

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CHARLES RIVER LABORATORIES, INC.,
Petitioner,

v.

SEIKAGAKU CORPORATION,
Patent Owner.

IPR2025-00440
Patent 11,236,318 B2

Before MICHAEL J. FITZPATRICK, SUSAN L. C. MITCHELL,
TAWEN CHANG, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*, Additional Views.

CHANG, *Administrative Patent Judge*.

PRELIMINARY GUIDANCE
PATENT OWNER'S MOTION TO AMEND
37 C.F.R. § 42.121(e)

I. INTRODUCTION

On September 9, 2025, we instituted trial as to claim 21 of U.S. Patent No. 11,236,318 B2 (“the ’318 patent,” Ex. 1001). Paper 14 (“Institution Decision” or “Dec.”). After institution, Patent Owner filed a Motion to Amend that is contingent on the patentability of claim 21. Paper 27 (“Motion” or “Mot.”). Petitioner filed an opposition to Patent Owner’s Motion. Paper 33 (“Opposition” or “Opp.”).

In the Motion, Patent Owner requests that we provide preliminary guidance concerning the Motion in accordance with 37 C.F.R. § 42.121(a)(1)(ii). Mot. 1; *see* 37 C.F.R. § 42.121(e)(1); *see also Rules Governing Motion to Amend Practice and Procedures in Trial Proceedings under the America Invents Act before the Patent Trial and Appeal Board*, 89 Fed. Reg. 76,421 (Sept. 18, 2024) (“Final Rule”). We have considered Patent Owner’s Motion and Petitioner’s Opposition.

In this Preliminary Guidance, we provide information indicating our initial, preliminary, non-binding views on whether Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend in an *inter partes* review and whether Petitioner establishes a reasonable likelihood that the substitute claim is unpatentable. 37 C.F.R. §§ 42.121(e)(1), (2); *see also* 35 U.S.C. § 316(d) (statutory requirements for a motion to amend); 37 C.F.R. §§ 42.121(a)(2), (a)(3), (b) (regulatory requirements and burdens for a motion to amend); *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 (PTAB Feb. 25, 2019) (precedential) (providing information and guidance regarding motions to amend). The reasonable likelihood standard this Preliminary Guidance applies is different from the preponderance of the evidence standard applied when ultimately deciding the Motion. *Compare* 37 C.F.R. § 42.121(e)(1), *with* 37 C.F.R. § 42.121(d). Finally, this Preliminary

Guidance is not a “decision” for purposes of rehearing under 37 C.F.R. § 42.71(d). 37 C.F.R. § 42.121(e)(2).

For purposes of this Preliminary Guidance, we focus on the proposed substitute claim, and specifically on the amendments proposed in the Motion. *See* 37 C.F.R. § 42.121(e)(1); Final Rule, 89 Fed. Reg. at 76,425. We do not address patentability of the originally challenged claim. *See id.* Moreover, in formulating our preliminary views on the Motion and Opposition, we have not considered the parties’ other substantive papers on the underlying merits of Petitioner’s challenges. We emphasize that the views expressed in this Preliminary Guidance are subject to change upon consideration of the complete record, including any revision to the Motion filed by Patent Owner. Thus, this Preliminary Guidance is not binding on the Board when rendering a final written decision or any other subsequent decision in this proceeding. 37 C.F.R. § 42.121(e)(2); *see Medytox, Inc. v. Galderma S.A.*, 71 F.4th 990, 1000 (Fed. Cir. 2023).

II. PRELIMINARY GUIDANCE

A. Statutory and Regulatory Requirements

Patent Owner bears the ultimate burden to show that its motion to amend complies with the requirements of 35 U.S.C. §§ 316(d)(1) and (3) and 37 C.F.R. §§ 42.121(a)(2), (a)(3), (b)(1), and (b)(2). 37 C.F.R. § 42.121(d)(1). For the reasons discussed below, at this stage of the proceeding, and based on the current record, it appears that Patent Owner has not shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend. *See* 37 C.F.R. § 42.121(e)(1).

