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Paper No. 13
Date: July 21, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ETON PHARMACEUTICALS, INC.,
Petitioner,

v.

EXELA PHARMA SCIENCES, LLC,
Patent Owner.

PGR2020-00086
Patent 10,653,719 B1

Before ULRIKE W. JENKS, SUSAN L.C. MITCHELL, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge.*

DECISION
Denying Petitioner's Request on Rehearing of Decision Denying Institution of Post Grant Review
37 C.F.R. § 42.71(d)

I. INTRODUCTION

Eton Pharmaceuticals Inc. ("Petitioner") requests rehearing of our Institution Decision ("Decision") denying post-grant review of claims 1–27 of U.S. Patent No. 10,653,719 B1 (Ex. 1106, "the '719 patent") entered on April 23, 2021 (Paper 11, "Dec."). Paper 12 ("Req. Reh'g").

We denied institution based on our determination that Petitioner's contentions relying on reasonable expectation of success based on overlapping ranges was not sufficiently supported by the evidence in the record. Dec. 15–26. We also determined that the Petition fails to meet the particularity requirement of 35 U.S.C. § 322(a)(3) with regard to Petitioner's assertion that the subject matter of the claims would have been obvious over the Sandoz Label in conjunction with the knowledge of a person of ordinary skill in the art. Dec. 17.

In its Request for Rehearing, Petitioner contends that the Board in the Decision misapprehends Petitioner's assertions based on reasonable expectation of success argument that does not rely on overlapping ranges to establish unpatentability, that the Sandoz Label encompasses the claimed aluminum range, and that the Board abused its discretion in finding lack of particularity. *See generally* Req. Reh'g.

Having reconsidered Petitioner's arguments in view of the Request for Rehearing we modify the Decision to incorporate and address Petitioner's contentions with respect to their reasonable expectation of success assertions. For the reasons discussed below, the modification of our Decision does not alter the outcome. As a result, we *deny* Petitioner's Request for Rehearing.

II. STANDARD OF REVIEW

A party requesting rehearing has the burden to show a decision should be modified by specifically identifying all matters the party believes were misapprehended or overlooked, and the place where each matter was addressed previously in a motion, opposition, or a reply. 37 C.F.R. § 42.71(d). When rehearing a decision on institution, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may arise if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors. *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *In re Gartside*, 203 F.3d 1305, 1315–16 (Fed. Cir. 2000).

III. ANALYSIS

In its Request for Rehearing, Petitioner contends that the Board in the Decision misapprehends Petitioner's reasonable expectation of success assertions, determination that the Sandoz Label discloses a range, and abused its discretion in finding lack of particularity in the Petition. *See generally* Req. Reh'g.

1.) Reasonable Expectation of Success

Petitioner argues that in the Petition they presented a separate reasonable expectation of success argument and therefore it is not a new argument but instead is based on the ability of a person of ordinary skill in the art to reach "the claimed aluminum levels by simply removing the known sources of aluminum contamination from the Sandoz Label product." Req. Reh'g 2; Pet. 33, 42–43. Petitioner contends that the Decision

overlooks that a person of ordinary skill in the art would have eliminated "known sources of aluminum" (Req. Reh'g 2), for example, from the component ingredients as well as glass containers. Req. Reh'g 3 (citing Pet. 32–33, section VIII.E).

Even if we were to agree with Petitioner that the Petition included a separate "reasonable expectation of success argument" that did not rely on overlapping ranges, we again find that Patent Owner has the better position. In our Decision, we agreed with Petitioner that there was ample motivation for reducing aluminum levels in parenteral solutions. *See* Dec. 22. In the Decision, however, we explained that motivation alone is not sufficient for reaching a conclusion of obviousness because it does not, without more, provide a path for how to achieve the stated goal. *Id.*

The issue is not whether an ordinary artisan recognized sources of aluminum contamination that could potentially be eliminated; the question is whether there is reasonable expectation that removing an aluminum source results in a product that contains less than about 150 ppb and "is substantially free of visually detectable particulate matter and suitable for use as an additive in a parenteral nutrition composition for administration to an individual" as defined by the '719 patent. We agree with Patent Owner's response that "the kinetics and equilibrium chemistry of the various L-cysteine and cystine species in any particular L-cysteine solution are complex and influenced by multiple interacting variables of that environment, including oxygen levels, pH, and the presence of trace metals." Prelim Resp. 19–20. Patent Owner further explains that "removing Aluminum may have the unintended consequence of increased [cystine] precipitation and product failure in the presence of even small amounts of

oxygen in the container." *Id.* at 21 (citing Ex. 1106, 5:19–23 ("[R]emoving Aluminum may have the unintended consequence of increased precipitation and product failure in the presence of even small amounts of oxygen in the container. This was unexpected.")); *see id.* at 44. In other words, the removal of aluminum has the unintended consequence of making the product more susceptible to oxygen, resulting in product precipitation, and thereby rendering the product unsuitable for parenteral administration. *Id.* at 46–47 ("[T]he POSITA would have had to know before attempting any optimization that particulate matter was relevant to solving the aluminum problem with L-cysteine solutions.").

Petitioner contends that they provided unrebutted expert testimony supporting its position. Req. Reh'g 3–4. "The Board has broad discretion to assign weight to be accorded expert testimony." Consolidated Trial Practice Guide[1] ("CTPG") 35 (Nov. 2019). Here, we evaluate Petitioner's expert testimony against the backdrop that it took more than a decade to develop a cysteine containing parenteral composition that met the established FDA requirements. Considering the great pressure given by the FDA recommendation to lower aluminum content in parenteral solutions to avoid aluminum toxicity in vulnerable patients and the length of time it took the industry to produce such a product, we find that on balance this suggests that the solution to the problem was not straight forward as urged by Petitioner. *See* Prelim Resp. 8, 44 (citing *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1354 (Fed. Cir. 2013) ("If these discoveries and advances were routine and relatively easy, the record would undoubtedly have shown that some

[1] Available at https://www.uspto.gov/TrialPracticeGuideConsolidated.

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