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Paper 11
Date: November 7, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

BOEHRINGER INGELHEIM INTERNATIONAL GMBH,
Patent Owner.

PGR2022-00037
Patent 11,078,265 B2

Before GRACE KARAFFA OBERMANN, JAMES A. WORTH, and DEVON ZASTROW NEWMAN, *Administrative Patent Judges.*

NEWMAN, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 324

I. INTRODUCTION

A. Background and Summary

Sandoz Inc. ("Petitioner") filed a Petition requesting post-grant review of claims 7−10, 14−16, 19−22, and 27−28 of U.S. Patent No. 11,078,265 B2 (Ex. 1001, "the '265 patent"). Paper 2 ("Pet."). Boehringer Ingelheim International GMBH ("Patent Owner") filed a Preliminary Response to the

Petition. Paper 6 ("Prelim. Resp."). With authorization, Petitioner filed Petitioner's Rely to Patent Owner's Preliminary Response (Paper 8, "Reply") and Patent Owner filed Patent Owner's Sur-Reply (Paper 9, "Sur-Reply").

Under 35 U.S.C. § 324(a), a post-grant review may be instituted only if "the information presented in the petition . . . demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." Post-grant review is available for patents that issue from applications that at one point contained at least one claim with an effective filing date on or after March 16, 2013. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), §§ 3(n)(1), 6(f)(2)(A).

After considering the briefing and the evidence of record, for the reasons set forth below, we determine that Petitioner has not shown that the '265 patent is eligible for post-grant review. Accordingly, we do not institute a post-grant review of the challenged claims of the '265 patent.

B. Real Parties in Interest

Petitioner identifies the real parties-in-interest as Sandoz Inc. and Sandoz AG. Pet. 81. Patent Owner states that the real parties-in-interest are "Boehringer Ingelheim International GmbH, AbbVie Biotechnology Ltd, and AbbVie Inc." Paper 4, 1. Patent Owner states that "Boehringer Ingelheim International is the assignee of the entire right, title, and interest in U.S. Patent No. 11,078,265" and that AbbVie Biotechnology Ltd, "a wholly-owned subsidiary of AbbVie Inc." is the exclusive licensee of the '265 patent. *Id*.

C. Related Matters

Petitioner identifies no related matters. Pet. 81. Patent Owner states that the '265 patent claims the benefit of U.S. Provisional Application No. 61/642,032 filed May 3, 2012, and that U.S. Application No. 17/356,366 filed June 23, 2021, is a continuation of the application leading to the '265 patent. Paper 4, 2.

D. The '265 Patent (Ex. 1001)

The '265 patent, titled "Anti-IL23 Antibodies," issued on August 3, 2021, from U.S. Application No. 13/870,061 ("the '061 application"), filed on April 25, 2013. *Id*. 1001, codes (21), (22), (45), (54). The '061 application claims priority to U.S. Provisional Application No. 61/642,032, filed on May 3, 2012 ("the priority application").

The '265 patent relates to anti-IL-23p19 binding compounds, including humanized anti-IL-23p19 antibodies, pharmaceutical compounds and therapeutic and diagnostic methods for use of the same. *Id*., code (57). The specification explains that IL-23 is a "member of the IL-12 cytokine family with a distinct role in the immune response." *Id*. at 1:34–35. IL-23 "supports the development and maintenance of . . . CD4+ T helper cells termed HJ17 cells" and has a "unique p19 subunit." *Id*. at 1:37–44. "[M]ounting evidence that IL-23 is involved in chronic autoimmune inflammation" suggests that the ability to modulate IL-23 activity "could provide promising therapies against autoimmune diseases." *Id*. at 1:45–48. Among the disclosed embodiments, the specification discloses "pharmaceutical compositions for antibody molecules, in particular for anti-IL23pg antibodies" including "pharmaceutical compositions for antibody molecules with favorable stability and storability." *Id*. at 2:4–9.

The '265 patent discloses an exemplary humanized antibody, "Antibody A[1]," with a light chain amino acid sequence, SEQ ID No: 174 and a heavy chain amino acid sequence SEQ ID No. 176. *Id*. at 22:3–7.

The '265 patent discloses testing data reflecting "high affinity" binding of recombinant IL-23 with the p19 subunit and data fitting a 1:1 binding model for anti-IL-23p19 antibodies bound to IL-23. *Id*. at 85:32–86:42.

Example 11 of the '265 patent discloses pharmaceutical compositions "suitable for an antibody" including Antibody A. *Id*. at 92:23–95:25. An exemplary aqueous formulation containing an antibody, Formulation 1, is disclosed in the component chart below as follows:

Components	Concentration [mmol/L]	Concentration [g/l]	Nominal Amount [mg/vial] V = 10.0 ml
Antibody		10.0	100.0
Succinic acid	0.7	0.083	0.8
Disodium succinate hexahydrate	24.3	6.564	65.6
Sodium chloride	125	7.305	73.1
Polysorbat 20	0.16	0.20	0.20
Water for Injection	—	Ad 1 L	Ad 1 mL

The chart above reflects the components and their concentrations in Formulation 1. *Id*. The '265 patent states that the "pH of formulation 1 is typically in the range of pH 6.0 to 7.0, for example pH 6.5. This formulation is particularly suitable for intravenous administration." *Id*.

