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Paper 74
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-00551
Patent 8,457,988 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. 8,457,988 B1 (Ex. 1001, "the '988 patent") to be unpatentable. Paper 70 ("Decision" or "Dec."); Paper 71 ("Rehearing Request" or "Req. Reh'g"). Par Pharmaceutical, Inc. and Amneal Pharmaceuticals LLC (together "Petitioner") filed a Response to Patent Owner's Rehearing Request. Paper 73 ("Opp."). Patent Owner seeks reconsideration of the Board's determination that claims 1–15 of the '988 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 misapprehended or overlooked certain evidence when (i) determining that Korfhage does not teach away from the use of distributed database systems, and (ii) construing the following claim limitation: "the prescription requests containing information identifying narcoleptic patients, the prescription drug, and various credentials of the any and all medical doctors." *Id.* at 1–2. Petitioner opposes the Rehearing Request. Opp. 2–9.

Having considered the parties' submissions concerning 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

A. Our Consideration of Korfhage and Dr. Bergeron's Testimony

Patent Owner asserts that the Board "overlooked and/or misapprehended" Patent Owner's argument and expert testimony that the Korfhage reference teaches away from the use of "distributed databases," as recited in claims 2 and 10. Req. Reh'g 2–3; Dec. 56–59. Our Decision explained that Korfhage "suggests that a single query can operate over the distributed database computers to accommodate user preference 'to view the system as accessing a single logical database in response to a query, even when the system must consult multiple physical databases.'" Dec. 57 (quoting Ex. 1037 at 276). We explicitly considered Patent Owner's submission that Korfhage teaches away from the use of distributed databases because of "problems" that may arise. *Id.* at 57–58 ("Patent Owner further argues that Korfhage teaches away from using distributed databases because Korfhage discloses that 'three **major problems** arise' when attempting to have a single query operate over multiple physical databases.") (citing PO Resp. 59 (which cited Dr. Bergeron's declaration testimony, Ex. 2047 ¶¶ 62–65)). We considered, but were not persuaded by, Patent Owner's and

Dr. Bergeron's interpretation of Korfhage, including any supposed teaching away:

> We also agree with Petitioner that Korfhage does not teach away from the use of distributed databases systems, particularly given the acknowledgement of Dr. Bergeron that Korfhage offered solutions to the problems identified.

Id. at 59 (citing Ex. 1037, 276–77; Ex. 1054, 317:13–320:12).

We did not overlook or misapprehend Patent Owner's argument and evidence, rather, we declined to credit them in view of the text of Korfhage, Dr. Valuck's testimony, and Dr. Bergeron's deposition testimony. Dec. 56–59. The pages of Korfhage cited and quoted in our Decision disclose multiple factors "driving information systems to the use of distributed document sets and distributed processing," and set up "[t]hree major problems" only to discuss "simple solution[s]," a position supported by Dr. Valuck. Dec. 57–59 (citing Ex. 1007 ¶ 157; Ex. 1037 at 276–77). Under cross-examination by Petitioner's counsel, Dr. Bergeron readily acknowledged that Korfhage's discussion of data redundancy and matching document evaluation "problems" were paired with disclosed solutions, which undercut his declaration testimony (Ex. 2047 ¶¶ 56–65) relied upon by Patent Owner. Ex. 1054, 317:13–320:12. Our Decision credits Dr. Bergeron's deposition testimony, which acknowledges the distributed

database system solutions disclosed in Korfhage, rather than the speculative new problems hypothesized in his declaration and Patent Owner's Response.

For example, Patent Owner argued that if the prior art ACA system for distributing Xyrem were to be run on a distributed database of the type suggested by Korfhage, such a system

> might create a false indication of duplicate prescriptions that could prevent a patient from receiving her prescription drug. Ex. 2047 ¶ 64. On the other hand, if the duplicate prescription data is "eliminat[ed]" because a pharmacist believes it was caused by data redundancy, then a potential abuse situation would be overlooked. *Id.*

PO Resp. 60. We did not find such testimony persuasive, or particularly credible, in view of Korfhage's express disclosures, Dr. Valuck's testimony, and Dr. Bergeron's deposition testimony. Dec. 57–59 (citing Ex. 1007 ¶ 157; Ex. 1037, 276–77; Ex. 1054, 317:13–320:12; Ex. 2047 ¶ 57–59). Patent Owner's argument is not persuasive given that the ACA drug distribution system was designed to allow a pharmacist to identify and resolve duplicate prescriptions before deciding whether to distribute the drug to a patient (or delete a duplicate caused by data redundancy). Ex. 1003, 184:24–185:7; Ex. 1005, 314 ¶ 6. We also were persuaded by Dr. Valuck's testimony that it would have been obvious for one of ordinary skill to modify the ACA system "such that the data stored in the central data repository was distributed across multiple databases, as disclosed by Korfhage in order to accommodate cost, efficiency, and the number of

prescription requests and associated data." Ex. 1007 ¶ 157 (cited at Dec. 57–58[1]).

In sum, Patent Owner's "teaching away" argument and evidence were fully considered in our Decision. Dec. 56–59. Therefore, Patent Owner's request for rehearing on this basis is denied.

