UNITED STATES PATENT AND TRADEMARK OFFICE
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BEFORE THE PATENT TRIAL AND APPEAL BOARD
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KVK-TECH, INC. and
FLAT LINE CAPITAL, LLC,
Petitioners,

v.

SILVERGATE PHARMACEUTICALS, INC.,
Patent Owner.

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Case PGR2017-00039
Patent 9,463,183
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SILVERGATE'S REHEARING REQUEST
37 CFR §42.71(d)(1)

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I.   PRECISE RELIEF REQUESTED

The patent owner ("Silvergate") respectfully requests rehearing of the institution decision (Paper 8) on points the Board misapprehended or overlooked. Silvergate further requests modification of the institution decision, to deny institution on Ground 3. 37 CFR §42.71(d)(1).

II.   REASONS FOR RELIEF
A. Introduction

In three instances, the decision overlooks argument supported with evidence and authority contrary to the decision's preliminary holdings. In each case, the overlooked argument identifies unsupported positions in the petition that are nevertheless adopted in the decision to Silvergate's prejudice. Neither the patent owner nor the Board should have to bear the cost of a trial over a facially deficient petition.

B. Insufficient showing of pH between about 4 and about 5

Page 17 of the decision states that the petition sufficiently shows that an ordinary artisan would have been prompted to buffer the formulation to within the claimed pH range of about 4 to 5. The decision discusses argument on pages 46-48 of the preliminary response (Paper 7), but overlooks relevant discussion at pages 35-36 of the preliminary response. Specifically, the preliminary response explained (at 35-36, original emphasis):

According to the results of Beidel, for the varied pH formulations stored at 45°C, the formulation at **pH 5.8** exhibited the highest % lisinopril remaining at 210 days (*i.e.*, 88%), compared to the other samples stored at 45°C (*i.e.*, pH 4.2 (80%); pH 5.2 (67%); 4.8 (85%)). Ex. 1005, Results. Consistent with this reading, Beidel concludes "[a] lisinopril solution will show acceptable stability (at least 2 years) if buffered to pH 5.75 and stored in the refrigerator at 5°C." Ex. 1005, Conclusion.

The preliminary response further explained (at 36):

Dr. Kibbe asserts in his Declaration "[a] person of ordinary skill in the art would recognize that Beidel's reference to 'pH 5.75' in this conclusion was a typographical error since the results do not support this conclusion." Kibbe Decl. at n. 4 (Ex. 1002 at 36). Yet, Dr. Kibbe does not state how this can be true when only one pH was tested at 25°C, and the formulation at pH 5.8 was the most stable of the samples having different pH values stored at 45°C. Further, the Declaration of Benjamin Beidel, the first author of the Beidel reference, does not corroborate this alleged typographical error; indeed Mr. Beidel is silent as to any errors in the reference. Ex. 1021.

Overlooking this material is prejudicial to Silvergate because it directly undermines the petition's premise for the pH selection, which the decision found sufficient. As the preliminary response explained, "the premise that a POSA would select a buffer having a pK_a of 4.8 is not supported by the references, because the references do not establish that lisinopril is most stable at a pH of 4.8." Paper 7 at 36. While the decision broadly dismisses argument on these pages as "bare

attorney argument assigning contrary views and understandings to the ordinary artisan." (Paper 8 at 19), Silvergate's arguments about what Beidel actually shows are not directly addressed or refuted.

The petitioner's expert is unreliable: his expert testimony is not only baseless but actually contrary to the express teaching of the reference, and his fact testimony (about the typographical error) is uncorroborated and facially inconsistent. Precedent has long counseled that unsupported testimony about what was known in the prior art "must be regarded with suspicion and subjected to close scrutiny." *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986). Attorney argument, while not evidence in itself, is an appropriate method for highlighting the facial flaws in the petitioner's evidence, particularly when the argument is well-grounded in petitioner's own exhibits.

Although, Dr. Kibbe's testimony calls into question whether any of the values in the Beidel reference can be trusted, his "litigation-driven testimony" about an uncorroborated typographical error on the very point that the petitioner must prove is not entitled to weight. *Velander v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003) (author's post-litem testimony inconsistent with reference is entitled to little weight). His testimony does not establish that an error necessarily exists, much less that it must be corrected in the manner he asserts. Certainly Dr. Kibbe's unsupported testimony is not entitled to more weight than the reference on

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