A second exemplary formulation, Formulation 2, is disclosed in the component chart below as follows:

[1] Antibody A has subsequently been named rizankizumab. Prelim. Resp. 8 (citing Ex. 1001, SEQ ID NOs: 174 and 176, and Ex. 2005, 1).

Components	Concentration [mmol/L]	Concentration [g/l]	Nominal Amount [mg/syringe] V = 1.0 ml
Polysorbat 20	0.16	0.20	0.20
Water for Injection	—	Ad 1 L	Ad 1 mL

The chart above reflects the components and their concentrations in Formulation 2. *Id*. The '265 patent states that the "pH of formulation 2 is typically in the range of pH 5.5 to 6.5, for example pH 5.5 to 6.1, for example the pH is 5.8. This formulation is particularly suitable for intravenous administration." *Id*.

A third exemplary formulation, Formulation 3, is disclosed in the component chart below as follows:

Components	Concentration [mmol/L]	Concentration [g/l]	Nominal Amount [mg/syringe] V = 1.0 ml
Antibody	0.6	90.0	90.0
Sorbitol	240	43.733	43.733
Polysorbat 20	0.16	0.20	0.20
Water for Injection	—	Ad 1 L	Ad 1 mL

The chart above reflects the components and their concentrations in Formulation 3. *Id*. "The pH of formulation 3 is typically in the range of pH 5.5 to 6.5, for example pH 5.5 to 6.1, for example the pH is 5.8. This formulation is particularly suitable for intravenous administration." *Id*.

Example 12 of the '265 patent discloses stability testing of the claimed pharmaceutical compositions. *Id*. at 94:14–36. Formulations 2 and 3 of Example 11 were stored for 8 weeks at 40° C in a syringe. *Id*. The following properties were measured initially and after 8 weeks in storage, as disclosed in the chart below:

	Formulation 2 (initial/after 8 weeks storage)	Formulation 3 (initial/after 8 weeks storage)
pH	5.7/5.8	5.6/5.7
Osmolarity	298/301	312/308
Turbidity (FNU)	7/8	2/3
Monomer %	99/97	99/97

Id. The chart above shows characteristic measurements of Formulations 2 and 3 before and after 8 weeks of storage at 40° C in a syringe. *Id*.

E. Challenged Claims

Petitioner challenges claims 7−10, 14−16, 19−22, and 27−28 ("the challenged claims"). Pet. 1. Claim 7 is independent and recites:

> 7. A liquid aqueous pharmaceutical formulation comprising (a) an anti-IL23p19 antibody in a concentration of 90 mg/ml, (b) a detergent, and (c) a tonicity agent, wherein the anti-IL23p19 antibody comprises a light chain amino acid sequence shown as SEQ ID NO: 174 and a heavy chain amino acid sequence shown as SEQ ID NO: 176, wherein the formulation is stable, isotonic, has a pH in the range of 5.5 to 6.5, and wherein the formulation optionally comprises a buffer.

Ex. 1001, 189:62–190:27.

Claim 19 is identical to claim 7 but removes the "antibody in a concentration of 90 mg/ml" limitation. *Id*. at 190:60–67.

The remaining challenged claims are all dependent on either claim 7 or claim 19 and recite specific formulation components (e.g., specifying a buffer) or characteristics (e.g., "wherein the formulation is stable following storage in a syringe for 8 weeks at 40° C").

F. Asserted Grounds

Petitioner asserts that claims 7−10, 14−16, 19−22, and 27−28 are unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §[2]	Reference(s)/Basis
7−10, 14−16, 19−22, 27−28	112	Lack of Written Description
7−10, 14−16, 19−22, 27−28	112	Lack of Enablement

Pet. 4. Petitioner relies on the Declaration of Alexander M. Klibanov, Ph.D., (Exhibit 1002) in support of these grounds.

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner contends that a person having ordinary skill in the art (POSA) "would have had an advanced degree in biology, biochemistry, pharmaceutics, or a related discipline" and would also have had at least two years of experience in the development or manufacture of therapeutic protein formulations. Pet. 33 (citing Ex. 1002 ¶ 21). Petitioner contends the ordinary artisan could have a higher level of education in substitution for less experience or vice versa. *Id*. Patent Owner states that "[f]or purposes of this Preliminary Response, Patent Owner does not dispute Petitioner's definition of a POSA." Prelim. Resp. 5, n2.

Petitioner's proposed definition is consistent with the disclosure of the '265 patent, and we adopt it for purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art

[2]The Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. § 112. Because we determine that the challenged claims of the '265 patent have an effective filing date before the effective date of the applicable AIA amendment, we refer to the pre-AIA version of 35 U.S.C. § 112. For the purposes of our analysis, post-AIA § 112(a), as argued by Petitioner (Pet. 4), is substantively identical to pre-AIA § 112, first paragraph.

itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985))).

