Paper No. ___
Filed: July 27, 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' OPPOSITION TO PATENT OWNER'S 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. INTRODUCTION

Petitioners file this Opposition to Patent Owner's Motion to Exclude the testimony of Mylan's declarants, Drs. Calman (EX1039) and Bloch (EX1040), under F.R.E. 402, 403, and 702 and Mr. Hofmann (EX1041) under F.R.E. 402, 403 (Paper 43) in accordance with the Board's Scheduling Order (Paper 10). Patent Owner must establish entitlement to the requested relief. 37 C.F.R. § 42.20(c).

II. ARGUMENT

A. Allergan's Motion Fails to Satisfy Board Rules.

Allergan failed to satisfy Board rules for motions to exclude. 77 Fed. Reg. 48756, 48767 (Aug. 14, 2012). Allergan did not comply with requirements (a) and (b) because it (1) failed to list which specific paragraphs of the declarations should be excluded, and under which bases; (2) did not identify specifically where it objected to each paragraph, citing Paper 40 only generally (Mot'n at 2); and (3) failed to identify where specific declaration paragraphs were relied upon by Petitioners, instead asserting only generally that "Mylan's Reply relies upon the Calman and Bloch declarations (EXs. 1039 and 1040) in its reply[*sic*]." Mot'n at 3.

Allergan's motion also violates 37 C.F.R. § 42.64 because its objections (Paper 40) only discuss a subset of the declaration paragraphs. Paper 40 (objecting to EX1039, ¶¶67-71, EX1040, ¶¶10, 26, 33, 35-38, 65-68). Allergan's motion fails to provide a listing of paragraphs specifically for exclusion, but discusses several

declaration paragraphs that are not identified in Allergan's objections. Paper 43 (discussing ¶¶45-47, 56, 60-61, 65-66 of EX1039, ¶¶28-32, 34, 39-64 of EX1040, which were not identified in Paper 40). Allergan's attempt to exclude paragraphs of the declarations that Allergan failed to specifically identify in its Objections (Paper 40) violates both the Trial Practice Guide and 37 C.F.R. § 42.64. Allergan's motion should thus be denied.

B. Petitioners' Reply Declarations Were Appropriately Submitted.

Allergan contends that Mr. Hofmann's analysis of Allergan's asserted commercial success case "properly belonged in Mylan's original petition as part of Mylan's *prima facie* case," and that this alleged renders "the [Hofmann] declaration inadmissible under F.R.E. 402 and 403." Mot'n at 1-2. With respect to the Calman and Bloch declarations, Allergan does not argue that their testimony should have been part of the *prima facie* case, but merely that Dr. Bloch's statistical analysis of Sall Figure 2 and Dr. Calman's clinical materiality analysis of Sall Figure 2 are impermissible, new arguments such that Allergan was allegedly "deprived…of the opportunity to respond meaningfully" to them. *Id.* at 1. Allergan's arguments mischaracterize the law and the facts.

1. Allergan Had Adequate Notice of Petitioners' Statistical Significance, Clinical Materiality, and Commercial Success Arguments.

The Petitions and Amiji declarations provided Allergan with notice of Petitioners' argument that Allergan's evidence of alleged unexpected results failed

to demonstrate both statistical significance and clinical materiality. *See, e.g.*, IPR2016-01127, Paper 3 ("Pet.") at 2 ("The data relied upon by applicants lack scientific parameters necessary to demonstrate statistical significance and materiality and…appear to be…previously published graphs from… Sall.").

They also provided Allergan with notice of Petitioners' argument that neither Sall nor the exhibits that Dr. Schiffman apparently adapted from Sall (by removing the error bars) established superiority of the 0.05% CsA emulsion over the prior art. Pet. at 5 ("As noted by Dr. Amiji, the data presented by applicants lacked scientific parameters necessary to demonstrate ***statistical significance and materiality***."); *id.* at 39 (Sall taught that either CsA concentration is "therapeutically effective" in increasing tear production and noted that there was "'***no dose-response effect***' between the two percentages of CsA"); *id.* at 47-57 (No Unexpected Results); *id.* at 50-51 ("Sall had previously reported that the decrease in corneal staining and the increase in Schirmer score ***were comparable*** between the 0.05% CsA and 0.10% CsA emulsions….At best, Schiffman Exhibit D merely confirms the teachings of the prior art that the 0.05% and 0.10% CsA emulsions had ***similar results***."); *id.* at 55 ("Stevenson and Sall…both reported that variations between emulsions containing 0.05% and 0.10% CsA ***were not significant***."); *id.* at 56 ("However, using ratios instead of raw numbers can exaggerate the importance of very small and immaterial differences.").

The Petitions and Amiji declarations also provided Allergan with notice of Petitioners' argument that small changes in corneal staining or categorized Schirmer scores are clinically immaterial. Pet. at 52-54 ("[C]hange in Schirmer score of 2 units for the 0.10% CsA group in Fig. 2 of Schiffman Exhibit B is not even statistically significantly different from 0 (baseline)…. [E]ven if statistically significant, the differences in Phase 2 results between the 0.05% and 0.10% CsA emulsions cited by Dr. Schiffman appear to be immaterial. Despite what appears to be a large gap between the 0.05% and 0.10% CsA emulsions….").

They also provided Allergan with notice of Petitioners' argument that PK studies must determine there is "any significant or material difference between the tested emulsions," including whether "materiality of any observed differences" had been established in light of the fact that "the minimal concentration of CsA needed in ocular tissues for therapeutic effectiveness was already known." Pet. at 54.

They also provided Allergan with notice of Petitioner's arguments that "Allergan failed to establish a nexus between sales [of Restasis®] and the claims," that the "sales were not attributable to using the 0.05% CsA emulsion," that the Ding '979 patent "blocked the entry of both the claimed emulsion and comparable emulsions until 2014," that Allergan's "decade-long marketing efforts" and "narrow definition of the relevant market" undermined any nexus between the sales and the claims, and that Sall teaches that the 0.10% CsA emulsion was "as

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