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Paper 12
Entered: January 27, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA, LLC and FRESENIUS KABI SWISSBIOSIM GmbH
Petitioner

v.

COHERUS BIOSCIENCES, INC.
Patent Owner

PGR2019-00064
Patent 10,155,039 B2

Before SUSAN L.C. MITCHELL, CHRISTOPHER G. PAULRAJ, JOHN H. SCHNEIDER, *Administrative Patent Judges.*

PAULRAJ, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Requests for Rehearing
37 C.F.R. § 42.71(d)

I. INTRODUCTION

Fresenius Kabi USA, LLC and Fresenius Kabi SwissBioSim GmbH (collectively, "Petitioner") filed a Request for Rehearing of our Decision Denying Institution of *inter partes* review. Paper 11 ("Req. Reh'g"). To summarize, Petitioner filed a petition seeking *inter partes* review of U.S. Patent No. 10,155,039 B2 (Ex. 1001, "the '039 patent"). Paper 3 ("Pet."). Coherus BioSciences, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp."). We denied institution based upon our consideration of the merits of the challenges presented, including the lack of written description and enablement grounds. *See* Paper 10 ("Decision").

In its Request for Rehearing, Petitioner contends that the "Decision erroneously excluded the inventors' preferred embodiments from the claims, misapplied the law regarding the written description and enablement requirements of 35 U.S.C. § 112, and is not supported by substantial evidence in the record." Req. Reh'g 1.

Having considered Petitioner's arguments, we deny the Request for Rehearing and do not modify our prior Decision.

II. DISCUSSION

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).

A. Construction of "Stable"

In its Request for Rehearing, Petitioner challenges our construction of "stable" in claims 1–12. Req. Reh'g 2–6. Specifically, Petitioner argues that our construction of "stable" was in error because we construed that term to exclude the inventors' preferred embodiments, including those "that do not lose more than 5% of their activity during two years of long-term storage." *Id.* at 2–3. Petitioner contends a construction of "stable" that excludes the inventors' preferred embodiments contravenes well-established claim construction law. *Id.* at 4 (citing *SynQor, Inc. v. Artesyn Tech., Inc.*, 709 F.3d 1365, 1378–79 (Fed. Cir. 2013)).

Petitioner's arguments are unpersuasive because our construction of "stable" does not exclude the preferred embodiments. As Petitioner acknowledges, "[t]he Board did not construe 'stable' to be *limited* to formulations that are as stable as Humira or lose 20% of activity upon storage." *Id.* at 3. Although our construction encompasses the "most" preferred embodiment (e.g., those that do not lose more than 5% of their activity during two years of long-term storage), it also encompasses other embodiments that are considered less preferred but nonetheless within the scope of what is defined to be "stable" in the specification, i.e., compositions that do "not lose more than 20%, or more preferably 15%, or even more preferably 10%" of activity. Ex. 1001, 9:28–33. Furthermore, consistent with the specification, our construction of "stable" encompasses embodiments in which stability is determined by comparison to the commercial formulation of adalimumab known in the prior art, i.e., Humira. Decision 8–9. We find no basis to construe "stable" to be limited to the *only* most preferred embodiment by

requiring a loss of no more than 5% activity. *See Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) (stating "a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment").

Petitioner further argues:

> the Board also clearly erred when it "agree[d] with Patent Owner that '[a] POSA would not interpret the claims as covering a genus of formulations having a range of different stabilities . . . , especially because the claims simply do not recite a range of stability values to be achieved over different periods of time

Req. Reh'g 5 (citing Decision 9). Petitioner contends that "[a] claim need not recite a range to be a genus claim." *Id.* As noted above, we agree that the claims encompass a genus of formulations with different levels of stability. Nonetheless, that conclusion does not support Petitioner's argument that "since the claims include all of the preferred embodiments, and those embodiments span a range of stabilities, the claims span a range of stabilities." *Id.* Nor is the relevance of Petitioner's argument entirely clear. For instance, Petitioner argues that "under the Board's construction, the broadest claim—claim 1—would be anticipated by a narrow species in the prior-art: a formulation that met all of the ingredient limitations of the claim and achieved the inventors' most-preferred level of stability (5% loss over two years of storage)." *Id.* at 5–6. Petitioner, however, did not raise an anticipation challenge in this proceeding, and we decline to opine on whether or not the claims would be anticipated by any prior art formulation under our construction.

Accordingly, Petitioner has not established that we erred in our construction of "stable."

B. Enablement for Claims 1–12

Petitioner argues in their Request for Rehearing that we erred in our determination that Petitioner did not meet their burden of demonstrating that it is more likely than not that claims 1–12 are unpatentable for lack of enablement. Req. Reh'g 6–8. Specifically, Petitioner contends:

> The Board erred when it held that "we do not find that the claims must necessarily be enabled" for formulations that meet the most-preferred level of stability, reasoning that "the specification only discloses that a loss of no more than 5% is 'most preferabl[e],' but is not otherwise required to achieve a stable pharmaceutical composition."

Id. at 6 (citing Decision 17). Petitioner contends this is an error because the full scope of the claims must be enabled. *Id.* Petitioner further contends that only one embodiment, formulation D-12, included accelerated testing but "the specification does not disclose any information from which a POSA could conclude that Humira loses no more than 5% of activity over two years of storage, or that formulation D-12 meets this level of stability." *Id.* at 7. Petitioner further argues that "the level of stability that a particular combination of ingredients will achieve is unpredictable" and "a POSA seeking to practice the most preferred embodiments is essentially left to perform the same laborious trial-and error experimentation that the inventors engaged in and received a patent for." *Id.* at 7–8 (citing Pet. 41–42, 60–61; Ex. 1002 ¶¶ 150–51, 186–87).

These arguments are also unpersuasive. As stated in the Decision:

> [W]e find that the specification provides a detailed disclosure of the testing used to assess stability (using Humira as the control), and identifies specific ingredients to be included and excluded from the claimed composition, and further identifies the pH that is necessary to achieve the claimed stability. Although there may be certain concentrations of adalimumab or certain types of buffers and sugars that may render the compositions more difficult to stabilize, Petitioner

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