B. Claim Construction

Petitioner proposes construction of three terms, "wherein the formulation is stable," "liquid aqueous pharmaceutical formulation," and "comprising." Pet. 34–38. Of these terms, Patent Owner only addresses the construction of "stable." Prelim. Resp. 15–22. For purposes of determining whether to institute trial of the challenged claims, we determine it is not necessary to construe "liquid aqueous pharmaceutical formulation," "comprising," or any other term not addressed by the parties. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy."); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co*., 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs*. in the context of an AIA proceeding).

The meaning of the term "wherein the formulation is stable" (hereinafter, "stable") is recited in each challenged claim and requires discussion. *See* Ex. 1001, 189:62–192:6. Petitioner notes that "stable" is not defined in the '265 patent, and argues that the term as it applies to claim 7 "must be construed to encompass stability under the conditions recited in claim 14" because "independent claims are presumed to be broader than, and encompass, the subject matter in dependent claims." Pet. 34 (citing, et. al., *Littelfuse, Inc. v. Mersen USA EP Corp*., 29 F.4th 1376, 1380 (Fed. Cir. 2022)). For this reason, Petitioner argues, "stable" in claim 7 "should be construed to encompass at least a subgenus of formulations that are 'stable

following storage in a syringe for 8 weeks at 40° C.'" *Id*. at 34–35. Petitioner cites as further support the specification's disclosure that the pharmaceutical compositions are "'stable . . . for example when stored for 8 weeks at 40° C." Pet. 35 (citing Ex. 1001, 84:20−26). Petitioner also argues that Patent Owner's statement during prosecution regarding the stability of formulations 2 and 3 as shown in the data of Example 12 is informative, and that "stable" should be construed to include the ability to be stored for 8 weeks at 40° C. *Id*. at 35 (citing Ex. 1004, 7380; Ex. 1001). Finally, Petitioner argues that other statements by Patent Owner regarding the claimed stability as shown in Examples 9, 11, and 12 provide information as to how Patent Owner understood the patent. *Id*. at 36 (citing Ex. 1004, 7380 and *Phillips*, 415 F.3d at 1317). In this regard, Petitioner argues that "stable" should be "construed to encompass a second subgenus of formulations that are stable following storage at '4° C. for at least 4 months,'" citing Patent Owner's argument during prosecution that the stability was demonstrated where the antibody of Example 9 showed minimal aggregation after storage in these conditions. *Id*.

Patent Owner argues that Petitioner fails to construe "stable," justifying denial of the Petition under 37 C.F.R. § 42.204(b)(3) and (4). Prelim. Resp. 15–16. According to Patent Owner, Petitioner's arguments that "stable" should be construed to encompass formulations disclosed in the challenged claims fail to define "stable." *Id*. at 16. Patent Owner argues that importing limitations from the specification (e.g., the embodiment of Example 9, which does not meet the claimed formulations) is improper and, further, proposes that "stable" should be construed to have its plain and

ordinary meaning, "which requires that the formulation maintain stability suitable for its pharmaceutical application." *Id*. at 18–22.

On Reply, Petitioner also argues that it complied with 37 C.F.R. § 42.204(b)(3) and (4) and construed "stable" as "*including, but not limited to*, two subgenera of formulations that are stable following storage (1) in a syringe for 8 weeks at 40° C; and/or (2) at 4° C for at least 4 months." Reply 3 (citing Pet. 34–37, Ex. 1002 ¶¶ 160–167). Petitioner argues its proposed construction "*is* a plain and ordinary meaning, informed by the doctrine of claim differentiation." *Id*. at 4. Petitioner argues that Patent Owner's proposed construction "seeks to import a requirement that a person of ordinary skill in the art . . . would understand to select only those excipients found in commercial antibody formulations" despite that this limitation is absent from the claims and specification. *Id*. at 5 (citing Prelim. Resp. 24–26).

Patent Owner responds that Petitioner's contention that its proposed construction is a plain and ordinary meaning is a new argument that conflicts with its declarant's testimony and should be disregarded. Sur-Reply 2. Patent Owner further argues that Petitioner's attempted construction "still does not define what the term 'stable' actually means" and that Petitioner makes unauthorized arguments on reply as they are addressed to substantive arguments, not claim construction. *Id*. at 2–3.

In a post-grant review, we apply the same claim construction standard as would be used by a district court to construe a claim in a civil action involving the validity or infringement of a patent. 37 C.F.R. § 42.200(b) (2021). Under that standard, claim terms are given their ordinary and customary meaning, as would have been understood by a person of ordinary

skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id*.; *Phillips v. AWH Corp*., 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc); *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365–66 (Fed. Cir. 2012). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc*., 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17).

We agree with Patent Owner that Petitioner has not offered a straightforward construction of "stable," but find that Petitioner's efforts to interpret formulation stability as it is used in the specification and in statements made by Patent Owner about its meaning during patent prosecution are relevant to construction pursuant to the case law cited above, and, therefore, we do not find grounds to deny the Petition under 37 C.F.R. § 42.204(b)(3) and (4).

