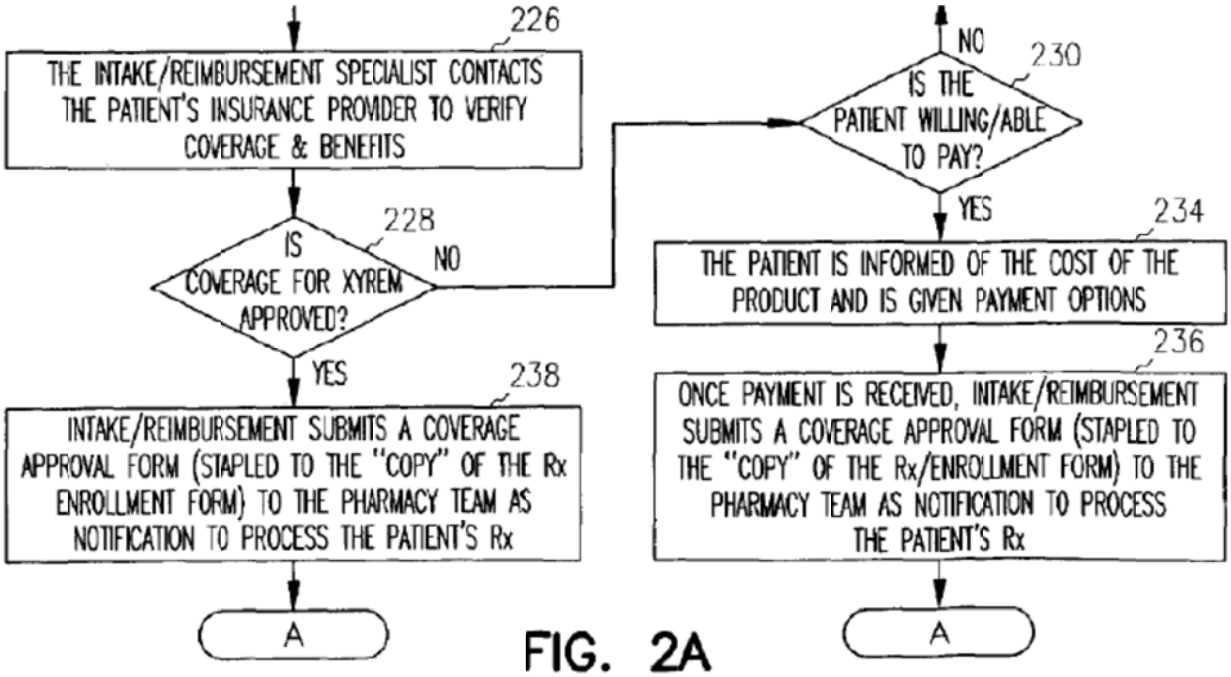

FIG. 2A

Figure 2A depicts steps for verifying insurance coverage or ability to pay. *Id.* at 2:22–24, 4:45–61. 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.