1. Reasonable Number of Substitute Claims

A motion to amend must propose a reasonable number of substitute claims. 35 U.S.C. § 316(d)(1)(B); 37 C.F.R. § 42.121(a)(3).

Patent Owner proposes to substitute claim 22 for claim 21 if claim 21 is found to be unpatentable. Mot 1–2, App. A-1. The proposed one-to-one substitution is reasonable. *See* 37 C.F.R. § 42.121(a)(3) (“The presumption is that only one substitute claim would be needed to replace each challenged claim, and it may be rebutted by a demonstration of need”).

2. Respond to Ground of Unpatentability

A motion to amend must respond to a ground of unpatentability involved in the proceeding. 37 C.F.R. § 42.121(a)(2)(i).

Patent Owner asserts that proposed substitute claim 22 “responds to Petitioner’s arguments that claim 21 of the ’318 Patent is not entitled to its December 10, 2013 priority date.” *See* Mot. 3. Patent Owner contends the “amendment[s] . . . narrow[] the residual activity limitations to overcome the priority date challenge, thus rendering Petitioner’s unpatentability Grounds 1 and 2 moot because the relied upon references are not prior art.” *Id.*

Petitioner does not dispute Patent Owner’s proposed amendments attempt to respond to a ground of unpatentability. *See generally* Opp. Petitioner asserts, however, that substitute claim 22 “would still have been obvious over the prior art at issue in the two instituted Grounds . . . of this trial.” Opp. 6–24.

Based on our review of the current record, it appears that Patent Owner has met the requirement to respond to a ground of unpatentability, by amending claim 21 to address Petitioner’s arguments regarding priority date based on the residual activity ranges recited in claim 21. We note, however, that Patent Owner’s proposed amendments do not address Petitioner’s priority arguments

based on the particular horseshoe crab species (*L. polyphemus*) recited in claim 21, or the substance of Petitioner's obviousness grounds to the extent the references cited in the grounds are determined to be prior art.

3. Scope of Amended Claim

A motion to amend may not enlarge the scope of the claims of a patent. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii). Patent Owner's proposed substitute claim 22 is reproduced below as presented in Appendix A to the Motion, with "[u]nderlining indicat[ing] proposed additions to the original claim 21 and double brackets indicat[ing] proposed deletions from the original claim 21." Mot. (App'x A-1).

Claim 22. [Propose substitute for claim 21] A horseshoe crab Factor C protein having activity of Factor,

wherein the horseshoe crab is *Limulus polyphemus*, and wherein the horseshoe crab Factor C protein is produced through being recombinantly expressed from a Human Embryonic Kidney (HEK) 293 cell, and

wherein the Factor C protein exhibits a higher residual activity [[of at least one selected from the group consisting of:]]

[[(1) 10% or higher in the presence of 21 mM sodium citrate; and]]

[[(2) 15% or higher in the presence of 16 mM magnesium sulfate]] in the presence of 21 mM sodium citrate and 16 mM magnesium sulfate, as compared with the corresponding *Limulus polyphemus* Factor C protein expressed in a Sf9 cell or a native *Limulus polyphemus* Factor C protein.

Id.

Patent Owner asserts that the proposed amendments do not broaden the scope of claim 21 because proposed substitute claim 22 requires that "the Factor C protein exhibit a 'higher' residual activity in the presence of both 21 mM sodium citrate and 16 mM magnesium sulfate, as opposed to the original claim 21 that only

required a certain residual activity in one of these salt solutions.” Mot. 3–4. Patent Owner also contends “substitute claim 22 further narrows the scope of the claim by incorporating a specific comparator for the residual activity . . . as compared to original claim 21 that required a residual activity over a claimed minimum threshold.” *Id.* at 4.

