Paper No. ___
Filed: August 3, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC. and AKORN INC.,[1]
Petitioners,

v.

ALLERGAN, INC.,
Patent Owner.

Case IPR2016-01127 (US 8,685,930 B2)
Case IPR2016-01128 (US 8,629,111 B2)
Case IPR2016-01129 (US 8,642,556 B2)
Case IPR2016-01130 (US 8,633,162 B2)
Case IPR2016-01131 (US 8,648,048 B2)
Case IPR2016-01132 (US 9,248,191 B2)

PETITIONERS' REPLY IN SUPPORT OF PETITIONERS' MOTION TO EXCLUDE EVIDENCE

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[1] Cases IPR2017-00576 and IPR2017-00594, IPR2017-00578 and IPR2017-00596, IPR2017-00579 and IPR2017-00598, IPR2017-00583 and IPR2017-00599, IPR2017-00585 and IPR2017-00600, and IPR2017-00586 and IPR2017-00601, have respectively been joined with the captioned proceedings. The word-for-word identical paper is filed in each proceeding identified in the caption pursuant to the Board's Scheduling Order (Paper 10).

I. Petitioners' Motion Did Not Violate the Board's Order

Allergan contends that Petitioners' motion to exclude violated a Board e-mail denying Mylan's request to file a response to Allergan's surreply (Paper 51, 2-3, 7-8), but the motion was filed the day before the Board's e-mail issued. EX1136 (July 21, 2017 email). Petitioners could not have violated an e-mail that did not exist. In contrast, Allergan's belated Sur-reply arguments and evidence violate an ***existing Board order***. Paper 10, 3 ("[A]ny arguments for patentability not raised in the response will be deemed waived."). Further, the Board did not foreclose Petitioners from seeking to exclude EX2077-2079 and has confirmed Petitioners may address the substance and impropriety of the sur-replies. EX1136.

Allergan's contention that its impropriety is excused by Petitioners' replies is false; Petitioners' replies are directly responsive to Allergan's Responses and are entirely consistent with the Petition arguments. Paper 52, 2-11. Allergan's complaint that it was not authorized to submit Sur-reply declarations is undercut by its failure to timely request them. *Id.*; EX1135. Even today, Allergan has failed to provide an adequate proffer identifying any specific declarant or testimony.

II. Allergan's Reliance on EX2008 and EX2078 Is Improper

Allergan mischaracterizes EX2008 and EX2078 and does not dispute that they are and contain hearsay, but contends that they satisfy the public record exception FRE 803(8). Paper 51, 2-3, 11. But the public record exception requires that the proponent provide foundation establishing the document qualifies as a

public record, which Allergan has failed to do. *See United States v. Smart*, 87 F.2d 1, 3 (5th Cir. 1936) ("[I]t must be established as within that class of official records or documents which are excepted from the hearsay rule."); F.R.E. 803(8) (proponent of alleged public record must establish that document is a record of a public office setting out office's activities and a matter observed while under a legal duty to report). Neither EX2008 nor EX2078 identify its source, how it came to be, what official purportedly observed the matters discussed therein, or whether that official had an official duty to report; nor do Allergan's Responses, declarants, or even exhibit lists. EX2083, 100:16-102:13 ("I mean who asked for this report [in EX2078] to even be done in the first place? Perhaps Allergan did.").

Even if either of the documents had been authenticated as a public record, this does not establish that the double hearsay contained in the document is admissible for the truth of the matters asserted therein. Allergan's reliance on EX2008 and EX2078 to explain the FDA's reasoning for approving RESTASIS® should be excluded and receive no weight. Even if Allergan had met the threshold requirements under F.R.E. 803(8), Petitioners' motion demonstrated that EX2078 contains obvious inaccuracies, indicating a lack of trustworthiness.

III. EX2024 ¶48 and EX2026 ¶47 Should Be Excluded

Allergan claims that Drs. Sheppard and Loftsson merely claim ***consistency*** with, rather than ***reliance*** upon, Schiffman Exhibits B, D-F and Attar Exhibits C-

D. Paper 51, 4. Regardless, Drs. Sheppard and Loftsson are relying upon evidence that is entitled to no weight to support their own opinions. *See* Paper 33, 3. Allergan cannot use its experts to launder evidence lacking evidentiary value.

IV. EX2038 and Allergan's Reliance Upon It Should Be Excluded

Allergan argues that expert testimony may rely on inadmissible testimony when other "experts in the field would reasonably have relied on such facts or data in forming an opinion[.]" Paper 51, 5; F.R.E. 703. Yet, the underlying document is not admissible for the Board's substantive reliance. F.R.E. 703 committee notes on rules—2000 amendment ("[T]he underlying information must not be used for substantive purposes."); *Flanagan v. Iran*, 190 F.Supp.3d 138,173 (D.D.C. 2016) ("[e]xpert opinions may be based on hearsay … [but] they may not be a conduit for the introduction of factual assertions that are not based on personal knowledge.").

With respect to Allergan's argument that EX2038 should remain in the record, Petitioners have not requested ***expungement*** of EX2038. Instead, Petitioners have rightfully requested that the exhibit be excluded as a source of independent evidence and that Dr. Maness's recitations of it be given no more weight than the evidence itself would be entitled. Because Mr. LeCause was not subjected to cross-examination in these proceedings, his deposition testimony is entitled to no independent evidentiary weight. *See* 37 C.F.R. § 42.51; 77 Fed. Reg. 48,756, 48,761; *HTC Corp. v. NFC Tech. LLC*, IPR2014-01198, Paper 41, 5.

Allergan fails to prove that Mr. LeCause's statements are the kind of evidence upon which experts in the field would reasonably rely. F.R.E. 703. "Where an expert's opinion is based on information supplied by others, the inquiry into reliability. . .should focus on the reliability of the opinion and its foundation[.]" *Loeffel Steel Products, Inc. v. Delta Brands, Inc.*, 372 F.Supp.2d 1104, 1119 (N.D. Ill. 2005). Dr. Maness gives no foundation for why an expert in his field would rely on the statements of Mr. LeCause; he admits he is unaware of whether or not Mr. LeCause had any economics, pharmaceutical, medical, or chemical expertise. EX1034, 68:23-70:7. The only qualification Dr. Maness provided for relying on Mr. LeCause's statements is Mr. LeCause's "current title is vice-president of sales and marketing for the eye care division of Allergan." *Id.* at 37:24-38:02. The sole qualification Dr. Maness appears to have relied upon is that Mr. LeCause is a mouthpiece for Allergan.

It is unclear to what extent Dr. Maness analyzed Mr. LeCause's statements as opposed to simply parroting them. *Id.* at 65:22-66:4 ("[Q: Are you…relying on Mr. LeCause as if he is an expert?] You know, I don't know."). Dr. Maness admits portions of his declaration are a mere recitation of his conversations with Mr. LeCause. *Id.* at 149:10-20. Allergan should not be permitted to use Dr. Maness to launder the opinions of Mr. LeCause. *U.S. v. Brownlee*, 744 F.3d 479, 482 (7th Cir. 2014) ("An expert who parrots an

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