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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ADELLO BIOLOGICS LLC,
APOTEX INC. and APOTEX CORP.,
Petitioners,

v.

AMGEN INC. and AMGEN MANUFACTURING LIMITED
Patent Owner.

Case PGR2019-00001
Patent No. 9,856,287 B2

Before ZHENYU YANG, CHRISTOPHER G. PAULRAJ, and J. JOHN LEE, *Administrative Patent Judges.*

YANG, *Administrative Patent Judge*.

DECISION
Institution of Post-Grant Review
35 U.S.C. § 324(a)

INTRODUCTION

Adello Biologics, LLC, Apotex Inc., and Apotex Corp. (collectively "Petitioners") filed a Petition (Paper 3, "Pet."), requesting a post-grant review of claims 1–30 of U.S. Patent No. 9,856,287 B2 (Ex. 1001, "the '287 patent"). Amgen Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 8 ("Prelim. Resp.").

We review the Petition under 35 U.S.C. § 324, which provides that a post-grant review may not be instituted unless "it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 324(a). On April 24, 2018, the Supreme Court held that a decision under 35 U.S.C. § 314 may not institute review on fewer than all claims challenged in the petition.[1] *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355–56 (2018). Moreover, "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." *See* Guidance on the Impact of *SAS* on AIA Trial Proceedings (April 26, 2018) ("USPTO Guidance," available at https://www.uspto.gov/patents-application-process/patent-trial-and-appealboard/trials/guidance-impact-sas-aia-trial).

For the reasons provided below, we determine that Petitioners have satisfied the threshold requirement under § 324. Thus, based on the information presented, and under *SAS* and USPTO Guidance, we institute a post-grant review of claims 1–30 of the '287 patent.

[1] Even though *SAS* addresses *inter partes* reviews, we see no reason to interpret the statute governing post-grant reviews differently.

Related Proceedings

According to the parties, the '287 patent is the subject of *Amgen Inc. v. Adello Biologics LLC*, Case No. 2:18-03347 (D.N.J.) and *Amgen Inc. v. Apotex Inc.*, Case No. 0:18-61828 (S.D. Fla). Pet. 3; Paper 4, 2.

The '287 Patent

The '287 patent issued on January 2, 2018, from U.S. Patent Application No. 15/422,327 ("the '327 application"), filed February 1, 2017. Ex. 1001, (21), (22), (45). On its face, the '287 patent claims priority to, among others, U.S. Application No. 12/820,087 ("the '087 application"), issued as U.S. Patent No. 8,952,138 (Ex. 1004, "the '138 patent").[2] *Id.* at 1:5–12.

The '287 patent discloses a method of refolding proteins expressed in non-mammalian cells. Ex. 1001, 2:62–64.

The '287 patent explains:

> Recombinant proteins can be expressed in a variety of expression systems, including non-mammalian cells, such as bacteria and yeast. A difficulty associated with the expression of recombinant proteins in prokaryotic cells, such as bacteria, is the precipitation of the expressed proteins in limited-solubility intracellular precipitates typically referred to as inclusion bodies.

Id. at 1:23–29.

Before the '287 patent, "various methods ha[d] been developed for obtaining correctly folded proteins from bacterial inclusion bodies." *Id.* at 1:41–43. Specifically, it was known that when cysteine residues are present in the protein sequence, "it is often necessary to accomplish the refolding in

[2] Previously, the Board concluded that claims 1–17 and 19–24 of the '138 patent are unpatentable. *Apotex Inc. v. Amgen Inc.*, IPR2016-01542, Paper 60 (PTAB Feb. 15, 2018).

an environment which allows correct formation of disulfide bonds (e.g., a redox system)." *Id.* at 1:53–57.

The '287 patent states that prior-art methods could not refold complex molecules, such as molecules comprising two or more disulfide bonds, at high concentrations, "with any meaningful degree of efficiency on a small scale, and notably not on an industrial scale." *Id.* at 1:58–60, 2:25–29. According to the '287 patent, the methods disclosed therein can refold proteins at high concentrations and at large scales, which translates into higher efficiencies and cost savings to a protein production process. *Id.* at 2:29–39.

Illustrative Claim

Among the challenged claims, claims 1, 10, 16, and 26 are independent. Claims 1 and 16 are illustrative. They read:

> 1. A method of refolding proteins expressed in a non-mammalian expression system, the method comprising:
>
> contacting the proteins with a preparation that supports the renaturation of at least one of the proteins to a biologically active form, to form a refold mixture, the preparation comprising:
>
> at least one ingredient selected from the group consisting of a denaturant, an aggregation suppressor and a protein stabilizer;
>
> an amount of oxidant;
>
> and an amount of reductant,
>
> wherein the amounts of the oxidant and the reductant are related through a thiol-pair ratio and a thiol-pair buffer strength,
>
> wherein the thiol-pair ratio is in the range of 0.001-100; and
>
> wherein the thiol-pair buffer strength maintains the solubility of the preparation; and

incubating the refold mixture so that at least about 25% of the proteins are properly refolded.

16. A method of refolding proteins expressed in a non-mammalian expression system, the method comprising:

preparing a solution comprising:

the proteins;

at least one ingredient selected from the group consisting of a denaturant, an aggregation suppressor and a protein stabilizer;

an amount of oxidant;

and an amount of reductant,

wherein the amounts of the oxidant and the reductant are related through a thiol-pair ratio and a thiol-pair buffer strength,

wherein the thiol-pair ratio is in the range of 0.001-100; and

wherein the thiol-pair buffer strength maintains the solubility of the solution; and

incubating the solution so that at least about 25% of the proteins are properly refolded.

Each of claims 10 and 26 requires that "about 30–80% of the proteins are properly refolded." They are otherwise similar to claims 1 and 16, respectively.

