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Paper 13
Date: February 23, 2023

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 Petitioner's Request on Rehearing of Decision Denying Institution of Post-Grant Review
37 C.F.R. § 42.71

I. INTRODUCTION

A. Background and Summary

On December 7, 2022, Petitioner filed a Request for Rehearing (Paper 12, "Req. Reh'g.") under 37 C.F.R. § 42.71(d) to seek modification

of the Board's Decision Denying Institution of Post-Grant Review (Paper 11, "Decision" or "Dec.") of claims 7−10, 14−16, 19−22, and 27−28 ("the Challenged Claims") of U.S. Patent No. 11,078,265 B2 (Ex. 1001, "the '265 patent"). We denied institution because we concluded that Petitioner had not identified any challenged claim with an effective filing date on or after March 16, 2013, thus rendering the '265 patent ineligible for post-grant review. Dec. 29. We reasoned that Petitioner had not sufficiently shown, as it had alleged in its Petition (Paper 2 ("Pet.") 48), 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." *Id.* at 24, 28.

In its Request for Rehearing, Petitioner contends we "adopted the incorrect legal standard for enablement by requiring Petitioner to provide a specific example 'of instability of any formulation falling within the limitations of [the] claim[s],'" we "misapprehended the law of written description for generic functional claims," and we "neglect[ed] the required analysis." Req. Reh'g. 1, 3.

Having considered Petitioner's arguments, we deny the Request for Rehearing and modify our Decision to incorporate the additional explanatory reasoning presented herein.

II. STANDARD OF REVIEW

When rehearing a decision on institution, we do not review the merits of the decision *de novo*, but instead review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion occurs when a "decision was 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) (citations omitted). The party requesting rehearing has the burden to show that the decision should be modified. 37 C.F.R. § 42.71(d). Additionally, the request for rehearing "must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply." *Id.*

III. ANALYSIS

A. Enablement

Petitioner argues that we erred in concluding that Petitioner had not sufficiently shown that the priority application failed to enable claim 14. Req. Reh'g. 5. According to Petitioner, our finding that Petitioner did not identify any inoperable embodiment falling within the limitations of claim 14, and our citation to *Atlas Powder*[1] in support of the conclusion that identification of an inoperable embodiment was necessary to establish lack of enablement, was both a misinterpretation of *Atlas Powder* and "an erroneous interpretation of the law." *Id.*

Petitioner argues that analysis of functional claims for enablement is performed under a different framework, by qualifying the effort needed to identify embodiments that would be outside the scope of the specification. *Id.* at 5–6 (citing *Amgen*,[2] *McRO*,[3] and *Wyeth*[4]). Petitioner further cites a district court case in which the court concluded nonenablement of claims

[1] *Atlas Powder Co. v. E.I. du Pont De Nemours & Co*., 750 F.2d 1569 (Fed. Cir. 1984)
[2] *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1087 (Fed. Cir. 2021)
[3] *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091 (Fed. Cir. 2020)
[4] *Wyeth & Cordis Corp. v. Abbott Lab'y*, 720 F.3d 1380 (Fed. Cir. 2013).

similar to the ones at issue in this case were not enabled, in reliance on *McRO*. *Id.* at 7 (citing "Memorandum Opinion and Order Following Bench Trial," *AstraZeneca AB v. Mylan Pharms. Inc*., Case No. 1:18-cv-00203 (N.D. W.Va.), November 9, 2022).[5] Petitioner argues that our analysis in the Decision "leans heavily on a single factual consideration: evidence of an inoperative embodiment" (*Id.* at 8), and that we neglected to take account adequately of the other relevant factual considerations required in a *Wands*[6] analysis. Petitioner asserts that the evidence presented in the Petition and by its Declarant, Dr. Klibanov, was sufficient to show that the ordinary artisan would have been required to engage in undue experimentation to identify stable formulations. *Id.* at 9. Petitioner further argues that our reliance on *Atlas Powder* is misplaced and not instructive because the claims in *Atlas Powder* were not "evaluated as functional" and the art was deemed not unpredictable as is the case here. *Id.* at 10.

We are not persuaded that our conclusion in the Decision was reached through an erroneous interpretation of law or is otherwise in error.

