UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

ALLERGAN, INC.
Patent Owner

Case IPR2016-01127[1]
Patent 8,685,930

PATENT OWNER'S EVIDENTIARY OBJECTIONS UNDER 37 C.F.R. § 42.64(b)

[1] Cases IPR2017-00576 and IPR2017-00594 have been joined with this proceeding.

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Pursuant to 37 C.F.R. § 42.64(b), Patent Owner hereby objects as follows to the admissibility of Petitioner's evidence:

EX. 1039: FRE 402/403/602/701/702/703/801/802. EX. 1039 includes opinions that are not admissible under FRE 701, 702, or 703, or *Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 579 (1993). Dr. Calman was retained by Petitioner as a "technical expert to provide [his] independent analysis in these proceedings." EX. 1039, ¶ 7. Dr. Calman provides "putative conversions" to the Schirmer Tear Test (with anesthesia) scores reported in Figure 2 of the Sall reference ("Sall") to generate "inferred raw STT scores" and uses these scores to conclude "no material clinical difference would be expected between the two CsA groups, as again the estimated raw values for the 0.05% and 0.1% CsA treatment groups at 6 months are only roughly half a millimeter apart." *See* EX. 1039, ¶¶ 68-71. Dr. Calman's analyses are inadmissible as they are not based on sufficient facts or data, are not the product of reliable principles and methods, and do not apply reliable principles and methods to the facts of the case. Dr. Calman admits his conversions are inferences and not "literal conversions" to actual raw Schirmer scores. *See* EX. 1039, ¶ 68. Instead, Dr. Calman conducts his analysis by estimating raw Schirmer tear test values (mm) from the categorized Schirmer scores reported in Sall Figure 2. *Id.* For example, Dr. Calman infers a Schirmer score of 4 corresponds to an

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estimated raw value of 11 mm. *See* EX. 1039, ¶ 68. But the Sall reference specifically states that the mean categorized Schirmer value of 4 relates to patients with raw values of 11, 12, 13, or 14 mm/5 min. *See* EX. 1007, at page 635. Dr. Calman's "opinions" as to whether a person of skill in the art viewing Sall Figure 2 would conclude there is no clinically meaningful difference between the 0.05% and 0.10% CsA formulations should be excluded as inadmissible under FRE 702.

In addition to relying on his own improper analysis, Dr. Calman also relies on Dr. Bloch's dubious analysis derived from "gleaning" the mean change from baseline values for each composition in Sall Figure 2 to the nearest hundredth decimal place. As discussed in more detail below, Dr. Bloch's analysis on unsubstantiated values is improper and unreliable, as it is not based on sufficient facts or data, is not the product of reliable principles and methods, and does not apply reliable principles and methods to the facts of the case. Thus, Dr. Calman's "opinions" which rely on Dr. Bloch's improper analysis to conclude that Sall does not disclose any statistically significantly different results between the 0.05% and 0.10% CsA formulations (EX. 1039, ¶¶ 67-71) should be excluded as inadmissible under FRE 702, as well as under FRE 801/802 as hearsay and FRE 602 for lack of personal knowledge.

Additionally, EX. 1039 includes opinions that are untimely and outside the scope of a proper reply and therefore not admissible under FRE 402 or 403. 37

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C.F.R. § 42.23(b), governing these proceedings, states that "[a] reply may only respond to arguments raised in the corresponding . . . patent owner response." *Id.* at § 42.23(b). The Office Patent Trial Practice Guide states that "[e]xamples of indications that a new issue has been raised in a reply include new evidence necessary to make out a *prima facie* case for the patentability or unpatentability of an original or proposed substitute claim, and new evidence that could have been presented in a prior filing." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756 at 48,767 (Aug. 14, 2012). Petitioner chose not to file a declaration from a clinician regarding the clinical results in Sall with its Petition. EX. 1039 is a declaration by Dr. Calman, a clinician, submitted with Petitioner's reply. Dr. Calman, for the first time, presents evidence that could have (and should have) been presented previously that Petitioner now relies on for a *prima facie* case of unpatentability. It should not be permitted on reply at this late date in the proceedings.

EX. 1040: FRE 402/403/701/702/703. EX. 1040 includes opinions that are not admissible under FRE 701, 702, or 703, or *Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 579 (1993). Dr. Bloch provides "statistical analyses for certain data reported in Stevenson, Sall Figures 1-2" and "Allergan's animal PK [pharmacokinetic] studies testing cyclosporine ophthalmic emulsions as used by

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Dr. Attar in her Exhibit B to her Declaration presented to the USPTO." *See* EX. 1040, ¶ 10. Dr. Bloch's analyses are inadmissible as they are not based on sufficient facts or data, are not the product of reliable principles and methods, and do not apply reliable principles and methods to the facts of the case. Neither Stevenson nor Sall provide data tables of the raw values graphed in the articles. *See* EX. 1040, ¶ 26. In the absence of such data, Dr. Bloch conducts his analysis by allegedly "glean[ing] through precise measurements of the y-axis and bars within each bar graph." *Id.* For example, from Figure 1 of Sall, which contains a y-axis that measures change in baseline in corneal staining to the tenth decimal place, Dr. Bloch "gleans" the mean change from baseline values for each composition tested to the hundredth decimal place, and conducts his analysis on these unsubstantiated values and improper analysis. *See* EX. 1040, ¶¶ 33, 35-38. Dr. Bloch's analysis of Exhibit B of Dr. Attar's Declaration is equally suspect. Despite Dr. Attar's testimony that she combined the upper and lower conjunctiva data from the 98-074 study to compare against the same data from the 00-163 study, Dr. Bloch nevertheless bases his analysis on the data from the lower conjunctiva in the 98-074 study. *See* EX. 1038, 167:8-169:24; EX. 1040, ¶¶ 65-68. After "simply magnifying the scale of Dr. Attar's exhibit," and drawing a set of rudimentary lines across the figure (which has a y axis with intervals of 0.5), Dr. Bloch goes on to conclude that Dr. Attar "did the wrong 'thing' (analysis) when

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