

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC AND
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,
Petitioners,

v.

ALMIRALL, LLC,
Patent Owner.

Case IPR2018-00608
U.S. Patent No. 9,161,926 B2

**PETITIONERS' OPPOSITION TO PATENT OWNER'S MOTION TO
EXCLUDE PETITIONER'S EVIDENCE UNDER 37 C.F.R. §42.64**

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INTRODUCTION

Seeking to distance itself from Dr. Julie Harper’s deep and long-standing consulting relationship with Allergan—Patent Owner Almirall’s predecessor-in-interest in the ’926 patent at issue here—Almirall moves to exclude Exhibits AMN1041-1048 as allegedly “unauthentic” and “irrelevant.” Exhibits AMN1041-47 are annual financial reports showing that Dr. Harper received at least \$213,344.70 to \$232,342.70 from Allergan between 2011 to 2017¹ for, among other things, promoting² ACZONE 5% Gel (which is highly relevant prior art to

¹ This amount does not even include payments to Dr. Harper for her promotional work relating to the AZCONE 5% Gel from its FDA approval in 2008 to July of 2011 (which is the first data available under the Sunshine Act). AMN1049, 8:26:3-9:30:14. As Dr. Harper was fond of saying at her deposition, she is “always compensated” for her time, so it is likely that she was compensated for these activities too. AMN1049, 10:34:5-7, 12:42:1-6, 42:163:1-19.

² To the extent that Almirall may try to draw some distinction between “promoting” a drug and “educating” physicians on the drug, *see, e.g.*, Sur-Reply, 2-3, Dr. Harper testified that she has “done promotional speaking,” which she defined as “educating [the audience] on the drug,” and that she is “always compensated” for such activities. AMN1049, 9:31:2-10:34:7. With respect to the prior art ACZONE 5% Gel, she testified that she has “spoken promotionally for

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the 7.5% dapsona formulation claimed in the '926 patent). Exhibit AMN1048

reflects the amount of money Dr. Harper took from 2013 to 2017 from Allergan specifically for to her work related to ACZONE. During that period, she brought in the fourth-highest ACZONE-related earnings of all doctors who promoted the product. AMN1048, 1. Almirall's motion fails on both procedural and substantive grounds and, therefore, should be denied.

Procedurally, Almirall's objections to AMN1041-48 were not timely. These exhibits were first entered into evidence at the March 11, 2019 deposition of Dr. Harper. Almirall's counsel did not object at that time, or even within five business days of service pursuant to 37 C.F.R. § 42.64(b)(1). Almirall objected two weeks after being served, on March 25, 2019. *See* Paper 32. Any objection to these exhibits has thus been waived.

Substantively, AMN1041-48 are both *authentic* and *relevant*. First, as shown below, AMN1041-48 are self-authenticating "official publications" under FRE 902(5) as they report payments from drug companies (*e.g.*, Allergan) to doctors (*e.g.*, Dr. Harper) as required by the federal Sunshine Act. The payment amounts disclosed in these exhibits were also authenticated by Dr. Harper herself during her deposition.

Aczone 5 Percent" beginning with its release in 2008 through the time when the 7.5% product launched in 2016. *Id.*, 10:35:7-11:38:15.

Next, these documents are also relevant to reveal Dr. Harper's potential bias in Almirall's/Allergan's favor, which the Board should consider in assessing her credibility as an expert witnesses. For example, AMN1041-48 reveal that Dr. Harper received more than \$200,000 from Allergan from 2011 to 2017, and nearly \$100,000 *specifically related to ACZONE* from 2013 to 2017. Additionally, given that AMN1041-48 reflect the considerable sums Dr. Harper received from Allergan for promoting the use of ACZONE 5% Gel, these documents are relevant in exposing Dr. Harper's inconsistent testimony in this proceeding where she appears to disparage the prior-art ACZONE 5% Gel (also disclosed in Amneal's primary reference, Garrett, AMN1004) and discount its usefulness as a monotherapy. Exhibits AMN1041-48 should not be excluded.

ARGUMENT

I. Almirall waived its objections to Exhibits AMN1041-48 by failing to timely object.

Almirall says that it "timely objected to Exhibits 1041-48" "[f]ollowing service of Amneal's Reply." *See* Paper 36 at 1. Almirall is wrong. In compliance with 37 C.F.R. § 42.53(f)(3), AMN1041-48 were marked and served at the March 11, 2019 deposition of Dr. Julie Harper. *See* AMN1049, 2:5:11-22, 39:152:15-19, 40:155:10-12, 40:156:14-19, 40:157:19-25, 41:158:18-21, 41:159:14-19, 41:160:23-161:4, 41:161:24-25; *see also* 37 C.F.R. § 42.53(f)(3) (All exhibits used during the deposition "must, if not previously served, be served at the

deposition.”). Indeed, at the beginning of Amneal’s questioning of Dr. Harper on AMN1041, Almirall’s counsel even acknowledged that these exhibits were being newly served. AMN1049, 39:152:20-153:3.

Notably, Almirall’s counsel conducted re-direct using several of these exhibits—AMN1041, 1042, and 1048 (*see* AMN1049, 43:167:1-169:5)—but failed to make any objection to these documents at any time during the deposition, as it was required to do under Rule 42.64(a). *See generally* AMN1049, 39:152:15-43:166:20; *see also* 37 C.F.R. § 42.64(a) (“An objection to the admissibility of deposition evidence must be made during the deposition.”). Even under a more generous reading of the rules, Almirall would have been required to object to AMN1041-48 within five business days of service, *i.e.*, by March 18, 2019. 37 C.F.R. § 42.64(b)(1) (“Once a trial has been instituted, any objection must be filed within five business days of service of evidence to which the objection is directed.”). But Almirall waited an *additional seven* days after that deadline (until March 25, 2019) to object. *See* Paper 32, 3-7, 9; Paper 36, 1.

By not timely objecting to AMN1041-48, Almirall has waived any evidentiary objection to these exhibits, and the Board should deny Almirall’s motion on this basis alone.³ *Sanofi-Aventis U.S. LLC et al. v. Immunex Corp.*,

³ For the same reason, Almirall’s statement that Amneal failed to serve curative evidence is irrelevant.

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