[5] Petitioner requests that we delay decision on this Request for Rehearing pending issue of the Federal Circuit's opinion on the appeal of this case. Req. Reh'g. 15. We decline to do so in the interest of a just and speedy resolution of the preliminary proceeding. *See* 37 C.F.R. § 42.1.

[6] *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). In *Wands*,[6] the Federal Circuit set forth the following factors to be considered when determining if undue experimentation is required to practice the invention: (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. 858 F.2d at 737.

However, for completeness with regard to our rationale in reaching this conclusion, we elaborate on our reasoning using the *Wands* factors below.

As stated in the Decision, Petitioner's claim for eligibility for post-grant review hinges on claim 14, which depends from claim 7. Dec. 16. Thus, we consider only Petitioner's evidence pertaining to enablement of claim 14 and those portions of claim 7 not narrowed by claim 14 in evaluating Petitioner's allegations of error.

Claim 7 is reproduced below:

> 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 14 further recites "wherein the formulation is stable following storage in a syringe for 8 weeks at 40° C." *Id.* at 190:44–45.

Petitioner addresses these factors through the testimony of Dr. Klibanov, who refers to the genus of claim 7 reciting liquid "Antibody A[7]" formulations that are stable following storage in a syringe for 8 weeks at 40° C as "Subgenus A." Ex. 1002 ¶¶ 179, 275–290. In our analysis of the factors, we address Dr. Klibanov's testimony as it relates to claim 14.

Petitioner alleges that the quantity of experimentation necessary, Factor 1, is "enormous and undue" for formulations within the scope of

[7] The '265 patent states "in one embodiment, a humanized antibody of the present invention comprises the light chain sequence of SEQ ID NO:174 and the heavy chain sequence of SEQ ID NO:176 (Antibody A)."

Claim 7 and 19.[8] Pet. 75–76 (citing Ex. 1002 ¶¶ 180−182, 220−221). Dr. Klibanov's testimony describes various complications in the art related to formulating antibody compositions, in and outside of liquid formulations. *Id.* Dr. Klibanov further opines that there were no techniques available by 2012 or 2013 that "would offer a meaningful shortcut" to the labor and resources needed to test such formulations. *Id.*

Patent Owner argues that Petitioner has failed to demonstrate that any experimentation is necessary in light of the guidance in the Specification, including example formulations. Prelim. Resp. 40–41 (citing Ex. 1001, Example 12 and *Atlas Powder*); 46–47.[9] Patent Owner argues that even if the threshold requiring demonstration had been met,[10] Petitioner has not demonstrated the required experimentation would be undue: Dr. Klibanov's testimony regarding the testing an ordinary artisan would need to perform examines individual components of the formulation rather than considering the teachings in the Specification regarding the composition; recites studies not related to the recited components (e.g., other antibodies and antibody fragments, antibodies repurposed for another use); and does not address the formulation in total. *Id.* at 24–27 (citing Ex. 1002 ¶¶ 180−182, 220−221, App'x B). Patent Owner cites Dr. Klibanov's testimony in another case to the effect that techniques such as high-throughput formulation can be used to

[8] Petitioner does not make allegations specific to claim 14.
[9] Patent Owner refers to the quantity of experimentation necessary in its brief as Factor 8 (Prelim. Resp. 46–47), but we understand these arguments to relate to Factor 1, and address them here.
[10] Patent Owner cites *Alcon Rsch. Ltd. v. Barr Lab'y, Inc.*, 745 F.3d 1180, 1189 (Fed. Cir. 2014) "(absent a 'threshold showing that any experimentation is necessary,' there is no basis for holding that claims are not enabled)."

screen for suitable components as support for its argument that the effort required to make and use the claimed formulation is lower than Dr. Klibanov suggests here. *Id.* at 46–47 (citing Ex. 2004, 146:19–147:10, 151:5–152:17).

We agree with Patent Owner that Dr. Klibanov's testimony on the topic of unpredictability often addresses issues outside the scope of the claims because the types of problems noted regard components not recited in the claims. Dr. Klibanov's testimony broadly discussing the recited components is helpful to understand the particular challenges an ordinary artisan would have faced. However, Dr. Klibanov provides little information pertinent specifically to the subject matter of claim 14 as a whole, that is, determining the stability of a liquid aqueous pharmaceutical formulation comprising liquid risankizumab[11] in a concentration of 90 mg/ml, 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, after storage at 8 weeks at 40°C.

