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' RESPONSE TO PATENT OWNER'S MOTION FOR OBSERVATIONS ON THE CROSS-EXAMINATION OF DR. DANIEL A. BLOCH

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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).

Petitioner submits this Response to Patent Owner Allergan's Motion for Observations on the Cross-Examination of Dr. Daniel Bloch ("Observations") pursuant to the Standing Order (Paper 9) and the Scheduling Order (Paper 10).

Dr. Bloch's Analysis of the Data in Sall Figure 2

1) Allergan omits relevant testimony and mischaracterizes the cited testimony. *Observations* at 1. Dr. Bloch characterized his measurements as "very good approximations," EX2083 at 79:16, which he was able to obtain from Sall Figure 2 using a ruler with demarcations in "fractions of millimeters." *Id.* at 42:22–23; *see also id.* at 43:15–19 (Dr. Bloch made "very accurate measurement[s]" with his ruler). Moreover, Dr. Bloch has used this method before in peer reviewed publications (*Id.* at 52:21–54:13), and he performed the measurements "many times to verify. [He] replicated it like a good scientist would do." *Id.* at 44:2–3.

2) Allergan omits relevant testimony and mischaracterizes the cited testimony. *Observations* at 1. Dr. Bloch stated in his declaration and during his deposition that he only calculated P values where Sall did not disclose P values. EX1040, ¶43 n. 3 ("The p-values in Table 2 for 'B vs A' at months 3 and 6 and 'C vs A' at month 6 are the values reported in Sall. Hence I did not need to measure the vehicle mean difference and standard error at month 6. In the Table 'N/A' means not applicable. I calculated the p-values for the remaining comparisons that were not reported in Sall."). Dr. Bloch explained that he did not calculate these

values because they were "disclosed already by Sall," and because Sall "had the actual values or he was given the P values I believe that somebody else then actually had the values for. And when he did that, I reported that the ones he did. I only calculated P values for the ones that he did not do or to disclose in his publication." EX2083 at 80:19–81:4. Dr. Bloch further testified, "It would not be correct for me to present P values when in fact the correct P values are actually known." EX2083 at 89:14–18.

3) Allergan omits relevant testimony and mischaracterizes the cited testimony. *Observations* at 1. While P values Allergan's attorney calculated using Dr. Bloch's measurements of Sall Figure 2 to compare the 0.05% CsA formulation to vehicle are slightly lower (more indicative of significance) than those reported by Sall based on the underlying data, Dr. Bloch testified that this minor variation is to be expected because Allergan withheld the underlying data. EX2083 at 88:23–24 ("Well, it would be off by something. It had to be. I didn't have the actual data."). Dr. Bloch confirmed that the P values Allergan's counsel calculated were very similar to those reported in Sall and that Dr. Bloch was confident in the accuracy of his measurements:

> I knew [my] measurements were accurate. I knew that. The difference in the ratio to get a 0.004 P value versus 0.009 is minuscule. Because if you know anything about T distributions with 500 observations, which is 250 or more than that, 580 observations, is that the P value, if

> you just move a small amount when you're that extreme the P value will become vanishingly smaller very quickly because of the exponential tail-off of the T distribution. It goes down very, very rapidly as you get out to the tails. So the ratio would have been almost identical. . . .

Id. at 91:4–20. Dr. Bloch also testified that if he had calculated the P value using his measurements he

> would have reported a [P value of] 0.004 and the conclusion, I think, would have been 'Oh, well, Bloch wasn't -- he's more conservative than the truth is.' In other words, the P value [0.009 in Sall] is twice as high here than I would [get using my measurements] -- actually, it [the P value reported in Sall] should even be smaller…. Yeah. My own measurements would have given them a smaller P value.

Id. at 89:6–90:4. *See also* EX1007 (Sall) at 635 ("CsA 0.05% group significantly greater than the vehicle group (P = 0.009)."); EX2080 (calculating P value of 0.0037, ~0.004); EX2083 at 85:12–88:14 (discussing EX2080 and 2081, marked respectively as deposition Exhibits 2081 and 2080).

Contrary to Allergan's arguments that Dr. Bloch's analysis "was scientifically unsound and inaccurate," (*Observations* at 1) the "difference" Allergan relies upon actually demonstrates that Dr. Bloch's measurements were very careful and accurate, and showed caution in Allergan's favor. Dr. Bloch confirmed in his deposition that there were no statistically significant differences between the 0.05% and 0.10% CsA formulation in Sall Figure 2:

- EX2083 at 81: 16–85:11 (P value of 0.246 for Sall Figure 2 was not statistically significant: "[T]he answer here is that it's very likely it's just a chance finding. The answer [P value] is 0.246. It's very, very far away from being statistically significant.");
- *id.* at 106:8–10 ("However, if it's not statistically significant, what you don't know is if in fact the result you see is real, if it's reproducible.");
- *id.* at 107:4– 9 ("But to answer your question, if you don't have statistical significance, you just don't know whether or not the result is real. It could just be a chance finding. That's not okay for scientists. They want to know if it's okay, if it's really real.");
- EX1040, ¶35 (reporting P values of 0.898, 0.914, 0.480, and 0.665 when evaluating the 0.05% and 0.10% CsA formulations for corneal staining in Sall Fig. 1); *id.* at ¶43 (reporting P value of 0.115 for Sall Figure 2 at month 3 and 0.251 at month 6).

Dr. Bloch's Scope of Work and EX2078

Allergan contends that "Dr. Bloch Failed to Review Clinical Evidence Demonstrating the 0.05% CsA Formulation Works Differently than the 0.1% CsA Formulation," referring specifically to Exhibit 2078. *Observations* at 2. Petitioner objected during the deposition to Allergan's presentation of Exhibit 2078 as "a

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