Prosecution History

"At Least About 25% of the Proteins Are Properly Refolded"

Each of claims 1 and 16 recites "at least about 25% of the proteins are properly refolded." This language does not appear in any application in the priority chain. Instead, in a preliminary amendment filed on February 2, 2017, the applicant added new claims including the language "wherein the thiol-pair ratio and the thiol-pair buffer strength yield at least about 25% properly refolded protein." Ex. 2008, 82. The applicant later amended the

claims to recite "wherein the thiol-pair ratio and the thiol-pair buffer strength are such that incubating the refold mixture achieves consistent yields of at least about 25% properly refolded proteins." *Id.* at 153.

The examiner rejected the new claims "under 35 U.S.C. § 112, first paragraph, as containing new matter which was not described in the specification." *Id.* at 844. Specifically, the examiner stated that "[t]he specification or the original claims as filed does not provide a written description the phrase '. . . refold mixture achieves consistent yield of at least 25% properly refolded proteins.'" *Id.* The examiner also rejected the new claims for "nonstatutory obviousness-type double patenting as being unpatentable over claims 1–24" of the '138 patent. *Id.* at 843.

In response, the applicant filed a terminal disclaimer to obviate the double-patenting rejection over the '138 patent. *Id.* at 900–01. The applicant also amended the claims to recite "incubating the refold mixture so that at least about 25% of the proteins are properly refolded." *Id.* at 876, *see also id.* at 880 (adding new claim reciting "incubating the solution so that at least about 25% of the proteins are properly refolded").

The applicant further argued that "[t]he specification provides support for claimed subject matter." *Id.* at 885. According to the applicant, "Figures 1A–1F represent a series of experiments where thiol pair buffer strength and thiol-pair ratio were varied and the % species distribution (y-axis) was determined. In each case, at least 25% properly refolded protein (solid lines) was achieved and was achieved on a consistent basis." *Id.* In addition, the applicant pointed out that "Example 3 describ[e]s protein refolding wherein approximately 30–80% properly refolded protein was obtained. Specifically, page 23 states that '[y]ields of desired product of

approximately 30–80% were obtained . . . depending on the redox condition evaluated.'" *Id.*

> Thereafter, the examiner allowed the claims, stating:
>
> Upon approval of the terminal disclaimer filed on 9/8/17, the nonstatutory obviousness type double patenting rejections have been withdrawn.
>
> . . . Further, the rejection under 35 U.S.C. 112 first paragraph has been withdrawn upon entry of response filed on 9/8/17. The support for the new matter rejection is found in p. 13, 23 and Fig 1A–F of the specification[.]

Id. at 911.

Prior Art

During prosecution, the examiner also rejected then-pending claims as obvious over the combination of Schlegl[3] and Hevehan,[4] two of the references asserted in this proceeding. Ex. 2008, 125–26. In response, the applicant argued that because "Schlegl discloses that redox chemicals are optional for refolding" of the purified model protein bovine α-LA,

> Schlegl fails to disclose that the amounts of the oxidant and the reductant are related through a thiol-pair ratio and a thiol-pair buffer strength. Also, Schlegl fails to disclose that the thiol-pair buffer strength maintains the solubility of the preparation and is effected based on a desired amount yield of properly refolded protein. Further, Schlegl fails to disclose that the thiol-pair ratio and the thiol-pair buffer strength are such that incubating the refold mixture achieves consistent yields of at least about 25% properly refolded proteins.

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[3] Schlegl, U.S. Patent Publication No. 2007/0238860, published October 11, 2007 (Ex. 1007).

[4] Hevehan and Clark, *Oxidative Renaturation of Lysozyme at High Concentrations*, 54 BIOTECHNOL BIOENG 221–30 (1997) (Ex. 1024).

Id. at 165. Hevehan, the applicant continued, does not overcome these deficiencies of Schlegl. *Id.*

The examiner agreed and, thus, withdrew the obviousness rejection. *Id.* at 842. In allowing the claims, the examiner stated that "the most pertinent prior art neither teaches nor suggests the final thiol-pair ratio or strength as set forth in [the] claims." *Id.* at 911.

Asserted Grounds of Unpatentability

Petitioners assert the following grounds of unpatentability:

1. claims 1–9 and 16–25 are unpatentable under 35 U.S.C. § 112 for lack of adequate written-description support;

2. claims 1–30[5] are unpatentable under 35 U.S.C. § 112 for lack of enablement;

3. claims 1–4, 7–19, and 22–30 are unpatentable under 35 U.S.C. § 102(a)(1) as anticipated by Vallejo;[6]

4. claims 1–4, 8–19, and 23–30 are unpatentable under 35 U.S.C. § 102(a)(1) as anticipated by Schlegl;

5. claims 7 and 22 are unpatentable under 35 U.S.C. § 103 as obvious over Schlegl and Vallejo;

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[5] Although the chart of the asserted grounds lists only claims 1–9 and 16–25 as not enabled, the text of the Petition addresses all challenged claims under this ground. *See* Pet. 33–36 (arguing lack of enablement for "about 30–80% of the proteins are properly refolded").

[6] Vallejo et al., European Patent Application Pub. No. EP1449848 A1, published August 25, 2004 (Ex. 1038).

6. claims 1–4, 7–19, and 22–30 are unpatentable under 35 U.S.C. § 103 as obvious over Ruddon[7] and Vallejo;

7. claims 5, 6, 20, and 21 are unpatentable under 35 U.S.C. § 103 as obvious over Vallejo and Hevehan; and

8. claims 1–15 are unpatentable under 35 U.S.C. § 112 for indefiniteness.

In support of their patentability challenge, Petitioners rely on the Declaration of Anne S. Robinson, Ph.D. Ex. 1002.

ANALYSIS

Real Party in Interest

Patent Owner argues that we should deny the Petition because Petitioners fail to—in the Petition—name Amneal Pharmaceuticals LLC ("Amneal LLC") as a real party in interest. Prelim. Resp. 7–16.