Petitioner responds that Patent Owner’s proposed substitute claim 22 broadens claim 21 by deleting the closed phrase “consisting of” and by removing the fixed lower ends of the claimed ranges for the residual activity in the recited ionic solutions. Opp. 1–6. Petitioner contends deleting the phrase “consisting of” “converts the closed limitation requiring that either of the residual activity requirements is met to an open[-]ended claim that requires the two noted residual activity requirements to be met, plus any other requirements as well.” *Id.* at 3 (emphasis omitted). Petitioner also argues that removing the fixed lower ends “allows for recombinant Factor C proteins that would infringe substitute claim 22, where the same proteins would not have infringed original claim 21.” *Id.* at 2.

On the current record, it appears that Patent Owner’s proposed amendment may enlarge the scope of claim 21. The proposed amendments replace the fixed lower limits of recited residual activities in claim 21 with limits based on the residual activities of comparator Factor C proteins. *See* Mot. App. A-1. As Petitioner argues, Patent Owner has not demonstrated that proposed substitute claim 22 would not read on any recombinant HEK293 *L. polyphemus* Factor C proteins with residual activity lower than 10% in the presence of 21 mM sodium citrate and lower than 15% in the presence of 16 mM magnesium sulfate. Such proteins would be outside the scope of claim 21 but could be within the scope of substitute claim 22, depending on the residual activities of the comparator Factor C proteins and recombinant HEK293 *L. polyphemus* Factor C protein in the presence

of a combination of 21 mM sodium citrate and 16 mM magnesium sulfate.

Opp. 1–6.¹ In other words, it is not clear on the present record whether substitute claim 22’s limits based on the residual activities of comparator Factor C proteins are narrower, *in all respects*, than the fixed lower limits of recited residual activities in claim 21. *Cf. Tillotson, Ltd. v. Walbro Corp.*, 831 F.2d 1033, 1037 n.2 (“A reissue claim that is broader in any respect is considered to be broader than the original claims even though it may be narrower in other respects.”).

4. New Matter

A motion to amend may not introduce new subject matter. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii).

In relevant part, and as noted above, the amendments in proposed substitute claim 22 recite: “wherein the Factor C protein exhibits a higher residual activity . . . in the presence of 21 mM sodium citrate and 16 mM magnesium sulfate, as compared with the corresponding *Limulus polyphemus* Factor C protein expressed in a Sf9 cell or a native *Limulus polyphemus* Factor C protein.” Mot. App. A-1.

Patent Owner contends proposed substitute claim 22 does not introduce new subject matter because the claim is supported by the specification of the ’318 patent and U.S. Patent Application No. 14/650,767 (the “’767 application,” Ex. 1006), which published as U.S. Patent Application Publication No.

¹ However, it does not appear that removing the phrase “consisting of” enlarges the scope of the claim as Petitioner asserts. Opp. 3. This is so because the *Markush* group of claim 21, to which the phrase “consisting of” applies, is not present in claim 22.

2015/0307864 A1 (“Mizumura,” Ex. 1009).² Mot. 4–6. Patent Owner asserts that the ’318 patent specification supports the amendments because it:

- (1) “explains that the ‘Factor C of the . . . invention may have low susceptibility to inhibition of activity by an ion’ and that this ‘refers to the state that the Factor C . . . exhibits a high residual activity in the presence of an ion’”;
- (2) “identifies recombinant Factor C expressed in insect cell Sf9 and native Factor C . . . as examples of . . . control Factor C”;
- (3) “identifies salt solutions to measure the residual activity, including the claimed 21 mM sodium citrate and 16 mM magnesium sulfate, and . . . further states the ‘Factor C of the . . . invention may have any one of the above properties singly or two or more of the above properties in combination’”; and
- (4) “demonstrates that recombinantly produced Factor C in HEK293 cells exhibited higher residual activity in each of 21 mM sodium citrate and 16 mM magnesium sulfate as compared to a control factor C of native Factor C (TAL) or Factor C recombinantly produced in Sf9 cells.”