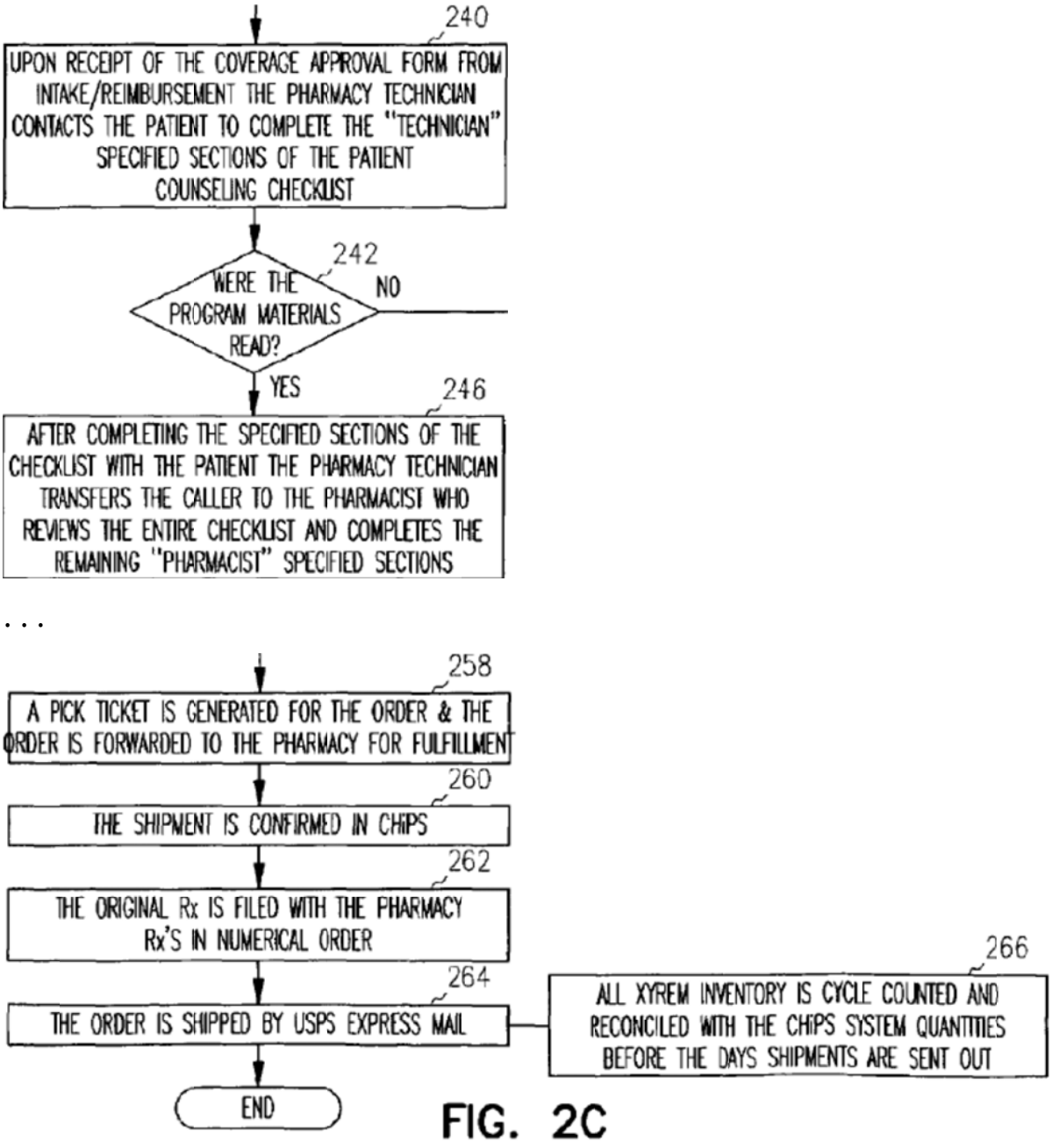

FIG. 2C

Figure 2C 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®."[4] *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).

C. 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:

> The invention claimed is:
>
> 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

[4] Xyrem is the brand name for gamma hydroxy butyrate, 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.*

> 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.

II. ANALYSIS

A. AIA § 18

Section 18 of the AIA governs the transitional program for "covered business method patent" reviews. AIA § 18(a)(1)(B) limits such reviews to a person, or the person's real party in interest or privy, who has been sued for infringement or charged with infringement of the patent at issue. As indicated above, the parties both represent that Petitioner has been sued for infringement of the '730 patent. Pet. 78; Paper 8, 2–3.

Section 18(a)(1)(E) states that a transitional proceeding may be instituted only for a "covered business method patent," which is "a patent that claims a method or corresponding apparatus for performing data

processing or other operations used in the practice, administration, or management of a *financial product or service*, except that the term does not include patents for technological inventions." AIA § 18(d)(1) (emphasis added). The Office considered the legislative intent and history behind the AIA's definition of "covered business method patent" when it promulgated rules for CBM patent review. *See* 37 C.F.R. § 42.301(a) (definition of CBM patent); *see also* 77 Fed. Reg. 48,734, 48,735 (Aug. 14, 2012 Final Rule)(Response to Comment 1: "[T]he legislative history explains that the definition of covered business method patent was drafted to encompass patents '*claiming* activities that are financial in nature, incidental to a financial activity or complementary to a financial activity.' 157 Cong. Rec. S5432 (daily ed. Sept. 8, 2011) (statement of Senator Schumer)." (emphasis added)).