The Petition identifies, in addition to Petitioners, Amneal Pharmaceuticals, Inc. ("Amneal Inc."), Apotex Pharmaceuticals Holdings Inc., Apotex Holdings, Inc., ApoPharma USA, Inc., and Intas Pharmaceuticals Limited as real parties in interest. Pet. 2. Petitioners later sought to amend their mandatory notices to add Amneal LLC as a real party in interest without altering the petition filing date. Paper 9. Patent Owner opposed Petitioners' request. Paper 10. Because we found Petitioners' delay in identifying all real parties in interest did not result in undue prejudice against Patent Owner, we exercised our discretion under 37 C.F.R. § 42.5(b) to allow Petitioners to add Amneal LLC as a real party in interest

[7] Ruddon et al, International Publication No. WO 95/32216, published November 30, 1995 (Ex. 1040).

while maintaining the original filing date. Paper 11. Thereafter, Petitioners added Amneal LLC as a real party in interest. Paper 12. Thus, we decline to deny the Petition for delayed identification of a real party in interest.

35 U.S.C. § 325(d)

Patent Owner asks us to exercise our discretion and deny the Petition under 35 U.S.C. § 325(d). Prelim. Resp. 17–31. We decline to do so.

Under the statute, in determining whether to institute an *inter partes* review, we "may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d).

According to Patent Owner, "the written description and enablement arguments on which *Petitioners stake their entire argument for PGR standing* were previously considered by the original Examiner who allowed the claims of the '287 [patent]." Prelim. Resp. 17. We are not persuaded.

We acknowledge that an issue of whether there was sufficient written description was addressed during prosecution with respect to the limitation "to consistently yield at least about 25% properly refolded protein . . . refold mixtures achieves consistent yield of at least 25% properly refolded proteins." Ex. 2008, 844. But the issued claims of the '287 patent do not require a "consistent yield," and it is not clear from the prosecution history that the examiner sufficiently considered whether the broader language of the issued claims also satisfies the written description requirement.

Moreover, as Patent Owner acknowledges, "there was no express discussion of enablement during prosecution." Prelim. Resp. 23. And as explained below, based on the evidence included with the Petition (including expert declaration evidence that was not before the Examiner), Petitioners

have shown that it is more likely than not that they would prevail in the enablement challenge. Under the circumstances, we decline to deny institution under §325(d) based on the written-description and enablement arguments presented in the Petition.[8]

Patent Owner also contends that the prior art Petitioners assert in this proceeding, as well as the arguments based thereon, are either identical to or substantially the same as those already considered and rejected by the examiner. *Id.* at 24–31. We are not persuaded by this argument either.

We acknowledge that during prosecution, the examiner rejected then-pending claims as obvious over the combination of Schlegl and Hevehan. Ex. 2008, 125–26. But Patent Owner does not dispute that Ruddon was not cited, let alone considered, during prosecution. In addition, Vallejo asserted in this proceeding (Ex. 1038) was not cited during prosecution either. Patent Owner, however, argues that a similar reference by the same author (Ex. 1014) "***was*** considered and expressly acknowledged by the Examiner during prosecution of the '287 as part of an Information Disclosure Statement (IDS) by Amgen." Prelim. Resp. 26. The IDS, however, listed hundreds of references, and there is nothing of record to suggest that the Examiner considered Exhibit 1014 in particular in determining patentability. Ex. 2008, 135–150. Thus, under the circumstances, we do not consider the Examiner's mere acknowledgement of the IDS as a sufficient basis to warrant denial of institution under § 325(d). *See Becton-Dickinson*, slip op.

[8] The factors set forth in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, Case IPR2017-01586, Paper No. 8 (PTAB Dec. 15, 2007) (informative) ("*Becton-Dickinson*") are not relevant to our § 325(d) analysis here because they each focus on prior art considered during prosecution.

at 17 (identifying "the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection" among non-exclusive factors to be considered under § 325(d)).

Thus, under the circumstances of this case, we decline to deny the Petition under 35 U.S.C. § 325(d).

Level of Ordinary Skill

Petitioners propose that an ordinary artisan "would have at least a Bachelor's degree (or the equivalent) in biochemistry or chemical engineering with several years' experience in biochemical manufacturing, protein purification, and protein refolding, or alternatively, an advanced degree (Masters or Ph.D.) in biochemistry or chemical engineering with emphasis in these same areas." Pet. 14 (citing Ex. 1002 ¶¶ 18–19). Patent Owner does not dispute, and we adopt, for purposes of this Decision, Petitioners' proposed definition of level of skill.

We further note that, in this case, the prior art itself demonstrates the level of skill in the art at the time of the invention. *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 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)).

Eligibility for Post-Grant Review

The post-grant review provisions apply only to a patent that contains a claim with an effective filing date on or after March 16, 2013. *See* Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284

(2011), §§ 3(n)(1), 6(f)(2)(A). The statute defines the "effective filing date" as

> (A) if subparagraph (B) does not apply, the actual filing date of the patent or the application for the patent containing a claim to the invention; or
>
> (B) the filing date of the earliest application for which the patent is entitled, as to such invention, to a right of priority under section 119, 365(a), or 365(b) or to the benefit of an earlier filing date under section 120, 121, or 365(c).

35 U.S.C. § 100(i)(1).

Entitlement to the benefit of an earlier date under §§ 119, 120, 121, and 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 application for which the benefit of the earlier filing date is sought. *See* 35 U.S.C. §§ 119(e), 120.

The '287 patent issued from the '327 application, filed February 1, 2017. Ex. 1001, (22). On its face, the '287 patent claims priority to two pre-2013 applications: a provisional application filed on June 22, 2009, and the '087 application, filed June 21, 2010, which issued as the '138 patent. *Id.* at 1:5–12. Petitioners argue that "at least claims 1–9 and 16–25 were not fully disclosed until added via amendments to the claims of the ['']287 patent application, and claims 1–30 were not enabled." Pet. 26. As a result, Petitioners conclude that the challenged claims "are not entitled to claim priority to any application with a filing date prior to March 16, 2013, the critical date for the AIA, and the ['']287 Patent is eligible for post-grant review." *Id.* at 24–25. Based on the current record, and for the reasons

below, we determine Petitioners have sufficiently established that it would prevail in this assertion.[9]

The written-description inquiry is a question of fact, is context-specific, and must be determined on a case-by-case basis. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). 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). Of course, in some instances, a patentee can rely on information that is well known in the art to satisfy the written-description requirement. *Ariad Pharm.*, 598 F.3d at 1351 ("[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.").