Mot. 4–5 (citing Ex. 1001, 4:5–9, 4:21–25, 17:20–24, 17:31–18:38, 35:25–43, Figs. 4, 7).

Petitioner contends substitute claim 22 adds new matter by “introducing [the] unknown and undescribed relationship” between residual activities of recombinant HEK293 *L. polyphemus* Factor C proteins and native or recombinant Sf9 *L. polyphemus* Factor C proteins. Opp. 9. Petitioner also argues that substitute claim 22 lacks written description support. Opp. 8–21. We address these

² It appears undisputed that the specification of the ’318 patent is largely identical to the specification of the ’767 application. See Mot. 4, n.1; Pet. 21–22.

arguments below in our preliminary guidance regarding the patentability of the substitute claim. For the same reasons it appears that Petitioner has demonstrated a reasonable likelihood that proposed substitute claim 22 is unpatentable for lack of adequate written description, it also appears, on this record, that Patent Owner fails to show a reasonable likelihood that substitute claim 22 introduces no new matter relative to the original disclosure.

B. Patentability³

Petitioner bears the ultimate burden to show that any proposed substitute claims are unpatentable. 37 C.F.R. § 42.121(d)(2). For the reasons discussed below, based on the current record, it appears that Petitioner has demonstrated a reasonable likelihood that proposed substitute claim 22 is unpatentable. *See* 37 C.F.R. § 42.121(e)(1).

1. Indefiniteness

Petitioner asserts that proposed amendment, “wherein the Factor C protein exhibits a higher residual activity . . . in the presence of 21 mM sodium citrate and 16 mM magnesium sulfate,” is indefinite. Opp. 24–25. Petitioner contends this claim language is indefinite because it may mean that the residual activity of the claimed Factor C protein is higher in the presence of each of 21 mM sodium citrate

³ Because enablement and sufficiency of written disclosure are determined as of the effective filing date, the patentability analysis with respect to substitute claim 22 may be impacted by our final priority date determination. Nevertheless, because both parties address whether substitute claim 22 is adequately described and enabled by the ’767 application rather than the ’318 patent specification, and because Patent Owner appears to assert an effective filing date of December 10, 2013 for purposes of the Motion (other than with respect to secondary considerations of non-obviousness), we refer to the ’767 application, rather than the ’318 patent specification, in our preliminary guidance regarding written description and enablement.

and 16 mM magnesium sulfate, or in the presence of a combination of 21 mM sodium citrate and 16 mM magnesium sulfate. *Id.* at 25.

Petitioner argues that proposed claim 22 is indefinite under either the standard set forth in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014), or *In re Packard*, 751 F.3d 1307 (Fed. Cir. 2014). Binding USPTO guidance directs the Board to “use the approach set forth by the Supreme Court in *Nautilus* . . . for assessing questions of indefiniteness in AIA post-grant proceedings.” USPTO Memorandum, “Approach to Indefiniteness under 35 U.S.C. § 112 in AIA Post-Grant Proceedings” (Jan. 6, 2021), 1–2.⁴ Accordingly, we provide preliminary guidance as to whether Petitioner has established a reasonable likelihood that substitute claim 22, “read in light of the specification . . . , and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus*, 572 U.S. at 901.

On the current record, it appears that Petitioner has not established a reasonable likelihood that substitute claim 22 is indefinite. In particular, it appears that, read in light of the specification and prosecution history, substitute claim 22 informs those skilled in the art, with reasonable certainty, that the claimed recombinant HEK293 *L. polyphemus* Factor C protein exhibits higher residual activity in the presence of a *combination* of 21 mM sodium citrate and 16 mM magnesium sulfate, as compared to the recited comparator Factor C proteins.

As noted below, however, it also appears that Petitioner has established a reasonable likelihood that substitute claim 22, so construed, lacks adequate written description and introduces new matter.

