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

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

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

Patent Owner moves to exclude six exhibits downloaded from FDA's website, which FDA maintains to provide the public with FDA communications, reports and package inserts with respect to FDA approved drug products.[1] Patent Owner has previously submitted similar exhibits in this case, also downloaded from FDA's or Patent Owner's websites. (e.g., EX2003, EX2004, EX2005.)

Nevertheless, Patent Owner moves to exclude all six exhibits as hearsay evidence, and three exhibits (1054-1056) as irrelevant to invalidity since they were dated after the priority date of the patent at issue in this IPR.

I. Patent Owner's Hearsay Objections

All the challenged exhibits are subject to the public record exception, F.R.E, Rule 803(8), which provides that a record of a public office is not hearsay if:

> **(A)** it sets out:
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> **(i)** the office's activities;
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> **(ii)** a matter observed while under a legal duty to report, but not including, in a criminal case, a matter observed by law-enforcement personnel; or
>
> **(iii)** in a civil case or against the government in a criminal case, factual findings from a legally authorized investigation; and

[1] Patent Owner also objected to (but has not moved to exclude) the Declaration of James McCracken, dated February 7, 2019 (EX.1045), because it did not include a proper oath. Pursuant to 37 CFR 42.64(b)(2), Petitioner served a Corrected Declaration of James McCracken on February 26, 2019, which is submitted herewith (EX.1058).

(B) the opponent does not show that the source of information or other circumstances indicate a lack of trustworthiness.

Here, all the exhibits are FDA records available on the FDA website, and each sets out (i) FDA's activities respecting its approval of certain drug products, including Adderall XR and Mydayis, (ii) matters FDA observed based on Patent Owner's applications to FDA for approval of Adderall XR and Mydayis, and (iii) factual findings by FDA in its review of those applications. (See Exhibit 1060, Declaration of Steven Roth ¶¶ 2-5, 7-9; EX1047, EX1049, EX1051, EX1054-56.)[2] Moreover, Patent Owner has not and cannot show that the FDA website is an unreliable source. Numerous cases have held that FDA letters, filings and reports are not hearsay under the public records exception. *See, e.g., Sabel v. Mead Johnson & Co*., 737 F. Supp. 135, 140-144 (D. Mass. 1990); *Fujisawa Pharm. Co., Ltd. v. Kapoor*, 1999 WL 543166 ** 1-2 (N.D. Ill, July 21, 1999); *Novartis Pharm. Corp. v. Teva Pharm. USA, Inc*., 2009 WL 3754170 **10-11 (D.N.J., Nov. 5, 2009). In addition, all the challenged exhibits, even if hearsay, are admissible under the Residual Exception, F.R.E, Rule 807.

At least two of the Exhibits are not even hearsay as they were not introduced for

[2] Petitioner served the Declaration of Steven Roth as supplemental evidence, pursuant to 37 C.F.R. 42.64(b)(2), within 10 business days of Patent Owner's Objection to these exhibits (Paper No. 34).

the truth of the matter asserted, but for Patent Owner's intent (Exhibits 1047 and 1051). Exhibit 1047 is an FDA pharmacology report in the Mydayis NDA file available to the public. It is referenced in Petitioner' Reply brief (Paper 33, at p. 2) as additional evidence (which is undisputed) that Patent Owner's intent in developing the three-bead product was to extend ADHD treatment. Exhibit 1051 is FDA's Summary Review of Mydayis, also available on the FDA website in the Mydayis file, and it is cited in Petitioner's Reply (at p. 15) to show that Patent Owner advised FDA that it abandoned the FDA application for 9 years because of "business reason," which is inconsistent with Patent Owner's current claim of long felt need. Thus, both exhibits are relevant to show Patent Owner's intent.

In addition, three of the exhibits (Exhibits 1054-1056) are admissible under F.R.E, Rule 703, even if they are hearsay and not subject to any exception, as they were relied on by Petitioner's expert, Dr. McCracken (Exhibit 1045 ¶¶101-102), and their probative value outweighs their prejudicial effect. These three exhibits are FDA approved package inserts for extended release amphetamine drug products. The probative value of these exhibits, as discussed more fully below, is that they demonstrate that the absence of a "food effect" is an inherent property of amphetamine extended release formulations, regardless of the formulation. *Id*. There is no prejudicial effect of admitting these exhibits.

II. Patent Owner's Relevance Objections (Exhibits 1054-1056)

Patent Owner objects to Exhibits 1054-1056 as irrelevant evidence as they post-date the priority date of the patents at issue. These exhibits are package inserts for various extended release amphetamine drug products, and are relevant to show that the compositions of claim 1, if obvious, inherently possesses the "no food effect" element of dependent claim 21. Evidence that an obvious product has an inherent feature is relevant, regardless of when the evidence was published.

Monsanto Tech. LLC v. E.I. DuPont de Nemours 878 F.3d 1336 (Fed. Cir. 2018) is on point. The case concerned the validity of a patent on a soybean plant obtained by (a) crossing two parent plant lines and (b) obtaining a progeny having certain properties. The Federal Circuit affirmed the PTAB's finding the patent anticipated and obvious over a single prior art reference ("Booth") teaching step (a) above, combined with non-prior art declarations ("the Kinney Declarations") demonstrating that the properties in step (b) were inherent. The Federal Circuit held that the "evidence [of inherency] need not antedate the critical date of the patent at issue." Id. at 1345. That's because the evidence is only showing what is necessarily present in an obvious product. And although the statement above was made in the context of anticipation, the Federal Circuit applied the same analysis in finding the claims obvious, including reliance on the non-prior art declarations to show that step (b) is inherent in the otherwise obvious plant progeny. *See*,

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