Petitioner bears the burden of demonstrating that the '730 patent claims a method "used in the practice, administration, or management of a financial product or service." AIA § 18(d)(1); 37 C.F.R. § 42.304(a). In making this determination, our focus is firmly on the claims. *See* 77 Fed. Reg. at 48,736 (Aug. 14, 2012 Final Rule)(Response to Comment 4: "[T]he definition . . . is based on what the patent claims."); *see also Int'l Sec. Exch., LLC v. Chicago Bd. Options Exch.,* Case CBM2013-00050, slip op. 9 (PTAB Mar. 4, 2014 (Paper 16)) ("For purposes of determining whether a patent is eligible for a covered business method patent review, the focus is on the claims."). A patent needs only one claim directed to a covered business method to be eligible for review. *Id.* For the reasons explained

below, we conclude Petitioner has not demonstrated that the '730 patent is a "covered business method patent" under AIA § 18(d)(1).

B. Financial Product or Service

1. The '730 Patent Claims

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 requires entering the physician, patient, and prescription information into an "exclusive computer database," then tracks all prescriptions and utilizes 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.

2. Analysis of whether a patent claim satisfies the statutory "financial product or service" requirement

a. Petitioner's arguments

Petitioner argues that at least claim 1 of the '730 patent is CBM-eligible because the claimed method "would be used in commerce," i.e., the claimed method of distributing a prescription drug "is financial in nature; and it is also incidental and complementary to financial activities." Pet. 12. Petitioner emphasizes the '730 patent's description of the steps for verifying insurance coverage or a patient's ability to pay for the prescription ("In one embodiment, cash payers are also identified" (Ex. 1001, 6:39–40)), pursuant to the intake reimbursement workflow process described above. Pet. 13–14 (citing Ex. 1001, 6:33–7:6[5]). Petitioner further argues that, because the claims recite "receiving all prescription requests," "checking the credentials of any and all doctors," and "mailing" or "providing" [6] the prescription drug to the patient, the claimed method comprises "running the very business of a mail order pharmacy that direct ships to consumers." Pet. 14. Petitioner relies on the Declaration testimony of Dr. Robert J. Valuck as evidence that filling a prescription necessarily involves checking a patient's insurance coverage or ability to pay, which "ultimately relate[s] to the financial transaction of providing a prescription drug." Ex. 1007 ¶¶ 47–48.

b. The language of the patent claims

The patent claims recite a method for controlling access to a prescription drug to guard against "potential abuse" or "diversion;" they do

[5] The intake reimbursement steps of Figure 4B, described in the cited passage, are functionally the same as in Figure 2A reproduced above.
[6] Claims 7, 8, and 11 recite "providing" the prescription drug to the patient. Ex. 1001, 10:7, 10:42, 12:39.

not recite a financial product or service. The issue in dispute is whether the claim language recites method steps used in the practice, administration, or management of a "financial" [7] product or service. Petitioner does not analyze the claim language, in detail and in context, to explain how the claim language recites method steps involving the movement of money or extension of credit in exchange for a product or service, e.g., the sale of a prescription drug. Pet. 12–15. Petitioner's argument that the '730 patent claims a "financial product or service" is conclusory and not supported by persuasive evidence or analysis.

The claim limitations quoted by Petitioner, "distributing a prescription drug," [8] "receiving all prescription requests," "checking the credentials of any and all doctors," "mailing" or "providing" the prescription drug to a "patient" (Pet. 12, 14), when considered in the context of the claim as a whole, do not recite or require an activity involving the movement of money or extension of credit in connection with the sale of a prescription drug. Prelim. Resp. 20–21. The claims also do not recite a product or service particular to or characteristic of financial institutions such as banks, insurance companies, and investment houses. For example, the claim

[7] "Finance" is "the way in which money is used and handled; . . . 2: the system that includes the circulation of money, the granting of credit, the making of investments, and the provision of banking facilities." *Finance Definition*, MERRIAM-WEBSTER, , available at http://www.merriam-webster.com/dictionary/finance (last visited December 16, 2014). Ex. 3001.