On balance, we find that the experimentation necessary is moderate but not undue. In addition, the two examples showing stable compositions provide guidance as a starting point to experimentation, as discussed below.

We consider together Factors 2 and 3, the amount of direction or guidance presented and the presence or absence of working examples. Petitioner characterizes the specification as providing "minimal" guidance with only narrow examples disclosed despite that the genus contains millions of formulations. Pet. 74–74 (citing Ex. 1002 ¶¶ 240–249, *Enzo*[12],

[11] Risankizumab is the name for the specific sequence-defined antibody recited in the Challenged Claims. Prelim. Resp. 1.
[12] *Enzo Biochem, Inc. v. Calgene, Inc*., 188 F.3d 1362 (Fed. Cir. 1999).

188 F.3d at 1372–1374, and *Idenix*,[13] 941 at 1161).

Patent Owner argues that two sample formulations that meet the claim limitations are disclosed, with both an ionic and nonionic tonicity agent taught, and "optionally a buffer (e.g., succinate, citrate, or no buffer), at a range of different concentrations." Prelim. Resp. 44 (citing Ex. 1001 Exs. 9, 12). Patent Owner argues that the Specification further teaches analytical ultracentrifugation and size-exclusion chromatography as methods to evaluate the stability of the resulting formulations. *Id.*

Patent Owner also argues that Petitioner's characterization of the size of the genus disregards the invention as a whole because Dr. Klibanov, for instance, identified potential excipients by looking "generally at 'injectable' formulations, including small molecules and other unrelated compounds, ***rather than aqueous formulations of antibodies***." Prelim. Resp. 24–25 (citing Ex. 1002, App'x B). Patent Owner further argues that Petitioner's focus on the limited number of examples provided misses the quality of the patent's disclosure, which addresses each component with representative examples and demonstrates stability following eight weeks in storage at 40° C in compositions with and without a buffer. *Id.* at 29–31 (citing Ex. 1001, 92:45–46; 93:11–13, 94:2–4). Patent Owner argues that Petitioner did not "identify any risankizumab formulation that meets the multiple structural limitations of the claims but is unstable." *Id.* at 30. Patent Owner argues the disclosures in the Specification, along with the art, teach a self-buffering capacity of highly concentrated protein solutions that can replace pH stabilization. *Id.* at 31 (citing Ex. 1018, 491). Patent Owner cites

[13] *Idenix Pharms., LLC v. Gilead Sciences, Inc.*, 941 F.3d 1149 (Fed. Cir. 2019).

multiple cases in which the disclosure was similar in extent to Patent Owner's and the reviewing court or PTAB upheld the disclosure as sufficient, and distinguishes Petitioner's cited cases as involving claims fundamentally different from the recited formulation.[14] *Id.* at 31–35 (citing cases). Patent Owner argues the common structural features of the components are disclosed together as a composition and are supported by stability and osmolality testing in the specification. *Id.* at 33 (citing Ex. 1001, Example 12).

On balance, Patent Owner has the better argument. The Specification describes various components with structural features: the buffer, tonicity agent, and risankizumab. Ex. 1001, 22:4–7; 83:10–84:19. The Specification also provides informative pharmaceutical ranges of the claimed compositions and provides working examples demonstrating testing composition stability with two exemplary formulations that match the limitations of claim 7 and dependent claim 14. *Id.*, 92:22–94:35. Dr. Klibanov's testimony specific to claim 14 is limited, but characterizes claim 14 as "encompass[ing] a similar number of possible formulations as in claim 7, because claim 14 does not specify the detergent, tonicity agent, or optional buffer, or their respective concentrations." Ex. 1002 ¶ 270. Dr. Klibanov's testimony refers in part to broader classes of components (e.g., other antibodies and fragments) that do not apply to the defined subject matter of the invention and, specifically, claim 14. *Id.* (reciting sections earlier in Declaration). In addition, Dr. Klibanov does not provide any

[14] Although Patent Owner's argument addresses cases related to Petitioner's written description argument, Petitioner has also cited these cases in support of its argument of non-enablement. *See, e.g.*, Pet. 2–3 (citing *Fresenius*); and 75 (citing *Enzo*).

evidence of a composition made within the scope of claim 14 that is unstable.[15] We thus find Dr. Klibanov's cited testimony less helpful as this factor relates to the issue of whether claim 14 is enabled. We find Factors 2 and 3 lean toward sufficient direction or guidance presented in light of the disclosure discussed above.

