

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ROXANE LABORATORIES, INC. and PAR PHARMACEUTICAL, INC.,
Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case CBM2014-00161 (Patent 7,765,106 B2)
Case CBM2014-00175 (Patent 7,765,107 B2)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

¹ This Decision addresses the same jurisdictional issue raised in both cases. The patents at issue in CBM2014-00161 and CBM2014-00175 are 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. *See Par Pharm., Inc. v. Jazz Pharms., Inc.*, Case CBM2014-00149/150/151/153, slip op. (PTAB Jan. 13, 2015) (Paper 12).

I. INTRODUCTION

Roxane Laboratories, Inc. (“Roxane”), and Par Pharmaceutical, Inc. (“Par”) (together, “Petitioner”) filed a Petition requesting covered business method (“CBM”) patent review of claims 1–8 (all claims) of US Patent No. 7,765,106 B2 (Ex. 1001, “the ’106 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 6 (“Pet.”). Jazz Pharmaceuticals, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 13 (“Prelim. Resp.”). We have jurisdiction under 35 U.S.C. § 324, which provides that a post-grant patent review, such as a 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 1–8 of the ’106 patent as unpatentable under 35 U.S.C. §§ 101, 102(b), and 103(a). Pet. 34–35. Based on the information presented in the Petition and Preliminary Response, we determine Petitioner has not demonstrated that the ’106 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 CBM2014-00161 as representative of both cases. All citations are to CBM2014-00161 unless otherwise noted. In CBM2014-00175, Petitioner challenges claims 1–6 of US Patent No. 7,765,107 B2 (“the ’107 patent”), which claims a “computerized method to control abuse of a prescription drug” followed by a series of control steps, including “determining . . . current and anticipated patterns of potential prescription abuse . . . from periodic reports generated only by the central database based on prescription request data” CBM2014-00175, Ex. 1001, 8:36–9:25 (claim 1).

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A. Related Proceedings

The parties identify the following as related district court proceedings regarding the '106 patent: *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, 2:10-cv-6108 (D.N.J.); *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 2:13-cv-391 (consolidated with 2:13-cv-7884) (D.N.J.); and *Jazz Pharms., Inc. v. Ranbaxy Labs. Ltd.*, 2:14-cv-4467 (D.N.J.). Pet. 79; Paper 11, 2–3.

The parties identify the following as petitions for covered business method review of patents related to the '106 patent: *Amneal Pharms., LLC v. Jazz Pharms., Inc.*, Case CBM2014-00149 (filed June 24, 2014) (US 7,895,059 B2); *Amneal Pharms., LLC v. Jazz Pharms., Inc.*, Case CBM2014-00150 (filed July 7, 2014) (US 8,457,988 B1); *Par Pharm., Inc. v. Jazz Pharms., Inc.*, Case CBM2014-00151 (filed July 9, 2014)(US 7,668,730 B2), and *Amneal Pharms., LLC v. Jazz Pharms., Inc.*, Case CBM2014-00153 (filed July 9, 2014) (US 8,589,182 B1). Pet. 79; Paper 11, 3.

Patent Owner identifies the following pending US patent applications claiming priority benefit from US Patent Application No. 10/322,348, from which the '106 patent also claims priority benefit: 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 11, 3.

B. The '106 Patent

The '106 patent, titled “Sensitive Drug Distribution System and Method,” issued July 27, 2010 from an application filed November 2, 2004.

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Ex. 1001.³ The '106 patent is directed to a method for treating a patient with a sensitive prescription drug and controlling access to the sensitive prescription drug, which is prone to potential abuse, misuse, or diversion, by utilizing a central pharmacy and database to track all prescriptions for the sensitive drug. *Id.* at Abstract, 1:44–46. Information regarding all physicians authorized to prescribe the drug and all patients receiving the drug is maintained in the database. *Id.* at 1:46–48. Abuses are identified by monitoring the database for prescription patterns by physicians and prescriptions obtained by patients. *Id.* at Abstract, 1:48–50.