⁴ Available at <https://www.uspto.gov/guidance>.

2. Written Description

Petitioner asserts that substitute claim 22 lacks adequate written description support for the proposed amendment that the claimed recombinant HEK293 *L. polyphemus* Factor C protein “exhibits a higher residual activity in the presence of 21 mM sodium citrate and 16 mM magnesium sulfate, as compared with the corresponding *Limulus polyphemus* Factor C protein expressed in a Sf9 cell or a native *Limulus polyphemus* Factor C protein.” Opp. 8–21.

For the reasons discussed below, it appears Petitioner has demonstrated a reasonable likelihood that substitute claim 22 lacks adequate written description.

As an initial matter, the parties disagree as to whether the disclosure in the ’767 application relating to *T. tridentatus* Factor C proteins reasonably conveyed to an ordinarily skilled artisan that the inventor had possession of the claimed subject matter — which relates to the Factor C proteins of *L. polyphemus*, a different horseshoe crab species — when considered in view of the knowledge available in the art as of the priority date asserted by Patent Owner. Opp. 8–21; Mot. 7–11. This dispute implicates substantially the same issues and evidence the parties have raised with respect to claim 21. *See, e.g.*, Pet. 22–31; Paper 26, 11–19, 21–27; Reply Br. 8–20. Because we do not address patentability of the originally challenged claim in this Preliminary Guidance, *see* Final Rule, 89 Fed. Reg. at 76,425, we will provide our determination on this dispute in our final written decision after consideration of all of the available evidence, and do not further address it here.

Petitioner further argues that substitute claim 22 lacks written description support if it “is interpreted to mean that the claimed recombinant Factor C have a higher residual activity than the comparator protein in a solution that has both 21 mM sodium citrate and 16 mM magnesium sulfate.” Opp. 21 (emphasis

omitted). Petitioner argues that the '767 application does not describe a solution containing both salts, and does not disclose testing a Factor C protein in such a solution. *Id.*⁵

On the current record, and without Patent Owner's response to this specific argument, it appears that Petitioner has demonstrated a reasonable likelihood that substitute claim 22 lacks adequate written description, because the '767 application does not appear to disclose the residual activity of any Factor C protein in a single solution containing *both* 21 mM sodium citrate and 16 mM magnesium sulfate.

3. Enablement

Petitioner asserts that proposed substitute claim 22 is unpatentable as lacking enablement for the same reasons discussed in the Petition with respect to claim 21. Opp. 22–23 (citing Pet. 35–45; Ex. 1002 ¶¶ 105–08, 119–26, 131–38, 140–46). In addition, Petitioner argues that the proposed amendment in substitute claim 22 covers recombinant HEK293 *L. polyphemus* Factor C proteins with residual activities “as low as any value slightly higher” than that of recombinant HEK293 *L. polyphemus* Factor C or the native *Limulus polyphemus* protein, or “as high as any unbound upper value that still surpasses the Sf9 or native values.” *Id.* at 22.

Petitioner asserts that

none of the '767 Application, PO, nor its experts, has any explanation for a POSA about how to produce such proteins at the lower end of this range, at the middle points of the range, or at the highest points of this range, nor is there any explanation

⁵ Patent Owner asserts that “any argument by Petitioner that the substitute claim 22 language requires possession of a wide range of residual activities . . . fails.” Mot. 10–11. Petitioner does not appear to have made this argument with respect to a lack of written description. Petitioner argues, however, that the '77 application does not enable the full scope of substitute claim 22. We discuss this argument below.

for how to produce such proteins falling with the range as distinct from those falling outside of it.

Id. at 22. Petitioner cites *Magsil* and *Epistar* in support of its argument. *Magsil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1379 (Fed. Cir. 2012); *Epistar Corp. v. Lowes Cos, Inc.* 2020 WL 771096 (C.D. Cal. Feb. 11, 2020).

