Trials@uspto.gov
Tel: 571-272-7822

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

---

[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.

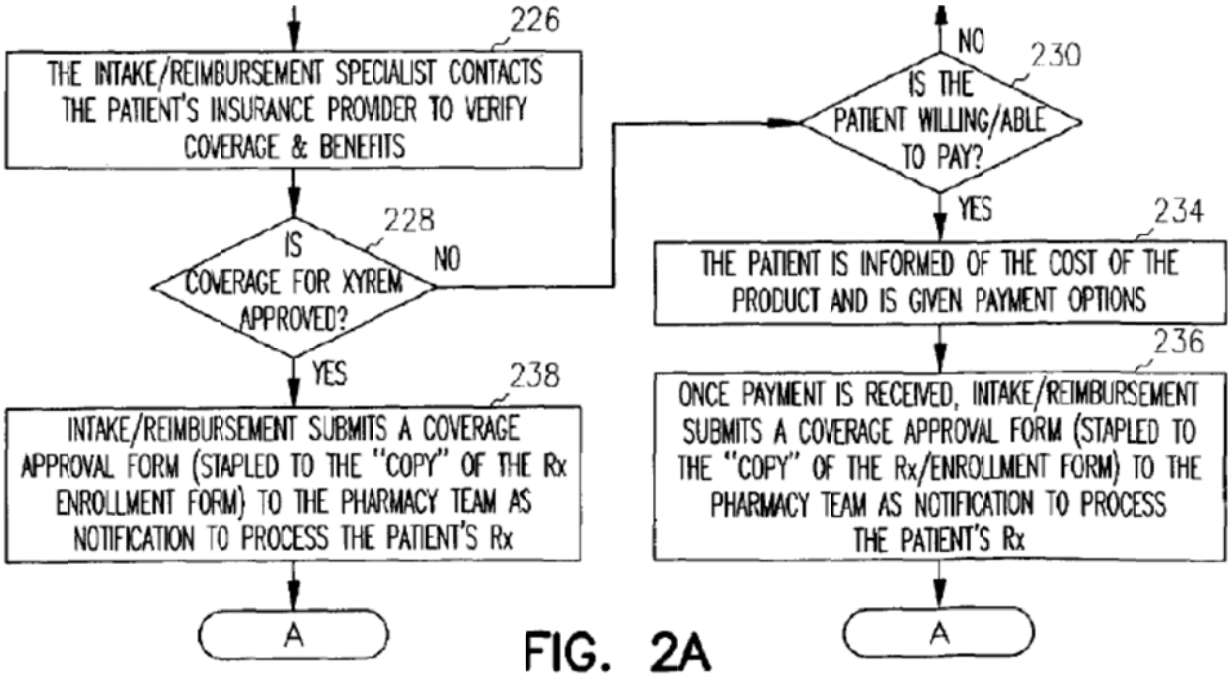

FIG. 2A

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.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.