To interpret "stable," we begin with how the term is used in independent claims 7 and 19. Both terms recite "stable" in relation to the pharmaceutical formulation as a whole by reciting "wherein the formulation is stable." Ex. 1001, 189:62–190:27. From this, we conclude that the ordinary artisan, as defined above to have a relevant advanced degree and at least two years of experience in development or manufacture of therapeutic protein formulations, would have understood that the components of a "stable" formulation would maintain their integrity and desired function following preparation, including when stored as described. This meaning is

supported by the following language in the specification pertaining to the disclosed pharmaceutical compositions:

> Pharmaceutical compositions according to the present invention are described in further details hereinbelow. In one aspect, the pharmaceutical compositions disclosed herein are physico-chemically stable and maintain the integrity of an antibody comprised in said pharmaceutical composition, for example when stored for 8 weeks at 40° C. as shown hereinbelow.

Ex. 1001, 84:20–26. We also note, as Petitioner argued, that the prosecution history supports that the formulation components needed to remain functional during storage, and that Patent Owner cited to formulation integrity after a storage period of 8 weeks at 40° C as evidence of such integrity. Ex. 1004, 7380. As disclosed in the '265 patent, Examples 9 and 12 measure function and identity of the components following storage to confirm formulation stability.

Example 9 discloses transfection of Antibody A expression vectors into NSO cells, scaled production and recovery of antibody and protein purification. Ex. 1001 at 89:62–91:10. Protein stability was confirmed by analytical ultracentrifugation (AUC) and size exclusion chromatography (SEC). *Id*. The stability of both measured antibodies using AUC and SEC was 96–100%. *Id*.

Example 12 tested the pH, Osmolarity, Turbidity, and Monomer identity of formulations 2 and 3 after 8 weeks of storage of the formulations at 40° C as compared to the initial formulation. *Id*. at 94:14–36. The following chart showing measurements of pH, Osmolarity, Turbidity and Monomer percentage reflects the changes in the Formulations 2 and 3 after storage:

	Formulation 2 (initial/after 8 weeks storage)	Formulation 3 (initial/after 8 weeks storage)
pH	5.7/5.8	5.6/5.7
Osmolarity	298/301	312/308
Turbidity (FNU)	7/8	2/3
Monomer %	99/97	99/97

The above chart reflects measurements of the components of Formulations 2 and 3 following 8 weeks of storage of the formulations at 40° C. *Id*.

After review of the briefing and evidence, we conclude that Petitioner's proposed construction is insufficiently precise as it does not identify what is stable within the formulation, e.g., the antibody and other formulation components. We further conclude that Patent Owner's proposed construction is vague with regard to "suitable for its pharmaceutical application" as the specification does not address nor demonstrate use of the formulations.

Based on the record presented, for purposes of this Decision, we determine that "wherein the formulation is stable" means "wherein the formulation maintains the functional integrity of the antibody and other components, for example when stored for 8 weeks at 40° C." This construction is consistent with the ordinary and customary meaning of the term in light of the specification and the prosecution history as discussed above.

III. ELIGIBILITY FOR POST-GRANT REVIEW

As a threshold matter, we must determine whether the '265 patent is eligible for post-grant review.

A. Legal Framework

First, post-grant review is only available if the petition is filed within nine months of the issuance of the challenged patent. 35 U.S.C. § 321(c) (2018). Here, the Petition was filed on May 2, 2022, which is within nine months of the '265 patent's August 3, 2021, issue date. Exhibit 1001, code (45).

Second, post-grant review is available only for patents that issue from applications that at one point contained at least one claim with an effective filing date of March 16, 2013 or later. The post-grant review provisions set forth in section 6(d) of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (September 16, 2011) ("AIA"), apply only to patents subject to the first-inventor-to-file provisions of the AIA. *See* AIA § 6(f)(2)(A) (stating that the provisions of section 6(d) "shall apply only to patents described in section 3(n)(1)"). Patents subject to the first-inventor-to-file provisions are those that issue from applications that contain or contained at any time—

> (A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after [March 16, 2013]; or
>
> (B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

AIA § 3(n)(1).

Our rules require that each petitioner for post-grant review certify that the challenged patent is available for post-grant review. 37 C.F.R. § 42.204(a) ("The petitioner must certify that the patent for which review is sought is available for post-grant review . . . ."). Petitioner has the burden of establishing eligibility for post-grant review. *See Mylan Pharms. Inc. v.*

Yeda Res. & Dev. Co., PGR2016-00010, Paper 9 at 10 (PTAB Aug. 15, 2016).

Determining whether a patent is subject to the first-inventor-to-file provisions of the AIA, and therefore eligible for post-grant review, is straightforward when the patentee filed the application from which the patent issued before March 16, 2013, or when the patentee filed the application on or after March 16, 2013, without any priority claim. The determination is more complex, however, for a patent that issues from a "transition application," that is, an application filed on or after March 16, 2013, that claims the benefit of an earlier filing date. *See* MPEP § 2159.04 (9th ed. Rev. 10.2019, June 2020). Entitlement to the benefit of an earlier date under 35 U.S.C. §§ 119, 120, 121, or 365 is premised on disclosure of the claimed invention "in the manner provided by § 112(a) (other than the requirement to disclose the best mode)" in the earlier application. *See* 35 U.S.C. §§ 119(e), 120. Thus, a patent that issues from a transition application is not available for post-grant review unless the claimed subject matter complies with the written description and enablement requirements of § 112(a) for an ancestor application filed prior to March 16, 2013.

