Paper No. ___
Filed: May18, 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 8,624,556 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)

PETITIONER'S MOTION FOR DISCOVERY FROM PATENT OWNER

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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. RELIEF REQUESTED

As authorized in Paper 22, Petitioner requests an order requiring Allergan to produce (i) the phase 2 clinical trial (192371-001) data, (ii) the phase 3 clinical trial data (192371-002 and -003), and (iii) the pharmacokinetic ("PK") data underlying Schiffman Exhibits B-F, Attar Exhibits B-D, and Sall Figures 1-4. Allergan relies upon these figures and the Schiffman and Attar declarations to allege criticality of, and unexpected results from, combining 0.05% cyclosporin A ("CsA") with 1.25% castor oil. The underlying data is necessary to evaluate how it was purportedly used to arrive at the values Allergan depicted in these figures and whether the data support the allegations of Allergan and its witnesses. 37 C.F.R. §§ 42.65(b). Thus, an order requiring production of the underlying data is in the interests of justice and is necessary to afford Petitioner a fair cross-examination of Allergan's witnesses. 37 C.F.R. §§ 42.51(b)(2)(i)-(ii).

Allergan has provided extremely limited deposition availability for each witness (Dr. Schiffman is said to be available only on June 1, 2017, and Dr. Sheppard is said to be available only on one day, beginning only at 5:00pm), and has insisted that it will not provide additional availability. Thus, Petitioner requests that the discovery be produced by May 25, 2017, or, as suggested by the Board during the call, that Allergan be required to make its witnesses available for depositions again at a later date if necessary.

II. FACTUAL BACKGROUND

Allergan relied upon the declarations of Drs. Schiffman and Attar (*e.g.*, IPR2016-01127, EX1004, 0190-0242) during prosecution to support the alleged criticality of, and unexpected results from, the claimed percentages of cyclosporin A and castor oil. Dr. Schiffman asserted (¶¶1, 6, 8, 13-19) that his Exhibits B and D respectively depicted the results of Allergan's phase 2 and phase 3 studies for Restasis® and that his Exhibits E-F compared the results of these trials.

Dr. Attar (¶¶9-13) adopted Schiffman Figures E-F as Attar Exhibits C-D. She also discusses (¶¶6-8) at least two "Pharmacokinetic studies [that] were performed in animal eyes" that she summarized in Exhibit B. One study evaluated cyclosporin tissue penetration when "the amount of oil present in the formulation was decreased and the "weight percentage of cyclosporin stayed the same" (0.05% CsA in 0.625% or 1.25% castor oil). Another study evaluated tissue penetration using a formulation having 0.10% CsA and 1.25% castor oil. Dr. Schiffman (¶¶9-12) adopted Attar's Figure B as Schiffman Exhibit C. The patents issued based on these figures. *See, e.g.*, IPR2016-01127, EX1004, 0273-0278.

The Petitions showed that these figures "failed to demonstrate unexpected results because they failed to provide parameters necessary for scientific interpretations, including raw data values and error rates." *See, e.g.*, IPR2016-01127 Petition at 47-57. The Board agreed, but stated that it was "appropriate to

allow further evidence to be developed during trial regarding any such alleged criticality." *See, e.g.*, IPR2016-01127, Paper 8 at 18 & n.4. That evidence includes not only the cross-examinations of Drs. Schiffman and Attar, but also the data underlying the study results upon which they rely. *Id.* at 22.

Allergan and its experts continue to rely on the Schiffman and Attar declarations and their summaries of the results of the phase 2, phase 3, and PK studies. POR at 21 n.5; EX2024, 48, 50. They also rely on the results of the phase 3 trials reported in Sall and on Allergan's pharmacokinetic studies. *See, e.g.*, POR at 2, 9; EX2024, ¶¶35-48; EX2025, ¶¶29-47. Notably, however, Allergan selectively produced only a single volume of its NDA (EX2001), and did *not* produce the remaining volumes of the NDA containing the data underlying the phase 2 and 3 studies and PK studies despite Petitioner's request for these documents. EX2001 at 217 (identifying "Study Report References" for 192371-001, -002, -003, and PK studies in Volumes 27, 40, 60, and 19 of the NDA, respectively); 60-109 (identifying additional PK studies and data in Volumes 19 and 23, and "Clinical Data" and "Statistical Appendices" for 192374-001, -002, -003 in Volumes 25-29, 40-46, 60-66, 90-91, 96, 102, and 106).

Further, Allergan produced only one PK study report summarizing the underlying data of the PK study that compared different doses of CsA at constant castor oil percentages (1.25%). Allergan did not produce any report summarizing

the data for the PK study referred to by Dr. Attar in which the same doses of CsA at different castor oil percentage (0.05% CsA in 0.625% and 1.25% castor oil) were compared, and did not produce the underlying data for either PK study. EX2026 at 9 & n.4, 10 (identifying the phase 2 trial as 192371-001 and the phase 3 trials as 192371-002, -003 and specifying use of constant castor oil concentration of 1.25% in PK-98-074); *id*. at 6, 13 (identifying lab notebooks L-1998-5707 and -5709 and explaining that "All data were compiled into Allergan laboratory logbooks…stored in Allergan's R&D Records Management"). Petitioner requested the data for each of the studies. Allergan refused.

III. ARGUMENT

The phase 2, phase 3, and PK study data relied upon by Allergan and its witnesses in Schiffman Exhibits B-F, Attar Exhibits B-D, and Sall should be produced pursuant to 37 C.F.R. §§ 42.51(b)(2)(i)-(ii), 42.65. In evaluating additional discovery, the Board considers whether: (1) it is "beyond speculation" that something useful regarding a contention of the party will be uncovered; (2) the request does not seek litigation positions; (3) equivalent information is not easily obtainable by other means; (4) instructions are easy to understand; and (5) requests are not overly burdensome. *Garmin Int'l Inc. et. al. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 26, 6-16 (precedential). Additional discovery is appropriate here, where evidence on an issue raised by Allergan (criticality and

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