Trials@uspto.gov
Tel: 571-272-7822

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

> does not explain sufficiently why a POSA would not have known how to adjust or select those ingredients in order to achieve the claimed stable aqueous pharmaceutical composition.

Decision 17. As further stated in the Decision:

> Moreover, even if a POSA would have needed to test whether a particular composition was stable, "[t]he fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation 'must not be unduly extensive." *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996) (citing *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984)). Indeed, even "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed." *Id.* (citing *Ex parte Jackson*, 217 USPQ 804, 807 (BPAI 1982)).

Id. at 17–18. Petitioner's arguments do not persuade us that we committed legal or factual error in making the foregoing determinations. Accordingly, we are not persuaded that we abused our discretion in determining that Petitioner did not satisfy its burden with respect to the lack of enablement ground for claims 1–12.

C. Written Description Support for Claims 1–12

Petitioner contends that we erred by finding that Petitioner failed to meet its burden of demonstrating that it is more likely than not that claims 1–12 are unpatentable for lack of written description support. Req. Reh'g 8–10. Petitioner argues that because "stable" includes embodiments having the most preferred stability, the specification of the '039 patent must demonstrate possession of a formulation with the most preferred stability. *Id.* at 8–9. Petitioner asserts "the Board concluded that the testing of a single formulation, D-12, was sufficient to demonstrate possession of all of the formulations of claim 1 because that testing

purportedly demonstrated that D-12 was as stable as the Humira control formulation." *Id.* at 9. According to Petitioner, "a POSA would not have been able to conclude from the specification that any of the disclosed formulations, including those as stable as Humira, meet the inventors' most-preferred levels of stability." *Id.* at 9–10 (citing Pet. 31–44; Ex. 1002 ¶¶ 154–63).

These arguments are unpersuasive. As stated in the Decision, the '039 patent discloses a formulation (i.e., D-12) that falls within the scope of claim 1. Decision 13. We further stated that:

> the specification identifies with sufficient clarity each of the ingredients that must be included as part of the claimed composition (i.e., adalimumab, a buffer, polysorbate 80, and a sugar) and further provides a reason to exclude the ingredients that must *not* be included in theclaimed composition (i.e., mannitol, a citrate/phosphate buffer combination, and sodium chloride).

Id. at 13–14. The Decision also explained how one of ordinary skill in the art would recognize that the inventors possessed the claimed invention:

> Patent Owner identifies teachings in the specification indicating the structural features required for achieving a stable adalimumab composition, which include: 1) avoiding the citrate/phosphate buffer combination in favor of another more stable buffer (such as an acetate buffer); 2) including polysorbate 80 as a stabilizer; 3) removing sodium chloride (NaCl) from the formulation; 4) using a sugar or polyol as the tonicity modifier in place of mannitol/NaCl; and 5) maintaining a pH of at least 5 (with an optimal pH near 5.2). *Id.* at 60 (citing Ex. 1001, 5:42–44, 21:40–47, 37:25–38:4, 38:1–7, 61:24–25). Patent Owner further asserts, and we agree, that the specification "provides working examples that demonstrate comparable or superior stability to the commercial Humira® formulation" and that Petitioner fails to demonstrate why a POSA would doubt that the formulations that demonstrated improved stability relative to Humira would be stable. *Id.* at 60–61.

Id. at 14.

Petitioner's arguments do not persuade us that we committed legal or factual error in making the foregoing determinations. Accordingly, we are not persuaded that we abused our discretion in determining that Petitioner did not satisfy its burden with respect to the lack of written description ground for claims 1–12.

D. Written Description Support and Enablement for Claims 9–12

In its Request for Rehearing, Petitioner also presents separate arguments alleging that the Board's finding that the specification adequately described and enabled the acetate formulations of claims 9–12 is not supported by substantial evidence. Req. Reh'g 10–15. Petitioner, however, did not present any unpatentability grounds in the Petition specific to claims 9–12. Rather, Petitioner only argued that the provisional applications on which the '039 patent relied upon for an earlier filing date did not provide written description or enablement support for claims 9–12, and thus the'039 patent is not PGR-eligible. Pet. 20–44. As noted in our Decision, we did not address Petitioner's priority date arguments and assumed *arguendo* that the '039 patent is PGR-eligible for purposes of our analysis. Decision 6. To the extent Petitioner now seeks to convert its PGR-eligibility arguments into unpatentability arguments with respect to claims 9–12, we decline to consider those arguments as they were not timely and specifically presented in the Petition. A rehearing request is not an opportunity to present new arguments.

III. CONCLUSION

For the foregoing reasons, Petitioner has not demonstrated that we abused our discretion, or that we misapprehended or overlooked any issue, in exercising our discretion to deny institution.

IV. ORDER

Accordingly, it is

ORDERED that Petitioner's Requests for Rehearing is *denied*.

FOR PETITIONER:

Linnea Cipriano
Huiya Wu
GOODWIN PROCTER LLP
Lcipriano@goodwinlaw.com
HWu@goodwinlaw.com

FOR PATENT OWNER:

Joseph Hynds
Jennifer Nock
Aydin Harston
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
jhynds@rfem.com
jnock@rfem.com
aharston@rfem.com