The application that matured into the '265 patent is a transition application, as it claims priority to an application filed before March 16, 2013. Specifically, the '265 patent issued August 3, 2021, from U.S. Application No. 13/870,061, filed April 25, 2013, and claims priority to U.S. Provisional Application No. 61/642,032, filed May 3, 2012 (the "priority application"). Ex. 1001, codes (45), (21), (22), (60).

To show that the ’265 patent is eligible for post-grant review, Petitioner bears the burden of proving that at least one of the challenged claims lacks the benefit of the filing date of the earliest application that supports the claim. In particular, Petitioner must show that at least one of the challenged claims “was not disclosed in compliance with the written description and enablement requirements of § 112(a) in the earlier application for which the benefit of an earlier filing date prior to March 16, 2013 was sought.” *Inguran, LLC v. Premium Genetics (UK) Ltd*., PGR2015-00017, Paper 8 at 11 (PTAB Dec. 22, 2015).

B. Petitioner’s Eligibility Allegations

In alleging that the ’265 patent is eligible for post-grant review, Petitioner states that the priority application did not comply with 35 U.S.C. § 112(a) by failing to “describe or enable claim 14 as issued in the ’265 patent and once-pending claim 44.” Pet. 48. Petitioner argues that the priority application “contains no more disclosure than the ’265 patent itself [and] does not convey to a POSA that the inventors had possession of the full scope of issued claim 14 and once-pending claim 44 (in the form presented to the Office on February 12, 2021).” *Id*. at 49. In support of this argument, Petitioner cites to its arguments on Grounds 1 and 2 for lack of written description and lack of enablement. *Id*. Thus, our analysis of whether the ’265 patent is eligible for post-grant review becomes whether claim 14 (and independent claim 7, from which claim 14 depends), are enabled and have written description support in the ’265 specification. We, therefore, turn to Petitioner’s arguments as to why challenged claims 7 and 14 lack written description and enablement.

C. Alleged Lack of Written Description for Claims 7, 14

1. Legal Standard

To satisfy the written description requirement under 35 U.S.C. § 112(a), the specification must "reasonably convey[] to those skilled in the art that the inventor had possession" of the claimed invention as of the filing date based on an "objective inquiry into the four corners of the specification." *Ariad Pharms., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1351–52 (Fed. Cir. 2010) (en banc). If this test fails, the '265 patent is not entitled to the benefit of the earlier filing date of the priority application and we would have jurisdiction under 35 U.S.C. § 324 to institute post-grant review.

The written description requirement is satisfied when the specification "set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed." *University of Rochester v. G.D. Searle & Co., Inc*., 358 F.3d 916, 928 (Fed. Cir. 2004). The specification does not have to provide exact or verbatim textual support for the claimed subject matter at issue. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996). The Federal Circuit has clarified that

> [a]lthough [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed . . . . The test for sufficiency of support . . . is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter."

Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (citations omitted). Moreover, "the written description requirement does not demand either examples or an actual reduction to practice." *Ariad*

Pharms., 598 F.3d at 1351. "[A]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Cordis Corp. v. Medtronic AVE, Inc*., 339 F.3d 1352, 1365 (Fed. Cir. 2003). Furthermore, "[a] specification may . . . contain a written description of a broadly claimed invention without describing all species that [the] claim encompasses." *Id*.

Finally, the written description inquiry is a question of fact, is context specific, and must be determined on a case-by-case basis. *Ariad Pharms.*, 598 F.3d at 1351 (citing *Ralston Purina Co. v. Far-Mar-Co, Inc*., 772 F.2d 1570, 1575; *Capon v. Eshhar*, 418 F.3d 1349, 1357–1358 (Fed. Cir. 2005)); *see also Vas-Cath*, 935 F.2d at 1562 ("Precisely how close the [original] description must come to comply with [the description requirement of] § 112 must be [determined on a] case-by-case basis.") (quoting *In re Smith*, 258 F.2d 1389, 1395 (CCPA 1972)). "[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad Pharms.* 598 F.3d at 1351 (citing *Capon*, 418 F.3d at 1357–1358). Factors used to evaluate the sufficiency of a disclosure include: 1) "the existing knowledge in the particular field"; 2) "the extent and content of the prior art"; 3) "the maturity of the science or technology"; and 4) "the predictability of the aspect at issue" (the "*Ariad* factors"). *Id*. (citing *Capon*, 418 F.3d at 1359).

2. Petitioner's Allegations

Petitioner argues that claims 7 and 14 lack sufficient written descriptive support in the specification for numerous reasons. Pet. 51–64. We begin with Petitioner's arguments regarding claim 7.