Each of independent claims 1 and 16 recites "at least about 25% of the proteins are properly refolded." Petitioners point out that "[t]his claim language, or even the range of 'at least about 25%,' does not appear anywhere in the [']138 patent specification, or the specifications of the intervening priority applications." Pet. 28. Indeed, as explained earlier, this language was added after February 1, 2017, the filing date of the '327 application. Ex. 2008, 82, 153, 876, 880. During prosecution, when the examiner rejected the language "at least 25% properly refolded proteins" in

[9] Either insufficient written description or non-enablement would render the '287 patent eligible for post-grant review. We focus our analysis of review eligibility on written description, and discuss non-enablement later in analyzing the patentability of the challenged claims.

the then-pending claims as new matter, the applicant argued that Figures 1a–1f and Example 3 provided written-description support. *Id.* at 885.

Petitioners contend that the figures fail to provide adequate support for the full scope of claims 1 and 16. Pet. 18. According to Petitioners, in Figures 1a–1f of the '138 patent,[10] the percentage of properly refolded protein species, which the applicant argued is represented by the solid lines, "never rises above about 35%, and in fact is often lower than 25%." *Id.* at 29.

Examples 3 and 4 of the '138 patent disclose refolding yields of "approximately 30–80%" and "approximately 27–35%," respectively. Ex. 1004, 15:8–10, 64–65. Petitioners argue that even so, the priority applications do not provide support for the full scope of "at least about 25%" because they "provide no disclosure for any percentages of properly refolded protein over 80%." Pet. 30.

Patent Owner faults Petitioners for not explaining whether and why the term "so that at least about 25% of the proteins are properly refolded" is limiting. Prelim. Resp. 33–37. For purposes of this Decision, we do not need to resolve this issue. Generally, whether certain language in a claim is "limiting" or not is considered when evaluating the scope of the claim as compared to the prior art, or in analyzing infringement. But neither issue is presented here. Instead, we are called upon to determine whether the

[10] The parties agree that the challenged '287 patent and the priority applications, including the one issued as the '138 patent, "share a common specification, varying only in the claims, assertions of priority, and non-material corrections." Pet. 23 n.3, 32; Prelim. Resp. 78. In analyzing the priority date of the challenged claims, we cite to the '138 patent, filed before March 16, 2013.

priority applications provide written description for the term "so that at least about 25% of the proteins are properly refolded." Even assuming the term is not limiting, the cases Patent Owner cited (*see* Prelim. Resp. 33–37) do not stand for the proposition that written-description support under § 112 is unnecessary for what is explicitly recited in a claim. Thus, we determine that, for purposes of this Decision, claims 1–9 and 16–25 are entitled to the pre-2013 priority date only if the priority applications provide written-description support for the term "so that at least about 25% of the proteins are properly refolded."

Also, Petitioners equate "at least about 25%" with "25%–100." Pet. 28. Patent Owner challenges that (1) "Petitioners never addressed the claims' '*at least about*' language, and do not explain why this range would start at *exactly 25%*" (Prelim. Resp. 37), and (2) Petitioners do not explain whether or why an ordinary artisan "would purportedly have understood the claimed range for refolding achieved in the claim to include '*100%*'"[11] (*id.* at 38). For purposes of this Decision, we do not need to resolve these issues either. Petitioners acknowledge that Figures 1a–1f show the percentage of properly refolded species "is often lower than 25%," and Example 4 discloses refolding yields of "approximately 27–35%." Pet. 29. Instead, Petitioners argue that "the priority applications provide no disclosure for any

[11] Patent Owner questions whether an ordinary artisan "would have understood this term ['at least about 25%'] to have had an upper limit, even if not precisely known." Prelim. Resp. 38. We are not persuaded by this unsupported attorney argument.

percentages of properly refolded protein *over 80%*," such as 85%, 90%, or 95%. *Id.* at 30 (emphasis added), 36.[12]

Patent Owner contends that the law does not require "explicit examples in the specification across the entire range of the results recited" in the claim. Prelim. Resp. 44. Patent Owner is correct. *See Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003) (explaining that a specification may "contain a written description of a broadly claimed invention without describing all species that [the] claim encompasses"). When there is substantial variation within the genus, however, a sufficient variety of species must be described to reflect the variation within the genus. *See AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014).

Based on the current record, we are persuaded that the percentage of properly refolded proteins disclosed in Figures 1a–1f and Examples 3 and 4 of the '138 patent do not constitute a representative number of species within the genus of "at least about 25%." As Petitioners argue, "the priority applications provide no disclosure for any percentages of properly refolded protein over 80%." Pet. 30. Dr. Robinson, Petitioners' expert, testifies that "[t]he higher the percentage of properly folded protein sought, the more difficult that percentage is to achieve." Ex. 1002 ¶ 83. And the specification of the '138 patent, Petitioners argue, "provides no indication

[12] To the extent that Patent Owner asks us to deny the Petition simply because Petitioners do not address the term "at least about 25%" under the claim-construction section, we decline to do so. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (explaining that "only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy").

that the inventors had possession of any percentages of properly refolded proteins at the higher end of the range" of "at least about 25%." Pet. 31.