[8] The preamble phrase "distributing a prescription drug" is not a substantive claim limitation because it is not "necessary to give life, meaning, and vitality" to the claims. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)(citations omitted). All steps necessary to execute the method are recited in the body of the claim.

language does not recite or require (i) the sale of a prescription drug, (ii) processing of payments, benefits, or insurance claims related to the sale of a prescription drug, (iii) a method of insuring a patient or determining the cost of insurance, (iv) a method of determining the cost of prescription benefits, (v) a method of facilitating payment of health care benefits, or (vi) the extension of credit for the purchase of a prescription drug. *Id.* at 21. We agree with Patent Owner that the activities recited in the claim language, in the context of the claim as a whole, constitute checks ("checking") and controls ("confirming") on "shipping," "mailing," or "providing" a prescription drug to an authorized "patient" to prevent "potential abuse" and "evaluate potential diversion patterns." *Id.*

Therefore, for the reasons given above, we are unpersuaded by Petitioner's argument that the '730 patent claims recite method steps "used in the practice, administration, or management of a financial product or service."

c. The written description of the '730 patent

The claim limitations of the '730 patent cited by Petitioner also do not recite or require the act of verifying a patient's insurance coverage or ability to pay for the prescription drug. Petitioner and Dr. Valuck do not explain, in detail with specific analysis of the claim language, why the claimed method steps recite or require verifying insurance coverage or a patient's ability to pay as described in Figures 2A, 4B, or 5 of the patent. Pet. 13–14 (citing Ex. 1007 ¶¶ 47–48); Prelim. Resp. 25–27. Petitioner and Dr. Valuck also do not explain why any of the claimed method steps should be considered "financial" when considered in the context of the claim

language as a whole. Their reasoning is circular – "[t]hese claimed steps are all financially related activities that are performed daily by pharmacies because they provide prescription drugs to consumers" (Ex. 1007 ¶ 47; Pet. 22–23) – and unpersuasive. We agree with Patent Owner; the act of verifying a patient's insurance coverage or ability to pay is not a claimed method step in the '730 patent. Prelim. Resp. 26–27.

Petitioner confirms our analysis with its own diagram that "maps each limitation of claim 1 to a representative flow diagram step from the figures of the '730 patent." Pet. 50–51. Petitioner identifies the method steps recited in claim 1 as steps 1.1 to 1.8. *Id.* at 51. Petitioner's diagram, with our notations of corresponding figure and step numbers in the right-hand margin, is reproduced below:

Annotated flow diagram of claim 1.

Pet. 51. Petitioner's diagram, above, omits all reference to method steps for verifying insurance coverage or a patient's ability to pay in Figures 2A (steps 226–238), 4B (steps 448–452, 458–466), and 5, even though other flow diagram steps from Figures 2A and 4B are represented in Petitioner's claim 1 diagram. The omission is telling. In short, the claimed method steps do not recite or require verifying insurance coverage or a patient's ability to pay for a prescription drug product. Prelim. Resp. 26–27 (citing, e.g., *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.,* 529 F.3d 1364, 1373 (Fed. Cir. 2008)("Our precedent is replete with examples of subject matter that is included in the specification, but is not claimed.")(citations omitted)).

We also agree with Patent Owner that in the three CBM decisions cited by Petitioner (Pet. 13, n.3, 4), the Board relied on the written description of the respective patents to support the "financial product or service" requirement because the claim limitations recited method steps used in the embodiments described in the relied-upon portions of the specifications. Prelim. Resp. 24–25 (citing *CRS Advanced Tech., Inc. v. Frontline Tech., Inc.*, Case CBM2012-00005, slip. op. 8 (PTAB January 23, 2013(Paper 17))(claimed method for substitute teller fulfillment system used in embodiment for retail banking system); *Google Inc. v. Inventor Holdings*, Case CBM2014-00002, slip op. 8–9 (PTAB April 1, 2014 (Paper 16))(claimed method of facilitating exchange of identities between two anonymous parties used in embodiment for matching employment candidates with employer); *Google Inc. v. Inventor Holdings*, CBM2014-

00003, slip op. 8–9 (PTAB April 1, 2014(Paper 12))(same, *id.*)).[9] Petitioner has not made a comparable or persuasive argument based on a close analysis of the claim language, considered in context as a whole, in view of the embodiments described in the '730 patent. Therefore, we find the cited authority inapposite to the facts of the present case.