Petitioner proposes, regarding Factor 4, that the nature of the invention is complex because it involves unpredictable interactions and characteristics between formulation components. Pet. 74 (citing Ex. 1002 ¶¶ 26−29, 32−34, 63–65, 70−85). Dr. Klibanov's testimony addresses potential interactions and characteristics that could contribute to unpredictability. *See, e.g.*, Ex. 1002 ¶¶ 32–34 (addressing challenges with antibody formulation such as aggregation). As noted above, this testimony is helpful to define challenges the skilled artisan would have in practicing the invention, but because Dr. Klibanov's testimony on the topic of unpredictability often addresses issues outside the scope of claim 14, this evidence is less helpful to defining the complexity of claim 14 specifically. Favoring less complexity, the Specification discloses two examples practicing claim 14, with no concrete evidence of a formulation falling within the limitations of claim 14 that is unstable. On balance, we find the nature of the invention of the subject matter of claim 14 to be moderately complex, with guidance provided to the ordinary artisan by the Specification examples and disclosures.

Petitioner proposes that Factor 5, the state of the prior art, is "not developed" due to a lack of an FDA-approved anti-IL23p19 antibody or

[15] We address Petitioner's argument regarding the requirement of evidence on this issue further below.

formulations of Antibody A. Pet. 73 (citing Ex. 1002 ¶ 278). Patent Owner counters that "Petitioner and its expert acknowledge that the specific excipient categories recited in the claims were well known, as were methods for assessing stability of pharmaceutical formulations." Prelim. Resp. 45, citing Pet. 9–11, 13, 21–22; Ex. 1002 ¶¶ 47, 59, 99, 100, App'x B; Ex. 2006 ¶ 95. Patent Owner further argues that FDA-approved formulations are not necessary to practice the claims. *Id.* On balance, we find the state of the prior art was moderately developed as it contained teachings regarding uses of each of the recited components of the formulation of claim 14, such that the ordinary artisan would have had sources to consult in formulating the claimed subject matter, as demonstrated by the references cited by Petitioner and Dr. Klibanov as stated above.

Factor 6, the relative skill of those in the art, was addressed in our Decision when we adopted Petitioner's undisputed definition, that an artisan of ordinary skill in the art "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. Dec. 7 (citing Pet. 33). We find this level of skill to be very high. Dr. Klibanov agrees. Ex. 1002 ¶ 280.

With regard to Factor 7, the predictability or unpredictability of the art, Petitioner proposes that the art is highly unpredictable. *See, e.g.*, Pet. 54; Ex. 1002 ¶¶ 281–283. Patent Owner argues that Petitioner's evidence "consists primarily of references describing unpredictability stemming from differences among antibodies (i.e., different amino acid sequences among different antibodies)" which is inapplicable where the claims recite a specific antibody. Prelim. Resp. 46. Dr. Klibanov's testimony, as noted by

Patent Owner (*id*.), addresses antibodies generally and does not address the claimed antibody; however, Dr. Klibanov opines generally that the behavior and properties of any component of a formulation could affect the behavior and properties of the other components of the formulation, including the antibody, and thus experimentation would be needed to determine if a given formulation would be stable. *See, e.g*., Ex. 1002 ¶¶ 70–93. On balance, we find this factor leans toward unpredictability, as to the technical field of the invention in general, but that, as described above, some of the evidence advanced by Petitioner is not applicable to the subject matter of claim 14 in particular (*id*.).