At this stage, Petitioners have shown sufficiently that the '138 patent does not provide adequate written description for "at least about 25% of the proteins are properly refolded," and thus, claims 1–9 and 16–25 of the '287 patent are not entitled to a priority date before March 16, 2013. Accordingly, based on the current record, we determine that the '287 patent is eligible for post-grant review.[13]

The Written-Description Ground

Petitioners argue that claims 1–9 and 16–25 are unpatentable under 35 U.S.C. § 112(a) because the specification of the '287 patent does not provide adequate written-description support. Pet. 32–33. The parties agree that the '138 patent and the '287 patent "share a common specification." Pet. 32; Prelim. Resp. 78. Thus, for the same reason explained above, we are persuaded that, based on the current record, it is more likely than not that claims 1–9 and 16–25 are unpatentable under 35 U.S.C. § 112(a) because the specification of the '287 patent does not provide adequate written-description support for "at least about 25% of the proteins are properly refolded," as recited in those claims.

The Enablement Ground

The test of enablement is "whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled

[13] Other requirements for post-grant review are satisfied also. The Petition was filed on October 1, 2018 (Paper 6, 1), within nine months of the grant of the '287 patent. *See* 35 U.S.C. § 321(c). Petitioners further certify that they have standing to seek post-grant review of the '287 patent. Pet. 2.

with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors include, for example, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, and the amount of direction provided by the inventor. *Id.*

Petitioners contend that claims 1–30 are unpatentable under 35 U.S.C. § 112(a) because the specification of the '287 patent fails to comply with the enablement requirement. Pet. 33–36. Petitioners argue that "[t]he challenged claims have a broad scope." *Id.* at 34. According to Petitioners, "[t]he claims recite that the thiol-pair ratio is in the range of 0.001-100, and do not place a numerical limit on the thiol-pair buffer strength, resulting in a vast number of possible redox conditions. Nor do claims 1, 10, 16 and 26 place any limitation on the proteins to be refolded." *Id.*

Each of independent claims 1 and 16 recites "at least about 25% of the proteins are properly refolded," and each of independent claims 10 and 26 recites "about 30–80% of the proteins are properly refolded." Petitioners assert that because of "the vast number of proteins and redox conditions covered by the claims," the specification of the '287 patent provides insufficient guidance as to how to achieve the claimed ranges. *Id.* According to Petitioners, "[a] POSA could not replicate the percentages of properly refolded species in Figure[s] 1a–f [and Examples 3 and 4] without undue experimentation, as neither the specific protein nor its concentration is provided." *Id.* at 35.

Moreover, Petitioners emphasize that "the specification provides no guidance for the higher ends of this range" of "at least about 25%." *Id.* Citing the testimony of Dr. Robinson, Petitioners contend that refolding is "a challenging task even at lower yields of properly refolded proteins, and far more difficult at higher yields." *Id.* (citing Ex. 1002 ¶¶ 46, 83; Ex. 1048; Ex. 1049). Because the '287 patent does not show how "the patentees were able to overcome the extreme difficulty in achieving the higher levels of properly refolded protein such as 85, 90, 95 or 100%," Petitioners conclude that undue experimentation would be required to achieve the higher ends of the range of "at least about 25%." *Id.* at 36.

Patent Owner contends that Petitioners have not shown "why any experimentation needed would be *undue*." Prelim. Resp. 48. For example, Patent Owner points to the '287 patent where it states optimizing the redox component thiol-pair ratios and thiol-pair buffer strength can be performed for each protein. *Id.* at 50–51 (citing Ex. 1001, 9:39–60). Patent Owner argues that despite their assertion that "the specification provides 'no guidance' for achieving properly refolded at the higher ends of the range," Petitioners "failed to show the guidance provided in the '287 specification with respect to how to vary the thiol-pair ratio and thiol-pair buffer strength in order to obtain 'at least about 25%' of proteins properly refolded for any protein . . . is insufficient for POSITA." *Id.* at 50.

Based on the current record, we find Petitioners' argument and evidence more persuasive. Indeed, Patent Owner does not dispute that, with a large number of redox conditions and no limitation on the proteins, the challenged claims have a broad scope. And Dr. Robinson's analysis supports Petitioners' contention that the guidance provided in the

specification of the '287 patent is insufficient to enable the challenged claims. *See* Pet. 35 (citing Ex. 1002 ¶ 82). For example, according to Dr. Robinson, the '287 patent used "a multifactorial matrix," and "a subset of the conditions . . . was then further evaluated . . . in a factorial screen," which suggests "a large number of conditions were tested by the patentees even within the scope of the given equations." Ex. 1002 ¶ 82 (citation omitted). Dr. Robinson testifies:

> Example 2 also states that identification of the refold buffer was performed for each protein. Thus a POSA would understand that there is no direct correlation between the thiol-pair ratio and the thiol-pair buffer strength that can be used for one protein and applied to another protein. Example 2 then discloses that once certain conditions are identified, like pH, arginine, etc., a subset of conditions was further evaluated in subsequent screens to evaluate a range of thiol-pair ratio and thiol-pair buffer strength (which is the same as redox buffer strength). The specification does not provide sufficient guidance to narrow the range of the conditions tested.

Ex. 1002 ¶ 82 (internal citation omitted). At this stage, Dr. Robinson's testimony is unrebutted by contrary evidence about, for example, whether the guidance in the specification would have been adequate for a person of ordinary skill in the art. Thus, based on the current record, we are persuaded that Petitioners have shown it is more likely than not that claims 1–30 are unpatentable under 35 U.S.C. § 112(a) for lack of enablement.

Having determined that Petitioners have demonstrated that it is more likely than not that claims 1–9 and 16–25 are unpatentable for failure to comply with the written description requirement, and claims 1–30 are unpatentable for lack of enablement, we institute a post-grant review as to all challenges raised in the Petition. *See* USPTO Guidance. We nevertheless offer the following observations on the other asserted grounds.

