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Paper 23
Date: August 1, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

IPR2022-01102
Patent 9,610,321 B2

Before SHERIDAN K. SNEDDEN, CYNTHIA M. HARDMAN, and MICHAEL A. VALEK, *Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge*.

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

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I. INTRODUCTION

Mylan Pharmaceuticals, Inc. ("Petitioner") requests rehearing of the Board's Decision (Paper 15) ("Decision" or "Dec.") denying institution of *inter partes* review of claims 1–16 of U.S. Patent No. 9,610,321 B2 ("the '321 patent," Ex. 1001). (Paper 17) ("Request for Rehearing" or "Req. Reh'g.").[1]

In our Decision, we declined to institute *inter partes* review of the challenged claims as obvious because the Petition did not sufficiently show that a person of ordinary skill in the art would have been motivated to use "an inert low moisture carrier," as recited in independent claims 1 and 3. Dec. 14. Petitioner seeks reconsideration of our Decision because it argues that we misapprehended the controlling obviousness standard, overlooked evidence supporting obviousness, shifted the agency's position, and imposed an impossible burden. Req. Reh'g. 1, 14–15.

For the reasons that follow, Petitioner's Request for Rehearing is *denied*.

II. LEGAL STANDARD

Pursuant to 37 C.F.R. § 42.71(d):

> A party dissatisfied with a decision may file a single request for rehearing without prior authorization from the Board. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended

[1] Petitioner has also filed Requests for Rehearing in related cases IPR2022-01103 (Patent 9,616,097), IPR2022-01104 (Patent 9,919,024), and IPR2022-01105 (Patent 9,925,231). Citations are to the record in IPR2022-01102, which is representative.

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> or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.

When reconsidering a decision on institution, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion exists where a "decision [i]s based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment." *PPG Indus. Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988).

A rehearing request is not an opportunity for the requesting party to reargue its case or merely to express disagreement with the underlying decision. Nor is it an opportunity for the moving party to present new arguments that were not in its original submissions.

III. ANALYSIS

A. Petitioner's Request for Additional Briefing

To begin, Petitioner contends that it was not given the ability to provide additional briefing to address its concerns regarding Patent Owner's arguments on the merits of the asserted obviousness grounds. Req. Reh'g. 14. Petitioner explains that it alerted the Board of Patent Owner's "improperly heightened obviousness standard," but the Board denied Petitioner the opportunity to provide additional briefing on this issue. *Id.* Petitioner argues that as a result, the Decision imposed an "unlawfully heightened burden," "improper standard," and "impossible burden." *Id.* at 1, 6, 14–15.

We first note that our procedure does not provide Petitioner a right to reply to Patent Owner's Preliminary Response. Patent Trial and Appeal

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Board Consolidated Trial Practice Guide November 2019[2], 51 ("The decision concerning whether the petitioner will be afforded a reply and the appropriate scope of such a reply rests with the panel deciding the proceeding to take into account the specific facts of the particular case."). Petitioner is afforded a request for rehearing in order to identify all matters it believes the Board misapprehended or overlooked. In that regard, Petitioner has now entered its Request for Rehearing identifying those matters it believes we misapprehended or overlooked, including its contention that we applied an improper obviousness standard, namely, a standard requiring specific motivation. *Id.* More specifically, Petitioner contends we 1) misapprehended the law and the record in dismissing Dr. Buckton's testimony as "conclusory" and the Lai reference as "equivocal"; 2) overlooked general teachings in the cited prior art regarding the moisture sensitivity of peptides; 3) misapprehended law rejecting any requirement for a specific teaching in the prior art that plecanatide is especially sensitive to water; and 4) overlooked Patent Owner's arguments from the Preliminary Response supporting Petitioner's position that a low moisture formulation is an expected improvement. Req. Reh'g. 7, 15.

Petitioner's concerns are addressed below.

B. Dr. Buckton's Testimony

In its Petition, Petitioner's alleged rationale for combining the cited prior art is that

> [persons of ordinary skill in the art] had good reason to use a low-moisture [microcrystalline cellulose ("MCC")] carrier (e.g., Mihranyan's Avicel PH112) to reduce plecanatide's moisture

[2] *Available at* https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf.

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> exposure from tablet excipients because peptides generally are subject to moisture-based degradation during storage. EX1002, ¶¶522, 143-144, 146-147; EX1016, 489; *see also* [Pet. at] §VI.A; EX1006, 731 ("moisture is one of the most important environmental factors that can affect solid-state stability").

Pet. 28. Dr. Buckton's testimony relied on by Petitioner states as follows:

> Moreover, . . . [persons of ordinary skill in the art] understood that peptides, in particular, were generally subject to degradation from moisture during storage. *See, e.g.*, EX1016 (Lai), 489; *see also* EX1029 (Aulton), 9. Thus, a [person of ordinary skill in the art] would have had reason to combine a low-moisture carrier with a peptide when preparing an oral-dosage formulation. More specifically, a [person of ordinary skill in the art] had good reason to evaluate commercially available grades of microcrystalline cellulose, taught more generally by Remington, that had low-moisture contents, to formulate the plecanatide peptide taught by Shailubhai.

Ex. 1002 ¶¶ 104, 144.

At page 17 of the Petition, Petitioner relies on Dr. Buckton's testimony for the premise that "[persons of ordinary skill in the art] recognized low-moisture MCC as a preferred inert carrier for direct-compression tableting of peptides." That testimony provides as follows:

> One main source of potential degradation for pharmaceutical formulations is the presence of moisture. *See* EX1029 (Aulton), 9. In particular, it was well known that peptides in particular are generally subject to degradation from moisture during storage. *See, e.g.*, EX1016 (Lai), 489.

Ex. 1002 ¶ 104.

In our Decision, we addressed Dr. Buckton's testimony and the information of record supporting the proposition that peptides are sensitive to degradation from moisture during storage. Dec. 14–18. As we explained in our Decision,

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