Petitioner argues that Factor 8, the breadth of the claims, is "vast," relying on Dr. Klibanov's testimony calculating the size of the genus. Pet. 71–72 (citing Ex. 1002 ¶¶ 181–182, 270). Regarding claim 14 specifically, Dr. Klibanov states "Claim 14 specifies that stability is assessed 'following storage in a syringe for 8 weeks at 40° C . . . .' A POSA would understand that stability condition to define the genus of claim 14 as having a particular property or function." Ex. 1002 ¶ 165 n. 7 (quoting Ex. 1001, 190:43–45). Dr. Klibanov further opines that claim 14's breadth is as large as claim 7 "because claim 14 does not specify the detergent, tonicity agent, or optional buffer, or their respective concentrations" and recites the same stability conditions encompassed by claim 7. Ex. 1002 ¶ 270.

Patent Owner argues that Petitioner overstates the breadth of the claims "by, for example, relying on excipients and concentration ranges that a POSA would appreciate were irrelevant to what is claimed: liquid, aqueous, pharmaceutical antibody formulations." Prelim. Resp. 43–44. On balance, we find the breadth of claim 14 to be moderately broad due to the

use of the open-ended term "comprising" and because the claim does not specify components aside from the antibody sequence and a pH range for the composition. However, because the skill level is very high and the art contains teachings regarding options for the various components, the ordinary artisan would have resources to consult about which particular excipients may be used in the claimed formulation. *See, e.g., Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co*., 276 F. Supp. 3d 629, 648 (E.D. Tex. 2016), *aff'd*, 739 F. App'x 643 (Fed. Cir. 2018) ("The broad genus of 'solubilizing agents' would not require representative species if persons of skill knew of many solvents that could dissolve the salt, and thereby serve as a 'solubilizing agent' in that invention. Patents in the chemical field may often involve claims that include well-understood genera.").

In summary, upon consideration of each of the *Wands* factors, we find: (1) the quantity of experimentation necessary is moderate but not undue; (2) the amount of direction or guidance presented and the presence or absence of working examples leans toward sufficiency; (3) the nature of the invention of the subject matter of claim 14 is moderately complex; (4) the state of the prior art was moderately developed as it contained teachings regarding uses of each of the recited components of the formulation of claim 14; (5) the level of skill is very high; (6) the invention leans toward unpredictability as to the technical field of the invention in general; and (7) the breadth of claim 14 is moderately broad due to the use of the open-ended term "comprising" and because the claim does not specify components aside from the antibody sequence and a pH range for the composition. On balance of the *Wands* factors, we find that Petitioner does not meet its burden to

show that it is more likely than not that the ordinary artisan would have been unable to make and use the invention without undue experimentation.

With regard to Petitioner's argument (Req. Reh'g. 5–11) that we adopted an erroneous statement of law for enablement and, in doing so, we misinterpreted or misapplied *Atlas Powder*, we are not persuaded. In *Atlas Powder*, the claims were directed to an emulsion blasting agent with specific ingredients and temperature requirements. 750 F.2d at 1572. The district court had found that the patent challenger did not establish that the patent was invalid for lack of enablement even though the patent disclosure listed numerous potential components among which the ordinary artisan would have had to select to find an operable emulsion; the court found the ordinary artisan would have known how to optimize those components to create suitable (e.g., functional) emulsions. *Id.* at 1566.

On review, the Federal Circuit declined to find, as the patent challenger there urged, that the disclosure should be construed to read only upon the emulsifiers capable of producing suitable emulsions and found, further, that the patent challenger did not demonstrate that the other disclosed emulsifiers were inoperable. *Id.* at 1577. Insofar as the purpose of the claimed invention was to create an emulsion agent[16], we disagree with Petitioner's argument that *Atlas Powder* is "not instructive" because the claims were not "evaluated as functional." Req. Reh'g. 10. In *Atlas Powder,* the court took note of the patentee's pre-filing efforts to conduct 300 experiments to create successful emulsions. *Id*. The testing records

[16] Claim 1 recites "An emulsion blasting agent" and requires that the "said occluded gas is held in said emulsion at a temperature of 70°F." *Atlas Powder*, 750 F.2d at 1572.

showed 40 percent of these experiments were listed as "failures" "in essence because they were not optimal under all conditions." *Id*. The court, having considered the very evidence Petitioner asks we consider – the efforts needed to identify embodiments that would fall within the scope of the specification (here, agents emulsified under the claimed conditions) – concluded that "such optimality is not required for a valid patent." *Id*. For this reason, we disagree that *Atlas Powder* is inapposite. We are further unpersuaded that our reliance on or application of *Atlas Powder* for its approval of the holding in a prior finding that claims need not exclude possibly inoperative embodiments and citing evidence of a patent challenger's failure to prove lack of enablement by not identifying inoperable embodiments was in error.

