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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.

PGR2020-00068
Patent 10,583,155 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 1–30 of U.S. Patent No. 10,583,155 B1 (Ex. 1001, "the '155 patent") entered on December 15, 2020 (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. 14–21.

In its Request for Rehearing, Petitioner contends that the Board in the Decision misapprehends Petitioner's assertions that do not rely on overlapping ranges to establish unpatentability, and that the Board abused its discretion in finding that the Sandoz Label does not overlap with the claimed range. *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, and abused its discretion in finding that the Sandoz Label does not overlap with the claimed range. *See generally* Req. Reh'g.

1.) Reasonable Expectation of Success

Petitioner argues that in the Petition it presented a separate reasonable expectation of success argument that is based on routine optimization, which does "not depend exclusively on or require overlapping ranges." Req. Reh'g 5; *see e.g.* Pet. 50 ("[T]he claimed range is the expected result of optimizing the Sandoz product in response to regulatory and market pressures to substantially reduce and eliminate aluminum from parenteral drug products.").

Petitioner further contends that the claimed aluminum levels were not new, and that a person of ordinary skill in the art would have had a reasonable expectation that the Sandoz Label product could be optimized to substantially eliminate aluminum. *See* Req. Reh'g 1–2. Specifically, Petitioner contends that the person of ordinary skill in the art would have known how to remove known aluminum sources. *Id.* at 3. Petitioner

contends that the Decision overlooks the dispositive impact of the knowledge one of ordinary skill in the art would have possessed about Schott coated glass vials in order to prevent aluminum leaching of the Sandoz product if packaged into such a vial. *See id.* at 4, n. 6.

Even if we were to agree with Petitioner that the Petition included a separate "reasonable expectation of success argument" that does 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. 19. 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.*

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 3), for example by packaging the Sandoz Label product into "Schott coated glass vials" to arrive at the claimed invention (*id.* at 4 (citing Pet. 39–40, 42–44, 50–51).

The issue is not whether an ordinary artisan would have recognized sources of aluminum contamination that could potentially be eliminated; the question is whether there would have been a reasonable expectation that removing an aluminum source would result in a stable product as defined by the '155 patent. We agree with Patent Owner 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. 17. Patent Owner further

explains "that 'removing Aluminum may have the unintended consequence of increased [L-cystine] precipitation and product failure in the presence of even small amounts of oxygen in the container.'" *Id.* at 18 (alteration in original) (quoting Ex. 1001, 5: 12–15 ("[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.")). 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 18.

Petitioner contends that it provided unrebutted expert testimony supporting its position. Req. Reh'g 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 FDA requirements. *See* Prelim. Resp. 3 (citing Ex. 1006; Ex. 1038; Ex. 2009; Ex. 2011; Ex. 2012). Considering the great pressure given by the FDA recommendation to lower aluminum content in parenteral solutions to avoid aluminum toxicity 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* Sur-reply 3–4; Prelim. Resp. 10, 17 (citing Ex. 1002 at 378–379), 44 (citing *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1354 (Fed. Cir. 2013) ("If these discoveries and advances were

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

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