For the reasons given above, we are unpersuaded by Petitioner's argument that the written description of method steps for verifying insurance coverage or a patient's ability to pay are recited or required by the '730 patent claims.

d. Petitioner's "used in commerce" argument

We agree with Patent Owner that Petitioner improperly attempts to expand CBM review to cover a claimed business method because it is "used in commerce." Pet. 12–14; Prelim. Resp. 10–12. Petitioner's argument is not supported by the plain language of the statute or the legislative history. Pet. 11–12; Prelim. Resp. 11 (citing *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253–54 (1992) ("[I]n interpreting a statute a court should always turn first to one, cardinal canon before all others . . . courts must presume that a

[9] In CBM2014-00149 (Pet. 12–13), CBM2014-00150 (Pet. 12) and CBM2014-00153 (Pet. 15–16), Petitioner also cites *Liberty Mutual Insurance Co. v. Progressive Casualty Insurance Co.*, Case CBM2012-00002 (PTAB Jan. 23, 2014) and *Gilllman v. Stoneeagle Servs., Inc.*, Case CBM2013-00047, slip op. at 8 (PTAB Feb. 18, 2014)(Paper 11) in further support of the argument that the written description of verifying insurance coverage or a patient's ability to pay is claimed in the '059, '988, and '182 patents. *Liberty Mutual* involved a claimed method for determining the cost of automobile insurance, and *Gillman* involved a claimed method for adjudicating a health insurance claim and processing payment for that claim. *Id.* Both cases are factually distinguishable from the present cases for the reasons given in sections 2.b. and 2.c. of this Decision.

legislature says in a statute what it means and means in a statute what it says there."). Petitioner does not provide a cogent argument or rationale for why the statutory phrase "financial product or service" should be interpreted to include a method for controlling access to a prescription drug that may be used in commerce. Pet. 11–14. Contrary to Petitioner's argument, Congress did not say in the statute that a business method patent "used in commerce" or covering "core activities" of running a business is eligible for CBM review. AIA § 18(d)(1); Prelim. Resp. 11–12, 17–18. To the contrary, the language of the statute excludes such a business method from CBM review unless a petitioner demonstrates that the method is "used in the practice, administration, or management of a financial product or service." AIA § 18(d)(1). Petitioner does not persuasively address the language of the statute or provide persuasive evidence or analysis from which we might conclude that the claimed method recites steps used in the practice, administration, or management of a financial product or service.

The legislative history, taken in context as a whole, also does not support Petitioner's argument. As Patent Owner emphasizes, when an adjudicator considers legislative intent "the Supreme Court has cautioned that the adjudicator must consider the legislative intent as a ***whole***—not just 'isolated fragments' of congressional comments." Prelim. Resp. 13 (citing *New England Power Co. v. New Hampshire*, 455 U.S. 331, 342 (1982) ("Reliance on such isolated fragments of legislative history in divining the intent of Congress is an exercise fraught with hazards . . . ."); *Offshore Logistics, Inc. v. Tallentire*, 477 U.S. 207, 220–21 (1986) (statements in the legislative history must be read in light of the statutory language and

legislative history as a whole)). With such caution in mind, we observe that members of Congress expressed varying views concerning the scope of a "covered business method patent" during the debate leading up to passage of the AIA on September 16, 2011. Prelim. Resp. 13–16.

Those views are exemplified on the one hand by Senator Schumer, co-sponsor of the transitional program for CBM patent review, who stated that "Any business that sells or purchases goods or services 'practices' or 'administers' a financial service by conducting such transactions . . . ." 157 Cong. Rec. S5432 (daily ed. Sept. 8, 2011). On the other hand, Senator Leahy, co-sponsor of the AIA, expressed a more limited view and stated that the program was intended to cover "only those business method patents intended to be used in the practice, administration, or management of financial services or products, and not to technologies common in business environments across sectors and that have no particular relation to the financial services sector." *Id.* at S5441. Senator Kyl, co-sponsor with Senator Schumer of AIA Section 18, entered into the record the Senate Manager's Amendment, which described a covered business method patent as "limited to data processing relating to just a financial product or service (rather than also to an enterprise[10])." *Id.* at S1367 (daily ed. Mar. 8, 2011).

