UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

ALLERGAN, INC.
Patent Owner

Case IPR2016-01129[1]
Patent 8,642,556

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

[1] Cases IPR2017-00579 and IPR2017-00598 have been joined with this proceeding.

I. INTRODUCTION

Mylan's motion to exclude is a surreply in disguise. After Allergan filed its surreply—a surreply that the Board authorized after Allergan objected to the new evidence and theories presented for the first time in Mylan's reply——Mylan sought leave to respond. The Board denied Mylan's request. The evidentiary objections Mylan now raises in its motion to exclude are actually pretexts for presenting substantive arguments that the Board prohibited Mylan from filing. Mylan's true objection is to the substance of Allergan's evidence and arguments. Mylan's motion is improper and should be denied.

II. EX. 2008 IS ADMISSIBLE

EX. 2008 is the RESTASIS® label. Allergan relies on EX. 2008 to show that RESTASIS® is indicated for increasing tear production. Allergan further relies on EX. 2008 to show that FDA relied on Schirmer tests with anesthesia in approving RESTASIS® for tear production. Mylan objects that EX. 2008 is hearsay. However, EX. 2008 falls within the public record exception set forth in F.R.E. 803(8). *See Sabel v. Mead Johnson & Co.*, 737 F. Supp. 135, 143 (D. Mass. 1990) (letter from an FDA director recommending a boxed warning be included on defendants' label fell within public record exception, as it "was prepared pursuant to the FDA's statutory responsibility to regulate the safe marketing of prescription

drugs."); *Musgrave v. Breg, Inc.*, No. 2:09-CV-01029, 2011 WL 4502032, at *6 (S.D. Ohio Sept. 28, 2011) ("FDA bulletins to healthcare professionals" fell within public record exception because "they are statements directly from the FDA setting forth matters observed pursuant to duty imposed by law as to which matters there was a duty to report."). Exhibit 2008 is admissible.

Mylan's real objection is to Allergan's argument that, taken together with EX. 2078, EX. 2008 demonstrates FDA concluded that the claimed 0.05% CsA/1.25% castor oil formulation was statistically better at increasing tear production than the 0.1% CsA/1.25% castor oil formulation and the castor oil vehicle for certain populations of patients. This is not an evidentiary objection. Rather, it is an attempt to circumvent the Board's order barring Mylan from submitting additional briefing.

III. PARAGRAPHS 48 OF EX. 2024 AND 33 AND 47 OF EX. 2025 ARE ADMISSIBLE

EX. 2024 is Dr. Sheppard's declaration. In Paragraph 48, Dr. Sheppard notes that Drs. Attar and Schiffman also reached the same conclusions that he independently reached.

EX. 2025 is Dr. Loftsson's declaration. Paragraph 33 sets forth Dr. Loftsson's analysis of the Phase 3 clinical data presented in Sall Fig. 2. In paragraph 47, Dr. Loftsson notes that Drs. Attar and Schiffman also reach the same conclusions that he independently reached.

As Mylan admits, both Dr. Sheppard and Dr. Loftsson made clear that they reached their opinions independently of the tear production and corneal staining data included in the Schiffman and Attar declarations. *See* EX. 1037 at 53:20-54:2, 54:22-55:4; EX. 1036 at 41:3-42:16. Both relied instead on the data presented in Sall and other evidence in the IPR record. Stating that their independent conclusions were ***consistent*** with the conclusions that Drs. Schiffman and Attar reached is completely different from ***relying*** on the tear production and corneal staining data included in the Schiffman and Attar declarations. Mylan's arguments to the contrary are baseless.

IV. EX. 2038 AND THE PARAGRAPHS OF DR. MANESS' DECLARATION THAT CITE IT ARE ADMISSIBLE

EX. 2038 is the deposition testimony of David LeCause obtained in the related district court litigation involving the RESTASIS® patents that is pending in the Eastern District of Texas. Dr. Maness (EX. 2028) relied on Mr. LeCause's testimony as well as conversations with Mr. LeCause. Mylan now seeks to exclude EX. 2038, as well as paragraphs of Dr. Maness' declaration that rely on Mr. LeCause, because Mylan did not have the opportunity to depose Mr. LeCause. Mylan's position is meritless.

First, Mylan is not entitled to depose Mr. LeCause simply because Dr. Maness relied on his deposition testimony or had conversations with him. Mr.

LeCause does not fall into any of the categories of routine discovery enumerated in 37 C.F.R. § 42.51(b)(1) (i)-(iii). In response to Mylan's request to depose Mr. LeCause, Allergan told Mylan to seek leave to file a motion for additional discovery if it wanted to depose Mr. LeCause. Mylan did nothing. By not availing itself of the appropriate procedures, Mylan waived any objection to Mr. LeCause's testimony and statements.

Second, as an expert Dr. Maness is entitled to rely on evidence regardless of whether the evidence itself is admissible. In IPR2015-00249, the Board addressed a similar situation. There, the Patent Owner's expert relied on the deposition testimony of a witness given in a different IPR proceeding. The Board held that because the Patent Owner's expert provided an opinion on the deposition testimony, the deposition should be admitted so that the expert's opinion could be properly considered. The Board stated:

> Patent Owner argues that even if the Spinak Deposition is hearsay, it is admissible under Fed. R. Evid. 703. We agree. Federal Rule of Evidence 703 permits an expert to base an opinion on facts or data in the case that an expert has been made aware of if experts in the field would reasonably have relied on such facts or data in forming an opinion …. Mr. Spinak testified regarding FDA validation of an aspetic bottling system, and it was reasonable for Dr. Sharon to rely upon such information.

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