United States Court of Appeals for the Federal Circuit

JAZZ PHARMACEUTICALS, INC.,
Appellant

v.

AMNEAL PHARMACEUTICALS, LLC,
Appellee

2017-1671, 2017-1673, 2017-1674, 2017-1675, 2017-1676, 2017-1677, 2017-2075

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2015-00545, IPR2015-00546, IPR2015-00547, IPR2015-00548, IPR2015-00551, IPR2015-00554, IPR2015-01903.

Decided: July 13, 2018

KATHLEEN M. SULLIVAN, Quinn Emanuel Urquhart & Sullivan, LLP, New York, NY, argued for appellant. Also represented by F. DOMINIC CERRITO, GABRIEL P. BRIER, FRANK CHARLES CALVOSA, EVANGELINE SHIH, ERIC C. STOPS; DAVID B. COCHRAN, Jones Day, Cleveland, OH.

STEVEN ARTHUR MADDOX, Maddox Edwards, PLLC, Washington, DC, argued for appellee Also represented by MATTHEW C. RUEDY.

Before NEWMAN, LOURIE, and REYNA, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Jazz Pharmaceuticals, Inc. ("Jazz") appeals from six *inter partes* review ("IPR") decisions of the United States Patent and Trademark Office Patent Trial and Appeal Board (the "Board").[1] Collectively, the decisions held certain claims of Jazz's U.S. Patents 7,668,730 ("'730 patent"), 7,765,106, 7,765,107, 7,895,059, 8,589,182, 8,457,988 ("'988 patent"), and 8,731,963 ("'963 patent") (together, the "patents in suit") invalid as obvious. Because the Board did not err in its conclusions of obviousness, we affirm.

BACKGROUND

The patents in suit are members of a family of patents owned by Jazz relating to a drug distribution system for tracking prescriptions of a "sensitive drug." '730 patent

[1] *Amneal Pharm., LLC v. Jazz Pharm., Inc.*, No. IPR2015-01903, 2017 WL 1096638 (P.T.A.B. Mar. 22, 2017) ("*'963 Decision*"); *Amneal Pharm., LLC v. Jazz Pharm., Inc.*, No. IPR2015-00545, 2016 WL 7985452 (P.T.A.B. Dec. 22, 2016); *Par Pharm., Inc. v. Jazz Pharm., Inc.*, No. IPR2015-00546, 2016 WL 7985429 (P.T.A.B. Dec. 22, 2016); *Par Pharm., Inc. v. Jazz Pharm., Inc.*, No. IPR2015-00547, 2016 WL 7985454 (P.T.A.B. Dec. 22, 2016); *Par Pharm., Inc. v. Jazz Pharm., Inc.*, No. IPR2015-00548, 2016 WL 7985430 (P.T.A.B. Dec. 22, 2016); *Par Pharm., Inc. v. Jazz Pharm., Inc.*, Nos. IPR2015-00551, IPR2015-00554, 2016 WL 7985458 (P.T.A.B. July 27, 2016) ("*'730/'988 Decision*").

Abstract.[2] "A sensitive drug is one which can be abused, or has addiction properties or other properties that render the drug sensitive." '730 patent col. 3 ll. 14–16.

One such sensitive drug is Xyrem®. Jazz exclusively markets Xyrem®, which the U.S. Food and Drug Administration ("FDA") has approved to treat symptoms associated with narcolepsy. However, the active ingredient in Xyrem®, gamma-hydroxybutyrate ("GHB"), may also be illicitly used as a "date-rape drug." *See* Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, Pub. L. No. 106-172, 114 Stat. 7 (2000). Accordingly, under the Controlled Substances Act any approved drug product containing GHB is classified as a Schedule III depressant. 21 C.F.R. § 1308.13. Because of its potential for abuse, the FDA approved Xyrem® under "restricted distribution regulations contained in [21 C.F.R. § 314.500] (Subpart H) to assure safe use of the product." J.A. 11055; *see* 21 C.F.R. § 314.520.

During the regulatory review process for Xyrem®, the FDA scheduled an advisory committee meeting for June 6, 2001. The meeting was announced in a May 14, 2001 Federal Register Notice, which stated that the meeting was open to the public and that "[a] main focus of the deliberations will be on risk management issues" associated with Xyrem®. Meeting Notice, 66 Fed. Reg. 24,391 (May 14, 2001) ("Notice"). The Notice also provided a hyperlink to an FDA website where background material would be posted before the meeting, and the meeting minutes, transcript, and slides would be posted after the meeting. *Id.* Collectively, the Board referred to the background materials and the meeting minutes, transcript, and slides on the FDA website as the Advisory

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[2] As the patents in suit share a substantially identical specification, for ease of reference we cite only the '730 patent.

Committee Art ("ACA materials"). Each of the Board's obviousness determinations relied on the ACA materials as prior art. The primary issue on appeal is whether the ACA materials were sufficiently accessible to the public to constitute prior art.

I

The claimed invention of the patents in suit involves tracking prescriptions of a sensitive drug through a database. '730 patent Abstract. Claim 1 of the '730 patent is illustrative, and recites:

> 1. A computerized method of distributing a prescription drug under exclusive control of an exclusive central pharmacy, the method comprising:
>
> receiving in a computer processor all prescription requests, for any and all patients being prescribed the prescription drug, only at the exclusive central pharmacy from any and all medical doctors allowed to prescribe the prescription drug, *the prescription requests containing information identifying patients, the prescription drug, and various credentials of the any and all medical doctors*;
>
> *requiring entering of the information into an exclusive computer database* associated with the exclusive central pharmacy for analysis of potential abuse situations, such that all prescriptions for the prescription drug are processed only by the exclusive central pharmacy using only the exclusive computer database;
>
> checking with the computer processor the credentials of the any and all doctors to determine the eligibility of the doctors to prescribe the prescription drug;

> confirming with a patient that educational material has been read prior to shipping the prescription drug;
>
> checking the exclusive computer database for potential abuse of the prescription drug;
>
> mailing the prescription drug to the patient only if no potential abuse is found by the patient to whom the prescription drug is prescribed and the doctor prescribing the prescription drug;
>
> confirming receipt by the patient of the prescription drug; and
>
> generating with the computer processor *periodic reports via the exclusive computer database to evaluate potential diversion patterns*.

Id. col. 8 l. 37–col. 9 l. 3 (emphases added).

Of particular relevance to this appeal are the "exclusive computer database," "information identifying," and "periodic reports" terms, italicized above. The specification describes an "exclusive central database" as including all data relevant to distribution of a sensitive drug, "including patient, physician and prescription information." *Id.* col. 2 ll. 10–12. Several types of such information are listed in the description of figure 2. "The prescriber information contains standard contact information as well as license number, DEA number and physician specialty. Patient and prescription information includes name, social security number, date of birth, gender, contact information, drug identification, patient's appropriate dosage, and number of refills allowed . . . ." *Id.* col. 4 ll. 18–23.

Reports may be run against information in the database to "reveal potential abuse of the sensitive drug, such as early refills." *Id.* col. 2 ll. 14–15. An early refill report is made when a specific event occurs: a patient requests a

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