The '730 patent's claimed method for controlling access to a prescription drug does not recite method steps involving the movement of

[10] An "enterprise" is distinguished from the more limited "financial product or service" in the USPTO's Manual of Classification, Class 705, which defines an enterprise as, *inter alia*, a "conventional business organization." Prelim. Resp. 15; *see* *http://www.uspto.gov/web/offices/ac/ido/oeip/taf/def/705.htm*.

money or extension of credit in connection with the sale of a prescription drug. The claims are more limited and define a decidedly different activity – controlling access to a prescription drug to guard against potential abuse or diversion. The claimed method, moreover, has no particular relation to the financial services industry and does not relate to just a financial product or service rather than to an enterprise, i.e., a conventional business organization. Therefore, in the absence of clear and compelling evidence of legislative intent to include any business method "used in commerce" within the definition of a "covered business method patent" pursuant to AIA § 18(d)(1), we are unpersuaded by Petitioner's argument.

e. Petitioner's Class 705 argument

Petitioner relies on the classification of the '730 patent in Class 705, subclass 2, which includes "*billing systems* based on entered medical codes," in support of the argument that "[b]illing systems encompassed within the '730 patent are activities that are financial in nature, incidental . . . or complementary to a financial activity." Pet. 14–15. Petitioner also relies on the citation of prior art billing systems by the Examiner during examination of the '730 application as further support for this argument. *Id.* at 15. Petitioner argues that, although not dispositive, the classification of the '730 patent in Class 705 and citation of art regarding prescription drug payment arrangements is persuasive evidence that the '730 method claims satisfy the statutory "financial product or service" requirement. *Id.* at 14–15.

Petitioner does not explain, however, how the claim language of the '730 patent recites method steps used in medical code billing systems or prior art payment systems. *Id.* As indicated by Patent Owner, the '730

patent claims do not recite method steps used in billing systems, and the patent does not even describe billing systems. Prelim. Resp. 29. In sum, in the absence of a more detailed analysis and explanation of how the claim language and prior art recite method steps used in billing systems, we are not persuaded that mere classification in Class 705 supports the inference that the patent claims satisfy the "financial product or service" requirement of AIA § 18(d)(1).

3. Conclusion

For the reasons given above, based on the present record and particular facts of this case, Petitioner has not demonstrated that at least one claim of the '730 patent recites or requires method steps "used in the practice, administration, or management of a financial product or service" as defined in Section 18(d)(1) of the AIA.

C. Additional arguments of Petitioner regarding whether the '059, '988, and '182 patents claim a method step "used in the practice, administration, or management of a financial product or service"

1. The '059 patent claim 8 (CBM2014-00149)

Petitioner argues that "claim 8 [of the '059 patent] is clearly CBM-eligible, because it expressly covers incidental activities related to a financial product or service—verifying insurance coverage and patient payment." Pet. 12.[11] Claim 8 does not recite a method step for "verifying" a patient's insurance coverage or payment for the prescription drug. Ex. 1001, 9:56–67. Claim 8 depends from claim 7, which depends from independent claim 6 that recites a "computerized method of distributing a prescription drug under

[11] All citations in this subsection are to the papers and exhibits in CBM2014-00149.

control of an exclusive central pharmacy" to guard against "potential abuse" or unauthorized "diversion" of the prescription drug. *Id.* at 9:13–14. Claim 8 recites additional controls on providing access to the prescription drug when the drug is dispensed to the patient by "another pharmacy," i.e., a pharmacy other than the exclusive central pharmacy. *Id.* at 9:56–67. Those additional controls include: "contacting the patient's insurance company, questioning early refill requests by the patient, flagging repeat instances of lost, stolen, destroyed or spilled prescriptions, flagging that the patient paid cash for the prescription drug, flagging early requests to refill the prescription drug, and limiting the prescription to a supply of limited duration." *Id.* at 9:61–67.

