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

Paper 73
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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*.

DECISION
Denying Patent Owner's Request for Rehearing
37 C.F.R. § 42.71(d)

I. INTRODUCTION

Jazz Pharmaceuticals, Inc. ("Patent Owner") filed a Request for Rehearing following our Final Written Decision determining all challenged claims of U.S. Patent No. 8,589,182 B1 (Ex. 1001, "the '182 patent") to be unpatentable. Paper 69 ("Decision"); Paper 70 ("Rehearing Request" or "Req. Reh'g"). Amneal Pharmaceuticals LLC and Par Pharmaceutical, Inc. (together "Petitioner") filed a Response to Patent Owner's Rehearing Request. Paper 71 ("Opp."). Patent Owner seeks reconsideration of the Board's determination that claims 19–25 of the '182 patent are unpatentable for obviousness over the Advisory Committee Art (Exs. 1003–1006, collectively "the ACA"). Req. Reh'g 1. Patent Owner argues that the Board: (i) misapprehended the limitation in independent claim 19 reciting "verifying two or more of the following using the computer processor prior to providing the single prescription 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;" (the "verifying" step) and (ii) overlooked the actual disclosures of the ACA in finding the ACA disclosed the "verifying" step. *Id.* Petitioner opposes the rehearing request. Opp. 2–5.

Having considered the parties' submissions on Patent Owner's Rehearing Request, Patent Owner's request is *denied*.

II. STANDARD OF REVIEW

A party who requests rehearing bears the burden of showing that a decision should be modified. 37 C.F.R. § 42.71(d). The party must identify

all matters the party believes we misapprehended or overlooked, and the place where each matter was addressed previously in a motion, an opposition, or a reply. *Id.* "A Request for Rehearing is not an opportunity to re-argue old arguments." *Histologics, LLC v. CDX Diagnostics, Inc.*, Case IPR2014-00779, slip op. at 4 (PTAB Oct. 16, 2014) (Paper 9). With the aforementioned principles in mind, we address the rehearing arguments presented by Patent Owner.

III. ANALYSIS

Independent claim 19 of the '182 patent recites a method step for entering patient identifying information into a computer database: "entering, using the computer processor, into the single computer database information sufficient to identify the narcoleptic patient." Ex. 1001, 11:9–11. The '182 patent describes a patient's identifying information—name, address ("contact information"), and the prescription amount located on the "Rx/enrollment form" received from the prescribing physician—as being input into the central computer database by an "intake reimbursement specialist" using a computer processor. *Id.* at 4:17–44, Fig. 2A (202–210). The '182 patent generally describes an intake reimbursement specialist "entering the patient and physician information into an application/database referred to as CHIPS . . . a client home infusion program (CHIP) for Xyrem®." *Id.* at 4:39–43, Fig. 2A (210).

Claim 19 also recites a step for

> verifying two or more of the following *using the computer processor* prior to providing the single prescription 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.

Id. at 11:23–29 (emphasis added). The '182 patent describes how an intake reimbursement specialist verifies the patient information that has been input into the computer database, as follows: "CONTACTS MD TO VERIFY RECIEPT & ACCURACY OF THE PATIENT'S RX & THIS CONTACT IS RECORDED IN CHIPS." *Id.* at Fig. 2A (220); 4:51–55 ("[T]he MD is contacted at 220 to verify receipt and accuracy of the patient's Rx. This contact is recorded in CHIPS [Client Home Infusion Program database]."). Thus, the '182 patent specification informs a person of ordinary skill in the art ("POSA") that the intake reimbursement specialist uses the computer processor to enter the patient's information into the computer database and then verifies the information by "contacting" the prescribing physician. *Id.* at 4:17–55. The '182 patent does not further describe or limit how the prescribing physician is contacted or how the intake reimbursement specialist verifies the patient information in the computer database.

Patent Owner's Rehearing Request repeats the same argument it made in the Patent Owner's Response, namely that the ACA discloses verification of the recited information "by a human" not "by a computer processor." *Compare* PO Resp. 26–30 *with* Req. Reh'g 2–3. The argument is based on an implicit claim interpretation by Patent Owner that would prohibit a human being, such as an intake reimbursement specialist, from contacting a prescribing physician by telephone to verify the recited patient information that had been entered into the database using a computer processor. Not only is such an interpretation at odds with the '182 patent specification, but

we considered and rejected Patent Owner's argument in our Decision. Dec. 42–45. We stated:

> 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.

Dec. 43. We further found "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.* at 44 (citing Ex. 1007 ¶ 62). Patent Owner's Rehearing Request overlooks the salient portions of

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