

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 IPR2018-00293
Patent 9,173,857

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

Patent Owner Shire LLC submits this Reply to Petitioner's Opposition to Patent Owner's Motion to Exclude Exhibits 1047, 1049, 1051, and 1054-1056.

I. Exhibits 1047, 1049, 1051, and 1054-1056 Are Inadmissible Hearsay

First, Petitioner fails to show that the offered evidence falls into any exception to the rule against hearsay under Fed. R. Evid. 803. The burden is on Petitioner to establish admissibility by a preponderance of the evidence. *See* Fed. R. Evid. 104(a); *Bourjaily v. United States*, 483 U.S. 171 (1987). Petitioner fails to carry its burden. In its Opposition, Petitioner merely restates Fed. R. Evid. 803(8) in its entirety without specifying what, if any, portion of the Rule applies in the present case. Paper 47, 2-3. Petitioner does nothing to show how the offered Exhibits embody "factual findings from a legally authorized investigation" and are a final product of the FDA's own legally mandated investigative efforts. *See* Fed. R. Evid. 803(8)(iii). Petitioner similarly fails to identify any legal duty or show how the Exhibits embody "a matter observed while under a legal duty to report." *See* Fed. R. Evid. 803(8)(ii).

Second, Petitioner's argument that EX1047 and EX1051 are excluded from the definition of hearsay is without merit. Petitioner introduces EX1047 to prove the truthfulness of a statement contained therein, *i.e.*, the rationale for developing of MYDAYIS. Similarly, Petitioner introduces the statement from EX1051 that "[t]he Applicant notified the Agency in 2007 that they intended to file an amendment to support approval; however, they later decided not to pursue further development of

SHP465 for business reasons,” for the truthfulness of that statement, *i.e.*, not filing the amendment was for business reasons. Contrary to Petitioner’s bald assertion, neither EX1047 nor EX1051 establish Patent Owner’s intent. *See* Paper 47, 4.

Petitioner also asserts, even if inadmissible as hearsay, EX1054-1056 are admissible under Fed. R. of Evid. 703, because Petitioner’s expert relied on them. Petitioner cites no case law to support this proposition. Rule 703 does not address the admissibility of evidence; it sets forth the proper basis for an expert opinion. *Id.* While Rule 703 provides that an expert *opinion* may in some circumstances be admissible if based on otherwise inadmissible facts or data, the Rule allows only the *opponent of the opinion*—in this case the Patent Owner—to disclose otherwise inadmissible evidence and “only if [its] probative value in helping the jury evaluate the opinion substantially outweighs [its] prejudicial effect.” *Id.* (emphasis added). Nothing in Rule 703 allows Petitioner to introduce otherwise inadmissible evidence, simply because an expert relies on it. Furthermore, Rule 703 does not place Petitioner’s expert in any position to assert the truth of hearsay statements involving FDA’s practices or Patent Owner’s intentions for MYDAYIS.

Exhibits 1047, 1049, 1051, and 1054-1056 all fall squarely within the definition of hearsay under Fed. R. Evid. 801. Petitioner failed to show that any exception to the rule against hearsay applies under Fed. R. Evid. 803. Therefore, the offered Exhibits should be excluded from this proceeding.

II. Exhibits 1054-1056 Are Inadmissible as Irrelevant

Petitioner cites no law to support its broad proposition that “[e]vidence that an obvious product has an inherent feature is relevant,” let alone that such evidence is relevant “regardless of when the evidence was published.” Paper 47, 5. Inherent obviousness is not inherent anticipation; it requires operative knowledge by a POSA before the invention. *Honeywell Int’l Inc. v. Mexichem Amanco Holding S.A.*, 865 F.3d 1348, 1354-55 (Fed. Cir. 2017). Regardless of how Petitioner now characterizes its argument or reframes the issue, Petitioner introduced evidence that post-dates the claimed invention to establish the challenged claims are obvious. Paper 31, 16-17. The issue remains whether a POSA had a motivation to combine and reasonable expectation of success in arriving at the claimed invention, which depends on what the POSA knew in 2006. Whether different products exhibited a food effect in 2007 is of no consequence to this issue. Evidence that post-dates the invention is of no consequence to whether an inherent quality was unexpected. Petitioner concedes as much. Paper 47, 7 (“*Honeywell* only held that . . . evidence of obviousness, such as motivation to combine and expected results must be known in the prior art.”).

Honeywell is directly on point. The Federal Circuit held the critical issue in the case of inherency in obviousness is what was known or expected to a POSA at the time of the invention. *Honeywell*, 865 F.3d at 1354-55 (“What is important regarding properties that may be inherent, but unknown, is whether they are

unexpected.”). The Court reiterated, “the use of inherency in the context of obviousness must be carefully circumscribed because ‘[t]hat which may be inherent is not necessarily known’ and that which is unknown cannot be obvious.” *Id.* Petitioner asks the Board to ignore these considerations and admit irrelevant evidence. Furthermore, the *Honeywell* court explained that a property that may be inherent in a single component of a formulation cannot be used to demonstrate obvious inherency of that property in a formulation containing additional components. *Id.* at 1353-55 (known miscibility of a refrigerant does not establish a composition containing the refrigerant in combination with other components is inherently miscible). That is precisely the situation before the Board. Petitioner is contending that amphetamine per se inherently has no food effect. Therefore, any formulation with amphetamine must inherently have no food effect. The *Honeywell* court held that is an improper application of inherent obviousness. The obviousness inquiry cannot be short-circuited, as Petitioner would have the Board do.

The case law relied upon by Petitioner is inapposite. In *Monsanto Tech. LLC v. E.I. DuPont De Nemours & Co.*, 878 F.3d 1336 (Fed. Cir. 2018), the Federal Circuit affirmed the Board’s holding of anticipation by inherent disclosure, which is not at issue here. Petitioner quotes the Federal Circuit out of context. Its statement that extrinsic evidence “need not antedate the critical date of the patent at issue” is limited to inherent anticipation, not inherent obviousness, as the Court’s analysis

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