B. Claim construction of the "identifying" element

Independent claims 1 and 9 of the '988 patent recite a method step for receiving prescription requests "containing information identifying narcoleptic patients, the prescription drug, and various credentials of the any and all medical doctors." *Id.* at 8:48–50, 9:49–51 (the "identifying" element). In its Response, Patent Owner argued that exemplary embodiments described in the '988 patent limit the "identifying" element by requiring specific types of information to be read into the "identifying" element. PO Resp. 27–34. We considered Patent Owner's arguments, construed the "identifying" element with particular reference to the '988 patent specification, explained our reasoning, and stated that the "identifying" element is not limited to the types of information proposed by Patent Owner "nor requires all of that information." Dec. 18–21.

Patent Owner's Rehearing Request argues that the Board overlooked portions of the '988 patent specification and certain extrinsic evidence, in the form of expert testimony, that was cited by Patent Owner in its Response

[1] Page 58 of our Decision contains a typographical citation error. We cited to page 53 of the Petition, which cited to Dr. Valuck's Declaration at Exhibit 1007 ¶ 157. Pet. 53. We incorrectly indicated a citation to paragraph 57 of Dr. Valuck's Declaration, rather than to paragraph 157.

to the Petition. Req. Reh'g, 5–11. Patent Owner then repeats its argument that the "identifying" element *requires* specific types of information to be read into the claim element. *Id.* We do not agree that we misapprehended or overlooked the evidence identified by Patent Owner in its Response and Rehearing Request. Rather, Patent Owner's Rehearing Request is an attempt to reargue the position rejected in our Decision.

Our Decision construing the "identifying" element includes extensive citation to, and discussion of, Patent Owner's arguments and evidence. Dec. 18–21. Our claim construction analysis begins by explicitly and repeatedly acknowledging Patent Owner's arguments and evidence, including the exact specification excerpt and expert testimony of Dr. DiPiro and Dr. Valuck on which Patent Owner's Rehearing Request relies regarding the "information identifying patients" language. *Id.* at 18 (citing PO Resp. 30–33; Ex. 2046 ¶¶ 39–44; Ex. 1001 at 4:8–22; 8:4–5, 8:40–44, 10:20–23; Ex. 2044 at 97:11–98:5, 99:18–100:10); *id.* at 18–19 (citing PO Resp. 31; Ex. 1001 at 4:20–22, 8:4–5, Fig. 9; Ex. 2044 at 97:11–23, 99:18–100:10).[2] We did not "overlook" this evidence or consider only Figure 9 of the '988 patent specification regarding the identification of patients, as Patent Owner argues.

[2] Patent Owner cited to the Abstract of the '988 patent in support of its proposed claim construction. PO Resp. 31, 34; Req. Reh'g 8, 10. With regard to the "identifying" element, the Abstract merely states that "[i]nformation is kept in the database regarding all physicians allowed to prescribe the sensitive drug, and all patients receiving the drug." Ex. 1001, Abstract. The Abstract, therefore, provides only general guidance for construing the "identifying" element.

See Req. Reh'g 7–8. We further stated that, rather than limiting our analysis to Figure 9,

> *nothing* in the specification suggests that excluding one or more pieces of information in the list of a "patient's name, social security number, date of birth, sex, and complete address information, including city, state, and zip code," as proposed by Patent Owner, means that a prescription fails to contain "information identifying the patient," as recited in the claims.

Dec. 19 (emphasis added).

We made clear that the controlling description of the specification outweighed Patent Owner's argument and supporting evidence that specific types of information are required to be read into the "identifying" element of the claims. *Id.* ("*Thus*, we construe 'prescription requests [for GHB] containing information identifying patients' to refer to information identifying a patient, which may include [Patent Owner's specifically listed information], but is not limited to that information *nor requires all of that information*.") (emphasis added). We also cited to all of the expert testimony on which Patent Owner relied for its claim construction, as an indication that we considered the testimony. *Id.* at 18 (citing Ex. 2044, 97:11–98:5, 99:18–100:10; Ex. 2046 ¶¶ 39–44). We did the same for the "information identifying . . . any and all medical doctors" language, concluding that:

> The specification does not suggest that failing to include on the prescription one or more pieces of information from the list of a "medical doctor's name, license number, DEA number, and physician specialty," as proposed by Patent Owner, means that a prescription fails to contain

> information regarding "various credentials," as recited in the claims.

Id. at 20–21 (citing PO Resp. 33–36; Ex. 1001, 2:22–24, 2:41–42, 4:7–8, 4:8–14, 4:18–20, 4:20–22, 4:7–5:67, 8:4–7, 8:40–44, 10:20–23, Figs. 2A–C, 9; Ex. 2044, 181:1–23; Ex. 2046 ¶¶ 45–49). Though we did not discuss the expert testimony, we considered it.

For example, on the same page of testimony cited by Patent Owner, Dr. Valuck testified that the information sufficient to identify a patient is "whatever the pharmacist believes is required to sufficiently identify the patient in their professional judgment." Ex. 2044, 98:2–16. Even so, our Decision puts primary emphasis on the claim language and relevant description of the "identifying" element in the specification, not the extrinsic expert testimony relied upon by Patent Owner. *See Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1012–13 (Fed. Cir. 2016) ("The legal part of claim construction is the determination of the meaning of the term in the claim in light of the patent's intrinsic record."); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 (Fed. Cir. 2005) (en banc) (stating that sources outside the specification should not be "used to contradict claim meaning that is unambiguous in light of the intrinsic evidence.").

In sum, Patent Owner's Rehearing Request is an attempt to reargue its claim construction positions, not an identification of claim language or evidence we misapprehended or overlooked. Therefore, Patent Owner's Rehearing Request is denied.

IV. ORDER

Accordingly, it is

ORDERED that Patent Owner's Rehearing Request is denied.

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