Paper No. __
Filed: April 1, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.

Patent Owner

Case IPR2015-00554[1]
Patent 7,668,730

PATENT OWNER'S OPPOSITION TO PETITIONERS' MOTION TO EXCLUDE EVIDENCE

[1] Case IPR2015-01818 has been joined with this proceeding.

I. INTRODUCTION

Petitioners seek to exclude highly relevant evidence regarding whether a person of ordinary skill in the art ("POSA") exercising reasonable diligence would have located the Advisory Committee Materials ("ACA") (Exs. 1003-1006) based on the Federal Register notice submitted as Ex. 1015 in this *inter partes* review ("IPR"). Petitioners' objections are based on alleged hearsay, irrelevance, and improper expert testimony. At the outset, Petitioners' Motion to Exclude ("Mtn.") should be denied because it is not based on "objections in the record" since Petitioners never satisfied the requirements of 37 C.F.R. § 42.64(b)(1) by filing their objections. *See* 37 C.F.R. § 42.64(c). The motion should also be denied because Petitioners' objections go to weight rather than admissibility, and for the specific reasons set forth below.

II. ARGUMENT

A. The objected-to portions of the DiPiro and Bergeron Declarations and Exs. 2049-2050 are relevant to public accessibility of the ACA

Petitioners argue that certain portions of the DiPiro (Ex. 2046) and Bergeron (Ex. 2047) Declarations, as well as Exs. 2049-2050 "are irrelevant to the issue of public accessibility of the ACA" because: (1) the Federal Register's notice function allegedly establishes public accessibility as a matter of law and (2) Dr. DiPiro's opinions are allegedly directed to "uninterested" POSAs. *See* Mtn. 3-8.

Petitioners' objections, however, failed to provide this particularity, i.e., the objections did not explain ***why*** the exhibits were allegedly irrelevant to public accessibility. Instead, Petitioners asserted only a boilerplate relevance objection:

> **JAZZ EXHIBIT 2046** are objected to under Fed. R. Ev. 401–402 because they are irrelevant to the question of whether, more than one year before December 17, 2002, PAR1004–PAR1006 were disseminated or otherwise made available to the public to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could locate it [sic].

Paper 53 at 1; *id.* at 2-3 (same for Exs. 2047, 2049, 2050). Thus, Petitioners failed to "identify the grounds for the objection with sufficient particularity to allow correction in the form of supplemental evidence." 37 C.F.R. § 42.64(b)(1). These objections should be denied for this reason alone. *See B/E Aerospace, Inc. v. MAG Aerospace Indus., LLC*, IPR2014-01510, Paper 106 at 6-7 (Mar. 18, 2016).

1. Petitioners erroneously equate the Federal Register's notice function with the standard for public accessibility

Petitioners object to Jazz's evidence showing that a POSA exercising reasonable diligence would ***not*** have located the ACA through the half-page entry in the Federal Register—out of the 67,700 pages of the 2001 version of the Federal Register—as irrelevant by arguing that "[u]nder Federal law, every person in the United States, which of course includes POSAs, is ***deemed*** to have been given sufficient notice for items published in the Federal Register." Mtn. 3-6 (emphasis

added). Petitioners' argument about the legal effect of the Federal Register is incorrect, and conflates a legal interest with a scientific or technical one.

Specifically, the "notice" the Federal Register provides is a legal construct to prevent individuals from later claiming ignorance of the law if their legally protected interests are adversely affected. Indeed, as the cases Petitioners cite explain, "[t]he purpose of notice is to 'inform [the recipient] that the matter [in which ***his protected interests*** are at stake] is pending.'" *Moreau v. F.E.R.C.*, 982 F.2d 556, 569 (D.D.C. 1993) (emphasis added); *see also N. Ala. Express, Inc. v. United States*, 585 F.2d 783, 786 (5th Cir. 1978) (explaining that the Administrative Procedures Act requires "[r]easonable notice to ***interested persons*** that their ***legally protected interests*** may be adversely affected by administrative action") (emphasis added); *id.* at 787 n.2 (noting that the Federal Register provides "legally sufficient notice to all ***interested persons***") (emphasis added).

Thus, the notice that the Federal Register provides is specifically directed to interested persons whose ***legally protected interests*** are at jeopardy of being adversely affected. *See id.* at 790 (requiring republication of inadequate notice in the Federal Register to inform competitors of a company granted increased operating capacity); *Moreau*, 982 F.2d at 569 (finding notice was given to individuals whose property interests were affected by a gas pipeline); *S. Terminal Corp. v. E.P.A.*, 504 F.2d 646, 654, 657 (1st Cir. 1974) (finding that "interested

persons"—persons whose legal interests were affected by an air quality transportation plan—had notice of a technical document in the Federal Register).

Petitioners try to conflate the Federal Register's "deemed" notice to individuals with a "legally protected interest," with a "person of ordinary skill in the art ***interested in the subject matter of the patents in suit*** and exercising reasonable diligence" actually locating prior art. *See Bruckelmeyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006) (emphasis added). There is simply no caselaw holding that the POSA's "interest[] in the subject matter of the patents in suit" is a "legally protected interest" that has the potential to be adversely affected. There is also no caselaw that equates "deemed" notice of a rule with the ability to actually locate that rule, when exercising reasonable diligence.[2] On the other hand, this Board has previously held that statements in the very same Federal Register notice at issue in this IPR do ***not*** show that the ACA "*actually*

[2] For example, just because a person might be on constructive notice of an obscure mining law published in the Federal Register, does not mean that person, exercising reasonable diligence, would be able to actually locate the mining law. The public accessibility caselaw requires that a POSA exercising reasonable diligence be able to ***actually*** locate the prior art in question.

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