The Indefiniteness Ground

Claim Construction

For post-grant petitions filed before November 13, 2018,[14] we interpret a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.200(b); *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Petitioners contend that the term "wherein the thiol-pair buffer strength maintains the solubility of the preparation," recited in claims 1 and 10, has two constructions. Pet. 20–23. In a post-grant review, "only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." *Vivid Techs.*, 200 F.3d at 803. As explained above, based on the present record, we institute post-grant review because Petitioners have demonstrated that it is more likely than not that claims 1–9 and 16–25 are unpatentable for failure to comply with the written description requirement, and claims 1–30 are unpatentable for lack of enablement. Those determinations do not depend on the claim construction

[14] *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (amending 37 C.F.R. § 42.200(b) effective November 13, 2018).

of this term. We nonetheless provide the following discussion regarding Petitioners' contentions about the term.

Under the plain language of claims 1 and 10, Petitioners argue that the term "would be interpreted to mean that the thiol-pair buffer strength maintains the solubility of the preparation itself." Pet. 21. In claims 1 and 10, the "preparation" comprises "at least one ingredient selected from the group consisting of a denaturant, an aggregation suppressor and a protein stabilizer," "an amount of oxidant," and "an amount of reductant." The preparation, however, does not contain proteins. *See* Ex. 1001, claims 1 and 10 (reciting "contacting the proteins with a preparation . . . to form a refold mixture"). But, "[t]he term 'preparation' as used in claims 1 and 10," Petitioners point out, "does not appear in the specification, and the specification does not disclose any information regarding its 'solubility.'" *Id.* at 22.

Alternatively, Petitioners argue that the term "'wherein the thiol-pair buffer strength maintains the solubility of the preparation' should be interpreted to mean that the thiol-pair buffer strength maintains the solubility of the proteins when the proteins contact the preparation, forming the refold mixture." *Id.* at 21. According to Petitioners, this construction is "the broadest reasonable interpretation in light of the specification." *Id.*

The '287 patent defines the term "solubilization" as "a process in which salts, ions, denaturants, detergents, reductants and/or other organic molecules are added to a solution comprising a protein of interest, thereby removing some or all of a protein's secondary and/or tertiary structure and dissolving the protein into the solvent." Ex. 1001, 7:28–33. Throughout the '287 patent, the only solubility the specification describes appears to be that

of proteins. *See, e.g.*, *id.* at 11:1–4 (stating "the present disclosure relates to a method of refolding a protein expressed in a non-mammalian expression system in an insoluble or limited-solubility form"), *id.* at 17:32–36 (stating "there is a clear relationship between thiol-pair buffer strength and thiol-pair ratio that can be identified to maintain the optimal species balance and thus facilitate efficient refolding of low solubility proteins").

Based on the current record, we find Petitioners' proposed construction of the term reasonable. We note, however, each of claims 16 and 26 recites "wherein the thiol-pair buffer strength maintains the solubility of the solution," and the solution comprises the proteins and the preparation. Adopting Petitioners' proposed broadest reasonable interpretation in light of the specification for "wherein the thiol-pair buffer strength maintains the solubility of the preparation" would mean claims 1 and 16 have essentially the same scope, and claims 10 and 26 have essentially the same scope. We recognize that, generally, "different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971–72 (Fed. Cir. 1999). The Petition, however, does not address the doctrine of claim differentiation.

Patent Owner does not explicitly propose a construction for the term. In countering Petitioners' indefiniteness argument, however, Patent Owner asserts

> Petitioners fail to consider that the term "wherein the thiol-pair buffer strength maintains the solubility of the preparation" may mean exactly what it says: that the thiol-pair buffer strength maintains the solubility of the solutes in the preparation, which include (1) at least one of a denaturant, an aggregation

> suppressor, and a protein stabilizer; (2) an oxidant; and (3) a reductant.

Prelim. Resp. 77–78.

As support, Patent Owner relies on a single sentence in the '287 patent. *Id.* at 78 (citing Ex. 1001, 13:12–15) ("The solubilized inclusion bodies are then diluted to achieve reduction of the denaturants and reductants in the solution to a level that allows the protein to refold."). It is unclear to us, however, how this disclosure supports Patent Owner's position, as it appears to discuss conditions in the "solution," which includes proteins, and not the "preparation," which does not include proteins.

Patent Owner also relies on expert and inventor testimonies presented in a district-court case.[15] *Id.* at 78–79 (citing Ex. 2010, 167:8–169:4; Ex. 2019, 312–14; Ex. 2020, 142:20–143:4). To the best of our understanding, Patent Owner argues that the solubility recited in claims 1 and 10, as well as in claims 16 and 26, means "the solubility of (at least) the oxidants and reductants in the preparation or solution." Prelim. Resp. 78. If our understanding is correct, Patent Owner has not sufficiently explained why this interpretation is consistent with the specification of the '287 patent, which appears to describe the solubility of proteins only.

Indefiniteness

During prosecution, a claim is indefinite if it contains words or phrases whose meaning is "unclear in describing and defining the claimed

[15] Patent Owner previously asserted the '138 patent against Apotex Inc., and Apotex Corp. *Amgen Inc. v. Apotex Inc.*, 712 F. App'x 985, 987 (Fed. Cir. 2017). After a bench trial, the district court held that Patent Owner had failed to prove infringement. *Id.* The Federal Circuit affirmed that ruling. *Id.*

invention." *In re Packard*, 751 F.3d 1307, 1311 (Fed. Cir. 2014). The Supreme Court has instructed that a claim in an issued patent is "invalid for indefiniteness if its claims, 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, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014).

Petitioners argue that we should apply the *Packard* indefiniteness standard, and that, under the plain-language construction, claims reciting, either directly or through dependency, "wherein the thiol-pair buffer strength maintains the solubility of the preparation" are indefinite. Pet. 79–81. According to Petitioners, if the solubility is of the preparation itself, and not that of proteins, "[i]t is unclear which ingredients of the preparation are the solvent and which are the solute" (*id.* at 22–23 (citing Ex. 1002 ¶¶ 64–67)), or "how the thiol-pair buffer strength maintains such solubility" (*id.* at 80–81 (citing Ex. 1002 ¶¶ 192–193)).