Petitioner argues that claim 7 encompasses "a broad genus of antibody formulations" that are recited in generic and functional terms because the claims do not specify particular components but recite that the formulations retain a specific pH range and are both "isotonic" and "stable." *Id*. at 51. Petitioner, through its declarant, argues that because claim 7 does not specify certain kinds of components but rather claims, e.g., "a detergent" and "a tonicity agent," the genus of potential formulations encompasses numbers in the millions. *Id*. at 53 (citing Ex. 1002 ¶¶ 181–183, 220–221, Appx. B). Petitioner acknowledges that two formulations disclosed in the specification, Formulations 1 and 2 of Example 11, fall within the scope of claim 7. *Id*. at 53–54 (citing Ex. 1002 ¶¶ 120–127).

Petitioner argues, through the testimony of its declarant, that the art is highly unpredictable and antibody interactions with formulation components are variable. *Id*. at 54 (Ex. 1002 ¶¶181−182, 220−221). Petitioner argues that statements made by Patent Owner during prosecution of the patent support the difficulty in formulating stable formulation conditions. *Id*. at 54–55 (citing Ex. 1004, 6371); Reply 6 (citing Patent Owner's argument that formulations of the same antibody could have "various effects" where buffers were replaced). Petitioner's declarant opines that "even subtle changes to any variable could significantly affect excipient-excipient and excipient-antibody interactions and formulation stability" as well as temperature, pH, and humidity. Pet. 55 (citing Ex. 1002 ¶¶ 70−85).

Petitioner further argues that the optional inclusion of a buffer as recited by claim 7 is problematic because no buffer-less antibody formulations had been FDA approved by 2013, and the specification does not describe self-buffering behavior. *Id*. (citing Ex. 1002 ¶¶ 56, 206). Further, Petitioner argues, the specification does not explain that an antibody's capacity to self-buffer only relates to stabilizing the pH, not to providing overall formulation stability. *Id*. at 55–56 (citing Ex. 1002 ¶ 55). Petitioner argues the ordinary artisan would have understood the array of factors that could affect formulation stability and make liquid antibody formulations unpredictable. *Id*. at 56 (citing Ex. 1002 ¶¶ 24−29, 20, 32−36). Petitioner argues the breadth of the claims encompasses intravenous and subcutaneous formulations, but the stability parameters are not equally applicable. *Id*. at 56–57 (citing Ex. 1002 ¶¶ 63, 169, 229–231). Petitioner contends that the two sample formulations in the specification are insufficient to guide the ordinary artisan in light of the size of the genus of the claims. *Id*. at 58 (citing Ex. 1002 ¶¶ 214, 229, 240−249).

Petitioner argues the specification fails to describe a "common structural feature" that would allow an ordinary artisan to visualize those formulations that would be stable. *Id*. at 58 (citing *AbbVie Deutschland Gmbh & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1301 (Fed. Cir. 2014); *Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Labs. Inc.*, 923 F.3d 1368, 1384 (Fed. Cir. 2019)). Petitioner argues that, without such guidance, the ordinary artisan would need to perform additional research to determine formulation stability. *Id*. at 59 (citing Ex. 1002 ¶¶ 239–243). Petitioner argues that the known factors in the formulation of claim 7, namely the antibody and its primary amino acid sequence, and the

target pH range, are insufficient for a skilled artisan to develop a stable antibody formulation, despite having the examples of the formulations in the specification. *Id*. at 59–61 (citing Ex. 1002 ¶¶ 70–93, 120–125, 245–249, 278). Petitioner argues that Dr. Klibanov's testimony "provides multiple pieces of evidence not previously considered by the Office." Reply 7 (citing exhibits, including Patent Owner's statements in Europe regarding unpredictability in the art).

Claim 14 depends from claim 7 (Ex. 1001, 189:62–190:27) and further recites "wherein the formulation is stable following storage in a syringe for 8 weeks at 40° C." *Id*. at 190:43–45. Specific to claim 14, Petitioner argues that "[t]he limitations regarding conditions under which the formulation is stable, as in claim 14 and once-pending claim 44, do not narrow the number of potential formulations encompassed by claim 7," and the genus of claim 14 encompasses millions of potential formulations that lack written description support for "substantially the same reasons." Pet. 63 (citing Ex. 1002 ¶¶ 240–249).

3. Patent Owner's Arguments

Patent Owner argues that the Petition should be denied because Petitioner does not adequately explain the meaning of the term stable "despite stability being fundamental to its challenges." Prelim. Resp. 16. Our analysis above, pertaining to the meaning of "stable," disposes of that argument.

Patent Owner also argues that Petitioner ignores that the claimed subject matter has multiple structural elements, including risankizumab, as defined by its known heavy and light chain sequences, and "a group of well-

known excipients that impart isotonicity and stability and a narrow pH range." *Id*. at 23 (citing Ex. 1002 ¶¶ 39, 48, 57 regarding the well-known function of claimed components by ordinary artisan). Patent Owner faults Petitioner's attempt to overpopulate the genus of claimed formulations by ignoring that the components of the genus are well understood in the art, and by including in the alleged complicating factors the use of compounds that are not included with aqueous formations of antibodies such as small molecules. *Id*. at 24–25 (citing Ex. 1002, App'x B, listing references cited by Dr. Klibianov). Patent Owner notes that several of the compounds identified in Petitioner's estimates of the genus of potential formulations had not been used in commercial antibody formulations as of 2012. *Id*. at 25.

