Trials@uspto.gov
571-272-7822

Paper No. 14
Date: December 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.

PGR2020-00064
Patent 10,478,453 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 1–22 of U.S. Patent No. 10,478,453 B1 (Ex. 1001, "the '453 patent") entered on November 18, 2020 (Paper 12, "Dec."). Paper 13 ("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. 12–22. 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 that do not rely on overlapping ranges to establish unpatentability, 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, and abused its discretion in finding lack of particularity in the Petition. *See generally* Req. Reh'g.

1.) Reasonable Expectation of Success

In the Decision, we determined that the product described by the Sandoz Label does not disclose a range for aluminum from 0 to 5,000 ppb. Dec. 22. Therefore, we were not persuaded "by Petitioner's position that there is a reasonable expectation that routine optimization would lead to aluminum concentrations as recited in claim 1 of the '453 patent based on optimizing overlapping ranges." *Id.*

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. 45 ("[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.").

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. 18. 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 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. 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.* (citing Pet. 38–39, 40–43, 46)). 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.

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 '453 patent. We agree with Patent Owner's response that "the kinetics and equilibrium chemistry of the various L-cysteine and L-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. 14–15. 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 16 (alteration in original) (quoting Ex. 1001, 5:4–9 ("[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 44 ("[O]nly in hindsight was the L-cysteine ***aluminum*** problem a 'puzzle,' i.e., a multifaceted problem with many interrelated pieces to be solved.").

Petitioner contends that the Decision "suffers from two fundamental misapprehensions of the record. First, it conflates the Sandoz product with the Sandoz Label. . . . Second, not only do the aluminum levels in the Sandoz product manufactured by Allergy Labs overlap with the claimed aluminum ranges, but also they corroborate the reasonableness of Dr. Rabinow's interpretation of the Sandoz Label." Req. Reh'g 7–8; *see id.* at 5 (arguing that the Decision "overlooks the unrebutted evidence that demonstrates that the ranges do in fact overlap").

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