As discussed above, because Petitioners have not addressed the doctrine of claim differentiation, and Patent Owner has not addressed the intrinsic evidence Petitioners rely on, we have not conclusively construed the term "wherein the thiol-pair buffer strength maintains the solubility of the preparation." Thus, the best course of action here is to permit the parties to fully develop the record during trial before resolving this dispute.

The Prior-Art Grounds

Vallejo-Based Grounds

Vallejo discloses

> a method of producing a biologically active recombinant cystine-knot protein comprising (a) solubilisation of inclusion bodies comprising said cystine-knot protein produced in a bacterium in

> the presence of a chaotropic agent; (b) renaturation of the solubilized cystine-knot protein in batch or by pulse addition of said solubilized cystine-knot protein to a refolding buffer . . . comprising (ba) an aggregation suppressor in a final concentration of at least 0.5 mol/L; (bb) a mixture of reduced and oxidized glutathione wherein the ratio of reduced to oxidized glutathione is equal or above 1:10; and (bc) a solubilizing chaotropic agent in a non-denaturing concentration.

Ex. 1038 ¶ 1.

Petitioners argue that claims 1–4, 7–19, and 22–30 are anticipated by Vallejo, and claims 5, 6, 20 and 21 would have been obvious over Vallejo and Hevehan. Pet. 38–50, 76–78. Patent Owner disagrees. Prelim. Resp. 56–65. Based on the current record, we find Patent Owner's arguments persuasive.

For example, all the claims challenged under these two grounds recite "wherein the thiol-pair ratio is in the range of 0.001-100." In the '287 patent, the thiol-pair ratio is defined in Equation 1, which is shown below:

Definition of Buffer Thiol-Pair Ratio (*TPR*) Equation 1

$$\text{Buffer } TPR = \frac{[\text{reductant}]^2}{[\text{oxidant}]} = \frac{[\text{cysteine}]^2}{[\text{cystamine}]}.$$

Ex. 1001, 6:50–55. As shown in Equation 1, the thiol-pair ratio "is defined by the relationship of the reduced and oxidized redox species used in the refold buffer." *Id.* at 6:46–48.

For this limitation, Petitioners rely on the disclosure in Vallejo that the ratio of the reduced glutathione to the oxidized glutathione is from 40:1 to 1:20. Pet. 43 (citing Ex. 1038, Fig. 2b, ¶¶ 42, 45). According to Petitioners,

> A POSA would understand these ratios to be molar ratios and would understand that this is a simple ratio of [reductant]/[oxidant]. The '287 Patent defines the thiol-pair ratio

> as [reductant]^2/[oxidant]. Therefore, Vallejo teaches a calculated thiol-pair ratio of 0.05 to 1600. Therefore, Vallejo discloses multiple examples of refolding a protein using a thiol-pair ratio within the range of 0.001–100. Ex. 1002 at ¶100.

Id. at 43–44 (footnote omitted). Dr. Robinson explains the range of 0.05 to 1600 is calculated because "[t]he '287 patent teaches the thiol-pair ratio as [reductant]^2/[oxidant] = [GSH]^2/[GSSG] = [40]^2/[1] =1600 and [1]^2/[20] = 0.05." Ex. 1002 ¶ 100.

Patent Owner contends that

> Petitioners claim that Vallejo discloses the ***ratio*** of the concentration of reductant to the concentration of oxidant, *not* that Vallejo discloses the ***actual concentrations*** of reductant and oxidant used. But a reader of Vallejo cannot determine, as a matter of arithmetic, the ***actual concentrations*** of reductant and oxidant used from knowing only that ***ratio***.

Prelim. Resp. 57. Patent Owner further explains that

> For example, knowing merely that the ratio of the concentration of reductant to the concentration of oxidant is 2, one cannot deduce the concentrations of the oxidant and reductant or the thiol-pair ratio: the concentration of the reductant could be 4mM and the concentration of the oxidant could be 2mM; or the concentration of the reductant could be 0.00004mM and the concentration of the oxidant could be 0.00002mM. Although both results in a ratio of concentration of reductant to concentration of oxidant of 2, the former results in a thiol-pair ratio of 8 ($4^2/2$), which is within the range recited in the claims; and the latter results in a thiol-pair ratio of 0.00008 ($0.00004^2/0.00002$), which is below the range recited in the claims.

Id. n.17. We find Patent Owner's explanation persuasive. Thus, it does not appear that Petitioners have sufficiently established that Vallejo teaches that the thiol-pair ratio is in the range of 0.001–100, as required in all challenged claims.

Schlegl-Based Grounds

Schlegl discloses a method for refolding bovine α-lactalbumin (α-LA). Ex. 1007 ¶¶ 73–83. First, "α-LA is denatured and reduced in a refolding buffer containing 0.1M Tris-HCl, pH 8.0, 6 M GdmHCl, 1 mM EDTA and 20 mM DTT." *Id.* ¶ 74. Schlegl discloses α-LA is then refolded "by Dilution," in which "[d]enatured and reduced aliquots at 16.5 mg/ml are rapidly diluted (batch-dilution) 32 fold into renaturation buffer consisting of 100 mM Tris-HCl, 5 mM $CaCl_2$, 2 mM cysteine and 2 mM cysteine, pH 8.5." *Id.* ¶ 75.

Petitioners argue that claims 1–4, 8–19, and 23–30 are anticipated by Schlegl, and claims 7 and 22 would have been obvious over Schlegl and Vallejo. Pet. 50–61. Patent Owner challenges these assertions from several aspects. Prelim. Resp. 65–71.