Although Petitioner highlights "contacting the patient's insurance company" and "flagging that the patient paid cash," they do not attempt to explain how the claim language, when read in context as a whole, recites or requires verifying insurance coverage or patient payment. To the contrary, when read in context, the method steps of claim 8 highlighted by Petitioner recite controls on access to the prescription drug to guard against "potential abuse" or "diversion," not to verify insurance or payment for the drug. Prelim. Resp. 22–23. The '730 patent defines the problem: "Some patients . . . will obtain prescriptions from multiple doctors, and have them filled at different pharmacies. Still further, an unscrupulous physician may actually write multiple prescriptions for a patient, or multiple patients, who use cash to pay for the drugs." *Id.* at 24 (citing Ex. 1001, 1:30–34). The claimed method solves the problem by monitoring the database for potentially abusive prescription patterns, including the steps of flagging cash payments

and contacting a patient's insurance company. *Id.* at 25 (citing Ex. 1001, 1:45–49).

In sum, the inventors could have claimed the steps of verifying insurance coverage or patient payment, but they did not. Petitioner does not provide a persuasive analysis for why we should find otherwise. Petitioner's argument that claim 8 recites method steps used in the practice, administration, or management of a financial product or service, rather than steps used to control access to a prescription drug to guard against potential abuse or diversion, is contrary to the plain meaning of claim 8. Therefore, we decline to accept Petitioner's argument with respect to claim 8 of the '059 patent.

2. The '988 patent claims (CBM2014-00150)

The preambles to the independent claims in the '988 patent, such as in claim 1, 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, 8:38–40.[12] The body of the claim recites very similar method steps as in the '730 patent for controlling access to a sensitive prescription drug. *Id.* at 8:41–9:13. Petitioners Amneal and Par cite the PTAB decision in *Saleforce.com* in support of their argument that "the claimed methods [of the '988 patent] have particular application involving ancillary activities related to a financial product or service." Pet. 11 (citing *Salesforce.com v. VirtualAgility*, Case CBM2013-00024, slip op. at 11 (PTAB Nov. 19, 2013 (Paper 16))). As Patent Owner correctly notes,

[12] All citations in this subsection are to the papers and exhibits in CBM2014-00150.

Petitioners Amneal and Par do not explain their citation to the *Salesforce.com* decision or otherwise offer any analysis of the case in support thereof. Prelim. Resp. 23. Therefore, we are unpersuaded by their citation to the *Salesforce.com* case.

3. The '182 patent claims (CBM2014-00153)

The independent claim preambles in the '182 patent, such as in claim 1, recite 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." Ex. 1001, 8:38–42.[13] The body of the claim then recites very similar method steps as in the '730 patent for controlling access to a sensitive prescription drug. *Id.* at 8:43–9:6. Petitioners Amneal and Par argue that the preamble "wherein" clause, describing the drug as one "sold or distributed by a company that obtained approval" for its distribution, has particular application in the practice, administration, or management of a financial product or service. Pet. 12–13. Petitioners Amneal and Par, however, do not provide supporting evidence, explanation, or analysis for this argument. *Id.* The preamble "wherein" clause is little more than a contextual description of a company approved by the Food and Drug Administration ("FDA") to sell or distribute the drug; a company not approved by the FDA is not authorized to sell the drug or perform the claimed method steps. Prelim. Resp. 24. In short, the descriptive "wherein" clause is not a method step used in the practice,

[13] All citations in this subsection are to the papers and exhibits in CBM2014-00153.

administration, or management of a financial product or service, including sale of a prescription drug. Therefore, we are unpersuaded by that argument.[14]

III. CONCLUSION

For the reasons given above, based on the present record and particular facts of these cases, we are not persuaded that the information presented in the Petition establishes that any claim in the '730, '059, '988, and '182 patents qualifies as a covered business method patent under Section 18 of the AIA. Petitioner, therefore, has failed to satisfy the jurisdictional requirements of Section 18.

IV. ORDER

Accordingly, it is ORDERED that the Petition is *denied*.

[14] Amneal and Par further argue that, because a method step recited in dependent claims 3, 10, and 21 ("wherein a pharmacy enters data into the single computer database") is "to be performed by a pharmacy – which itself is a business," the claims are related to the practice, administration, or management of a financial product or service. Pet. 13. That argument is part and parcel of the "used in commerce" argument addressed in subsection 2.d., above.

Case CBM2014-00149 (Patent 7,895,059 B2)
Case CBM2014-00150 (Patent 8,457,988 B1)
Case CBM2014-00151 (Patent 7,668,730 B2)
Case CBM2014-00153 (Patent 8,589,182 B1)

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