Patent Owner contends the '767 application enables proposed substitute claim 22. Mot. 11–17. In support of its argument, Patent Owner addresses the factors discussed in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Mot. 11–17.

Most of the parties' arguments focus on whether the '767 application enables making and using *L. polyphemus* Factor C protein generally. Because this issue is identical for both claim 21 and substitute claim 22, we will provide our determination on this dispute in our final written decision and do not further address it here.

With respect to the proposed amendments, Patent Owner argues that, “[t]o the extent the Board agrees with Petitioner that claim 21 as originally written requires residual activity values across a wide claimed range, . . . substitute claim 22 removes that requirement by merely requiring a comparative analysis that the inventive Factor C’s residual activity be **higher** than the residual activity in control Factor C.” Mot. 11–12.

Having reviewed the parties' arguments, it appears that proposed amendment may not implicate the same enablement concerns as the residual activity limitations in claim 21.

The cases cited by Petitioner appear to be inapposite. In particular, in *Magsil* and *Epistar* the claim limitations at issue were, respectively, “a change in resistance of at least 10%,” and “wherein the light-emitting structure has a light output power of more than 4 mW at 20mA current.” *Magsil Corp. v. Hitachi*

Global Storage Techs., Inc., 687 F.3d 1377, 1379 (Fed. Cir. 2012); *Epistar Corp. v. Lowes Cos, Inc.* 2020 WL 771096 (C.D. Cal. Feb. 11, 2020). In both cases, therefore, the claim limitation recited a particular level of a property (i.e., change in resistance and light output power, respectively). In *Magsil*, moreover, the claim term was expressly construed to cover “resistance changes beyond 120% and up to infinity.” *Magsil*, 687 F.3d at 1381.

Substitute claim 22, however, recites a “higher residual activity” as compared to *L. polyphemus* Factor C protein expressed in a Sf9 cell or a native *L. polyphemus* Factor C protein, without reciting a particular level or percentage of residual activity that must be achieved.

The proposed substitute claim 22 thus appears closer to the claim in *Alcon*, which involved a method of “enhancing the chemical stability” of the recited composition by adding a “chemically-stabilizing amount” of an ingredient. *Alcon Rsch. Ltd. v. Barr Lab ’ys, Inc.*, 745 F.3d 1180, 1184 (Fed. Cir. 2014). In reversing the district court’s determination that the claim was not enabled, the Federal Circuit held in that case that no undue experimentation was required to practice the claim where the claims “merely require . . . some increase in . . . stability, but do not require a particular level of stability or a particular magnitude of increase,” and where the disclosure details how compositions within the scope of the claims are prepared from commercially-available ingredients” and “step-by-step procedures for adding [the ingredient] to [the compositions] in a way that embodies the claimed invention.” *Id.* at 1189.

As noted above, however, we have not considered, for purpose of this Preliminary Guidance, whether substitute claim 22 may be unpatentable for lack of enablement in other respects — e.g., because the ’767 application does not enable an ordinarily skilled artisan to practice the claim with respect to the claimed

horseshoe crab species *L. polyphemus* — for the same reasons explained in our Institution Decision with respect to claim 21.

4. Obviousness

Petitioner asserts that proposed substitute claim 22 is unpatentable because it would have been obvious over the prior art references applied in the Petition against claim 21 for the same reasons. Opp. 1, 6, 23–24.

Patent Owner asserts that the proposed amendments “overcome the priority date challenge,” thus mooting Petitioner’s obviousness challenges by rendering the relied upon references unavailable as prior art. Mot. 3, 7. For the reasons discussed above with respect to written description and enablement, it appears Petitioner has established a reasonable likelihood that the references relied on for its obviousness challenges in the Petition are also available as prior art to substitute claim 22. See 35 U.S.C. § 120 (explaining that a patent application is entitled to assert priority to the filing date of a prior application “for an invention disclosed [in the prior application] in the manner provided by [35 U.S.C. §] 112(a) (other than the requirement to disclose the best mode)”).