Specifically, with regard to Dr. Klibanov's testimony regarding the "millions of potential formulations," Patent Owner argues that Dr. Klibanov's assumptions fail to account for normal "shortcut" steps and experimental design strategies that lessen the numbers of experiments necessary. *Id*. at 26 (citing Ex. 2004, 146:19–147:10, Dr. Klibanov testimony in another matter that steps are routinely taken in the art to minimize the scope of testing required to develop formulations).

Patent Owner argues that Dr. Klibanov's testimony regarding "unpredictability in the art" does not relate to stability of the types of formulations claimed, but focuses on "differences among antibodies or even other proteins," from formulation to formulation. *Id*. at 27. Moreover, Patent Owner argues, the instability issues identified by Petitioner do not relate to the function of risankizumab, noting that every formulation in the '265 patent is stable and "Petitioner has not identified any formulation of risankizumab that is not stable." *Id*. at 28. For this reason, Patent Owner

argues, Petitioner has failed to demonstrate that the ordinary artisan would not have believed that other members in the genus would perform similarly to the disclosed members. *Id*. at 28–29.

Patent Owner argues that the formulations disclosed in the '265 patent describe a variety of representative excipients for each claimed excipient category. *Id*. at 30 (citing examples). Patent Owner argues that each disclosed formulation was stable, including the risankizumab formulation without a buffer that was stored in a syringe at an elevated temperature for eight weeks. *Id*. at 30–31. Patent Owner argues that no minimum number of examples is required to provide adequate written description. *Id*. at 31 (citing *Fresenius Kabi USA, LLC v. Coherus Biosciences, Inc*., PGR2019-00064, Paper 10 at 11–18 (PTAB Mar. 19, 2020) ("*Fresenius*") and other cases). Regarding claim 14, Patent Owner argues that "Petitioner fails to introduce evidence that any risankizumab formulation meeting the structural limitations of claim 14 is not stable following storage in the disclosed conditions." *Id*. at 38. Patent Owner further argues that the material provided by Dr. Klibanov is not new evidence and is cumulative to what the Office already considered. Sur-Reply 6.

4. Analysis

We agree with Patent Owner that Petitioner has not satisfied its burden of showing that claim 7 or 14 lacks written description support in the priority application, which Petitioner has conceded provides the same support as the '265 patent specification. In this regard, we agree that the reasoning in *Fresenius* likewise applies: there is no legal requirement that a patent specification must include test results or working examples demonstrating stability for every possible composition that is covered by the

claims. *Fresenius* at 13, citing *Ariad Pharms.*, 598 F.3d at 1352 (stating that "the written description requirement does not demand either examples or an actual reduction to practice"). Formulations 2 and 3, disclosed in the '265 patent specification, which Petitioner acknowledges falls within the scope of claims 7 and 14 (Pet. 26–27 (citing Ex. 1002 ¶¶ 134, 135)), were shown to be stable for 8 weeks in a syringe. Moreover, the ordinary artisan was provided with guidance in making such formulations from the teachings of the specification and has additional knowledge from the art. *See* Ex. 1001, 85:32–94:35. Claims 7 and 14 identify specific structures (risankizumab) and required excipients within a defined pH range, which are stable as confirmed by testing results presented in the specification. Prelim. Resp. 33; Ex. 1001, 94:14–36.

On this record, we conclude that the evidence presented does not establish that it is more likely than not that an ordinarily skilled artisan would not have reasonably believed that the inventors of the '265 patent possessed the claimed subject matter, each limitation of which is demonstrated as supported in the specification. As we have interpreted the claim term "wherein the formulation is stable" to mean "wherein the formulation maintains the functional integrity of the antibody and other components, for example when stored for 8 weeks at 40° C," the specification supports maintenance of functional integrity as shown by the stability of Formulations 2 and 3, including when stored for a period of time. For this reason, we find that Petitioner has not shown that the ordinary artisan would not have understood the inventors of the '265 patent possessed the subject matter of claims 7 and 14 as of the filing date of the priority application.

D. Alleged Lack of Enablement for Claims 7, 14

1. Legal Standard

"Enablement requires that 'the specification teach those in the art to make and use the invention without undue experimentation.'" *Idenix Pharm. LLC v. Gilead Sci. Inc*., 941 F.3d 1149, 1154 (Fed. Cir. 2019) (quoting *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). The factors to be considered when determining if undue experimentation is required to practice the invention include: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. *Wands*, 858 F.2d at 737.

2. Petitioner's Arguments

Petitioner alleges the breadth of the claims is "vast" and that the skilled artisan could only determine the stability of a formulation by way of testing. Pet. 71–72. Petitioner alleges that such testing is necessary because stability is unpredictable. *Id*. at 72. Petitioner argues thus that *Wands* factors 7 and 8 weigh strongly against enablement.

With regard to *Wands* factors 4, 5, and 6, Petitioner argues the ordinary artisan would not have known whether any given formulation, because it involved liquid antibodies, was stable absent testing, despite the ordinary artisan's high level of skill. *Id*. at 73–74. For *Wands* factors 1, 2, and 3, Petitioner argues that the genus "encompassing millions of formulations" is insufficiently informed by the teachings of the

specification, leaving an undue quantity of experimentation needed to practice the full scope of the claims. *Id*. at 74–76.