Figures 2A, 2B, and 2C comprise flow charts representing “an initial prescription order entry process for a sensitive drug” *Id.* at 4:13–14. In overview, a physician submits prescriber, patient, and prescription information for the sensitive drug to a pharmacy team, which enters the information into a computer database. *Id.* at 4:13–39, 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 4:51–55. Steps 226–230 and 234–238 of Figure 2A are reproduced below:

³ The '107 patent issued from a divisional application of US 10/322,348 (“the '348 application”). CBM2014-00175, Ex. 1001, 1:6–9.

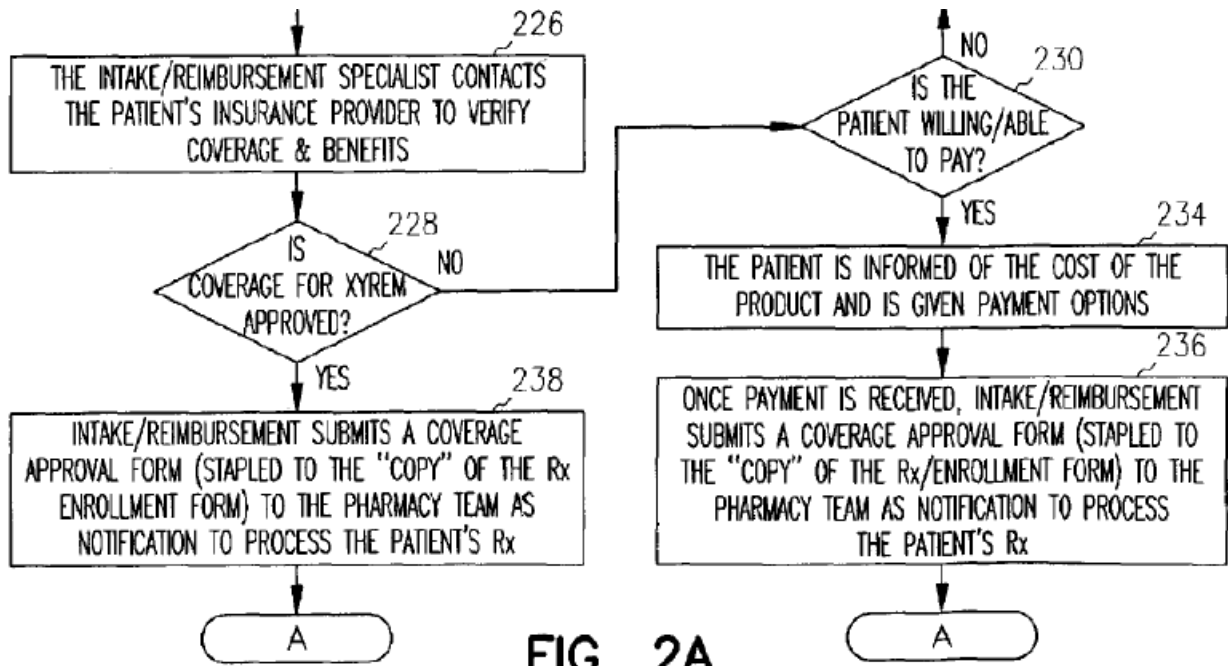


FIG. 2A

Figure 2A depicts steps for verifying insurance coverage or ability to pay. *Id.* at 2:28–30, 4:51–67. The “pharmacy” workflow includes verifying prescribing physicians’ credentials. *Id.* at 5:7–19, Fig. 2B (steps 274–280). Filling the prescription includes confirming the patient has read sensitive drug educational materials, confirming the patient’s receipt of the sensitive drug, and daily cycle counting and inventory reconciliation. *Id.* at 5:31–6:4. Figure 2C steps 240, 242, 246, and 258–266 are reproduced below.

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