We agree with Petitioner that, as stated in *McRO*,

> In cases involving claims that state certain structural requirements and also require performance of some function (e.g., efficacy for a certain purpose), we have explained that undue experimentation can include undue experimentation in identifying, from among the many concretely identified compounds that meet the structural requirements, the compounds that satisfy the functional requirement.

McRO, 959 F.3d at 1100, n 2. However, we do not agree that this framework is the sole method for evaluating claims reciting a functional limitation. As the Federal Circuit stated in *McRO*, the inquiry into undue experimentation "can include" rather than "must include" evidence about the effort required toidentify compounds that satisfy the claimed functional requirement. *Id.* The cases cited in the footnote in *McRO* were particularly suited to consideration of such evidence because both involved compounds with components that could be altered or substituted within the limits of the claims, yet the disclosure contained limited information as to suitable

options to satisfy the functional requirements. *See Idenix*, 941 F.3d at 1156 (claims reciting a method of treating hepatitis C virus by administering compounds having a specific chemical and stereochemical structure in which substituent atoms or groups of atoms could be added in certain positions); *Enzo*, 188 F.3d at 1344 (claims relating to non-radioactive labeling of polynucleotides where the label is attached at the phosphate position of a nucleotide, and claims encompass all polynucleotides with labels attached to a phosphate, as long as the polynucleotide remains hybridizable and detectable upon hybridization).

On that point, the cases cited in the footnote in *McRO* are distinguishable, because none related to claims as specific as claims 7 or 14, which identify with particularity the antibody component of the composition. When we consider the specificity of claims 7 and 14, in light of the disclosures of the Specification and the knowledge in the art, we find those cases do not control, or demand a different result, under the particular and unique circumstances at hand. As shown in our analysis of the *Wands* factors above, we have considered the evidence Petitioner provided as to experimentation in all regards, along with the fact that Petitioner did not provide concrete evidence of a nonfunctional embodiment falling within the scope of claim 14. As held by the Federal Circuit, 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." *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d

1558, 1564 (Fed. Cir. 1996) (citing *Ex parte Jackson*, 217 USPQ 804, 807 (BPAI 1982)). We are unpersuaded that our holding was in error.

B. Written Description

Petitioner argues we erred in concluding that Petitioner did not establish that the priority application lacked sufficient disclosure where the priority application did not disclose sufficient information to distinguish stable from non-stable formulations or disclose a representative number of species falling within the scope of the genus or structure features sufficient to permit the skilled artisan to identify genus members. Req. Reh'g. at 11–12 (citing *Ariad Pharm.*[17], *Juno*,[18] and *AbbVie*[19]). Petitioner argues the Decision failed to "explain how Formulations 2 and 3 are sufficiently representative of the full scope of claims 7 and 14" and that Petitioner provided substantial evidence that predicting stability of the formulation would require extensive testing. *Id.* at 13 (citing Pet. 58−62; Ex. 1002 ¶¶ 240−249).

Petitioner asserts that Patent Owner did not and could not establish inherent stability for any claimed composition and that antibody presence would not necessarily render a composition stable. *Id.* (citing Pet. 53−62; Ex. 1002 ¶¶ 190−249).

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[17] *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352−53 (Fed. Cir. 2010)
[18] *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1336 (Fed. Cir. 2021).
[19] *AbbVie Deutschland GmbH Co. KG v. Janssen Biotech Inc.*, 759 F.3d 1285, 1299 (Fed. Cir. 2014).

Petitioner further contends our Decision did not explain how the Specification reflects possession of the full scope of the broad, claimed genus in light of Petitioner's "substantial evidence" that Formulations 2 and 3 provide insufficient guidance of the full claimed genus. *Id.* at 13–14 (citing Pet. 51−58; Ex. 1002 ¶¶ 179−239).

These arguments are unpersuasive. In our Decision, we found:

> 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.