Specific to claim 14, Petitioner argues the "minimal guidance" in the specification and the art would have left the ordinary artisan having to make large amounts of Antibody A, performing "an impractically large number of stability studies, each study involving a process requiring months for a single formulation, or on the order of eight weeks following storage in a syringe at 40°C," and analysis. *Id*. at 76–77 (citing Ex. 1002 ¶¶ 36−37, 99, 104−105, 107, 181−182, 270, 291, 295, 300). Petitioner concludes that claim 14 "does not meaningfully narrow the scope of the claimed genus of formulations relative to claim 7" and is not enabled for the same reasons. *Id*.

3. Patent Owner's Arguments

Patent Owner argues that Petitioner fails to satisfy its burden to show lack of enablement of claims 7 and 14. Prelim. Resp. 40– 51. Patent Owner argues that, similar to the written description challenge, Petitioner's case rests on "sheer conjecture that a significant number of formulations otherwise within the scope of the challenged claims are not stable, necessitating the alleged trial-and-error quest." *Id*. at 41. Patent Owner notes that Petitioner has provided no concrete evidence of instability of any formulation, and thus fails to make a threshold showing that some experimentation is necessary. *Id*. (citing, e.g., *Atlas Powder Co. v. E.I. du Pont De Nemours & Co*., 750 F.2d 1569, 1577 (Fed. Cir. 1984) for the proposition that a finding of lack of enablement based on inoperability fails where no evidence of actual inoperability is provided).

Patent Owner further argues that Petitioner's showing on the *Wands* factors is deficient as it understates the guidance provided in the

specification and overstates the complexity of the recited formulation, relying on references that address components and circumstances not at issue. *Id*. at 42–43. Patent Owner argues that when the teachings of the specification are applied to creating the claimed subject matter, the ordinary artisan's tasks are not as broad as Petitioner claims, and that Patent Owner's declarant has testified about the more realistic path such an artisan would take in similar situations. *Id*. at 44–46 (citing Ex. 2004, 146:19–147:10, 151:5–152:17). Patent Owner distinguishes the cases relied on by Petitioner as applying to circumstances with insufficient guidance for method claims as opposed to the formulation claims at issue here with specific formulation examples, similar to *Fresenius*. *Id*. at 47–49.

Patent Owner argues that claim 14 is particularly supported as the "specification provides stability data obtained using these precise storage conditions," in Example 12. *Id*. at 51. Patent Owner argues that Petitioner has not established why undue experimentation would be required where the claim recites an eight-week storage period, noting that a higher level of experimentation in the biochemical arts is not unexpected, as supported by other cases. *Id*. at 51.

4. Analysis

We agree with Patent Owner that Petitioner has not satisfied its burden of showing that claim 7 or 14 lacks enabling support in the priority application or the '265 patent specification.

As we have interpreted the claim term "wherein the formulation is stable" to mean "wherein the formulation maintains the functional integrity of the antibody and other components, for example when stored for 8 weeks at 40° C," the specification supports the ability of the ordinary artisan to

make and use a formulation with maintainable functional integrity over the recited storage period as shown by Formulations 2 and 3, which Petitioner has acknowledged falls within the scope of claim 14. *See* Pet. 26–27.[3]

We acknowledge that in the *Fresenius* case, the extensive testing disclosed in that specification supported the ordinary artisan's ability to formulate stable compounds using such guidance, and that the specification here discloses less testing. *See, e.g.*, Sur-Reply. 8–9. Nevertheless, it is Petitioner's burden on this issue, and we are not persuaded that the concerns raised by Dr. Klibanov provide sufficient evidence of actual instability to justify institution on this record. *See, e.g., Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984) (finding lack of evidence that district court erred in upholding claims as enabled where defendant did not identify inoperable embodiments despite extensive testing).

In particular, we are persuaded that, on this record, Petitioner's lack of evidence of instability of any formulation falling within the limitations of claim 14 indicates that Petitioner has not established sufficiently, for purposes of trial institution, that it is more likely than not that an ordinarily skilled artisan would not have been able to practice the full scope of claim 14 invention based on the teachings of the specification.

[3] Petitioner's acknowledgment identifies two caveats: that the formulation is "stable" and has a pH between 5.5 and 6.1. *See* Pet. 26–27 (e.g., "Assuming that Formulation 2 is "stable" and has a pH between 5.5 and 6.1, Formulation 2 is within the scope of the challenged claims.") (citing Ex. 1002 ¶ 134). The data in the specification confirms that Formulations 2 and 3 meet the requirements of both caveats. *See* Ex. 1001, 94:14–36.

Accordingly, we find that Petitioner has not identified any challenged claim that has an effective filing date on or after March 16, 2013. For this reason, we find that Petitioner has not shown sufficiently that the '265 patent is eligible for post-grant review.

IV. CONCLUSION

After considering the evidence and arguments presently before us, we determine Petitioner has not shown that the '265 patent is eligible for post-grant review. Accordingly, we do not institute a post-grant review.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 324(d), the Petition is *denied*.

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