Paper No. __
Filed: April 8, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC,
PAR PHARMACEUTICAL, INC., and WOCKHARDT BIO AG,
Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-00547[1]
Patent 7,765,107

PETITIONERS PAR PHARMACEUTICAL, INC.'S AND AMNEAL PHARMACEUTICALS LLC'S REPLY TO PATENT OWNER'S OPPOSITION TO PETITIONERS' MOTION TO EXCLUDE EVIDENCE

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[1] Case IPR2015-01820 has been joined with this proceeding.

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I. INTRODUCTION

The Board should exclude paragraphs 50-57 of Ex. 2046 and paragraphs 36–38 of Ex. 2047—the objected-to portions of the DiPiro and Bergeron Declarations—and Exs. 2049–2050 and 2054 as irrelevant because they do nothing to show whether a POSA could have located the Federal Register notice of the Xyrem Advisory Committee meeting (Ex. 1015). The Board should also exclude Exs. 2054 and 2057 because they are hearsay, and Jazz's arguments and evidence do not support their admissibility.

II. ARGUMENT

A. The Board should exclude the objected-to portions of the DiPiro and Bergeron Declarations, and Exs. 2049–2050 and 2054.

1. Petitioners' objections provided sufficient notice to Jazz.

Jazz asserts that Petitioners' objections to the DiPiro and Bergeron Declarations and Exs. 2049–2050 were insufficiently particular to provide them the opportunity to serve supplemental evidence. Paper No. 63 ("Opp.") at 2. Petitioners, however, identified specific objectionable portions of the Declarations, and the legal basis for those objections.

2. Whether a POSA *would have* reviewed Ex. 1015 is irrelevant to whether a POSA *could have* located the ACA.

Jazz repeatedly misstates the legal standard for public accessibility, and in doing so demonstrates why the DiPiro and Bergeron Declarations, as well as Exs.

2049–2050 and 2054, are irrelevant. Jazz repeatedly states that public accessibility turns on a POSA "actually locating prior art." Opp. at 4, 5; *see also id.*at 4 n.2. But that is not the standard: public accessibility of prior art turns on whether a POSA "exercising reasonable diligence ***could*** locate it." *See Bruckelmeyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006) (emphasis added). Moreover, "[a]ccessibility goes to the issue of whether interested members of the relevant public ***could obtain the information if they wanted to***. If accessibility is proved, there is no requirement to show that particular members of the public ***actually received*** the information." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988) (emphasis added).

Under this correct standard, Jazz's evidence regarding whether a POSA ***would have*** reviewed the Federal Register notice (Ex. 1015) is irrelevant to public accessibility of the ACA. Congress has legislated that notices such as Ex. 1015 are ***deemed given*** to ***every person*** in the United States upon publication. 44 U.S.C. § 1508. And, despite Jazz's assertion to the contrary, this notice function extends to both legally protected interests as well as "scientific or technical one[s]." Opp. at 2–3. For example, at least one court has held that a Federal Register statement that a technical support document was available was sufficient notice for interested individuals to seek out not only that document, but the technical data *underlying*

that document. *See S. Terminal Corp. v. E.P.A.*, 504 F.2d 646, 659 (1st Cir. 1974).[2] Whether a POSA actually ***would have*** reviewed Ex. 1015 is irrelevant to the ACA's public availability, as a POSA ***could have*** located the ACA from Ex. 1015.

Jazz's evidence directed to whether Ex. 1015, and thus the ACA, ***would have*** been located by a POSA is therefore irrelevant. *See* Opp. at 4-5. Since there is no requirement to show that a POSA ***actually reviewed*** publicly accessible information, Jazz's evidence has no probative value, and should be excluded.

B. Ex. 2054—the Van Buskirk deposition—is inadmissible hearsay.

Jazz does not dispute that Ex. 2054 is hearsay under Rule 801.[3] Nevertheless, Jazz asserts it is admissible under the residual exception of Rule 807, or because Dr. DiPiro relied upon it in a declaration served as supplemental evidence. *See* Ex. 2059. Neither is true.

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[2] The technical document supported an Environmental Protection Agency plan restricting "parking spaces available for use" in certain areas of Boston-hardly a legally protected interest. *S. Terminal Corp.*, 504 F.2d at 657.

[3] Contrary to Jazz's assertion, Ex. 2054 is not an excerpt of a deposition from "the co-pending district court litigation addressing the patents-at-issue in the IPR." Opp. at 7. Claims and discovery regarding the patent at issue here were bifurcated and stayed in that case at Jazz's request. *See Jazz Pharm., Inc. v. Roxane Labs., Inc.*, No. 10-cv-6108, ECF No. 316 (D.N.J. Mar. 24, 2013) (Ex. 1061).

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