Patent Owner further contends that, even if substitute claim 22 is not entitled to a December 10, 2013 priority date, secondary considerations support the non-obviousness of substitute claim 22, because *L. polyphemus* Factor C protein “exhibits unexpectedly superior residual activity values in the claimed 21 mM sodium citrate and 16 mM magnesium sulfate solutions as compared to the residual activity observed for Factor C from *Tachypleus tridentatus*.” *Id.* at 18.

Patent Owner’s arguments on unexpected results appear to be identical for claim 21 and substitute claim 22. Opp. 23–24. Patent Owner has not explained how its unexpected results evidence may apply differently based on the proposed amendment. For example, Patent Owner does not argue that its unexpected results

evidence bears a stronger nexus to, or is more commensurate with the scope of, claim 22 than claim 21. *See Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (“[E]vidence of secondary considerations must have a ‘nexus’ to the claims, i.e., there must be ‘a legally and factually sufficient connection’ between the evidence and the patented invention.”); *In re Dill*, 604 F.2d 1356, 1361 (CCPA 1979) (“The evidence presented to rebut a *prima facie* case of obviousness must be commensurate in scope with the claims to which it pertains.”). Because we do not, in a preliminary guidance, express a view on the patentability of original claims, we decline to provide our preliminary views on the merits of Patent Owner’s evidence and arguments with respect to secondary considerations in this Preliminary Guidance.

Accordingly, for the reasons discussed above, and without taking into account Patent Owner’s evidence and arguments with respect to secondary considerations, it appears based on the current record that Petitioner has demonstrated a reasonable likelihood that claim 22 would have been obvious over the prior art references applied in the Petition for the reasons discussed in the Institution Decision.

III. CONCLUSION

This concludes our Preliminary Guidance. Patent Owner has the option to reply to this Preliminary Guidance *or* to file a revised motion to amend (“MTA”) by DUE DATE 3. 37 C.F.R. §§ 42.121(e)(3), (f); Papers 15, 30. Patent Owner’s reply or revised MTA may only respond to this Preliminary Guidance or Petitioner’s Opposition and may be accompanied by new evidence (including declarations). 37 C.F.R. § 42.121(e)(3). Petitioner has the option to file a sur-reply responsive to this Preliminary Guidance, Patent Owner’s reply, or Patent Owner’s revised MTA but may not present new evidence in any case. 37 C.F.R.

§ 42.121(e)(3). Petitioner may also file a reply to the preliminary guidance in the case Patent Owner does not file a reply or revised MTA. 37 C.F.R. § 42.121(e)(4).

In addition, Patent Owner is reminded that amendments of the challenged claim may also be pursued in a separate reissue or reexamination proceeding before, during, or after an AIA trial proceeding, including subsequent to the issuance of the Final Written Decision. We draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. §§ 42.8(a)(3), (b)(2).

FITZPATRICK, *Administrative Patent Judge*, Additional Views.

The instant Order is not a decision by the panel, but rather a statement of the panel's guidance. I write separately to provide additional guidance regarding the prohibition against enlargement of claim scope. *See* 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii).

To obviate any concern that claim 22 may capture subject matter outside the scope of claim 21, I suggest not omitting any limitations recited in claim 21 from the proposed substitute claim. In other words, I suggest preserving the limitation of claim 21 reciting “wherein the Factor C protein exhibits a residual activity of at least one selected from the group consisting of: (1) 10% or higher in the presence of 21 mM sodium citrate; and (2) 15% or higher in the presence of 16 mM magnesium sulfate” and *additionally recite* the further limitation reciting “wherein the Factor C protein exhibits a higher residual activity in the presence of 21 mM sodium citrate and 16 mM magnesium sulfate, as compared with the corresponding *Limulus polyphemus* Factor C protein expressed in a Sf9 cell or a native *Limulus polyphemus* Factor C protein.”

IPR2025-00440

11,236,318 B2

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