Paper No. ___
Filed: July 20, 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' MOTION TO EXCLUDE EVIDENCE
37 C.F.R. §42.64

---

[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

Pursuant to 37 C.F.R. §§ 42.62 and 42.64(c), Petitioners respectfully move to exclude (A) Patent Owner's reliance on EX2008 to prove a difference between the 0.05% and 0.10% CsA formulations; (B) paragraphs 48 and 33, 47 respectively of the Sheppard and Loftsson declarations (EX2024 and EX2025) relying on Schiffman and Attar Exhibits and testimony that are entitled to no weight pursuant to Paper 33; (C) the LeCause deposition transcript (EX2038); (D) paragraphs (*e.g.*, 31, 34, 36-38, 50-51, 59-60, 65, 67-68, 74-76, 88-89, and 96) of the Maness declaration (EX2028) relying on the LeCause deposition transcript (EX2038); and (E) three new exhibits (EX2077-EX2079) belatedly served with Allergan's Sur-Reply to assert new arguments fourth months after Allergan's PORs were due.

The Federal Rules of Evidence apply to *inter partes* proceedings. 37 C.F.R. § 42.62; *LKQ Corp. v. Clearlamp, LLC*, IPR2013-00020, Paper 17, at 3 (Mar. 5, 2013). This Motion addresses issues in Petitioner's Objections to Evidence (Paper Nos. 11, 17, 48 and the July 12-14, 2017 depositions of Petitioners' witnesses.

II. ARGUMENT

A. EX2008 Should Be Excluded Under F.R.E. 801-805.

Allergan describes EX2008 as "RESTASIS® label." Sur-Reply at *i*. Petitioner objected to EX2008 "To the extent that Patent Owner relies on EX. 2008 or on any statements in EX. 2008 for the truth of the matter asserted" because

"such statements are inadmissible hearsay when offered by Patent Owner." Paper 11 at 5-6 (citing F.R.E. 801, 802, 803, 805). Allergan cited EX2008 to argue that "FDA relied upon the Schirmer tests with anesthesia in approving RESTASIS®…." POR at 11-12 (citing EX2008 at 5 (clinical studies)). In its Sur-Reply, Allergan argued for the first time ever that "FDA concluded that the 0.05% CsA emulsion was statistically better at increasing tear production…than both the 0.1% CsA emulsion and vehicle for certain patient populations. EX. 2078 at 26. On this basis, FDA approved RESTASIS® for increasing tear production." Paper 42 at 6-7 & n.4 (citing EX2008 at 1).

Each of these statements is an improper attempt by Allergan to rely on out-of-court statements contained in EX2008 without the benefit of any expert analysis. Notably, EX2008 contains no comparison between the two CsA formulations and thus contradicts Allergan's unsupported attorney argument that sub-group results purportedly discussed in EX2078 were the basis for FDA's decision. Allergan's mischaracterization of the statements in EX2008 illustrates why out-of-court statements should be subjected to cross-examination. The statements relied upon by Allergan are inadmissible hearsay for the purposes for which Allergan offers them, and they should be excluded to the extent Allergan relies upon them as asserting superiority of the 0.05% CsA formulation over the 0.10% CsA formulation.

B. Paragraphs 48 of EX2024 and 33 and 47 of EX2025 Should Be Excluded or Afforded No Weight Per Order of Paper 33.

Following Allergan's refusal to provide the data underlying Schiffman Exhibits B, D-F and Attar Exhibits C-D, the Board issued an order establishing that these exhibits, as well as testimony and arguments based thereon would be "entitled to no weight." Paper 33 at 3 (Board ruling "because Patent Owner will not produce the clinical trial data underlying Schiffman Exhibits B, D, E, F and Attar Exhibits C and D, those exhibits and related testimony are entitled to no weight and will not be considered in determining the patentability of the challenged claims"); *see also* Paper 22 at 2 (order authorizing Motion for Discovery for "the data underlying the study results…rel[ied] upon to establish criticality of, and unexpected results for, the claimed combination of cyclosporin A and castor oil."); Paper 23 (Motion for Discovery); Paper 28 at 5 (order granting-in-part Petitioners' Motion for Discovery).

EX2024 and EX2025 are the Sheppard and Loftsson declarations, respectively. Drs. Sheppard and Loftsson both confirmed they studied the declarations of Drs. Schiffman and Attar prior to submitting their declarations in the current proceeding. EX1037 (Sheppard deposition transcript), 52:14-55:4, 259:16-260:5; EX1036 (Loftsson deposition transcript), 22:4-23:23, 41:3-42:16. Despite asserting that they did not rely on these declarations to form their own opinions, Drs. Sheppard and Loftsson admitted to (1) adopting language from the

Schiffman and Attar declarations into their own declarations (EX1037, 260:7-261:7 (Dr. Sheppard's inclusion of the phrase "'optimal therapeutic effectiveness' in paragraph 48" of his declaration was "not anything I meant. That's something they[Drs. Schiffman and Attar] said.")); (2) drawing conclusions of "unexpectedly and surprisingly critical results" that must be viewed in the "context [of] referring to these declarations by Drs. Schiffman and Attar," (*id.*); and relying upon Schirmer Tear Testing figures embedded in the Attar declaration for their analysis of Sall Figure 2. EX1036, 200:20-201:22 (Dr. Loftsson clarifying the basis for his conclusions in paragraph 33, and noting he "notice[d]…some comparison there of these two formulations which confirmed my observation" within "Attar declaration figures" which included "figures about Schirmer tear testing."); *id.* at 204:4-14 (when asked if he had "any recollection of relying on anything other than Sall," responded "Like I said before, I did see – I did mention Attar before").

Thus, pursuant to the Board's orders, paragraph 48 of EX2024 and paragraphs 33 and 47 of EX2025 and Drs. Sheppard and Loftsson's analysis of Sall Figure 2 relying on the excluded portions of the Schiffman and Attar declarations should be excluded.

C. EX2038 Should Be Excluded Under F.R.E. 602, 901, 801-805, and 37 C.F.R. § 42.53(a).

Allergan describes EX2038 as the deposition testimony of Allergan employee David LeCause. POR at 12. This deposition testimony was obtained in

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.