For example, all the claims challenged under these two grounds require a preparation or a solution comprising "at least one ingredient selected from the group consisting of a denaturant, an aggregation suppressor and a protein stabilizer," "an amount of oxidant," and "an amount of reductant." According to Petitioners,

> Schlegl also discloses that compounds may be added to the refolding buffer to "suppress or completely prevent unfolding/aggregation" that were "known in the art," including "L-arginine, Tris, [and] detergents." Ex. 1005 at 40; Ex. 1007 at [0041]. Schlegl further discloses a refold buffer containing "0.1 M Tris-HCl" (a protein stabilizer and aggregation suppressor) and "6 M GdmHCl" (a denaturant). Ex. 1005 at 38; Ex. 1007 at [0074]; Ex. 1002 at ¶119.
>
> Therefore, Schlegl teaches a refold buffer containing an aggregation suppressor, protein stabilizer, and a denaturant. Ex. 1002 at ¶120.

Pet. 54–55. In addition, Petitioners argue that "a POSA would understand that the addition of cysteine and cystine here serve as the redox system or redox component for bovine α-lactalbumin." Pet. 55–56; Ex. 1002 ¶ 122 (citing Ex. 1007 ¶ 75).

Patent Owner contends that

> Petitioners glossed over Schlegl's teaching of two different types of buffers—a "refolding buffer" and a "renaturation buffer"—and used them interchangeably in attempting to map them on the claimed preparation and solution. Compare EX1007, ¶74 with EX1007, ¶75; Pet., []53-56. In Schlegl's only example, the refolding buffer is used to denature the protein (¶74), and the renaturation buffer is used to renature or refold the protein (¶75).

Prelim. Resp. 67–68. Patent Owner points out that cysteine and cystine, which Petitioners map as the redox system or redox component, are in the renaturation buffer, whereas the other components, which Petitioners map as the aggregation suppressor, protein stabilizer, and denaturant, are in the refolding buffer. *Id.* at 68.

At this stage, Patent Owner's observation appears consistent with the teachings of Schlegl. Nonetheless, because we are instituting a post-grant review, the parties may more fully develop the record during trial before we resolve this dispute.

Ruddon-Based Ground

Ruddon teaches "methods for expressing subunits of [glycoprotein] hormones in procaryotic cells and re-folding the subunits *in vitro*, to produce biologically active glycoprotein hormones in quantities sufficient for clinical use." Ex. 1040, 1:11–15.

Petitioners argue that claims 1–4, 7–19, and 22–30 would have been obvious over Ruddon and Vallejo. Pet. 61–76. Patent Owner challenges this assertion from several aspects. Prelim. Resp. 71–74.

For example, all the claims challenged under this ground require a certain percentage of the proteins are properly refolded. According to Petitioners, "[o]ne way a POSA would know whether a protein was properly refolded to its native form would be to determine if it regained the biological activity of the native form of the protein." Pet. 70 (citing Ex. 1002 ¶ 169). Petitioners argue that Ruddon teaches that its refolded rehCG-β is biologically active. *Id*. at 71 (citing Ex. 1040, 52:22–25) ("These *in vitro* and *in vivo* results indicate that rehCG-β folded and assembled with hCG-α in a conformation very similar to that of glycosylated hCG-β that is made in human cells.").

Patent Owner emphasizes that Ruddon discusses a method of refolding, not proteins, but subunits of a protein. Prelim. Resp. 71. According to Patent Owner, "Ruddon's refolding of subunits of protein, however, does not result in the production of a biologically active protein. As stated in Ruddon, the subunits, instead, must be subsequently assembled into the biologically active dimeric protein." *Id.* at 71–72 (citing Ex. 1040, Abstract) ("Unfolded glycoprotein hormone subunits are expressed in procaryotic cells, then re-folded in vitro in a thiol redox buffer *to form* ***assembly-competent subunits***. The subunits *are assembled to produce* ***active hormones***.") (emphases added by Patent Owner).

Patent Owner's observation appears consistent with the teachings of Ruddon, including the passage Petitioners rely on. The '287 patent, however, defines the term "protein" to "mean any chain of at least five

naturally or non-naturally occurring amino acids linked by peptide bonds." Ex. 1001, 6:4–7. Thus, subunits of a hormone in Ruddon are proteins, and Ruddon teaches a method of refolding proteins. Patent Owner has not pointed to persuasive evidence at this stage to show an inactive subunit protein would, after assembly, form an active hormone.

CONCLUSION

Based on the current record, we find the information presented in the Petition, Preliminary Response, and accompanying evidence establishes that it is more likely than not that claims 1–30 of the '287 patent are unpatentable. Under USPTO Guidance, we institute a post-grant review on all challenges raised in the Petition.

At this stage of the proceeding, the Board has not made a final determination as to the construction of any claim term or the patentability of any challenged claim. Thus, our view with regard to any conclusion reached in the foregoing could change upon completion of the record.

ORDER

Accordingly, it is

ORDERED that pursuant to 35 U.S.C. § 324(a), a post-grant review is hereby instituted to determine

(1) whether claims 1–9 and 16–25 are unpatentable under 35 U.S.C. § 112 for lack of adequate written-description support;

(2) whether claims 1–30 are unpatentable under 35 U.S.C. § 112 for lack of enablement;

(3) whether claims 1–4, 7–19, and 22–30 are unpatentable under 35 U.S.C. § 102(a)(1) as anticipated by Vallejo;

(4) whether claims 1–4, 8–19, and 23–30 are unpatentable under 35 U.S.C. § 102(a)(1) as anticipated by Schlegl;

(5) whether claims 7 and 22 are unpatentable under 35 U.S.C. § 103 as obvious over Schlegl and Vallejo;

(6) whether claims 1–4, 7–19, and 22–30 are unpatentable under 35 U.S.C. § 103 as obvious over Ruddon and Vallejo;

(7) whether claims 5, 6, 20, and 21 are unpatentable under 35 U.S.C. § 103 as obvious over Vallejo and Hevehan; and

(8) whether claims 1–15 are unpatentable under 35 U.S.C. § 112 for indefiniteness.

FURTHER ORDERED that pursuant to 35 U.S.C. § 324(d) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

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