Dec. 24. We found this same information would demonstrate to an ordinary artisan that the inventors possessed the claim invention: "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." *Id.* (citing Ex. 1001, 94:14–36). We applied the reasoning in *Ariad Pharms*., 598 F.3d at 1352 (stating that "the written description requirement does not demand either examples or an actual reduction to practice") (Dec. 23–24), which Petitioner acknowledges. Req. Reh'g. 11–12.

In an attempt to satisfy its burden to explain why the Specification's disclosures are insufficiently representative of the full scope of claim 14, Petitioner cites Dr. Klibanov's testimony. Pet. 58−62 (citing Ex. 1002 ¶¶ 240−249). We have discussed this testimony above as Petitioner also relied upon it for its case for lack of enablement. *See*, *e.g.*, Req. Reh'g. 13. Dr. Klibanov's testimony that is specific to claim 14 is limited, but he characterizes claim 14 as "encompass[ing] a similar number of possible

formulations as in claim 7, because claim 14 does not specify the detergent, tonicity agent, or optional buffer, or their respective concentrations." Ex. 1002 ¶ 270. Dr. Klibanov's testimony regarding those problems refer in part to broader classes of components (e.g., antibodies and fragments) that do not apply to claim 14. We agree with Patent Owner that the specification describes various components with structural features (i.e., the buffer, tonicity agent, and risankizumab), provides illustrated pharmaceutical ranges of the claimed compositions, and further provides working examples demonstrating testing composition stability and two exemplary formulations that match the limitations of claim 7 and dependent claim 14. Ex. 1001, 22:4–7; 83:10–84:19; 92:22–94:35.

With regard to the cases Petitioner cites in support of its reasoning that we applied the wrong standard in our written description analysis, we are unpersuaded that the facts and reasoning of those cases should alter the outcome here. Petitioner's citation to the holding in *Juno* (Req. Reh'g. 11–13) as an example of unsupported written description is distinguishable here based on the scope of the claims at issue. In *Juno*, the claims were directed to a nucleic acid polymer encoding three separate nucleic acid regions with only one of the nucleic acid regions specified by a sequence ID, and where the other two nucleic acid regions were undefined. 10 F.4th at 1338–39. The court found that the fact the target binding region (one of the three required nucleic acid regions) was undefined was a significant factor in the written description analysis. *Id.* The court noted the specification did not disclose structural features common to specific binding targets or a way to distinguish them. *See*, *e.g.*, *id.* at 1338:

> To satisfy written description, however, the inventors needed to convey that they possessed the claimed invention, which

> encompasses all scFvs, known and unknown, as part of the claimed CAR that bind to a selected target. Even accepting that scFvs were known and that they were known to bind, the specification provides no means of distinguishing which scFvs will bind to which targets.

This is not the case here, where the sole antibody recited in the claim has a defined sequence and the specification includes representative examples of that antibody's stability in solution. Ex. 1001 92:45–46; 93:11–13, 94:2–4. Specimens of the remaining formulation components were known in the industry along with methods for evaluating them, as Dr. Klibanov acknowledges. *See*, *e.g.*, Ex. 1002 ¶¶ 46–49 (describing an ordinary artisan's knowledge of then-available detergents and buffers).

Petitioner's citation to *AbbVie* (Req. Reh'g. 11–12, citing 759 F.3d at 1299, 1301) is similarly unpersuasive as the cited language merely states the written description requirement for genus claims, which we have previously addressed. Petitioner's citation to *Ariad* (Req. Reh'g. 11, citing 598 F.3d at 1352–53) is likewise unhelpful as the cited portion of *Ariad* discusses cases not applicable to the facts presented here. For example, *Ariad* discusses cases where "the specification did not describe any specific compound capable of performing the claimed method and the skilled artisan would not be able to identify any such compound based on the specification's function description." As described above, that is not the case here, where the claim recites a particular antibody with identified heavy and light chain sequences, and we are unpersuaded that our holding was in error.

IV. CONCLUSION

Petitioner does not persuade us that we overlooked or misapprehended any matter or that not instituting a post-grant review of

claims 7−10, 14−16, 19−22, and 27−28 of the ’265 patent was otherwise an abuse of discretion.

V. ORDER

It is

ORDERED that Petitioner’s Request for Rehearing is denied.

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