IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KVK-Tech, Inc.,
Petitioner,

v.

Shire LLC,
Patent Owner.

Case IPR2018-00290
Patent 8,846,100

PATENT OWNER'S MOTION TO EXCLUDE EXHIBITS 1047, 1049, 1051, & 1054-1056

Pursuant to 37 C.F.R. 42.64(c), Patent Owner Shire LLC ("Shire") submits this motion to exclude Exhibits 1047, 1049, 1051, and 1054-1056 filed by Petitioner in support of the Petitioner's Reply (Paper 33).[1]

I. INTRODUCTION

With its Reply, Petitioner submitted six documents it says are published on the FDA's website: EX1047—Clinical Pharmacology/Biopharmaceutics Review for NDA No. 22-063 (Mydayis®); EX1049—Chemistry Review for NDA No. 21-303 (Adderall XR®); EX1051—FDA Summary Review for NDA 22-063 (Mydayis®); Ex. 1054—Dexedrine® Spansule® Sustained Release product label; EX1055—Dyanavel XR® product label; and EX1056—Adzenys ER® product

[1] In response to Patent Owner's Objections (Paper 34), Petitioner served an additional document—EX1059 (Physicians' Desk Reference 2005)—on February 26, 2019. Petitioner alleged EX1059 to be "supplemental evidence." The following day at the Deposition of Dr. McCracken, Patent Owner objected to this exhibit as untimely. Petitioner has not relied on EX1059 in any paper filed in this case. To the extent Petitioner attempts to rely on this document, however, Patent Owner reserves the right to move to exclude EX1059 as untimely. Patent Owner also notes that EX1059 is an entirely new document that does not respond to objection raised by Patent Owner.

label. As discussed in below, each of these documents is offered by Petitioner to prove the truth of various statements contained therein. Accordingly, they are hearsay under Fed. R. Evid. 801(c). These documents furthermore are not excluded from the definition of hearsay under Fed. R. Evid. 801(d), do not fall into any hearsay exception under Fed. R. Evid. 803, and are inadmissible under Fed. R. Evid. 802.

Moreover, each of the product labels submitted by Petitioner are dated after the filing date of the challenged patent. The '100 patent has a priority date of at least May 12, 2006. But EX1054 is dated 2007, and EX1055 and EX1056 are dated 2017. Accordingly, these documents are irrelevant to the validity of the '100 patent and should be excluded under Fed. R. Evid. 402.

II. LEGAL STANDARD FOR MOTION TO EXCLUDE

"A party wishing to challenge the admissibility of evidence must object timely to the evidence at the point it is offered and then preserve the objection by filing a motion to exclude the evidence." Trial Practice Guide, 77 Fed. Reg. 48765, 48767 (Aug. 14, 2012) (citing 37 C.F.R. § 42.64). "A motion to exclude evidence must: (a) Identify where in the record the objection originally was made; (b) Identify where in the record the evidence sought to be excluded was relied upon by an opponent; (c) Address objections to exhibits in numerical order; and (d) Explain each objection." *Id*.

"Admissibility of evidence [in an IPR] is generally governed by the Federal Rules of Evidence." 77 Fed. Reg. 157, at 48758. "Irrelevant evidence is not admissible" under Rules 401 and 402, when the evidence does not tend "to make a fact more or less probable than it would be without the evidence" or the fact is not of "consequence in determining the action." Fed. R. Evid. 401 and 402; *see also Daubert*, 509 U.S. at 587 (1993); *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 961 (Fed. Cir. 1997).

Hearsay evidence is inadmissible under Fed. R. Evid. 801 and 802, when a statement, other than one made by the declarant, is offered in evidence "to prove the truth of the matter asserted." *Air Land Forwarders, Inc. v. US*, 172 F. 3d 1338, 1342 (Fed. Cir. 1999).

The proponent of the evidence, in this case Petitioner, has the burden of establishing admissibility by a preponderance of the evidence. *See* Fed. R. Evid. 104(a); *Bourjaily v. United States*, 483 U.S. 171 (1987).

III. ARGUMENT

A. Identify Where in the Record the Objection Originally was Made

Patent Owner originally objected to Exhibits 1047, 1049, 1051, and 1054-1056 on February 14, 2019, which was within five business days of the February 7, 2019 Petitioner Reply. *See* Paper 34.

B. Identify Where in the Record the Evidence Sought to be Excluded was Relied Upon by an Opponent

Petitioner relied on Exhibits 1047, 1049, 1051, and 1054-1056 in its Reply. *See* Paper 33, pp. 2 (Ex. 1047), 7-8 (Ex. 1054), 15 (Ex. 1051), 16-17 (Exs. 1054-56), and 25 (Ex. 1049).

C. Address Objections to Exhibits in Numerical Order

Patent Owner objections to Exhibits 1047, 1049, 1051, and 1054-56 are addressed below in numerical order.

D. Explain Each Objection

1. EX1047 is Inadmissible Under Fed. R. Evid. 802

EX1047 is inadmissible as hearsay. Petitioner cites EX1047 in support of its allegation that "[p]rior to 2006, doctors often prescribed a morning dose of Adderall XR followed by a booster of Adderall IR taken 8-10 hours later." Paper 33, p. 2. Specifically, Petitioner quotes the following sentence from EX1047: "[t]he rationale for the development of SPD465 (Long Acting Adderall XR) is to enable primary adult and adolescent ADHD patients to benefit from ADHD symptom control throughout the entire day and extend those benefits into the early evening hours." Thus, this statement is hearsay under Fed. R. Evid. 801 because Petitioner is offering this statement from EX1047 to prove the truthfulness of the statement contained therein, i.e., the specific rationale for the development of Mydayis. Further, this statement in EX1047 is not excluded from the definition of hearsay in Fed. R. Evid.

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.