

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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KVK-Tech, Inc.,  
Petitioner,

v.

Shire LLC,  
Patent Owner.

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Case IPR2018-00290  
Patent 8,846,100

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**PATENT OWNER'S OPPOSITION TO  
PETITIONER'S MOTION TO EXCLUDE**

Pursuant to the Scheduling Order (Paper 16, 4), Patent Owner Shire LLC (“Shire”) submits this Opposition to Petitioner’s Motion to Exclude EX2083 and a portion of EX2082. As set forth below, Petitioner’s motion should be denied for at least two independent reasons. First, Petitioner failed to timely object to the disputed evidence. Second, EX2082 and the disputed portion of EX2083 address the credibility of Petitioner’s expert, Dr. McCracken.

### **I. PETITIONER’S OBJECTIONS ARE WAIVED AS UNTIMELY**

EX2082 is the deposition transcript of Petitioner’s expert, Dr. McCracken, and EX2083 was introduced during that deposition. EX2082, 184:4-174. Under 37 C.F.R. § 42.64(a), “[a]n objection to the admissibility of deposition evidence must be made during the deposition.” *See also* 2012 Office Trial Practice Guide, 77 Fed. Reg. at 48772 (“An objection at the time of the examination—whether to evidence, to a party’s conduct, to the officer’s qualifications, to the manner of taking the testimony, or any aspect of the testimony—must be noted on the record . . . .”). Petitioner, however, failed to object to either EX2083 or the portion of 2082 it now moves to exclude during the deposition. EX2082, 184:4-187:20. Tellingly, Petitioner’s motion to exclude does not point out where any objection was made, even though required by the Office’s Rules. *See* 37 CFR 42.64(c) (“The motion [to exclude] must identify the objections in the record . . . .”). Accordingly, because

Petitioner did not timely object to EX2082 or EX2083, those objections are waived. Petitioner's motion should be denied for this reason alone.

## **II. EX2083 ADDRESSES THE CREDIBILITY OF PETITIONER'S EXPERT**

Petitioner incorrectly alleges that evidence of a witnesses' credibility is limited only to "evidence 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)." Paper 46, 2. The types of evidence set forth by Petitioner do address credibility, but Petitioner's list is not exclusive. As shown below, such evidence is not limited to statements by the witness either.

Petitioner offers Dr. McCracken as an expert witness. Thus, there are many factors that should be considered when addressing the credibility or reliability of Dr. McCracken's testimony. For example, in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-94 (1993), the Supreme Court listed several factors that a court can consider when determining the reliability of an expert's testimony under F.R.E. 702, including "whether the theory . . . has been subjected to peer review and publication" and whether the theory has "general acceptance" in the scientific community. *See also Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1297 (Fed. Cir. 2015) ("In *Daubert*, The Supreme Court has delineated certain factors to assist courts in evaluating the foundation of a given expert's testimony, while carefully emphasizing the non-exhaustive nature of these factors. Suggested

considerations include whether the theory or technique the expert employs is generally accepted, whether the theory has been subjected to peer review and publication, whether the theory can and has been tested, whether the known or potential rate of error is acceptable, and whether there are standards controlling the technique's operation.”). But even Daubert recognized that there are many different factors to consider when assessing an expert’s testimony. *Daubert*, 509 U.S. at 593 (“Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test.”). Further, the Supreme Court and Federal Circuit have indicated that “the presentation of contrary evidence” is a proper means of attacking the credibility of expert testimony:

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. *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1314 (Fed. Cir. 2014), *overruled en banc in part not relevant here, Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015). Indeed, “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 596.

*Summit 6*, 802 F.3d at 1296.; *see also Moberly v. Sec’y of HHS*, 592 F.3d 1315, 1325-26 (Fed. Cir. 2010) (“Assessments as to the reliability of expert testimony often turn on credibility determinations, particularly in cases such as this one where there is little supporting evidence for the expert's opinion.”)

Patent Owner questioned Dr. McCracken on EX2083 (EX2082, 184:4-187:20) and submitted EX2083 to show that Dr. McCracken is now providing expert

testimony on a theory that is inconsistent with the “consensus opinion” of the scientific community. Paper 42, 9 (quoting EX2083, 3). Briefly, Dr. McCracken testified that acute tolerance is not an issue for amphetamines and ADHD, based on certain of his work in 2003. *See, e.g.*, EX1045, ¶¶ 31-39. Dr. McCracken conceded that he is taking a position inconsistent with that of Dr. Swanson, a co-author of the article he relies on in this case (EX1037) as well a companion article (EX1057). EX2082, 187:3-5. Dr. Swanson is also an author of EX2083, a subsequent peer review article that directly addresses the subject matter of Dr. McCracken’s testimony. EX2082, 184:19-22, 187:3-20. Further, Dr. McCracken’s testimony specifically criticized Dr. Swanson’s expertise. *See, e.g.*, EX2082, 187:3-20. Accordingly, EX2083 is highly probative of Dr. McCracken’s credibility, *i.e.*, whether his testimony withstands “peer review” and has “general acceptance” in the scientific community. *See Daubert supra*. Specifically, EX2083 establishes that Dr. McCracken’s testimony regarding acute tolerance is not credible.

### **III. EX2082 ADDRESSES THE CREDIBILITY OF PETITIONER’S EXPERT**

Petitioner asks the Board to exclude portions of EX2082 (184:4-186:24) “[f]or the same reason” as EX2083. Paper 46, 3. Accordingly, Patent Owner submits this portion of EX2082 is admissible for the same reasons discussed above.

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