UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KVK-Tech, Inc.,
Petitioner,

v.

Shire LLC,
Patent Owner.

Case IPR2018-00293
Patent 9,173,857

PETITIONER'S REPLY IN SUPPRORT OF ITS OBJECTIONS AND MOTION TO EXCLUDE

Patent Trial and Appeal Board
P.O. Box 1450
Alexandria, VA 22313-1450

I. Petitioner Timely Objected

Patent Owner argues Petitioner did not object to Exhibit 2083. That is untrue. This motion (Paper No. 44) is both an objection and a motion to exclude, as evident from its title and opening line, and, pursuant to 37 C.F.R. 42.64(b)(1), it was made within 5 business days (in fact the same day) of Patent Owner's filing and service of Exhibit 2083 with its Sur-Reply, on March 7, 2019.

II. Exhibit 2083 Should be Excluded

During the February 22, 2019 conference call with the Board, Patent Owner represented that it only intended to present new evidence with its Sur-Reply if it related to the "impeachment" of Petitioner's declarant, Dr. James McCracken. Petitioner agreed to these terms and, on February 25, 2019, the Board ruled that "any additional evidence submitted in connection with the briefing will be restricted to evidence related to the credibility of Petitioner's additional declarant." (Paper No. 36, p. 4.) The Order reflected the parties' agreement, as noted in the Order. *Id*.

Patent Owner relies on this new reference on page 9 of its Sur-Reply as evidence of an alleged "consensus opinion" in 2009 concerning the issue of acute tolerance of amphetamines. Patent Owner argues that this reference was properly submitted to challenge the credibility of Dr. McCracken. Patent owner is wrong for several reasons.

First, Patent Owner did not challenge Dr. McCracken's credibility with this

reference during his deposition. Dr. McCracken is not an author of this reference, and testified that he had never seen this reference (McCracken Dep. EX. 2082 184:4-18). Patent Owner asked Dr. McCracken to read two passages from the reference into the record, without asking any substantive questions about those passages or any other passages. (*Id*. 184:23-186:24.)

Now, without any substantive expert testimony concerning EX. 2083 – either from Patent Owner's or Petitioner's experts – Patent Owner seeks to introduce this article, and all its contents, into evidence under the pretext of attacking Dr. McCracken's credibility.

Second, Patent Owner grossly mischaracterizes this reference. It does not disclose a 2009 consensus opinion, nor does it implicate acute tolerance in amphetamines. Rather, it discusses an alleged "consensus opinion" from the 1980s that "stimulant drugs required bolus doses and a PK profile with peaks and valleys to produce and maintain clinical efficacy, which implied an inherent limitation on CR [controlled release] formulations." (First full paragraph, EX. 2083 p. 3.)

No expert in the case has or can provide an opinion on whether there was such a consensus opinion in the 1980s. There is no one to opine on this because Patent Owner did not introduce this exhibit with any of its experts, not did it ask for Dr. McCracken's opinion.

Even assuming there was such a consensus opinion in the 1980s, it's not relevant to the opinions of Dr. McCracken on acute tolerance because his opinions

are largely based on his amphetamine study from 2003, EX.1037 (and additional studies in the 1990s, e.g., EX.1052 and 1053). Patent Owner's new reference (EX.2083) even recognizes that opinions on acute tolerance have changed. Indeed, it states (on p. 11) that the "fundamental principle of acute tolerance is not understood or recognized by all, which is reflected in the second generation CR formulations (see the absence of acute tolerance in the reviews by Banaschewski et. al., 2006 and Conner & Steingard, 2004) and by some investigators who have participated in the development of new CR formulations without an ascending drug profile …." *Id*. p. 11.

Third, evidence of impeachment or of a witnesses' credibility is governed by the Federal Rules of Evidence, and consists of the witnesses' character or reputation (F.R.E 608(a)), the witnesses' prior conduct (F.R.E 608(b)), or the witnesses' prior inconsistent statements (F.R.E. 613). None of these categories are applicable here. Exhibit 2083 is not authored by Dr. McCracken, nor addressing Dr. McCracken's conduct, character, or reputation. Nor can Patent Owner point to any inconsistent statement by Dr. McCracken in Exhibit 2083 as he is not quoted.

Patent Owner argues that it should be allowed to introduce evidence that could be considered in a *Daubert* hearing. But Patent Owner did not request the right to introduce evidence that would be relevant in a *Daubert* hearing; it only requested the right to introduce impeachment evidence. *Daubert* factors are inapplicable as they relate to the of the *admissibility* of an expert's testimony, not the *credibility* of

the expert. The inquiry in *Daubert* is whether the expert's opinion is based on reliable scientific principles and methodology. *See*, *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579, 592-594 (1993). "But the question of whether the expert is credible or the opinion is correct is generally a question for the fact finder, not the court." *Summit 6, LLC v. Samsung Electronics Co., Ltd*., 802 F.3d 1283, 1295 (Fed. Cir. 2015).

Patent Owner argues that whether acute tolerance is generally accepted is relevant to *Daubert* and therefore credibility. It's not relevant to either. It's the general acceptance of the expert's methodology that is a factor in *Daubert*; not the expert's conclusions. *Daubert*, at 595 ("The focus, of course, must be solely on the principles and methodology, not on the conclusions that they generate."); *Summit 6*, at 1296 ("where the methodology is reasonable and its data or evidence are sufficiently tied to the facts of the case, the gatekeeping role of the court is satisfied, and the inquiry on the correctness of the methodology and of the results produced thereunder belongs to the factfinder.")

Patent Owner's submission of Exhibit 2083 with Patent Owner's Sur-Reply is contrary to the Board's Order and agreement of the parties, is unrelated to impeachment (and even *Daubert*), and no expert has offered any opinion on it. Therefore, it should be excluded.

III. Exhibit 2082

For the same reasons, Petitioner objects and moves to exclude the portion of

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.